

PRIORITY INITIATIVES

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46.	<u>Communication 'The EU, Africa and China: Towards trilateral dialogue and cooperation on Africa's peace, stability and sustainable development'</u>
47.	<u>Communication 'Economic Development and regional integration in the ACPs'</u>
48.	Forest package
	<u><i>a) Green Paper on measures to reduce deforestation</i></u>
	<u><i>b) Communication on the prevention of the placing on the market in the EU of illegally harvested timber and timber products (with possible accompanying legislative proposal.)</i></u>

ROADMAP

Title of the initiative: **Budget review**

Expected date of adoption of the initiative: **4th quarter 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The budget review stems from an agreement between the Council, the European Parliament and the Commission asking the Commission 'to undertake a full, wide ranging review covering all aspects of EU spending, including the CAP, and of resources, including the UK rebate, to report in 2008/9'. Preparatory steps for this review include:

- a consultation paper launching an open consultation with a broad number of stakeholders – 12 September 2007;
- three external studies on EU expenditure (focusing respectively on evaluation results of current EU spending, the future financing of the EU, and EU spending) and a series of sectoral studies;
- a scientific conference in April 2008, based on scientific inputs on a series of questions relevant to the review;
- a closing conference of the consultation – 27 May 2008; and
- a document synthesising and analysing the contributions made during the consultation.

What are the main problems identified?

In December 2005, Heads of State and Government, considering that Europeans are living through an era of accelerating change and upheaval and convinced that the increasing pace of globalisation and rapid technological change continues to offer new opportunities and present new challenges, have decided that the EU should carry out a comprehensive reassessment of the financial framework, covering both revenue and expenditure, to sustain modernisation and to enhance it, on an ongoing basis. They invited the Commission to undertake a full, wide ranging review covering all aspects of EU spending, including the CAP, and of resources, including the UK rebate, to report in 2008/9. The European Parliament, the Council and the Commission shared this analysis and formally endorsed the invitation of the Commission to undertake this review in Declaration n° 3 annexed to the Inter-institutional Agreement of 17 May 2006.

Is EU action justified on grounds of subsidiarity?

The review aims at a thorough analysis of the extent to which EU financial action provides added value compared to action at national and regional level and thus at reinforcing coherence of spending policies with the subsidiarity principle. As reflected in the mandate given to the Commission, an analysis and reform of the EU budget can only be undertaken at the European level.

B. Objectives of EU initiative

What are the main policy objectives?

The objective is to examine what reforms are needed to optimise Europe's contribution in addressing key challenges of the next decade, based on the principles of added value in pursuing the common interest and effectiveness of spending. This analysis is therefore potentially an important input to proposals to be presented by the next Commission for a new multi-annual financial framework, covering the period from 2014 onwards.

Does the objective imply developing EU policy in new areas or of strategic importance?

The budget review is an entirely open, no-taboo reflection, covering all existing spending areas and potentially also new areas.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The budget review is a broad strategic discussion about the future spending priorities and the way the EU budget is financed. The policy options with regard to the principles that will be defined are, at this stage, almost entirely open. They will draw heavily on the results of the consultation and may also be inspired by the results of the studies and the outcome of the conferences.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The budget review will in principle cover most policy areas. It will be important to ensure that other reflections undertaken by the Commission about the future objectives and funding of specific policies are coordinated in an appropriate manner with the budget review, in order to ensure coherence.

Do the options respect the proportionality principle?

The nature of the review is entirely in the spirit of respecting the principle of proportionality.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The policy options presented in the budget review would have an economic impact across the EU, depending on whether and how they would be taken up at a later stage. They are also likely to have social and environmental impact, through the optimisation of spending policies aiming at improving the Union's contribution in meeting societal and environmental challenges.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The review will by its nature have an impact on the EU budget to the extent that the policy options would be taken up at a later stage. However, this will only materialise after the proposals on the next Multi-annual Financial Framework have been made by the Commission and approved by the other institutions.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Such a simplification is one of the objectives of the review.

Who is affected?

Given the very broad scope of this exercise, the budget review could affect a large number of stakeholders across the EU and beyond.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Three independent studies have been commissioned. The replies to the consultation on the issues paper will be analysed by the Commission services.

Which stakeholders & experts have been/will be consulted, how and at what stage?

A broad consultation is currently taking place and will last until April 2008. It is open to all interested stakeholders. The Commission will actively encourage interested parties to make their voices heard. A specific Commission web site is dedicated to the consultation and a series of meetings and conferences have already been and will continue to be organised in various Member States throughout this period. The consultation will be closed by a conference on 27 May 2008 in Brussels. A specific scientific conference will also take place in April 2008. Prominent academics have been asked to submit written contributions in view of the conference.

ROADMAP

Title of the initiative: **Commission Communication on EMU@10**

Expected date of adoption of the initiative: **May 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In May 2008, it will be the 10th anniversary of the crucial decisions on the transition to the 3rd stage of EMU. After a decade, ECFIN is drawing up an in-depth assessment of the functioning of EMU and to distil lessons from the experience gained so far for its future improvement. As guardian of the Treaty, the Commission has a key role to play in promoting and ensuring a smooth functioning of EMU which represents the most advanced stage of economic integration in the EU.

What are the main problems identified?

The main challenges related to the functioning of EMU are currently being investigated by the Commission services and will be reported upon in detail in the EU Economy 2008 Review.

Is EU action justified on grounds of subsidiarity?

Yes. Governance of the economic and monetary union requires an action on the supra-national level.

B. Objectives of EU initiative

What are the main policy objectives?

EMU is the most advanced stage of economic integration within the Union. As such it provides the nucleus of further integration within the Union at large as also countries not yet participating in the euro area are expected to join it in due course when the necessary conditions have been met. A smooth functioning of EMU is clearly in the interest of the Union at large. The review of EMU should allow drawing lessons on how the various Community and national policies can be better geared towards an optimal functioning of EMU.

Does the objective imply developing EU policy in new areas or of strategic importance?

This depends on the results of the review which is ongoing. Possibly extension of EU economic surveillance instruments

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

This depends on the results of the review which is ongoing. Most improvements are, however, likely to be best implemented within the context of already existing procedures and surveillance mechanisms, which is more in the area of soft law rather than legislation per sé

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

This depends on the results of the review which is ongoing.

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Since concrete policy options have not yet been identified, this question cannot be answered at this stage.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No.

Who is affected?

As indicated before the functioning of EMU is of primordial importance for all EU Member States. In this sense all Member States will be affected by initiatives to strengthen and smoothen its functioning. But obviously countries already participating in the euro area will be most directly affected by any measures aimed at strengthening surveillance and/or economic governance within the euro area.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

ECFIN undertakes extensive monitoring and analysis of developments in EMU participants, including in the context to the policy co-ordination and surveillance procedures foreseen by the Treaty. The specific analysis underlying any possible initiatives will be presented in the Commission's EU Economy 2008 Review.

Which stakeholders & experts have been/will be consulted, how and at what stage?

A large number of internal and external stakeholders is being and will be consulted in the context of the Commission's preparatory work and upon the presentation of its findings.

ROADMAP

Title of the initiative: **Green Paper on European territorial cohesion**

Expected date of adoption of the initiative: **3rd quarter 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Debate on territorial cohesion has been going on since the beginning of the 90's with the publication of the Commission document EUROPE 2000. Member States reached a first consensus on this issue with the European Spatial Development Perspective adopted in 1999. The concept was first made operational at Community level with the INTERREG initiative and the European Spatial Planning Observatory Network. It received much attention during the constitutional debate with the addition of the word "territorial" to the economic and social cohesion. Since then, successive Presidencies have re-launched the discussion which culminated in the adoption by Ministers responsible for spatial planning and regional development of the Territorial Agenda in May 2007. In that context, Ministers invited the Commission to prepare a report on territorial cohesion.

The Green Paper will therefore constitute the Commission's contribution to the Territorial Agenda, while simultaneously improving its internal thinking on an important dimension of the constitutional debate. It will further provide analytical and policy support for the assessment of the programmes co-financed under cohesion policy during the period 2007-2013.

What are the main problems identified?

Lack of a common definition of territorial cohesion in the Member States;
Diversity of governance systems (vertical and horizontal coordination) in the member states;
Low level of implementation of territorial cohesion issues in the programming under cohesion policy;
Lack of integration of the concept in sectoral policy designing.

Is EU action justified on grounds of subsidiarity?

Yes, because major territorial challenges to be faced are at European level and common tools must be coordinated at European level.

B. Objectives of EU initiative

What are the main policy objectives?

In the new Constitutional Treaty, territorial cohesion will be added, beside economic and social cohesion, as a shared competence. In this context, the policy objectives are:

- to provide for a common definition of the concept at EU and Member States level;
- to report on how the concept is implemented in the governance systems and in the programming under cohesion policy in the Member States;
- to propose possible operational tools to better integrate this dimension in cohesion policy and in the sectoral policies having a territorial impact;
- to initiate an in depth dialogue between Member States (on the basis of the Territorial Agenda) and the Commission.

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Not Applicable: no policy option and no legislative impact proposed but rather a policy framework and some operational tools

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Do the options respect the proportionality principle?

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Not applicable

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No

Who is affected?

All territorial levels (EU, National, Regional, Sub-regional) are affected
Cohesion policy and sectoral policies having a territorial impact are also affected.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Data from EUROSTAT and from the ESPON programme are available at several geographic level (NUTS 2 and NUTS 3 particularly).

Internal work on some indicators will be done from September to December.

Additional work on indicators and territorial impact assessment should be determined for the future.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Members of the Territorial cohesion and Urban Matters (TCUM) subcommittee of the COCOF have been and will be consulted.

ROADMAP

Title of the initiative: **Amendment of Capital Requirements Directives 2006/48/EC and 2006/49/EC**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The Capital Requirements Directive for Credit Institutions (CRD) has certain specific areas that were 'left open' at the time of its adoption in 2006 on the understanding and commitment with the EP and the Council that these would be addressed subsequently through additional 'policy measures'. There are also certain modifications that need to be put through as a result of the extensive work carried out during the transposition of the Directive and that reflect the Commission's commitment to reducing unnecessary administrative burden for firms; some of these changes are possible through the Comitology procedure. Further to the request to the Commission by ECOFIN meeting, this proposal also purports to clarify and further underpin the EU financial crisis management framework and respond to financial market turbulence.

What are the main problems identified?

The Impact Assessment is intended to address the shortcomings of the current framework, especially in the areas of large exposures, hybrid instruments, crisis management, the role of the consolidating supervisor, the treatment of certain risks in the 'Trading Book', the waiver of Cooperative Banks from certain requirements of the CRD and technical changes and clarifications of specific provisions in the CRD.

LARGE EXPOSURES

The regulation of banks' concentration risk ('large exposures'), as currently contained in the Banking Directives, is 15 years old. Some limited technical changes were made to the large exposures rules when the CRD was adopted (such as the recognition of the use of certain credit mitigation techniques etc), but given the limited number and extent of these amendments, they cannot be said to constitute a review of the large exposures rules themselves. In recognition of this fact, Article 119 of 2006/48/EC and Article 28(3) of 2006/49/EC required a more in-depth review of the existing requirements "together with any appropriate proposals" to be submitted to the European Parliament and to the Council by 31 Dec 2007. [The suggested proposals will respond to that commitment.]

The Commission and Member States' Finance Ministry representatives meeting in the European Banking Committee (EBC) have been working on this review since 2005. In December 2005 a call for advice for a stock-take of current supervisory and industry practices relating to the large exposures regime was issued to the EU Banking Supervisors' Committee (CEBS). The advice received and the results of a parallel industry consultation highlighted certain shortcomings of the current regime.

In general, larger and more complex firms highlighted that the current rules do not adequately reflect industry practice in credit/concentration risk management or risk mitigation techniques. Firms have complained about unnecessary administrative compliance costs that this brings (available estimates indicate costs of ...-to be updated).

Overall, the industry feedback has indicated that for some firms, particularly the larger and more complex ones, the existing limits are not effective / they do not 'bite', as the larger/more complex institutions reportedly target a lower level of possible loss severity than the one implied by the current large exposures limits. In addition, the methods of calculation of exposures used in the context of the large exposures regime significantly vary from methods used for internal risk management purposes. The industry has particularly identified the treatment and definition of acceptable forms of collateral and treatment of credit derivatives as areas where they consider the regulatory treatment to be overly conservative.

There is also a high level of divergence in how the rules are applied by the national supervisory authorities. This is a result of the numerous options¹ offered (there are 19 options for Member States), the number of permutations of the take up of these options that is possible, and some differences and difficulties arising from inconsistent interpretations of definitions. The result is that while all Member States have a supervisory treatment that appears to be legally compliant, any given exposure might receive very different treatments from Member State to Member State which creates an uneven playing field. The lack of a consistent approach across the EU is a major concern for industry as the effects of disparate approaches to large exposures has a direct effect on a firms' ability to properly and fairly compete in another Member State. The different applications of the legislation in different Member States are particularly burdensome for firms operating cross-border.

There are also uncertainties related to definitions such as what constitutes a 'credit exposure', who can be considered a 'counterparty' and when can counterparties considered to be 'connected'². Clarity in these areas will be important to reflect lessons drawn from the market turbulence and to capture inter-bank market exposures as requested by the ECOFIN Council of October 2007.

Furthermore, the appropriateness and the relevance of the current rules to certain specialised firms have also to be reviewed. Industry consultation revealed concerns, among others, of investment managers and factoring companies that the regime was not 'fit for purpose' in relation to their business. As a result, the current LE rules appear to create an unnecessary compliance burden for certain types of firms.

HYBRIDS

The CRD does not provide for an EU framework for the recognition of 'hybrid' capital instruments (instruments with some characteristics of both debt and equity) in banks' original own funds. The criteria related to loss absorption, flexibility in payments and permanence, critical for determining an instrument's inclusion as a component of original own funds, were agreed at G10 level in 1998, but have never been transposed into EU directives. The latter have proved inadequate in preventing divergence within the EU. As hybrids are a very important source of capital in some Member States, it is critical that the framework provides clarity on the principles and the application thereof.

The EBC has been working on the definition of banks' own funds since 2004 and in June 2005 a call for advice was issued to CEBS for (i) a stock-take of current national rules; (ii) an analysis of the capital instruments recently created by the industry; (iii) the development of guiding principles behind own funds and (iv) a quantitative analysis of the types of capital held by credit institutions within the EU. In 2006, the European Commission asked CEBS to conduct an additional specific quantitative analysis on hybrids instruments as well as a technical assessment of the relevant characteristics which should underpin prudential recognition in banks' original own funds.

The advice received highlighted the materiality of hybrid capital instruments both in the EU capital markets and for banks' capital needs. In particular, hybrids represent a significant portion of the EU financial market (approximately €13 bn); the relevant incidence on original own funds is also material at 11.5%.

The lack of an EU-wide legislative text has entailed a wide dispersion of national approaches. Firstly, differences in treatment between Member States directly impacts on the relative issuance costs associated with these instruments since the domestic regulatory treatment may significantly affect the inherent risk of the instrument itself and its pricing. Secondly, banks may be exposed to unforeseen risks with regard to their reliance on these instruments when they most need them e.g. in a crisis situation.

Furthermore, recent proposals for insurance regulation ('Solvency II') now include the concept of hybrids; the banking sector also needs to move in parallel on this issue. It is important that the concepts and principles remain consistent between the sectors; otherwise there will be the risk of arbitrage between sectors, especially by mixed bank-insurance Financial Conglomerate groups operating in both sectors.

¹ The current Directives offer a number of "discretions" or options as to how each Member State may treat a certain type of exposure. For example, the Member State can choose to recognise less than 100% of the exposure value (applying a less than 100% weighting) or exempting it altogether.

² Industry has in particular expressed concerns about the difficulties they face in establishing the existence of an economic relationship between clients.

CRISIS MANAGEMENT

Large cross border banks now dominate the European banking landscape and cross-border consolidation is accelerating. 46 Large cross border banks hold about 68% of EU banking assets. Quantitative research of the IMF³ suggests that although 'spill overs' within domestic banking systems generally remain more likely, the potential for extreme events to spill over from one bank to another appears to have increased, both among domestic banks and across borders and it put special emphasis on the collective costs facing EU states if large cross-border financial institutions would fail. This supports the need for greater cross-border supervisory cooperation in the EU.

Clear home/host responsibilities involving defined tasks and command lines are crucial when dealing with a financial crisis. Although the current EU legislation ('CRD') is relatively clear, responsibilities of host and home authorities may not necessarily lead to an optimum crisis resolution process as the current framework limits the incentives to work toward a common EU-wide stability framework. The Ecofin Council of 10 October 2007 considered the recommendations of a high level working group of Member States / Commission representatives and endorsed further work in 3 areas where current supervisory arrangements are deemed sub-optimal.

Host supervisors of significant branches

Supervisors of branches that are significant for the stability of the banking system of a Host Member State that receive little information about these establishments may be informally invited in colleges of supervisors. Detailed coordination and cooperation requirements only apply to legal entities ('subsidiaries') within a group. Since branches are not legal entities, home supervisors are not required to invite host supervisors to cooperate and coordinate in relation to branches. In 'stressed' situations, informal agreements do not prove effective and the rights and entitlements of supervisors of host countries should therefore be improved.

Central banks and Ministries of Finance

While the CRD requires the home (consolidating) supervisor to 'alert' central banks and Ministries of Finance in emergency situations, current confidentiality safeguards may limit or even impede flows of information between competent authorities, central banks and Ministries of Finance. This may be detrimental to a smooth crisis management process which may involve not only competent authorities but also central banks or Ministries of Finance.

Crisis affecting more than one banking group

There is no mechanism for banking supervisors to rapidly share information. Even though EU banking legislation legally requires supervisors to share relevant information, in particular if it affects subsidiaries in other Member States, present nationally based supervisory responsibility does not carry incentives for supervisors to share information to the extent desirable. Recent financial market turmoil has demonstrated this shortcoming of the current banking supervisory structures. The CRD only requires cooperation and coordination of competent authorities to take place in the context of a specific banking group's supervision. It does not address crisis situations affecting more than one group, which need a timely and coordinated supervisory answer to potentially re-establish mutual trust in markets. The current arrangements therefore need to be improved.

CONSOLIDATING SUPERVISOR

The supervision of the subsidiaries of a financial group in another Member State remains the responsibility of that 'host' Member State. A subsidiary is a separate legal entity, incorporated and authorised in its ('host') Member State of establishment and is thus supervised on a 'solo' basis by the authorities of that 'host' country. The home authority ('consolidating supervisor') is however responsible for the group-consolidated overview of a firm's financial health, including a group's parent, branches and subsidiaries.

Over the past years, financial institutions have reconfigured their business strategies and reorganised their internal organisation. Importantly, this has involved the centralisation of business and key management functions. In pan-European institutions risk, liquidity and capital management are central functions that are executed centrally for all organisational units, irrespective of their legal status as branch or subsidiary. Groups are increasingly organised according to business lines. As a consequence looking at individual business entities in isolation is becoming less and less meaningful for purposes of prudential supervision. It may even be misleading, including for host supervisors which do not necessary have access to the relevant information. Furthermore:

³ IMF Country report N° 07/260 Euro Area Policy: 2007 Article IV consultation

- The fragmented structure of financial supervision has resulted in duplicated reporting duties and inconsistent requirements for internationally active financial institutions.
- This fragmentation also manifests itself by way of un-coordinated regulatory action.
- Without appropriate reinforced cooperation mechanisms, consolidated supervision would not live up to all of the potential that the CRD was supposed to deliver both in terms of efficiency and effectiveness. The powers of the consolidating supervisor working with other relevant supervisors for the Group in a college of supervisors to take decisions affecting subsidiaries of a banking group in another Member State could therefore be improved to a certain extent.

The level playing field between firms may be impeded by diverging regulatory and supervisory practices between approaches adopted within colleges. There are no convincing mediation mechanisms and/or involvement of CEBS to make sure that consolidated supervision in terms of model validation does not give rise to divergent practices between banking groups.

TRADING BOOK

At a late stage of the CRD negotiations in 2005, provisions were introduced in the Basel framework and the Directive text (via parliamentary amendments) that require banks and investment firms to hold capital for 'default risk' that goes beyond the default risk already covered by the 'value-at-risk' measure for market risk. However, the current framework does not provide precise guidance as to how this 'incremental default risk' may be captured for determining the corresponding capital requirement. This lack of guidance leads to considerable uncertainty on the side of the industry about how to implement this requirement and about what its impact would be on firms' capital positions. From a policy perspective, this situation raises concerns regarding the international level playing field. This shortcoming is particularly important given the recent turmoil in the markets that to an important part relates to trading book risks driven by the defaults in mortgage loan portfolios underlying traded debt instruments. Going forward, it is critical that a sound and consistent basis is put into place.

Member States, apart from some preliminary guidance in the UK, have no regulatory provisions in place to address this incremental risk.

CO-OPERATIVE BANKS (Extension of the exemptions under Article 3)

Article 3 of the CRD allows Member States to grant a waiver to Co-operative banks from certain requirements of the CRD; these include minimum capital.

According to Article 3, the waiver may only be granted to co-operative banks that were established as such by 15/12/1977 while meeting certain qualifying requirements by 15/12/1979. Certain Member States have 'adapted' these dates to read them as the date of their accession to the EU. Although this is in keeping with the spirit of the original provision it is still technically illegal. Other Member States have adapted the date to other events.

A strict application of the 1979 date would effectively prevent co-operative banks in Member States that have joined the EU since the 1980 from taking advantage of the waiver and would thus subject them to higher financial costs.

TECHNICAL CHANGES

Since the adoption of the Banking Directives and during the work carried out by the Capital Requirement Directive Transposition Group over the last two years material technical difficulties have been identified where a specific prudential treatment does not work in practice or results in disproportionate costs when compared with existing market practices. These will have to be reviewed and changed, either through comitology or through co-decision, in line with the Commission's commitment to review administrative burden for firms in the EU.

Is EU action justified on grounds of subsidiarity?

Given that the problems enumerated above are pan EU in nature and pertain to existing EU directives, action at the level of the EU is imperative and indispensable.

B. Objectives of EU initiative

What are the main policy objectives?

General objective: render the regulatory framework even more responsive to market conditions thus:

- Enhancing financial stability;
- Safeguarding the interest of creditors;
- Ensuring international competitiveness of the EU Banking sector;
- Further promoting the integration of the Internal Market.

Does the objective imply developing EU policy in new areas or of strategic importance?

Although areas such as supervisory arrangements are of strategic importance they are not new *per se*.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Given the detailed nature of the existing CRD, the policy options may differ for each of the 'problems' defined above. The options may thus include:

- Maintaining the status quo while monitoring developments in the market;
- Clarifying certain provisions in response to difficulties encountered when implementing the CRD;
- Evaluating progress on certain issues in broader international for and examining developments in the market to consider adaptations of the current framework;
- Consider addressing supervisory convergence issues through CEBS.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

DG ECFIN, for crisis management related issues.
DG Enterprise for Large Exposures
DG Competition on Cooperative Banks

Do the options respect the proportionality principle?

Yes.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The impact would be felt at a legal level in terms of certainty and clarity within the existing legal framework. Given the risk sensitivities of the financial sector, especially in light of recent events, it is critical that more transparency and certainty is instilled into the framework; this will go a long way in addressing and mitigating crises that would otherwise have far reaching socio-economic consequences.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

NA

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

There should be a general reduction in administrative burden; on the subject of relations with third countries, clarity and transparency within the EC will give us a stronger negotiating position and allow us to propagate a 'best in class' benchmark. A more robust framework will in any case benefit institutions from third countries operating in the EU.

Who is affected?

- Credit Institutions operating in the EU
- Ministries of Finance, central banks and competent authorities.
- From a socio-economic perspective the broader public (depositors, investors, borrowers, etc...)
- International banks via change in competitiveness of the EU industry.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

There is considerable data available from level 3 committees (CEBS) and sub groups; additional information will be collated by conducting a public consultation.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Industry, regulators, Member States and the broader public. Some of this is on going and some will need to be launched and completed in the first quarter of 2008.

Large Exposures: technical advice has been sought from CEBS. This work will be completed in 2008. A survey of thirty leading financial institutions was also conducted in 2006 by their associations. The Commission itself is conducting an assessment of the costs related to reporting. This work will also be completed in 2008.

Hybrids: The European Banking Committee (EBC) has been working on the definition of banks' own funds since 2004 and in June 2005 a call for advice was issued to CEBS for (i) a stock-take of current national rules; (ii) an analysis of the capital instruments recently created by the industry; (iii) the development of guiding principles behind own funds and (iv) a quantitative analysis of the types of capital held by credit institutions within the EU. CEBS published the surveys referred to in Parts (i) and (ii) of the above Call for Advice on 23 June 2006 ('the CEBS June Surveys')(4). In 2006, the European Commission asked CEBS to conduct an additional specific quantitative analysis on hybrids instruments as well as a technical assessment of the relevant characteristics which should underpin prudential recognition in banks' original own funds. The quantitative analysis of the characteristics of hybrids eligible as original own funds in the EU and the one referred to point (iv) above were published in March and June 2007 respectively.

⁴ http://www.c-eps.org/Advice/OF_part1_rules.pdf

The waiver of co-operative banks: a survey of Member States was conducted in 2007 to identify the exact extent of the problem.

Trading Book: Work is on going at Basel and the latter's guidelines are currently subject to a public consultation that is expected to be completed by early 2008.

Supervisory arrangements: there have been discussions at different fora including the most recent Ecofin of 10 October 2007.

Technical adjustments: are mainly a result of stakeholder queries with regard to the implementation of the CRD.

The Commission in any case will launch its own public consultation to supplement and consolidate the findings of the consultation and work that is already being carried out at different fora.

ROADMAP

Title of the initiative: **European Private Company Statute**

Expected date of adoption of the initiative: **September 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The initiative on the European Private Company statute (EPC) was one of the mid-term measures foreseen in the EU Company Law and Corporate Governance Action Plan adopted in 2003. For larger companies the statute for a European Company (SE) provides for a European legal form where the minimum capital requirement is 120,000 euros.

The initiative is in line with the principles of Better Regulation and it complements the Community action on simplification of the regulatory environment for businesses and reduction of the administrative burden⁵.

There is support for the initiative among European businesses, as confirmed in the public consultation on the future of the Company Law and Corporate Governance Action Plan (December 2005 to March 2006)⁶. Several Member States are also very supportive of an EPC.

The European Parliament also attaches great importance to this initiative. Its Legal Affairs Committee has drafted an own-initiative report and a resolution on the EPC. It was adopted by the EP on 1 February 2007⁷. The European Parliament urges the Commission to adopt a proposal on the EPC shortly.

What are the main problems identified?

The feasibility study of the Directorate General for Enterprise and Industry⁸ and the recent general consultation on the future of the Company Law and Corporate Governance Action Plan⁹ showed that companies, especially SMEs, face obstacles when they want to operate their business cross-border, in particular companies wishing to set up joint ventures or operate a network of subsidiaries in different Member States. The costs and risks involved in having to deal with several different national legal systems often prevent the companies from expanding their activities abroad. In addition, lack of trust in foreign corporate legal forms, in particular those from new EU Member States, makes penetration of internal market by those SMEs difficult. The existing measures facilitating the mobility of companies, i.e. the Cross-border Merger directive and Regulation on a European Company as well as the recent case law of the Court of Justice¹⁰, do not address all SMEs' needs.

Is EU action justified on grounds of subsidiarity?

In order to enhance the cross-border mobility of companies (SMEs) and reduce compliance costs in all Member States, Community action is necessary. Action by individual countries would be insufficient to achieve the objectives; because of its scale and effect, it can be better achieved at EU level.

⁵ http://ec.europa.eu/internal_market/company/simplification/index_en.htm

⁶ http://ec.europa.eu/internal_market/company/consultation/index_en.htm

⁷ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2006-0434+0+DOC+PDF+V0//EN&language=EN>

⁸ http://ec.europa.eu/enterprise/entrepreneurship/craft/craft-priorities/craft_spe_event.htm

⁹ See footnote 2.

¹⁰ http://ec.europa.eu/internal_market/company/seat-transfer/index_en.htm#jurisprudence

B. Objectives of EU initiative

What are the main policy objectives?

The objective of a possible measure is to enhance the mobility and competitiveness of European SMEs and make it easier for them to conduct cross-border business by providing them with basic common rules in the Member States. The possibility to operate in various Member States following the same corporate rules could reduce compliance costs. The aim would be to provide SMEs with an instrument facilitating the formation of new businesses in other Member States and/or the restructuring of existing businesses into simpler structures (e.g. easier and cheaper creation and operation of subsidiaries for groups of companies in the EU).

Does the objective imply developing EU policy in new areas or of strategic importance?

No.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The 3 main options to be examined are the following:

- 1) No action. In this case the Commission would not present any initiative.
- 2) Harmonisation of the national company laws for private companies in order to reduce compliance costs.
- 3) Propose to create a new European legal form.

The legislative or soft law instruments that could be considered are the following:

- A) Recommendation. This would allow Member States to decide if and to what extent they implement the proposed EU rules.
- B) Directive. Member States could choose the means for achieving the objectives set by EU law.
- C) Regulation. The EU rules would be directly applicable in the Member States.

The up-date of existing legislation would not be sufficient to reach the policy objectives.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No.

Do the options respect the proportionality principle? This will be subject to the impact assessment.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- 1) No action. Without EU action SMEs would continue using the national legal forms when running business in other countries. The costs of legal counsel would remain significant. Only modest improvement of the situation can be expected following the slow convergence of the national company law regimes.
- 2) The harmonisation of national company laws for private companies could reduce compliance costs. However, only extensive harmonisation could result in noticeable reduction of compliance costs. Such extensive harmonisation would be complex and would make it more difficult for Member States to up-date and modernise their national law on private companies regularly.
- 3) The creation of a new European legal form (EPC) would provide a new option for SMEs to conduct business in other Member States according to one set of corporate rules which could significantly reduce compliance costs. It would not affect the rules on the national company forms. The European legal form would provide SMEs with a European label.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The initiative would provide companies with a new option and could make it easier and cheaper for companies', in particular SMEs', to operate their cross-border business. By providing them with basic common rules in the Member States the initiative could contribute to the simplification of regulatory environment for businesses. However, the size of its impact on the simplification of business regulations would depend on the extent of the use of the instrument by companies.

Who is affected?

The options may open important new possibilities for companies. Their shareholders, creditors and employees of companies would also be affected.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The following studies and proposals on the subject are available:

- a 2005 feasibility study on the European statute for SMEs (with the involvement of external consultants: AETS - European Application of Technology and Services)¹¹
- a proposal on the European Private Company Statute prepared by the Chambers of Commerce of Paris and the MEDEF (1998)¹²
- The European Parliament Resolution on the EPC with recommendations on the content of a possible proposal¹³

Further information will be gathered from the public consultations (see below), internal research and analysis as well as input from the inter-service steering group.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The following consultations were/are organised on the EPC:

- stakeholders were consulted on the need for the EPC statute within a general public consultation on the future of the Company Law and Corporate Governance Action Plan (December 2005 to March 2006)¹⁴
- a specific consultation on the EPC and its possible contents (July-October 2007) and a European Business Test Panel on the EPC (October 2007)¹⁵
- consultation with the Advisory Group on Company Law and Corporate Governance and the Company Law Expert Group (CLEG). These Groups will be further consulted in December 2007 and February 2008.
- BusinessEurope Company Law Panel (November 2007),
- consultations with SME organisations will take place in November-December 2007.
- possible company law conference organised by the Slovenian Presidency (March-April 2007).

¹¹ See footnote 4.

¹² <http://www.etudes.cciip.fr/dossiers/spe/gb/index.html>

¹³ See footnote 3.

¹⁴ See footnote 2.

¹⁵ http://ec.europa.eu/internal_market/company/epc/index_en.htm

ROADMAP

Title of the initiative: **A Small Business Act for Europe**

Expected date of adoption of the initiative: June 2008.

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In November 2005, the Commission launched Modern SME policy to integrate SMEs in the renewed Lisbon Partnership for Growth and Jobs (COM(2005) 551). The principal objective of the policy is to mainstream SMEs' concerns into EU and national policies by applying the "Think Small First" principle. In addition, the Commission set out five priority areas where Member States and the Commission have made efforts to create a better business environment and to encourage more people to become entrepreneurs. These are:

- (1) cutting red tape
- (2) improving SMEs' access to markets
- (3) promoting entrepreneurship and skills
- (4) improving SMEs' growth potential
- (5) strengthening dialogue and consultation with SME stakeholders.

A Mid-term review on Modern SME policy (COM (2007) 592), adopted in October 2007, takes stock of the progress that the Commission and the Member States have made in implementing Modern SME policy. The Communication concludes that SMEs are now part of most Community policies, like competition, cohesion policy and research. The Commission has also increased the SME focus within major EU spending programmes for the period 2007-2013. The Commission has taken important steps towards creating a more SME-friendly regulatory environment by proposing, among others, ten fast-track actions in areas where such actions are likely to have the greatest impact, such as statistics and company law.

Member States have made efforts to deliver on the five priority actions requested by the 2006 Spring European Council, thus contributing to the implementation of the "Think Small First" principle throughout the European Union. In particular, the majority of Member States have established a one-stop-shop for setting up a company and most of them have reduced the time required to do so. Many of them have taken measures to develop entrepreneurial mindsets through education although progress is relatively slow.

Despite the progress made, more emphasis needs to be put on SMEs in the context of the next Lisbon cycle 2008-2011 to fully release their potential to grow and create new jobs. Therefore, the Commission will prepare a "Small Business Act" for Europe which will contain economically and politically significant initiatives tailored for SMEs according to the "Think Small First" principle. It will draw together SME elements present in various policies and laws, with the aim of reducing further the administrative burden on SMEs, increasing SMEs participation in EU programmes, increasing SMEs share in public procurement, improving SME access to standardisation and reducing obstacles to cross-border trade thus fostering further innovation and growth. The Small Business Act was announced in the Commission discussion paper for EU Heads of State and Government at the Lisbon informal summit on 18-19 October. It is also part of the initiatives announced in the Communication "A Single Market review for 21st century Europe" (COM (2007) 724 final).

What are the main problems identified?

The roughly 23 million small and medium-sized enterprises which account for 99% of all business and represent two third of total employment have a strong potential to contribute to the growth and job creation in the EU. They encounter, however, proportionally more difficulties than large companies, for example in terms of coping with regulatory burden, running cross-border activities and accessing finance, innovation and skills. Also, the EU does not adequately exploit its entrepreneurial potential. 45% of Europeans state that they prefer self-employment compared to 61% in the USA. Europe generates fewer start-ups relative to the USA and after start-up enterprises demonstrate lower expansion rates.

Overall, good progress has been made in implementing Modern SME policy. However, there is still room for improvement, both at Community level and in the Member States, in particular in the following areas:

The “Think Small First” principle and reducing the regulatory burdens

Although the progress made in applying the “Think Small First” principle is encouraging, the objective is to make it a leading principle in all law and policy making that should be applied systematically when drafting new laws and policies.

The benefits of better regulation need to be felt at all levels. It has been estimated that where a big company spends one Euro per employee because of a regulatory duty, a small business might have to spend on average up to ten Euros. To cut the burdens for SMEs who are disproportionately affected by such burdens, there should be a presumption that SMEs will not be covered by administrative requirements of EU legislation unless there is a clear need to do so and the issue can not be better tackled at national, regional or local level. Where SMEs are covered by EU legislation, special measures should be designed to help them. More generally, the EU needs to find ways to cut existing burdens wherever circumstances allow.

SMEs access to markets

SMEs have more difficulties than large enterprises to engage in cross-border activities. Only 8% of them are involved in export. The main constraints to exports are the lack of knowledge of foreign markets, the import tariffs/custom duties in the destination countries and the lack of capital.

The Single Market is set to guarantee access for enterprises to a wide common market operating on a common set of rules. However, SMEs do not fully benefit from the opportunities provided by the single market largely because of the lack of information on business opportunities and applicable rules in another Member States.

SMEs access to public procurement

In 2005, EU SMEs obtained 42% of public procurement contracts above EU thresholds. More than half of these contracts were won by medium-sized enterprises which seem to be performing relatively well when considering their contribution in the economy. This however is not the case of micro- and small enterprises. There is, therefore, scope for action to encourage Member States to make a better use of the possibilities the European public procurement Directives offer to promote SMEs’ participation in public tenders. Training and awareness-raising measures could be used to improve the skills level and knowledge on procurement procedures.

SMEs’ access to finance

Innovative and high growth SMEs typically look for venture capital that can finance fast growth and quick market entry. However, the fragmentation of the European venture capital market along national lines seriously limits the growth of early-stage capital for innovative SMEs. Venture capital funds limited to their national markets face problems reaching the critical mass they need to spread their portfolio risk and cover their costs. It also hinders efficient specialisation. Facilitating cross-border operations is necessary to overcome this hurdle and increase the overall supply of early-stage capital.

Many start-ups do not promise very rapid growth and are not interesting for venture capital investors. Other SMEs cannot access (further) debt financing and not wish to dilute ownership via equity finance. Transfer of businesses benefits from financing that does not change the ownership structure. In all these cases mezzanine finance can be a practical solution. To improve SMEs’ access to this type of finance, the crucial range of demand is between €100 000 and €1 million, where supply is not sufficient.

Most entrepreneurs require only small amounts of external financing to get started, but accessing small amounts is often difficult. The SME guarantee facility (SMEG) has provided guarantees for microcredit (loans up to €25 000) for financial intermediaries. It is important to find ways on how to strengthen the microcredit schemes in the EU.

Is EU action justified on grounds of subsidiarity?

The Lisbon strategy re-launched in 2005 has placed competitiveness firmly at the centre of political attention. It calls for action to deliver growth and competitiveness and to make Europe a more attractive place to invest and work. When working towards these objectives, the activities proposed are based mainly on Articles 95 (Internal Market), 157 (Competitiveness) and Title XVIII (Innovation and Research) of the Treaty.

Although most of the factors which determine the environment in which firms operate are the responsibility of national, regional and local authorities, the Commission has a complementary role in supporting coherence, addressing certain market failures, ensuring consistency in implementation and establishing a level playing field for SMEs throughout the EU.

B. Objectives of EU initiative

What are the main policy objectives?

The objective of the EU initiative is twofold:

- to set out minimum requirements/common principles for the Member States and the EU in order to release the full potential of SMEs to create jobs, to grow and to contribute to economic and social cohesion in the EU.

to launch major initiatives with the aim to boost SMEs' competitiveness. To this end, it will address the existing market gaps, improve the transparency and flow of information and strengthen the exchange of good practices in the areas which are the most relevant to SMEs, such as access to markets, finance, and better regulation.

Does the objective imply developing EU policy in new areas or of strategic importance?

Yes, it implies developing EU policy in areas of strategic importance.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option of "do nothing option":

The existing policy actions and programmes at Member States and EU level operating under a large umbrella of Modern SME policy would be continued, based essentially on the open method of coordination.

A "legislative" option:

The legislative option would set binding objectives and principles to be implemented by Member States in various policy areas which have an impact on SMEs. A Regulation would be directly applicable in the Member States. A Directive would have the benefit of fixing common targets but leaving the implementation open to the Member States. This option implies a close involvement of the European Parliament and the Member States.

A "non-legislative" option:

The Commission would adopt the Small Business Act as a Commission Communication/Recommendation and invite the Member States and the EU institutions to support the overall strategy, to adopt the key measures proposed and to support their implementation using mainly the open method of coordination.

A "mixed" option

The initiative could consist of a mixture of legally binding principles and specific actions targeted to SMEs in a wide range of policy areas. New policy/legislation would be included.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes.

Do the options respect the proportionality principle?

Yes, the Commission will act only when there is a clear added value identified from its action vis-à-vis to the action by the Member States.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Impact of "do nothing option":

The policy will remain of a series of interrelated policy actions at Member States and EU level operating under a large umbrella of Modern SME policy. Limited impact of the actions taken in terms of review and feedback on performance. Limited visibility of actions. Sometimes lack of coherence.

Impact of “legislative” option:

The legislative option would have the benefit of setting common objectives/obligations to the Member States. This option would increase transparency, consistency in implementation and ensure a better monitoring of Member States’ performance. It would not, however, be possible or even appropriate to apply it systematically in all areas where the desired policy result could be better achieved by soft law measures (awareness-raising, exchange of good practices etc.).

Impact of “non-legislative” option:

With such an option, the Commission would invite the Member States and the EU institutions to support the overall strategy, to adopt the key measures proposed and to support their implementation using the open method of coordination. This solution would add only little value to the recently adopted policy measures and could be perceived as a unnecessary multiplication of Communications on SME policy.

A “mixed” option

The mixture of legally binding and other initiatives would provide a differentiated approach to improving SMEs competitiveness by using both legislative and non-legislative instruments. It could have a strong impact in improving the business environment in areas which are the most problematic for SMEs by setting out legally binding, common principles. These principles would then be completed by targeted, economically and politically significant actions in favour of SMEs.

This option would strengthen an integrated approach to SME policy and increase further the main-streaming of the Think Small First principle in main policies.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

One of the main objectives of the SBA is to further contribute to simplification and the reduction of administrative burden for SMEs and to help them accessing 3rd country markets.

Who is affected?

The Commission and the Member States. End beneficiaries: 23 million SMEs.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A wealth of information is already available (studies, surveys, policy papers, position papers etc.). The remaining information will be gathered internally. Some initiatives to be included in the SBA will have a separate impact assessment

Which stakeholders & experts have been/will be consulted, how and at what stage?

A public hearing to collect feed-back from the main SME stakeholders (Member States, SME organisations, European institutions) will be organised in February 2008. An Internet consultation will be launched to broaden the consultation and to get views from all relevant stakeholder groups including SMEs.

ROADMAP

Title of the initiative: **Review of existing legislation on VAT reduced rates**

Expected date of adoption of the initiative: **July 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

All the rules concerning VAT rates are set in the VAT Directive (Directive 2006/112/EC).

The current situation as regards VAT rates remains highly disparate and very complex. The complexity of the situation is mainly due to the plethora of different temporary derogations granted to individual Member States, but refused to others, outside the general scheme, and the lack of common definitions for the categories eligible for a reduced rate. Moreover, the rationale behind the choice of these categories is difficult to understand for traders. This leads to a complicated rate structure that generates substantial compliance costs for business and tax administrations. Compliance costs are the mirror of non harmonised rules: the more that different rules are applied within the EU the more business has to spend to comply with the regulations in the various Member States. Some companies give up doing business in other Member States for this reason or simply because of fearing the expensive consequences of an erroneous application of rates, even in good faith. The complexity prevents them from having the benefit of a proper internal market.

Given that this situation is not satisfactory, the European Council requested in February 2006 the Commission to present an overall assessment report on the impact of VAT reduced rates in terms of job creation, economic growth and the proper functioning of the internal market, on the basis of a study carried out by an independent economic think-tank.

Consequently, on 5 July 2007, the Commission adopted a Communication from the Commission to the Council and the European Parliament on VAT rates other than standard VAT rates (COM(2007)280) which presents the main results of the study mentioned, material for discussion and explores ways forward. This global evaluation is the first stage of a process which, subsequently will lead to the proposal for the new revision of the VAT rates.

Because of the sensitivity of the subject the Commission has launched a debate in the Council, the European Parliament and with other stakeholders to obtain all relevant views in order to develop a sustainable and well balanced proposal on reduced rates.

Several provisions on VAT rates will come to an end on 31/12/2010: standard rate, temporary derogations on labour-intensive services, temporary derogations granted to some Member States.

A review of existing legislation on VAT rates is thus necessary.

Consistency with the other policies and objectives of the Union

As a follow-up to the political debate in the Council, the European Parliament and with the other stakeholders launched in 2007 by the Commission with its Communication on the reduced rates (COM(2007)380), the proposal at issue aims at a reviewing the future scope and level of VAT rates on the basis of the results of this debate, which among other things, will have to address the usefulness of the reduced VAT rates instrument for the purposes of other policies. In this respect, the Communication also provided for careful consideration to be given to the use of reduced rates of VAT as an instrument of Community policy in other areas (employment; social, educational, or cultural issues; environment, etc.), and it strongly encouraged the Council to organise this debate taking the findings of the study into account.

Other criteria need to be taken into consideration, such as policy coherence (does it make sense to allow for a reduced rate on gas or electricity if we assume that this would generate more energy consumption?) and sustainability and legal certainty for stakeholders (use of reduced rates for the promotion of certain goods depends largely on political priorities that can evolve over time).

The proposal should be fully in line with established EU VAT policy as well as other policies and objectives of the EU, in particular those relating to the Lisbon strategy aiming at growth, more jobs and increased competitiveness of European business; it therefore stresses the need for a true internal market and simplifications.

The Commission aims at bringing consistency in the field of reduced VAT rates. It intends to define a coherent and achievable long term policy and to establish a new framework for reduced rates: which should be more rational, more transparent and simple for business and Member States, and at the same time offer more flexibility for the Member States without hampering the proper functioning of the internal market. The improved definition of the scope of VAT reduced rates will eliminate an uncertainty for businesses and citizens and reduce compliance costs.

What are the main problems identified?

In January 2006, the Council could not reach a unanimous agreement on the Commission proposal of 2003, but confirmed legally a political agreement on VAT rates, imposing on the Commission an obligation to present an overall assessment of the impact of reduced rates by June 2007 – based on a study by an independent economic think tank. Having in mind this compromise and a necessity to achieve a more uniform application of VAT reduced rates in now the enlarged EU-27 in order to improve the functioning of the internal market, the Commission adopted a Communication based on this study as the first stage for its preparation of a global evaluation, subsequently accompanied possibly by the present proposal for the new revision of the scope of reduced rates.

However, there is currently highly political pressure on the Commission to present very quickly a new proposal, in order to review the current scope of reduced rates and respond to political internal debates in some Member States.

Due to the unanimity rule concerning the taxation field, the main problem will be to find a common agreement on the results of the study and on the way forward as regards reduced VAT rates considering the opposed views of the 27 Member States on the use of VAT rates.

Is EU action justified on grounds of subsidiarity?

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community. The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons.

The Community has already laid down provisions on harmonisation of the application of VAT reduced rates, namely in Council Directive 2006/112/EC. These provisions may only be amended or extended by a Community act and the legislations of the Member States cannot deviate from the harmonised rules.

Therefore, only Community action can achieve the objectives of the proposal and ensure equal treatment of Member States in the European Union. The proposal therefore complies with the subsidiarity principle.

B. Objectives of EU initiative

What are the main policy objectives?

As regards reduced VAT rates, a less complicated rate structure would generate substantial savings in compliance costs for business and tax administrations. It could also reduce distortions in the functioning of the internal market. Finally, it is likely to improve "consumer welfare" compared with the current situation. Moreover, the need to establishing a clear logic of the purposes for which a reduced rate should be used should also be addressed. Therefore, the Commission aims at simplification and rationalisation, to reduce the administrative burden on business (increasing competitiveness of businesses) and/or to avoid hampering the proper functioning of the internal market, as well as ensuring equal treatment of all Member States. It thus aims at developing a global coherent approach of VAT rates offering a sustainable and a well balanced solution for the EU as a whole.

On the other hand, a new reduced rates framework should also provide for some flexibility for the Member States to apply reduced rates for specific needs based on rational decisions under the strict condition that the proper functioning of the internal market is not jeopardized. These specific needs should be clearly identified and it should be assessed prior to any proposal that a VAT reduction is an effective and efficient tool to serve the specific objective. It is obvious that a major concern will be to find the right balance between harmonisation and flexibility

In July 2007, on the basis of the results of the independent think tank study on the impact of reduced rates notably in terms of job creation, economic growth and the proper functioning of the internal market, the Commission adopted a Communication on other VAT rates than the standard rate (COM(2007)380) with a view to launch a debate in the Council, the European Parliament and with other stakeholders.

All relevant views collected on this very sensitive issue will serve to initiate a sustainable and well balanced proposal on VAT rates, which will also have to be consistent and coherent with established policy objectives.

The clarification and harmonisation across the Member States of the scope of VAT reduced rates would eliminate uncertainty for businesses and citizens.

Does the objective imply developing EU policy in new areas or of strategic importance? No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

A proposal for a Council directive is the only possible way to change Community provisions on the application of VAT reduced rates currently in force.

The content of the proposal is not easy to predict at this stage. Depending on the outcome of the political debate in the Council, the European Parliament and with other stakeholders, different possibilities might come up: changes in the level of the rates, changes in the scope of the reduced rates, changes in the structure of the reduced rates, suppression or maintenance of the option of applying a reduced rate, limitation or abolition of temporary derogations, etc.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Possible, depending on the option retained after political debate and consultation.

Do the options respect the proportionality principle?

The proposal complies with the proportionality principle for the following reasons:

The Directive allows any Member State to apply reduced VAT rates. It imposes no obligation.

Given the limited scope of the modifications to be envisaged, at this stage the measure is proportionate to the aim pursued. The directive involves no financial cost to the Community. Although reduced rates of VAT may involve a reduction in revenue for States, they place no financial burden on economic operators, and consumers should, in principle, benefit from the continued reduction in rates, in so far as this will be reflected in final prices.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The impact will largely depend on the results of the orientations that will derive from the political debate and consultations to take place.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries? No

Who is affected?

Everybody for different reasons but mainly businesses, taxation administrations and final consumers (see above under point D.)

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The following documents will be part of the impact assessment work:

- The "Study on reduced VAT applied to goods and services in the Member States of the European Union" presented in 2007 by Copenhagen Economics ApS, Nyropsgade 13/1, DK-1602 Copenhagen;
- Communication COM(2007)380;
- Commission staff working document COM(2007)910

Collection of other information and data is not determined at this stage:

- feedback provided by sectors (e. g.: building sector, publishers, restaurants, etc...),
- analysis of sectors' position,
- feedback provided by Member States,

Which stakeholders & experts have been/will be consulted, how and at what stage?

See above

The stakeholders would generally be our usual correspondents: the sectors or their representatives at national or EU level directly concerned by reduced rates, sectors such as, building, restaurants, other local services (hairdressers, ...); publishers (books and press); SME's; producers, retailers and fitters of energy saving materials; etc...

Timetables and consultation tools planned: not defined yet

ROADMAP

Title of the initiative: **Communication on the Future of the Single Market in Pharmaceuticals for Human Use**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The European pharmaceutical industry makes an irreplaceable contribution to Europe's well-being through the availability of medicines, economic growth and employment. The pharmaceutical sector has been and remains a key strategic sector for Europe.

Since 1965, Community action in the field of medicines for human use has always had the dual mission of safeguarding public health while providing an environment that stimulates innovation and supports the competitiveness of the EU industry. Much has been achieved in the last forty years, but more remains to be done and new challenges are emerging.

The Commission is committed to improve the regulatory, non-regulatory and RTD framework for pharmaceuticals. The last Communication on pharmaceuticals and the single market was published in 1998. With new challenges ahead, the Commission intends to address a Communication to the Council of the European Union and to the European Parliament on the future of the EU single market in pharmaceuticals for human use, outlining its vision and strategy for the sector, as well as concrete action items.

What are the main problems identified?

At the beginning of the 21st century Europe is now facing new public health, scientific and economic challenges:

- the globalisation of the sector and the increasing internationalisation of the value chain;
- the smooth functioning of the internal market in a widening Europe; and
- advances in science and technology.

Globalisation brings both challenges and opportunities. The emergence of worldwide health threats, such as the increasing number of counterfeit medicines or pandemic influenza, the internationalisation of the value chain and the rise of new players in the global competition provide compelling grounds to intensify international cooperation. Two objectives must be met: first, to better protect the health of EU citizens; but also, to strengthen the competitiveness of European companies by removing regulatory and non-regulatory barriers which impede access to foreign markets and by ensuring fair international competition.

Today's globalisation also means that, due to structural factors which go beyond the pharmaceutical sector (e.g. labour costs), the centre of gravity for worldwide R&D investment in the field is gradually moving to the United States and Asia. Europe should strive to regain territory it covered for most of the 20th century, when it used to be the home for pharmaceutical innovation.

The smooth functioning of the EU internal market is also a major challenge for the future. On the regulatory side, the implementation and interpretation of Community legislation by Member States still create obstacles to the free movement of medicines. Overburdening requirements also affect competitiveness, especially for small and medium-sized enterprises, without always bringing public health benefits. There is scope for better regulation, e.g. in the area of variations to existing authorisations and possibly also for clinical trials.

On the non-regulatory side, and despite efforts currently carried out under the Pharmaceutical Forum, different national pricing & reimbursement schemes still coexist, leading to market fragmentation, parallel trade, disparities in prices and time-to-market delays. In certain countries, medicines are not even made available due to administrative requirements and poor economic rewards. A lack of transparency and harmonisation with regard to pricing, reimbursement and relative effectiveness remains a challenge.

Recent events such as the 'Vioxx' case or the failed clinical trial in the UK demonstrate that the safety of medicines remains a major EU internal market issue. Recent analysis has demonstrated the existence of multiple and sometimes inefficient requirements as regards pharmacovigilance in the EU. The challenge is thus to strengthen and rationalise drug safety monitoring, while avoiding unnecessary requirements that would impair patients' access to treatments.

The Commission services are also analysing patients' safety aspects of medicines in the distribution chain, including aspects related to parallel trade and to counterfeiting of medicines. In light of the outcome, it will consider appropriate policy action.

Another trend shaping the EU pharmaceutical sector is the increasingly proactive role of patients regarding their health. Patients require better access to quality information. At the same time, information provided currently varies amongst Member States, and media such as the internet may not always provide reliable data. The industry possesses information on their medicines but today this information cannot, for legal reasons, always be made available to patients throughout the EU.

Finally, new technologies, therapies and medicines are emerging. This includes in particular regenerative medicine, more personalised treatments, and the development of nanomedicines. These developments are already affecting the business strategy of EU companies, the industry structure -with the creation of highly innovative small and medium-sized enterprises-, the design of clinical trials and the way medicines are prescribed. These elements have to be gradually translated into the EU pharmaceutical framework of the 21st century.

Is EU action justified on grounds of subsidiarity?

This Communication is intended to outline the Commission's vision, strategy and action plan for the pharmaceutical sector. Action of Member States alone may not be sufficient to address the challenges faced by the sector (e.g. globalization).

B. Objectives of EU initiative

What are the main policy objectives?

This Communication will provide an opportunity to:

- outline the challenges ahead;
- set out a vision for the future of the sector; and
- propose deliverables for the Commission and Member States over the next few years.

The main theme of this Communication will be on building-up a genuine and sustainable single market that benefits both patients and industry. Three pillars underpin this theme: enhancing public health, stimulating innovation, and strengthening the competitiveness of the European-based pharmaceutical industry. The Communication will not cover the veterinary sector.

Does the objective imply developing EU policy in new areas or of strategic importance? No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The Communication will refer to a variety of regulatory and non-regulatory instruments designed to address the main strategic challenges faced by the pharmaceutical sector in the future, in terms of public health, innovation and competitiveness. In each case (i.e. for each challenge), the various policy options will be considered.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The action has an interface with other policy areas, in particular the 7th Framework programme for research and technological development (DG RTD), work in the field of public health by DG SANCO, and work on internal market and international barriers to trade by DG MARKT and DG TRADE, respectively.

Do the options respect the proportionality principle?

The proportionality principle is not applicable to the Communication itself, but rather to the policy initiatives which will be outlined in the Communication. For each of these initiatives, compliance with the principle of proportionality will be ensured.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The Communication is designed to give only a broad overview of the challenges, vision and policies envisaged. All the concrete policies and initiatives outlined in this Communication will, individually, be the subject of an impact assessment in accordance with the European Commission Impact Assessment Guidelines. The Communication itself will be subject to a proportionate impact assessment assessing the overall impact in a qualitative way.

Actions will be analysed, taking into consideration alternative policy options, in particular those concerning:

- social impacts (consequences for patients, health professionals, health systems and public health);
- economic impacts (consequences of for industry, health systems and regulatory systems);
- environmental impacts, if identified

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The Communication should not have an impact on the EU budget. However, the budgetary impact of each policy action outlined in the Communication will be analysed individually.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Several policy proposals outlined in the Communication will have a significant impact on simplification/administrative burden as well as on relations with third countries. In particular, simplification of the regulatory framework and reduction of the administrative burden is one of the key objectives of the Commission to ensure a smooth functioning of the internal market in pharmaceuticals for human use.

Who is affected?

- EU citizens/patients
- European Institutions
- Regulators: European and national medicines agencies
- Industry: innovative, generic, biotechnologies, Small and Medium-sized Enterprises etc.
- Health care professionals: physicians, pharmacists, nurses etc.
- The research community: universities, hospitals, academia etc.
- Other health-related stakeholders, e.g. healthcare insurance providers

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The Communication itself will be subject to a proportionate impact assessment assessing the overall impact in a qualitative way.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Key European stakeholders have been individually informed of the initiative in March 2007 and invited to contribute.

Moreover, a public consultation on the future of pharmaceuticals for human use in the Community has been launched on 19 July 2007¹⁶. The public consultation is running until 12 October 2007. This consultation will ensure that all concerned stakeholders, in particular Small and Medium-sized Enterprises can make their views known on this key issue. The public debate will comply with European Commission standards as regards public consultation.

¹⁶ <http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm#j07>

ROADMAP

Title of the initiative: **Directive on Pharmaceuticals - Information to patients**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Since 1992 the Community legislation clearly differentiates between advertisement and information on medicines. While EU rules banned advertisement on medicines subject to prescription to the public and allowed advertising for other medicines under certain conditions, information provisions did not lead to harmonisation amongst the Member States.

Several Commission initiatives and repeated public debates focused on the need to address this lack of a Community framework on information to patients in order to respond better to the needs of patients, in the overall interest of health. However, the legal situation has not changed fundamentally over the last 15 years.

In 2002 a High Level Group on Innovation and the Provision of Medicines (G-10), the first major initiative of the European Commission addressing information to patients, invited in its report the European Institutions, in co-operation with stakeholders, to produce a workable distinction between advertising and information that would allow patients actively seeking information to be able to do so, and to develop standards to ensure the quality of such information.

In response to the Report, in July 2003 the Commission issued the Communication “A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient- A call for Action” in which it outlined practical proposals for the implementation of the G10 recommendations. Further to the Commission Communication, the Council of the European Union adopted a Resolution on “Pharmaceuticals and public Health challenges-focusing on the patients” in which it invited the Commission to explore together with Member States the possibility of setting up a European Information System for patients and health professionals, with the objective to provide information on medicines and related conditions that is of high quality, objective, transparent, comprehensive, reliable and up-to-date.

In line with its political commitments, the Commission had made a number of proposals in the context of the review of the pharmaceutical legislation launched in 2001, to improve the quality and availability of information to patients, health professionals and the public in general. Some of these proposals are now part of the current legislation, and as such are implementing part of the G10 recommendations in the area of information to patients. These new provisions addressed mainly product related information, by improving its access and readability and transparency measures.

However, more far reaching mechanisms to improve and harmonize the access of patients to information have been rejected in the legislative process with reference to the bureaucratic burden caused by enforcement mechanisms and the lack of a clear distinction between advertisement and information. Instead, an article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, calls upon the Commission to present a report to the European Parliament and the Council in 2007 on “current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients”. Article 88a also provides that “the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability”.

As a response to the evolution of society and in view of the three most crucial issues outstanding from the G10 Medicines process (Information to Patients, Relative Effectiveness and Pricing/Reimbursement), the European Commission created in June 2005 the Pharmaceutical Forum . Three technical working groups, supported by a Steering Committee, have been established for each of these subjects. The objective of the Information to Patients Working Group is to develop proposals for improving the quality and accessibility of information to patients on medicines and health issues.

What are the main problems identified?

Recently, patients have become more empowered and proactive regarding the treatment of their illnesses.

Information needs of patients as regards medicinal products range from information on adverse effects to information about efficacy of the medicine to treat the disease concerned, including also information about the costs and duration of treatments.

As a result of a lack of clear separation between information provision on medicinal products and advertising, at present there are different approaches at Member States' level concerning practices on the provision of information on medicines to patients, particularly on prescription-only medicines by the pharmaceutical industry (including statutory information). Some Member States allow direct provision of information to the public by industry, while others apply very restrictive rules. This comprises information approved by regulatory authorities.

Some Member States foresee a quite extensive role of public authorities, namely medicines regulatory agencies, in the provision of various kinds of information, while other Member states allow information activities performed under partnerships of public and private organisations, including health professionals' associations, patients' organisations and the pharmaceutical industry. This results in unequal access of patients, and the public at large, to information on medicinal products.

At the same time the quality of information is currently very variable, in particular in view of the increasing role of internet, which is becoming a central information channel for those who are seeking information and where the providers have no or limited accountability toward EU citizens. On the other hand patients may also still have difficulties in finding valid information on medicines authorised in the EU by national authorities.

Is EU action justified on grounds of subsidiarity?

Considering existing EU legislation, functioning of the single market and the increasing share of centrally authorised medicinal products, the objectives of this legal proposal cannot be achieved by an action of Member States alone and can be better achieved at Community level. Given that this will make it possible to take advantage of the widest possible market and avoid the dispersion of limited resources, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty.

B. Objectives of EU initiative

What are the main policy objectives?

In order to put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and address the question of the information source's liability, following general policy objectives are pursued:

- I. Establishing a framework for providing citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines.
- II. Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information.
- III. Maintaining the confidence of citizens, regulators and healthcare professionals, while putting the interests of patients first.
- IV. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- No EU action (focus on implementation of current legislation)

As the current provisions regulating provision of information to patients are set out in the Directive 2001/83/EC, following policy options require amendments to the current legislation:

- Ex-ante validation of information (which could provide a system for national authorities to assess and validate information to patients on diseases and treatment options information prior to its provision to the general public)

Regulatory body could be either:

- Regulatory authority (regulation)
- Specific body with private parties (co-regulation)

Ex-post validation of information with 3 sub-options

- “Tell and do” (competent regulatory body is notified by the information provider in advance and has an opportunity to act prior to provision of information to the general public).

Regulatory body could be either:

- Solely regulators (regulation)
- Stakeholders + Experts nominated by regulators (co-regulation)
- Stakeholders without any involvement of regulators (self-regulation)

- “Do and tell” (the information provider continuously notifies the competent regulatory body)

Regulatory body could be either:

- Specific body with private parties (co-regulation)
- Self regulatory body (self-regulation)

- “Do” (ad hoc screening based e.g. on complains)
 - Self-regulation according to an agreed code of practice.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The action has an interface with Information to Patients Working Group of the Pharmaceutical Forum. Moreover there has been identified a link to the 7th Framework programme for research and technological development, DG INFSO e-Health project and the DG SANCO led Patient safety initiative.

Do the options respect the proportionality principle?

In accordance with the principle of proportionality, as set out in Article 5 of the Treaty, this proposal does not go beyond what is necessary in order to achieve the objective of the proposal.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Draft report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products identifies considerable weaknesses of the current status (see above). The option of ‘no EU action’ would presumably lead to the persistence of the system weaknesses described above.

The impacts of the above proposed policy options will be analysed, taking into consideration all proposed policy options, in particular those concerning:

- Social / health impacts:
 - consequences for patients, health professionals, health systems and public health:
 - consequences of new regulatory provisions or strategies based on policy options for patient protection and safety, particularly their timely access to high quality information;
 - consequences of new regulatory provisions or strategies based on policy options for medical care, particularly relationship between patients and health care providers.
- economic impacts:

- consequences of for industry, health systems and regulatory systems:
 - costs and/or cost savings for industry in general and for small and medium size enterprises (SMEs) in particular, to implement new regulatory provisions
 - balance of costs for implementing measures versus benefits for industry in general, and for SMEs in particular,
 - costs and/or cost savings for regulators to implement new regulatory provisions
 - costs and/or cost savings for health care systems
- environmental impacts, if identified

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

There is no impact on the EU budget envisaged.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Co-regulatory and self-regulatory mechanisms should be line with Commission Better Regulation initiative. The issue of “Consumer access to information about legal pharmaceuticals” has been also included in the agenda of Transatlantic Economic Council.

Who is affected?

- EU citizens/patients
- Regulators: European and national medicines agencies
- Industry: innovative, generic, biotechnologies, SME
- Health care professionals: physicians, pharmacists, nurses etc.
- Other health-related stakeholders, e.g. healthcare insurance providers
- Media

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Draft report on current practice with regard to the Provision of Information to Patients on Medicinal Products and relevant bibliographic references, taking into account adaptations arising from internal and external consultations.

The Pharmaceutical Forum’s Working Group on Information to Patients had developed an example of the information pack for a specific disease (diabetes) which was subject to a public consultation. Information on good practices in various health care settings (primarily hospitals and pharmacies) had also been compiled. This had been supplemented by a set of draft quality principles.

A Commission Communication on the final Report on current practice with regard to the Provision of Information to Patients on Medicinal Products will be transmitted to the European Parliament and the Council on which comments are expected.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The impact assessment plan foresees an extensive consultation process, involving the broad range of stakeholders with an interest in the area of provision of information to patients. This includes members of the Pharmaceutical Forum’s Working Group on Information to Patients and of the Patients' Working Group of the European Medicines Agency, which are being regularly updated on the progress of the initiative and their views have been sought.

Collection of data and additional expertise, which is an indispensable component of the impact analysis, runs throughout the whole impact assessment process, including several rounds of questionnaire surveys and interviews with stakeholder representatives.

The first formal public consultation was conducted between April and June 2007 on a Draft report on current practices with regard to the provision of information to patients on medicinal products, summarising the current state of play without presenting yet any political orientations or proposals.

Within this consultation DG ENTR received 73 contributions from the following stakeholders:

- Patients organisations - 14
- Consumer and citizen organisations - 4;
- Pharmaceutical industry organisations and companies - 18;
- Healthcare professionals organisations - 16;
- Regulators - 9;
- Individual citizens - 3;
- National and EU social insurance organisations - 2;
- Media and others - 7.

The next public consultation on the draft legislative proposal is foreseen for the 1st half of 2008, where all stakeholders will be approached.

ROADMAP

Title of the initiative: **A Regulation amending Regulation (EC) 726/2004 and a Directive amending Directive 2001/83/EC on Modernising Pharmacovigilance for Pharmaceuticals**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Pharmacovigilance is the process of monitoring the safety of medicines and taking action to reduce risks to the public. Within the EU is governed by a Directive of the European Parliament and the Council which lays down the rules for manufacture, distribution, authorisation and post-authorisation supervision of nationally authorised products (Directive 2001/83/EC as amended), in a corresponding Regulation of the European Parliament and the Council for centrally authorised products (Regulation (EC) No 726/2004), in a Commission Regulation (Regulation (EC) No 540/95) and in Commission guidance (Volume 9A of Eudralex).

Although the pharmaceutical legislation was reviewed in 2004 (the so-called "2001 Review") the changes to the pharmacovigilance provisions were relatively minor. Importantly there was no thorough review of the pharmacovigilance provisions and as a result the current provisions have become gradually more complex over time and do not reflect the evolution in science and technology that has occurred, including the opportunities for rationalisation offered by the full use of modern information technology.

What are the main problems identified?

While recognising that medicines can save lives and relieve suffering, it should also be recognised that adverse reactions to medicines are the 5th most common cause of death in hospital and there is abundant evidence of the massive public health burden that adverse drug reactions cause. Scientific literature suggests that the frequency of adverse reactions to medicines varied from 5% to 10% of all treated patients and leads to hospitalisation in about 1% of patients. Pouyenne et al. estimated using national statistics that each year in France 134,159 hospital admissions were caused by adverse drug reactions resulting in 1,285,256 days spent in hospital.

Different implementation of current legal provisions by Member States has led to complex and diverse reporting requirements for the industry and this clearly interferes with the functioning of the single market for medicinal products. As a consequence, both industry and regulator resources are diverted away from public health protection to meeting duplicative administrative requirements. Furthermore, slow EU decision making and action in response to drug safety alerts means that patient safety is not best protected.

Due to unclear legal provisions on referrals, when a Member State considers an important safety issue relating to a nationally authorised product, the Community referral procedures are rarely used. Instead the existing 'Pharmacovigilance Working Party' of the Committee for Medicinal Products for Human Use informally discusses important safety issues, but its conclusions are rarely implemented and certainly not implemented comprehensively and consistently across all Member States (as they are not legally binding on the Member States or companies). This leads to divergent safety action by the Member States which represents a weakness of public health protection. Failure for effective EU action on important EU safety issues leads to a failure of confidence of citizens in the safety of medicines and this also has a negative impact on investor confidence. In addition, communications about drug safety are usually not coordinated at EU level leading to contradictory messages when patients access media from different Member States.

Risk Management Plans, which are requested in order to ensure prospective safety evaluation of products, are frequently not agreed or when agreed the industry may not comply with them.

Currently in EU legislation there are no guiding principles and there is no oversight in legislation of non-interventional safety studies and divergent national measures (including legislation in some Member States) make the conduct of these studies difficult. Studies are often of poor quality and are frequently promotional.

The current organisation of product information (SPC and Patient Information Leaflet) makes it difficult for patient to identify the most important safety warnings: this results in key safety measures / warnings being missed. Patients some Member States are not allowed to report directly the side effects they experience to their medicines but not in others.

In summary, based on an independent study, a public consultation, and analysis by Commission services, it is

clear that the current EU system of pharmacovigilance places significant administrative burdens on industry and competent authorities while weaknesses in the system continue. The EU legal framework is complex and duplicative and there is a lack of clear roles and responsibilities. It is in the interest of public health to ensure that important safety issues are rapidly and robustly dealt with across the EU.

Is EU action justified on grounds of subsidiarity?

Considering existing EU legislation, functioning of the single market and the increasing share of centrally authorised medicinal products, action of Member States alone could not be sufficient to bring full harmonisation of Pharmacovigilance rules between Member States and the objectives of this legal proposal can only be fully achieved at the Community level.

Furthermore a common EU approach allows sharing of best practices and aggregation of nationally collected safety data and thus enhances sensitivity of safety risk detection. Given that this will make it possible to take advantage of the widest possible market and avoid the dispersion of limited resources, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty.

B. Objectives of EU initiative

What are the main policy objectives?

The overall objective of the Community pharmaceutical legislation is to remove disparities between national provisions to ensure proper functioning of the internal market for medicinal products, while at the same time safeguarding a high level of public health protection.

Both the independent assessment and the public consultation suggest that there is an opportunity to better protect health of the EU citizens by strengthening and rationalising the EU Pharmacovigilance system. Resources of both industry and regulators should be diverted away from meeting duplicative administrative requirements to public health protection.

Rationalising the system would both strengthen it (resources reallocated to useful tasks) and would help to complete the single market in medicinal products. Rationalised EU decision-making on drug safety issues should deliver fast, robust decisions that are equally and fully implemented for all relevant products and across all markets and prevent unnecessary patient exposure to serious risks.

Robust post-authorisation safety monitoring should allow authorisation of medicines earlier in their development and this would be of crucial benefit to patients with unmet medical needs by stimulating innovation and increasing investor confidence.

Does the objective imply developing EU policy in new areas or of strategic importance? No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- No EU action
- Improved implementation of the current framework by non-legislative measures, which can include but not be limited to:
 - working with the Commission's Directorate General for Research on funding of studies into the safety of medicines as well as studies into the methodologies used to conduct pharmacovigilance.
 - Working with the Member States to identify and resolve implementation issues, including and administrative practices that interfere with the single market.
 - Working with the EMEA to strengthen its coordinating role including supporting full compliance and maximum utilisation of the EU pharmacovigilance database 'Eudravigilance'.

- Simplification and modernisation of the legal framework with a focus on:
 - Maintaining the current split of competences between the Member States and the EMEA, while making clear the respective roles and responsibilities and minimising duplication of effort.
 - Strengthening the rules on transparency relating to pharmacovigilance data, assessment and decision-making and involve stakeholders (e.g. patient and healthcare professional groups) in the processes including reporting (including patient reporting).
 - Establishing clear standards ('Good Vigilance Practices - GVP') for the conduct of pharmacovigilance by both the industry and regulators.
 - Freeing up resource by rationalising and simplifying the reporting of suspected adverse drug reactions (ADRs), both expedited and periodic reporting, making best use of current information technology (including Eudravigilance) and matching the reporting requirements with the level of knowledge about the safety of a specific product.
 - Stimulating innovation by establishing a clear legal requirement to conduct post-authorisation safety studies including those in risk management systems.
 - Rationalising EU decision-making on drug safety issues to deliver fast, robust decisions that are equally and fully implemented for all relevant products and across all markets.
- Holistic approach integrating both better implementation of the current system at the Community level and proposals to change the legal framework for pharmacovigilance in the EU.
 -

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The action has an interface with the 7th Framework programme for research and technological development and the DG SANCO led Patient safety initiative.

Do the options respect the proportionality principle?

In accordance with the principle of proportionality, as set out in Article 5 of the Treaty, this proposal does not go beyond what is necessary in order to achieve the objective of strengthening and rationalizing pharmacovigilance.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The impacts of all proposed actions are analysed, taking into consideration proposed policy options, in particular those concerning:

- social impacts:
 - consequences for patients, health professionals, health systems and public health:
 - consequences of new regulatory provisions or strategies based on policy options for patient protection and safety;
 - consequences of new regulatory provisions or strategies based on policy options for medical care.
- economic impacts:
 - consequences of for industry, health systems and regulatory systems:
 - costs and/or cost savings for industry in general and for small and medium size enterprises (SMEs) in particular, to implement new regulatory provisions;
 - balance of costs for implementing measures versus benefits for industry in general, and for SMEs in particular;
 - costs and/or cost savings for regulators to implement new regulatory provisions;

- costs and/or cost savings for health care systems
- environmental impacts, if identified

Problem analysis shows that the current EU system of medicines safety monitoring needs rationalisation and strengthening. The option of ‘no EU action’ would thus be detrimental to the safety and well-being of EU patients due to the persistence of the system weaknesses described above.

While recognising that medicines can save lives and relieve suffering, it should also be recognised that adverse reactions to medicines are the 5th most common cause of death in hospital and there is abundant evidence of the massive public health burden that adverse drug reactions cause.

By making clear the roles and responsibilities for pharmacovigilance, by simplifying reporting rules and by ensuring that robust safety studies are performed to support rapid EU decision-making, the reformed EU Pharmacovigilance system would better protect public health and support the safe use of new and innovative medicines.

Empowering patients to report their side effects and clearer safety warnings in product information will increase their confidence in safety monitoring and the safety of medicines in general. Resources freed up by eliminating of unnecessary administrative burden for both industry and regulators can be consequently reinvested into efforts more closely linked to health protection and promotion.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No impact greater than 5 Mio € on the EU budget is envisaged.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Proposed actions are in line with ongoing bilateral and multilateral harmonisation forums (e.g. International Conference on Harmonisation, Transatlantic dialogue) with third countries aiming on simplification of administrative practices and minimisation of the unnecessary administrative burdens.

Who is affected?

- EU citizens/patients
- Regulators: European and national medicines agencies
- Industry: innovative, generic, biotechnologies, SME
- Health care professionals: physicians, pharmacists, nurses etc.
- The research community: universities, academia etc.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Currently available data sources:

- Independent “Fraunhofer” study “Assessment of the Community System of Human Pharmacovigilance”
- Responses collected within Public consultation (regulators, industry, academia, others)
- Survey of Industry Resources in Pharmacovigilance

- Information on industry litigation costs and insurance liability
- Structured literature search

Within the inter-service steering group several additional data sources were suggested, which will be taken into account:

- The “Pharmaceutical Group of the European Union” booklet - Patient Safety - maximising patient safety in Europe through the safe use of medicines
- The Council of Europe's recent report on medication safety
- Eurobarometer study on medical errors
- Draft recommendation on Patient Safety
- Medication safety report

Which stakeholders & experts have been/will be consulted, how and at what stage?

A public consultation on the Pharmacovigilance system assessment has already been carried out (from 16 March to 12 May 2006). The Commission consultation received 48 contributions, in summary:

- 7 responses from patient, consumer and victim groups;
- 10 from healthcare professional groups of which 4 represented doctors, 3 pharmacists and one nurses;
- 16 from industry including all the relevant European Industry Associations;
- 10 from regulators including the European Medicines Agency Committees and individual medicines agencies;
- 5 others, including the World Health Organisation Uppsala Monitoring Centre and the International Society for Pharmacoepidemiology.

In addition two workshops were held to facilitate the public consultation at the Commission offices in Brussels in April 2006. On 20 April 2006 a workshop was held with healthcare professional and patient groups and the meeting was also attended by a representative of a thalidomide victim association. On 21 April 2006 a workshop was held with industry groups. Further public consultation is anticipated on draft legal proposals in 2007.

ROADMAP

Title of the initiative: Follow-up to the Commission on "Modernising social protection for greater social justice and economic cohesion: taking forward the active inclusion of people furthest from the labour market" - Recommendation on Active Inclusion

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Context: At the start of 2008, political attention within the EU will be driven by the lessons drawn by the Commission from the Social Reality Stocktaking exercise. The active inclusion initiative which constitutes the final stage of a process initiated in 2006 (art. 138 based consultation), which will form an integral part of the Commission's response, aims to promote the integration of those most excluded from the labour market.

History: In 2006 the Commission launched a public consultation (including a consultation of social partners on the basis of Article 138) on the active inclusion of people furthest from the labour market, based on three pillars: a link to the labour market through job opportunities or vocational training, income support at a level that is sufficient for people to have a dignified life and better access to quality services. Based on the results of the first stage consultation, the Commission will adopt a follow-up Communication (including the second-stage of social partners) in October 2007.

Response: The key policy instrument defined in the 2nd phase consultation on active inclusion will consist in deepening the Open Method of Coordination in this area through the adoption of common principles in all three strands of the active inclusion approach (income support, inclusive labour markets and access to quality services) and their subsequent monitoring and evaluation through the OMC. In order to promote the identification and adoption of the common principles and to detail the elements of the active inclusion strategy, the Commission intends to issue a Commission Recommendation, which would constitute the basis for Council conclusions and a European Parliament resolution. This recommendation is linked to the Communication on deepening the OMC planned in 2008 and, because of the relevance of access to quality services, to the Communication on Social Services of General Interest, to be adopted in November 2007.

What are the main problems identified?

Despite being one of the richest regions in the world, the EU and its Member States are still far away from the objective set by the Council at the launch of the Lisbon strategy to take a decisive impact on the eradication of poverty by 2010. The extent of multiple disadvantage and deprivation still present in Europe is widely perceived as socially, morally and economically unsustainable.

Finally, concern with the effectiveness of MI schemes have been raised, as a significant share of those targeted by such schemes may not actually benefit from them, social assistance schemes may be poorly targeted or benefit levels insufficient.

Is EU action justified on grounds of subsidiarity?

The purpose of common principles on active inclusion to be monitored within the framework of the Open Method of Coordination is not to set homogeneous targets at EU level for social assistance levels. The objective is to develop an ambitious and effective process to identify the best policy responses to the important common social challenges that the EU faces, taking into consideration the diversity between Member States and respecting the principle of subsidiarity at local, regional and national level.

The Recommendation will acknowledge the autonomy of Member States in these areas, but also the need for more effective action at EU level and more visibility for common social objectives. At the same time, the flexibility of the open method of coordination will ensure that the specific ways to implement the common principles will be tailored to the needs of each Member State.

B. Objectives of EU initiative

What are the main policy objectives?

Following from the highly symbolic 1992 Recommendation on sufficient resources and social assistance and linked to the Lisbon strategy, the Recommendation will propose basic social principles (right to live in dignity; access to work; access to basic services). A Commission Recommendation could constitute the basis for Council conclusions and a European Parliament resolution in order to detail common principles to reinforce the social OMC in this area. This process will provide guidance to Member States while respecting the subsidiarity principles.

Although most Member States (all of them except IT, EL and HU) have national minimum income schemes, more needs to be done for the full implementation of the 1992 recommendation, in particular in clarifying the criteria and statistical tools that can be used as a benchmark to define an adequate and effective level for the minimum income schemes.

The problem of adequacy was identified also in the Joint Report on Social Protection and Social Inclusion 2006, which stated that "Minimum social assistance levels are already, in most Member States, below the at-risk-of-poverty line and, from a social inclusion perspective, the scope for attaching conditions to them needs to be carefully monitored. The growing emphasis on benefit conditionality is not, to date, accompanied by systematic monitoring of its impact on the most marginalised groups"

Many people fail to gain employment or benefit from minimum income protection. The poverty and social exclusion indicators agreed in the OMC framework show that 16% of Europe's population is at risk of financial poverty, one in five lives in sub-standard housing, 10% live in households where nobody works, long-term unemployment approaches 4% and the proportion of early school leavers is over 15%. All this suggests that additional efforts are needed to improve the effectiveness of existing schemes.

Although the 1992 Recommendation has positively influenced the development of national minimum income schemes, more needs to be done in terms of coverage, adequacy and effectiveness. Besides the need to better address the issues of non take-up and poor targeting, there is a clear need for a more integrated approach dealing with multiple disadvantages and including a link to the labour market and better access to quality services.

Does the objective imply developing EU policy in new areas or of strategic importance?

Not at this stage.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The proposal of deepening the OMC in this area through the adoption of common principles provides an effective and proportionate response to the requests and the concerns expressed in the first stage of the consultation. In fact, relying on existing forms of cooperation (essentially the "no action" scenario) and proposing a directive (to define adequate levels of MI, the range of services which should be provided and the standards of active labour market policies) have been excluded on the basis of the first consultation. Respondents confirmed the need for further action at EU level but the vast majority of them did not support a prescriptive legislative instrument, at least at this stage, given the diversity of situations within the EU and the national competencies in this area.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The active inclusion initiative, in the framework of the Lisbon strategy, is complementary to the flexicurity approach by envisaging an active welfare state that enables individuals and families to help themselves and that provides effective support for those who are not in a position to do so.

Do the options respect the proportionality principle?

Yes: the common principles outlined in the Recommendation to be monitored and evaluated in the framework of the OMC are a flexible instrument based on a very close cooperation between the Commission and Member States.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The establishment of common principles will improve mutual learning and help spread best practices. The non-prescriptive nature of the measure proposed implies that Member States will continue to design policies in this area within their capacity and financial constraints. The Commission will provide guidance on methodology to identify trade offs and assess the budgetary impacts and the effectiveness in terms of poverty reduction and minimisation of work disincentives.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Not at this stage.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No.

Who is affected?

The final beneficiaries of enhanced efforts at EU level will be the EU citizens and disadvantaged people.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The social situation in the EU as a whole and in individual Member States, as well as their respective challenges and actions, are subject to regular assessment on the basis of common European indicators, Member States National Strategic Reports, reports from the network of independent experts established within the peer review process and transnational projects and studies financed within the Social Exclusion Programme. In particular, the final results of the *Impact assessment of EU basic requirements on measures to promote the integration of persons excluded from the labour market - VT/2006/003* – will be available in November 2007.

The 1992 Recommendation was followed by a report from the Commission in 1999 [COM(1998)774 of 25 January 1999] as requested by the Recommendation. The 1999 report concluded that the 1992 recommendations (92/441/EEC and 92/442/EEC) had helped to structure and encourage the debate between Member States on the role and development of MI schemes, fostered the convergence of such schemes across Member States and provided a basis for bringing about more systematic EU cooperation efforts in fighting social exclusion and poverty. The 1999 report was also intended to offer "material with which to develop the debate and prepare the ground for implementing the new article 118 of the future Treaty (article 137 of the consolidated version)".

Which stakeholders & experts have been/will be consulted, how and at what stage?

Apart from the studies mentioned above and the art. 138 consultation which, apart from social partners, is extended to all stakeholders, including public authorities at all levels and civil society organisations (first stage spring 2006, second stage Oct. 2007-Feb. 2008), this dossier was also discussed at the Fifth European Round Table on Poverty and Social Exclusion in October 2006, at the 6th Conference of people experiencing poverty in may 2007 and at a specific stakeholders' conference in June 2007. It will also be the main cross-cutting theme of the 6th European Roundtable on Poverty in October 2007.

ROADMAP

Title of the initiative: **Legal Framework for Construction and Operation of Pan-European Research Infrastructures**

Expected date of adoption by the Commission of the initiative: **July 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Research infrastructures play a critical role in the creation and exploitation of knowledge, providing the sophisticated and technologically advanced facilities European researchers need in order to carry out cutting-edge research in many areas of science. However, science and technology are not static, and there is a continuing need to update existing infrastructures and build new ones if Europe is to remain at the leading edge of advances in knowledge.

Supporting this process of renewal of infrastructures will be a valuable contribution to the revised Lisbon strategy. By keeping Europe at the forefront of scientific progress, while helping industry to strengthen its knowledge base and technological know-how, they will contribute to growth and employment. At the same time, the provision of world class infrastructures will help Europe to counter the loss of highly qualified staff to institutions abroad and to attract high level researchers from outside the EU. Research infrastructures also have a key role to play in tackling the challenges of climate change (for example through enabling better forecasting and monitoring technologies) and in developing sustainable and secure energy supplies.

While infrastructures are vital, they are typically very costly to construct and to maintain. At the same time, national public budgets are under increasing pressure. The only efficient approach is through pan-European cooperation aimed at integrating existing facilities, coordinating the construction of new facilities, and ensuring an optimum use of these scarce and expensive assets. Through pooling and sharing resources in this way, coordinated actions for infrastructures help to achieve more and better research results, and are one of the most effective and concrete initiatives for achieving the European Research Area. The Community has a long and successful track record of supporting integration in this area through infrastructure measures in successive RTD Framework Programmes.

The Research Infrastructure issue is today at the top of the political agenda. In 2004 the European Strategy Forum on Research Infrastructures (ESFRI) - comprising high-level representatives appointed by the Research Ministers – was mandated by the Competitiveness Council to produce a strategic ‘European roadmap on research infrastructures’ for the next two decades. The hard work done by ESFRI and the Commission was recognised by the May Competitiveness Council and in particular at the Hamburg conference in June 2007, organised under the German Presidency. The next presidencies, Slovenia and France, will also host specific conferences on this subject. The Czech presidency has already announced its intention to put Research Infrastructures at the top of the political agenda early in 2009.

In 2008 a first update of the ‘European roadmap on research infrastructures’ will be presented. Within the next ten years more than 40 new research infrastructures are foreseen to emerge.

What are the main problems identified?

The challenge now is for Europe to try and move forward in establishing the infrastructures it needs for the future, and the roadmap provides a solid foundation for planning the next steps. But the process of setting up new pan-European infrastructures is very complex and time-consuming. One of the key problems, it is widely agreed, is the choice of legal form for the new entities.

The creation of new pan-European research infrastructures with several partners from different countries typically involves long and complex negotiations concerning the appropriate legal form for the new establishment. The choice of legal form has long term implications for the running of the facility, notably on management, charging policy, financial issues, human resources, access arrangements and intellectual property rights. Currently, there are two options: using a national legal base, or negotiating international agreements case by case.

Recent work carried out under the auspices of the ESFRI, has shown that in most cases the legal bases - whether national, or case by case international agreements - have proven inadequate in meeting the needs of these new pan-European research infrastructures. On the one hand, the setting-up of intergovernmental entities sometimes takes many years before agreement can be reached and implies a specific staff management. This is one of the reasons why no new intergovernmental facility has been created in the last twenty years. On the other hand, national entities may be easier to be put in place, but the national context and liability problems often hinder the creation of international partnerships.

The development of a new easy-to-use legal framework adapted to pan-European infrastructures could be a crucial step. It should be designed so as to streamline and simplify the complex process of setting up such facilities, thus saving time and money, while speeding the emergence of the many new research infrastructures Europe needs in the coming years.

Is EU action justified on grounds of subsidiarity?

There is widespread agreement that the EU has an important role to play in developing a solution to these problems.

The EU is best placed to draw up and decide upon a European legal base for infrastructures. It would clearly be impossible for the Member States to do so on their own, and working via inter-governmental agreements would be hugely difficult. Moreover, the Treaty already provides a possible basis for such a legal framework in article 171, and it is therefore normal for the EU to play a coordinating role in using the article to this effect.

It should be added that the EU has long experience of coordinating European-level initiatives in this area, and of implementing infrastructure support measures in successive Framework Programmes.

B. Objectives of EU initiative

What are the main policy objectives?

To contribute to the successful implementation of the revised Lisbon strategy and the achievement of related key objectives concerning growth, competitiveness and jobs, sustainable development, and the realisation of the knowledge society;

To contribute to the achievement and attractiveness of the European Research Area (ERA) (Europe as a world partner);

To reinforce ERA through a new and effective legal framework, thus enabling it to respond to the needs of the European research community to strengthen its research capacities;

To facilitate (speed, cost, needed resources) the developing and establishing of new Research Infrastructures of pan-European interest and necessary for the efficient execution of Community programmes;

To indirectly help Europe to strengthen its base of knowledge and its technological know how.

To streamline and simplify the complex process of setting up new pan-European research infrastructures

Does the objective imply developing EU policy in new areas of strategic importance? **NO**

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- **Business-as-usual:** Under this option, stakeholders are limited to already existing national and intergovernmental legal bases to implement the pan-European infrastructure projects on the ESFRI roadmap. In addition, they have the option to use on a case by case basis legal entities of pan-European character using any legal existing framework (national, intergovernmental or article 171 of the Treaty)

- European initiative: Creation of a European legal framework for Pan-European research infrastructures giving improved possibilities for carrying out efficient Community research action. The framework regulation to be approved by the legislator based on Article 171 EC (at qualified majority) would set out the main characteristics of the Pan-European research infrastructures, as well as the rules and procedures governing their establishment, necessary for the efficient execution of Community programmes.
- This would speed up the emergence of the many new research infrastructures needed in the next years. The framework regulation would allow treating current issues related with Community research such as liability, taxation of staffing issues; it could also highlight the catalysing role of the European Commission in the setting-up of new legal entities at European level. Complementing national or inter-governmental schemes, the EC regulation would provide a common and easy-to-use legal frame, leaving a high amount of flexibility to the individual consortia to set up the adequate rules for the specific infrastructure at European level.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

YES. It will produce legislation that can be applied in any policy area concerned with research or technological development.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option, even if these impacts would materialise only after subsequent Commission initiatives?

1. No additional initiative: Already existing national and intergovernmental legal bases have proven to be effective in the past. But as the Union has become larger (and the number of stakeholders has increased), and research infrastructures have become more complex, the limitations of these legal tools have become clear. They are just too cumbersome: it takes an excessive amount of time to set up an inter-governmental body; nationally run infrastructures are characterised by problems concerning governance, liability and staffing; etc. That means that under this option, the objectives of the Research Infrastructures part of the Capacities specific programme, and thus FP7, will not be fully achieved. New research infrastructures will not be available to European researchers in a timely manner, impeding scientific progress, hampering researcher mobility, decreasing the attractiveness to youngsters of pursuing a research career, reducing training opportunities, weakening Europe's international attractiveness as a place to carry out research, etc. Indirectly, Europe, its Member States and their regions may not obtain the foreseen economic and social/societal impacts linked with the timely establishment of new research facilities in Europe.
2. Creation of a European legal framework for Pan-European research infrastructures: Under this option, the implementation of infrastructure projects on the ESFRI roadmap will be greatly facilitated, resulting in greater research and wider societal benefits:
 - Under this option, numerous legal obstacles will be eliminated in an a priori manner thereby significantly reducing the administrative burden accompanying and facilitating the implementation of infrastructure projects on the ESFRI roadmap. This will result in the much quicker availability to European researchers of the infrastructures and substantial cost savings. The benefits compared to the intergovernmental approach include time and cost savings and reduced concern about national returns on the project. The benefits compared to the national approach include a much stronger feeling of ownership by all stakeholders.
 - This option will contribute to the achievement of ERA in the area of research infrastructures. It will allow for the cost-effective construction and operation of research infrastructures, which are marked by high fixed costs and thus substantial economies of scale.
 - The quicker availability of infrastructures will give rise to an increased efficiency and consistency of Community research actions with increased capacity and performance of European infrastructures for world-class research, increased researcher mobility, more attractive scientific careers, increased training opportunities, and increased attractiveness of Europe as a place to carry out research.
 - Examples of further economic impacts, environmental impacts, and social/societal impacts would be the timely reinforcement of Research Infrastructures in the field of environmental sciences (often distributed and needing better coordination, of particular importance considering current challenges of global warming, etc), or in the field of biomedical research or of social sciences and humanities, in the context of an ageing, enlarging and multi-cultural Europe.

- On a more general level, the ability for the EU to move quickly in the establishment of new research infrastructure will boost the confidence in the effectiveness and efficiency of EU and European cooperation. This option will dispense with complex and long negotiations based on Article 171 and 169 of the EU Treaty, and equally of heavy and lengthy procedures for agreement of an intergovernmental treaty for setting up new pan-European research infrastructures.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Impacts on simplification / administrative burden or on relations with third countries?

The setting-up an intergovernmental treaty is still a valid and sound model for creating new large international research infrastructures as the recent experience of ITER shows but procedures for reaching the final agreement are heavy and lengthy. For these reasons and others and with the exception mentioned above, no new intergovernmental facility has been created since twenty years... On the other hand national entities may be easier to be put in place but the national context and liability problems often hinders the creation of international partnerships. The setting-up of facilities based on Article 171 and 169 of the European Union Treaty entails complex and long negotiations. Once in place they ensure the effective management of major programmes combining public and private sources of funding.

The objective of this initiative is to facilitate the formation of European consortia for the construction and operation of research facilities of Pan-European interest.

The EC regulation proposed would provide a common and easy-to-use legal framework, leaving a considerable amount of flexibility to the individual consortia to set up the adequate rules for the specific infrastructure at European level. The Regulation would contain provisions to ease the application for a status of "Pan-European research infrastructure" as well as clear procedures by which this status will be conferred by the legislator. This would make it possible for interested entities to take the initiative and to draw up the statutes based on this framework regulation. The regulation would also provide for an empowerment from the legislator to the European Commission for conferring this status. Ultimately a lot of time will be gained for the foreseen 30+ new large facilities which are foreseen within the next ten years, compared to repeated negotiations on each case.

In order to offer the maximum amount of flexibility to the beneficiaries of this legal framework (Research infrastructures stakeholders, major laboratories, ministries and research agencies...), the choice would also be given, either to (1) create an entity under national law and then apply for the status of "Pan-European research infrastructure" or (2) be governed by the model set up in the framework regulation.

This initiative should result in:

A minimisation of the administrative burden in the negotiation procedures needed for the setting up of new research infrastructure. A leaner and quicker decision process; a quicker availability to university and industrial researchers of, and an easier access for them to, advanced research infrastructures. An easier participation of third countries to European initiatives with reference to existing, less flexible, legal instruments.

Who is affected?

Research Infrastructures stakeholders, major public and private laboratories, ministries and research agencies, university and industrial researchers.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

What information and data is already available?

Two workshops have been organised in 2006 to analyse the subject and one working group set up in 2007 to carry out a feasibility study. The main conclusions of this work are given below:

First workshop (March 2006): The first workshop was organised by ESFRI and the European Commission on 23 March 2006 to open up the discussion. This workshop allowed high level experts and experience representatives of international research infrastructures to exchange experience on the operation of legal and management structures of their organisations. Their main conclusions were the following:

- in the coming years, as a result of the ESFRI roadmap, an increased number of Research Infrastructures will be realized at supra-national level, requiring adequate legal forms;
- the international organisation form may not be anymore a valid model: on the other hand setting up new Research Infrastructures as liability companies under national law is also not appropriate. The current EEIG format does not seem either a useful legal format (no limited liability, upper limit of employees, difficult for non-EU partners to join);
- Therefore the development of a new European legal form (positioned between national law and the status of an international organisation might be a way forward.

Second workshop (December 2006): A second workshop was organised on 14 December 2006 to pursue the debate and further clarify the issues. The workshop concentrated on the most appropriate legal forms for pan-European research infrastructures. The debate focused on the most common cases: infrastructures created by Member States, and mainly publicly funded.

Experts analysed the existing legal instruments at European level and their limitations. All the experts agreed that the existing European legal instruments are not suitable to be used for the creation of a pan-European research infrastructure. In conclusion, experts agreed that Article 171 EC could be used as a legal basis to develop a new legal instrument and it was recommended to create a small ESFRI working group to perform a feasibility study.

Working group on feasibility study on the creation of a European legal instrument for Pan-European research infrastructures (March - May 2007)

The working group (composed and animated by lawyers) worked during the first half of 2007. The working group reached the following conclusions:

- The purpose of the legislation creating the legal instrument in the field of research infrastructure should be to facilitate the formation of European consortia of research players for the construction and operation of research infrastructures of pan-European interest and necessary for the conduct of Community research programs. The solution would therefore be an EC regulation providing a common legal frame for research infrastructures of pan-European interest. This regulation would only provide a framework, leaving a considerable amount of flexibility to the individual consortia to set up the adequate rules for the specific infrastructure.
- The working group confirmed the opinion that Article 171 EC is the appropriate legal base for a framework regulation which defines a legal structure that can be used for pan-European research infrastructures necessary for the efficient execution of Community RTD programmes.

What further information needs to be gathered?

The Framework Regulation needs to be written. This will require a profound legal analysis by the DG involved in close cooperation with the Legal Service. This will cover the principal legal characteristics of a pan European research infrastructure, its membership, its nominal capital/equity and limitation of the liability, the bodies of the infrastructure (general assembly, board) and special advantages such as tax advantage.

How will this be done (e.g. internally or by an external contractor) and by when?

The work will be done internally mainly by the lead DG involved in close cooperation with the Legal Service.

What type and level of analysis will be carried out.

The framework regulation for Pan-European research infrastructures approved by the legislator based on Article 171 EC will set out the main characteristics of the pan-European research infrastructures, as well as the rules and procedures governing their establishment. In particular, the Regulation should contain provisions on the application for the status of pan-European research infrastructure and procedure by which this status will be conferred by the legislator, also based on Article 171 EC.

This would make it possible for interested entities to take the initiative. The aforementioned legal entities will be able to draw up the statutes designed to found the concrete pan-European research infrastructure based on the framework regulation already adopted by the legislator and submit the project to the Commission. It will be then up to the legislator to confer the status of "pan-European research infrastructure". The framework regulation should also provide for an empowerment from the legislator to the Commission for conferring this status.

In order to offer the maximum amount of flexibility, the choice between the following two options can be given to the consortia, either to

1. Create an entity under national law and then apply for the status of "pan-European research infrastructure" or
2. Be governed by the model set up in the framework regulation.

In both cases it is the legislator who confers the status of "pan-European research infrastructure" but, in the first case, the infrastructure has a legal personality based on national law, and in the second the legal personality is based on Community law and therefore valid in every Member State.

The legislator will, however, have to assert that this status of pan-European research infrastructure is "necessary for the efficient execution of Community research, technological development and demonstration programmes" (Article 171 EC).

This procedure does not require that the Community be a member of the structure. If the Community is not a member and does not contribute financially to the structure as such, the structure will not be considered as a Community body under Article 185 of Financial Regulation. This does not prevent the structure from being the beneficiary of grants according to the procedures established in the legislation in force.

- **Principal legal characteristics** of a Pan European research infrastructure governed by the model set up in the framework regulation
 - The entity will be governed by a contract of association.
 - The entity should have a legal personality different from its members and based on Community law. A provision should be inserted in the framework regulation stating that the publication of the status in the official journal is enough to oppose the entity to third parties and that registration in national registers is not necessary.
 - The structure shall be governed by the framework regulation and other Community law, the terms of its status and, on a subsidiary basis, by the law chosen by the members of the Pan-European research infrastructure in the status (normally the law of the place of establishment).
 -

- **Membership**

It is considered that any legal body governed by public, private or Community law as well as natural persons may be members. (Therefore, legal bodies established under Community law, such as Societas Europaeae, European Economic Interest Grouping, as well as the Joint Research Centre and other Pan-European research infrastructures have the option to become a member).

The entity must comprise at least two entities which have their central administrations in different Member States.

The regulation should not exclude the possibility of entities from third countries participating in an entity formed in accordance with the regulation where the legislation of a third country or agreements between Member States and third countries so allow. However, it is considered that the majority of the members should be established in a Member State.

- **Nominal capital/equity and limitation of the liability**

It is considered that a system similar to the one established on Article 12 of the European Grouping of Territorial Cooperation regulation, without imposing any condition to the limitation of the responsibility is a good option. This option will give flexibility and make it possible for members not to limit the responsibility. Therefore, the framework regulation will provide two options to the members:

- a) A capital/equity is not compulsory. In this case, a member can be liable for 'his part' of the grouping's debts. It means that the liability of a member is limited to his proportion in relation to the total contributions made by all the members together. Members' liability limited to their proportion of the contributions of the Grouping can only apply after the liquidation of a grouping is concluded, unless creditors have first requested the grouping to pay and payment has not been made within an appropriate period.
- b) Limitation of the liability of the members in the statutes. In this case, the word "limited" should be added to the name. The constitution of a capital will be compulsory.

- **Bodies of the infrastructure**

These bodies should be basically defined in the statutes, but the minimum requirements will be set up in the framework regulation:

- **general assembly** of members with at least 1 meeting per year (Control functions but at least: nomination of board members, vote of budget, approval of accounts) and,
- **board** of at least 2 persons (management functions)

Which stakeholders have been/will be consulted, how, at what stage?

Through the initiatives described above, the concerned stakeholders (Research Infrastructures stakeholders, major public and private laboratories, ministries and research agencies, decision makers and legislators) have already been consulted. A new consultation process will be carried when the proposal(s) for a new legal basis will be available. This consultation will take place in autumn 2008, following the adoption of the draft regulation by the Commission. It will involve ESFRI (forum of the representatives of Ministers for research). Two meetings are already planned in September and December 2008. EUROHORCs and EIROForum (representing the major national and intergovernmental research organisations) will also be consulted during the autumn 2008. Moreover, all the current contractors of the "infrastructures" actions in the framework of the PCRD will be consulted on-line as from September 2008. The conference under French presidency of 9-10 December 2008 will be the last occasion for a consultation of the various stakeholders.

ROADMAP

Title of the initiative: **Communication on the promotion of joint public research programmes in Europe**

Expected date of adoption of the initiative: **March 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives and to other EU policies?

Improving the generation and exploitation of knowledge is vital if Europe is to tackle its problems of growth and employment. To do this, it will need to invest more and better in research. However, in the last few years, macro-economic pressures have constrained Member States from expanding their R&D budgets significantly. Unless there are radical changes in these conditions, then it will continue to be difficult for them to invest more in the coming years. This means that the main option will be to look at ways of investing more efficiently and effectively through improvements in the planning and coordination of public research in Europe – an idea at the heart of the European Research Area project.

Joint public research programming is a possible strategy for rationalising European public research efforts. By pooling and sharing Member States' own public R&D resources – thus increasing the critical mass of research programmes and sharing the risks associated with research - it aims to reduce the fragmentation of public research spending in Europe, and to increase its effectiveness

A more efficient and effective research system will boost the creation and use of knowledge, and thus provide an invaluable contribution to the revised Lisbon goals for growth and employment in Europe. As a means of restructuring European research, joint programming is centrally associated with the building European Research Area, and closely linked to the Barcelona objectives regarding the better use of public research funds.

The idea of joint programming is not new, but was a core component of the "ERA-NET" and Article 169 projects launched under the 6th Framework Programme, and continued in the 7th FP. Although first results of these initiatives have been promising, progress in establishing joint public research programmes has so far been slow, and this Communication aims at proposing new ways of accelerating their emergence. In doing so, it can also benefit from the experience of certain Member States, such as the Nordic countries within the framework of the Nordic Research and Innovation Area (NORIA) launched in 2004.

What are the main problems identified?

European growth and competitiveness remain major challenges in the face of increasing competition from new global players. Yet, while knowledge is central to the EU's long-term economic strategy, efforts to raise public spending on research have been limited in their success (NB the 3% Barcelona objective for R&D expenditure).

Meanwhile, there is still much work to do with regard to the restructuring of the European research system and the creation of a true European Research Area. Seven years after the launch of the ERA, the EU research system remains fragmented. The vast bulk of public research in the EU is currently implemented independently by national or regional programmes. In a number of key areas, many national programmes lack the scale and scope required to tackle increasingly global research challenges, and there is also a need to remove unnecessary duplication of effort.

Over the last fifty years, significant steps have been taken in coordinating public research in Europe. Various strategies have been followed, from the setting up of Euratom, CERN, EMBL, the EU Framework Programmes for RTD, COST, Eureka and other such measures, to the more recent opening up of some national research programmes to other countries. However, it must continue to make efforts find new ways of planning and implementing its research activities in cooperation, and of pooling its resources, so that it can use these scarce funds more efficiently and to greater effect.

Joint programming offers a promising avenue for future action. It concerns that part of public R&D funding that is managed solely by the Member States themselves (i.e. it excludes the EU Framework Programme, Eureka, COST, EMBL, and other such trans-national research cooperation). It involves an action where several EU Member States (not necessarily all) commit themselves to fund together a joint programme in a selected research area, pooling their national funding. They should then define, implement and assess together the joint programme.

However, efforts to encourage joint programming have encountered difficulties. If joint programming is to take off and provide a solution, it is important to have a better understanding of where and how they can work, and of what obstacles need to be overcome. Crucially, it is also essential for the Member States (the owners of the research funds in question) to be fully committed to setting up joint programmes

Is EU action justified on grounds of subsidiarity?

The EU has the legal instruments for implementing joint programmes either as Community programme (Art. 163, 164 and 166) joint programmes with Member States (Art.169) or other mixed forms. Under Art 165 the Community and the Member States shall coordinate their R&D activities to ensure that national policies and Community policy are mutually consistent. The Commission may in close cooperation with the Member States take any useful initiative to promote such coordination.

It should be added that the EU is building experience of coordinating European-level joint programmes in the Research Framework Programmes. The current Framework Programme explicitly asks the Commission to coordinate non-Community research programmes through the ERA-NET scheme and the participation of the Community in jointly implemented national research programmes (through Article 169 of the Treaty).

B. Objectives of EU initiative

What are the main policy objectives?

- To ensure that Member States agree on a common definition of joint programming and are fully committed to the joint public research programming initiatives they are involved in
- To contribute to the achievement of the objectives of the revised Lisbon Strategy, notably growth and jobs
- To contribute to the achievement of one of the central European Research Area (ERA) objectives
- To contribute to the better use of public funds, the rationalisation of Europe's public research programs, and the enhancement of their impact
- To contribute to the minimization of the fragmentation (gaps, duplication, lack of critical mass) of European public research programs
- To ensure that joint public research programming initiatives are fully adapted to the needs of participating stakeholders

Does the objective imply developing EU policy in new areas of strategic importance?

It is possible that, in function of the eventually agreed joint programme area, EU policy is developed in new areas of strategic importance

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option 1: Doing nothing approach

Under this option, no major action will be undertaken and further progress in the field of joint public research programming depends, as it does now, on the ad hoc application of existing EU (FP, e.g. ERA-net) and inter-governmental (Eureka, COST) instruments to research fields and subjects defined in a bottom-up manner.

Option 2: EU driven "top-down" approach

Under this option, the EU takes a more proactive role and defines in more of a unilateral and top-down manner the research areas where Member States can collaborate and leads in achieving the implementation of forms of

joint programming.

Option 3: "Joint" EU-Member States approach with a real action plan

Under this option, the key challenge is involving Member States in a process that would identify the areas where joint programming would be most effective for these programmes to reach the critical mass, scale and scope required to have an impact at a global level. The strategy is to try and ensure a high-visibility political commitment to joint programming from Member States, i.e. for them to commit additional national funding to new joint public research programmes.

The Commission would respond to such a commitment with an Action Plan for achieving a small number of highly significant clusters of national programmes, likely to restore a European advantage. The Action Plan would maintain momentum in Council and facilitate groupings of countries around negotiated programme areas which, in turn, would become the subject of legislative proposals after 2010 as described in the fiche describing this priority initiative.

The Communication would insist that, while tools for joint programming are now widely available, the key steps still missing are (i) a process allowing to identify where joint programming would be beneficial and from which combination of contributors, (ii) a high level forum for analysis, negotiations and deliberations, (iii) effective (and flexible) forms of governance for the implementation phase with the committed involvement of Member States.

The proposed Action Plan would be novel in that it sets up such a process upfront, and puts Member States in a driving position thus turning the European Research Area into their playing field.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No. However DGs ENTR, INFSO and REGIO have been involved in the work of the ERA Green Paper expert group, but would need to be closely associated to the Communication

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option, even if these impacts would materialise only after subsequent Commission initiatives?

Option 1: Doing Nothing approach

- The initiatives in the field of joint European public research programming emerging in a bottom-up manner would be well adapted to the specific needs of the partners involved and also fully supported by them.
- However, making further progress in the field of joint public research programming would take too much time and be too much, as it is now, piecemeal given the rapid pace of globalisation and the intensity of technological competition.
- This approach would fail to identify and remove the obstacles to joint programming. Europe would not realise the benefits of pooling resources, a greater scale of research activities, risk-sharing etc. associated with the enhanced coordination of research efforts.
- The Union would continue to suffer from inefficient and dispersed Member State investment in research. Faced with several hundreds regional and national programmes, a proliferation of intergovernmental initiatives (EUREKA, COST, Intergovernmental Research Organisations) and the development of tools for programme cooperation under the research Framework Programme most stakeholders and Member States recognize that several of these programmes do not have the required scale and scope to reach their objectives.

Option 2: EU driven "top-down" approach

- This approach would have the potential of considerably speeding up progress in the field of joint public research programming in Europe.
- However, major risks would be associated with this approach. As notably suggested by the recent EDCPT evaluation, there are no guarantees that Member States would commit themselves to such EU driven top-down initiatives, without their real involvement from the start of the activities.

- The initiatives developed at EU level would also risk not being well adapted to the needs of stakeholders.
- Without genuine commitment of Member States this approach will not allow to reach the scale and scope required to solve the identified problems.
- The same benefits listed under option 1 would then be lost.

Option 3: "Joint" EU-Member States approach with a real action plan

- This approach would strike the necessary balance between, on the one hand, making sustained progress in the field of joint European public research programming and, on the other hand, ensuring that joint research efforts are widely supported and well targeted.
- This approach would facilitate commitment by Member States as each Member State could choose under a variable geometry format to participate in that initiative which best suits its local needs.
- It could lead to the identification of further areas for joint programming and, eventually, a better governance of the European Research Area.
- It should have an important impact on reducing the fragmentation of public research efforts in the EU and ensuring a more efficient use of public funds.
- Higher impacts would be expected from the resulting joint research programmes (due to larger scale, elimination of duplication, better dissemination, etc.).

In turn these impacts of more effective research will help to stimulate growth and employment (as well as producing environmental and societal benefits).

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Impacts on simplification / administrative burden or on relations with third countries? No

Who is affected?

- Research programme owners (Ministries) and programme Managers in Member States which would develop joint programmes.
- European research actors (researchers , companies, research centres, universities) : joint programming should make the funded projects more attractive and effective, allowing also trans-national collaboration. These collaborations allow to pool experience and practice, to raise standards to that of the most ambitious, to increase the options for partnerships (e.g. through the organisation of joint calls and joint programmes), and facilitate the mobility of research leaders and /or of entire projects.
- European industry would benefit from more competitive knowledge base (Metrology – IMERA)
- European citizens would benefit from more effective programmes being able to deliver solutions to problems of a European scale (Rare-diseases, Energy/Climate Change, Baltic Sea Research...)

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

- A substantial amount of quantitative and qualitative data on joint research programming tools is already available. Some data are already available on the achievements of ERA-NET and Art.169 initiatives. And some data are already available on joint investment under intergovernmental schemes such as EUREKA and COST and through EIROForum organisations (CERN, EMBL, ESO..). A meta-analysis will be undertaken of these data and of information available at national and regional level.
- In addition, the IA will draw upon the Horvat and Van Velzen reports, which have reviewed the new programme co-operation and integration tools offered by the Research Framework Programme and identified the need and key requirements for joint programming to be effective (Horvat and Van Velzen reports).

Finally, the IA will draw upon the output produced by a number of expert groups set up to guide the development of policies concerning the European Research Area. For instance, one expert group was set-up to report on the topic of "Optimizing Research Programmes and Priorities", including making proposals for joint programming. An initial roadmap with criteria and possible impacts to be developed by this expert group is expected in January 2008. Another expert group is analysing the overall rationale of the European Research

Area suggesting joint programming might be an option for public research programmes.

Which stakeholders have been/will be consulted, how, at what stage?

Stakeholders have been consulted on-line and through several events in 2007 on the Green Paper 'The European Research Area: New Perspectives', which makes the case and gives options for optimising research programmes and programming in the EU. A detailed analysis of the outcome of this stakeholder consultation is being undertaken

ROADMAP

Title of the initiative: **Convergence Report 2008; (possible) proposal(s) for a Council Decision under Art. 122(2) on euro area entry of one or more new Member States; (possible) proposal(s) for a Council Regulation on conversion rates of the currencies of the Member States concerned**

Expected date of adoption of the initiative: **May-June/2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

With the exception of Denmark and the UK, all Member States not participating in the euro area have the status of "Member States with a derogation". The Treaty foresees that, at least every two years, the Commission and the ECB examine which Member States with a derogation have achieved a "high degree of sustainable convergence" (as measured by low inflation and interest rates, high exchange rate stability and the absence of excessive fiscal deficits and public debt), which is required for euro area entry. The compatibility of legislation is also examined. If the Commission finds that one or more Member States fulfil the conditions for euro area entry, it submits a proposal to the Council, which takes the final decision. Based on a proposal from the Commission, the Council also has to decide on the irrevocably fixed conversion rates of the currencies concerned to the euro.

Since the introduction of the euro in 1999, convergence reports have been prepared on a two-yearly basis or at a request of a Member State, as required by Art. 122(2) of the EC Treaty. In 2000, 2006 and 2007, positive assessments have led to decisions on euro area enlargement (Greece, Slovenia, Cyprus and Malta).

What are the main problems identified?

Euro area enlargement is foreseen by the EC Treaty, i.e. it is not a new initiative. Nevertheless, it is an initiative of a great strategic importance since it vitally contributes to the deepening of economic integration within the EU. Thorough convergence assessments have to assure that a Member State adopting the euro has achieved a high level of sustainable convergence so that euro adoption can be beneficial both for the Member State concerned and for the euro area.

Is EU action justified on grounds of subsidiarity?

Yes. Governance of the monetary union, including decisions on euro area enlargement, requires an action on the supra-national level.

B. Objectives of EU initiative

What are the main policy objectives?

Euro adoption, based on sustainable convergence, is the key element of economic integration within the Union. Member States are allowed to adopt the euro when the necessary conditions are met, which serves both their interest and that of the euro area members. Participation in the single currency area underpins long-term growth prospects notably by allowing countries to fully benefit from the single market (lower transaction costs, higher price and cost transparency, enhanced trade integration) and by strengthening macroeconomic stability (elimination of intra-area exchange rate risk, higher resilience against external shocks, lower country risk premia on financial markets).

Does the objective imply developing EU policy in new areas or of strategic importance?

No.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The procedure is foreseen in the Treaty. There are no other options to consider.

When a Member State is deemed ready for euro adoption in the Convergence Report, the procedure for euro adoption is launched. The Commission submits a proposal for a Council decision to lift the derogation, i.e. to introduce the single currency in the Member State concerned. The Council takes the final decision. Based on a proposal from the Commission, the Council also has to decide, by means of amending a Regulation, on the irrevocably fixed conversion rates of the currencies concerned to the euro.

If not all criteria are met, no proposal for abrogation will be submitted. This will give the Member State concerned more time to adjust its economic policies to reach a high degree of sustainable convergence.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No direct impact.

Do the options respect the proportionality principle?

Not applicable, for the reasons mentioned above.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Not applicable, as the Treaty does not give a choice between different policy options.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No

Who is affected?

The convergence reports, prepared by the Commission and the ECB, cover all Member States currently having the status of a Member State with a derogation. In 2008, it is foreseen to examine the following ten Member States: Bulgaria, the Czech Republic, Estonia, Lithuania, Latvia, Hungary, Poland, Romania, Slovakia and Sweden. A possible decision on euro area enlargement affects primarily the Member State adopting the euro, but also the whole euro area, in terms of euro area governance as well as integration of a new market within the currency union. The legislative procedures involve the Commission, the Council, the European Parliament and the ECB.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

ECFIN undertakes extensive monitoring and analysis of developments in the Member States concerned, including in the context to the policy co-ordination and surveillance procedures foreseen by the Treaty. The specific information underlying the (possible) proposal for a Council Decision to enlarge the euro area by one or more countries will be contained in the Convergence Reports 2008 prepared by the Commission and the ECB

Which stakeholders & experts have been/will be consulted, how and at what stage?

The formal procedure following the Commission proposal for a Council Decision involves consultation of the ECB and the EP. Discussions with Member States on economic policy challenges in Member States are held under various headings on a regular basis in the Economic and Financial Committee and ECOFIN/Eurogroup. These include informal discussions on issues specifically relevant to the preparation of eventual euro area entry (incl. exchange rate policies). Dialogue with academics and other interested groups takes place in the context of conferences/seminars and on an ad-hoc basis.

ROADMAP

Title of the initiative: **Commission communication “Global Monitoring for Environment and Security – a new programme for Europe”**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The GMES concept dates back to 1998, with the ‘Baveno Manifesto’ calling on a mobilisation of observation capacities in Europe for improved environmental management. Starting in 2001, both the EU (with research funds) and the European Space Agency (ESA) took first steps towards the development and validation of Earth observation based services. The strategic importance of Earth observation was recognised and Europe chose to set itself the goal of having an operational capacity and value-added information services in order to be autonomous in crucial policy decisions. This is particularly true for security-related issues, but also applies for environmental change and international commitments.

In 2005, the Space Council at its 3rd meeting endorsed the phased approach, proposed by the Commission in its Communication, to develop a limited number of services to be available in 2008.

Resources have been made available both by ESA (dedicated programme for satellite development) and by the Community (FP7 Space programme). Furthermore, massive investments are made by Member States on Earth observation infrastructures enabling various activities, both public and private, to develop in a relatively new market.

With the objective of steering the development of services and preparing the financing and governance for the longer term, the Commission created by decision in 2006 a GMES Bureau within the Directorate General for Enterprise and industry. On the financing side, a preparatory action was proposed by the 2008 budget for a first ‘rapid mapping’ service to be developed outside R&D funding.

GMES supports numerous EU policies: its Earth observation-based services are meant to inform and support policy decisions that are proportionate and effective, while respecting subsidiarity. Beyond environmental policy, which is clearly the main beneficiary of GMES services, various other EU policies and user communities will benefit from GMES, e.g. fishing vessels will be guided to optimise their catch, while advanced vessel monitoring systems will prevent illegal fishing and discharges and control marine resource preservation; farmers will have information services to optimise the performance of their parcels (precision farming), while advanced systems will help agriculture and environment go hand in hand through control of agro-environmental measures and fighting fraud. Authorities will benefit from air quality information systems to control the pollution sources and regulate the traffic. Rapid mapping and other specific emergency situation services will help civil protections within and outside Europe to manage crises, as well as reconstruction needs. GMES services will also contribute to address security needs, including in the JLS and CFSP domains (border control; maritime surveillance, critical infrastructures, global stability etc.)

Being innovative and with growth potential, the Earth observation-based services market is also expected to be developed, mostly to the benefit of SMEs, therefore supporting the Lisbon objectives, and especially the competitiveness of the European society.

What are the main problems identified?

At a crucial stage when first services will become available, the 2008 Communication is meant to address two sets of problems linked to GMES long-term sustainability:

(1) a financing mechanism at EU level yet entirely based on research funds, which leads to a fragmented (project-based) approach and is at odds with the declared objective of developing an operational capacity; and

(2) a too loosely structured organisational set-up, which poses problems in terms of decision-making and financing (how to select services and relevant observation infrastructures to be financed; respective roles of the Commission, Member States and other entities such as ESA; relations with service providers and infrastructure developers and operators; how to ensure that requirements and feedback of users are taken into account;

assessing financial and in-kind contributions and the corresponding decision-making powers, etc).

Is EU action justified on grounds of subsidiarity?

EU action is needed – as recognised by Member States in several Council conclusions and resolutions – because GMES is a tool in support of EU policies and because it is an application of the European Space Policy (which in turn implements EU competencies enshrined in the future Treaty).

EU involvement will ensure best value for money if best use of all existing capacities in a broad sense (infrastructures, knowledge, institutions) is made.

While experience up to now has shown that the national/intergovernmental framework alone is inadequate to meet the challenge, action at EU level will not replace but rather match and complement actions at Member States and intergovernmental levels (ESA, EUMETSAT, etc.) in order to achieve the common policy objectives. The overall structure will be designed so that GMES remains user-driven, which in turn ensures that action does not exceed what is necessary to achieve the objectives. The step-by-step approach retained until now in the GMES development will be promoted.

B. Objectives of EU initiative

What are the main policy objectives?

The policy objectives of the 2008 communication are:

- To shape a programmatic approach for GMES development and implementation from research and development to deployment phase.
- To implement the Commission's contribution to the GMES roadmap that has been proposed by the German Presidency in April 2007 and welcomed by the Space Council (focussing on the need for continuity for operational budget after the preparatory action proposed in 2008 and for an appropriate governance scheme).

Specific objectives are:

- Allow sustainability of elements of service and contribution to infrastructure beyond research
- Define roles and responsibilities of different actors to ensure complementarity of national and intergovernmental assets with EU intervention.

Does the objective imply developing EU policy in new areas or of strategic importance?

GMES is a tool in support of existing EU policies as well as Member States' implementation of them. Among these, there are certainly areas of strategic importance such as climate change and security. GMES will also be a major implementation milestone of the European Space Policy, one of the new policies defined by the future Treaty.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

For the sake of clarity, policy options can be outlined separately for the two specific objectives of the Communication.

Concerning the sustainability (S) of elements of service and contribution to infrastructure beyond research, policy options at hand are:

- No change S-option: The 2008 preparatory action has no follow-up. The EU continues to limit its financial contribution to GMES to research funds, and leaves operation of the services and the infrastructure to other actors.
- Option S1: same as the previous option until 2013, but operational funds are made available in the next financial framework. A gap is left between the preparatory action (2008-2010) and 2014.

- Option S2: a Community programme, with dedicated non-research funds, is created to bridge the gap between 2010 and 2014, and to give continuity to the preparatory action.

Concerning the roles and responsibilities of different actors (governance - G), policy options at hand are:

- No action G-option: The GMES Bureau ends in 2009 and GMES development and operation is left to Member States and intergovernmental organisations such as ESA and EUMETSAT.
- Option G1a: Decentralised approach with the creation of a new external entity, e.g. an agency, or extension of the mandate of an existing entity;
- Option G1b: Decentralised approach with the Commission's services in charge of the supervision of the GMES programme.
- Option G2: Centralised approach, with a single governance body encompassing all GMES elements and representing all stakeholders.

These options can be implemented through a two-step approach (Communication first, then legislative acts later) or in package, depending on the level of maturity of the debate in autumn 2008.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes it cuts across several policy areas as GMES is a cross-cutting tool in support of EU policy making. Other department currently using GMES-like services could be affected in their way of doing it, with expected positive impacts through significant improvement of current capacities.

Do the options respect the proportionality principle?

Apart from options “no change scenario” which would not allow to meet the challenge described above, the other options are proportionate as the only central entities with EU direct involvement will be limited to the strict necessary and subject to an impact assessment.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Sustainability beyond research

The main effects sought through ensuring the sustainability of GMES in the shortest possible timeframe (option S2) are linked to the creation of a much improved evidence base to inform policy decisions. Significant positive impacts are expected for instance through better data on environmental and climate changes, as well as on the effectiveness of existing environmental protection policies. The development of GMES security elements would improve security in Europe and contribute to law enforcement capacities (border control, maritime surveillance...). Moreover, the 'public service' component of GMES is expected to drive the development of a downstream market, therefore stimulating innovation both upstream (space technologies etc.) and downstream (innovative applications and services). European companies would have a first-mover advantage and build/retain a technological *savoir faire* while creating jobs and growth.

Option S1 would in the best case delay these benefits as the development phase of GMES lingers on until 2014. However, it is expected that this option may induce current users to lose confidence in the project (and in EU's commitment to it), thereby putting the whole of benefits explained above at risk.

The no change scenario would maintain a positive impact of stimulating research and innovation, but would see all other benefits radically limited or non-existent. In particular, the EU would not have at its disposal the necessary tool for its policy making, and no downstream market would be created beyond what already exists.

Governance

The impacts of the different governance options are strictly related to the sustainability scenarios: no governance option would materialise GMES benefits in the absence of a programmatic approach to go beyond research.

As concerns more specifically governance, the no change scenario would perpetuate the decision-making problems described above and hinder EU's capacity to benefit from Earth observation. Option G1a and G1b would have the advantage of minimising administrative costs by using existing structures plus having a central coordination body. The choice among them would have to be done by assessing the extra costs of creating a

new body or extending the mandate of an already existing one vs. internal Commission management. Option G2 would provide easiest organisational arrangements but probably at high administrative costs and at unacceptable political conditions as existing actors would be sidelined. This option is also the most difficult to reconcile with the declared GMES principle of building on existing capacities.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Implementing a GMES programme would have a budget and human resources impact. The 2008-2010 Preparatory action will have to be enhanced and continued from 2011 to 2013 and the management of the programme will require extra posts. The setting up of a governance scheme would also have financial and staff impacts, as administrative structures would have to be created/expanded. The magnitude of these impacts depends on the option chosen and on the time frame of its implementation.

IA is to serve as ex-ante evaluation if the Communication is accompanied by legislative proposals

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

- GMES will have an impact on the streamlining of reporting requirements imposed by European legislation on the member states through consistent data and information approaches from European to national and regional levels. GMES will contribute to and benefit from the SEIS – Shared Environmental Information System, for which legislative proposals are listed in the 2008 simplification section of CLWP.
- GMES is intended to implement dedicated services for Africa
- GMES will provide the core of the European contribution to GEOSS (Global Earth Observation System of Systems)

Who is affected?

- Public authorities at all levels (as users and contributors)
- industry (infrastructure building and operating, service provision, downstream applications development)
- intergovernmental organisations (ESA, EUMETSAT, ECMWF...)
- final users (regional and local authorities, public institutions including universities, research centres, even single citizens)

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Information already available:

- Benefits analysis performed by PWC on ESA's request (macro-economic approach)
- IA of the European Space Policy, including GMES
- Eurogroup EO market survey
- GOSIS study (funded under FP6) on GMES governance models
- JRC analysis of the EU Earth observation needs
- Results of various Research projects
- SEIS Impact assessment (once available)

Further information to assess the best degree of EU involvement and the best governance scheme needs to be gathered. This will be done mainly internally and through stakeholders' consultation. An external contractor may be asked to address the downstream market analysis and potential.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Since the launching of the GMES initiative in 1998, numerous studies have been carried out and stakeholders have been consulted through the organisation of specific forums (e.g. GMES Forums 1- 4 during the initial period of GMES); and workshops and conferences organised within the context of the European Space Policy including GMES (e.g. Green and White paper processes, Earth and Space Week). Additional events have been organised by ESA.

More recent consultation elements include the following.

As foreseen in the Commission Decision creating the GMES Bureau:

- Internally to the Commission, an interservice group of DGs has been set up to steer the GMES Bureau (within DG ENTR) and ensure that GMES is developed in support to their policy needs. This group is regularly consulted and informed on all GMES-related matters.
- Staff detached by other Commission services and agencies ensure the follow-up of more detailed technical aspects.
- Specific arrangements have been put in place with the JRC to make best use of available technical expertise and experience.

Externally, the GMES Bureau is assisted by the GMES Advisory Council, bringing together Member States, ESA, EUMETSAT, ECWMF and EU institutions and agencies. This is the main forum for testing and having advice on GMES-related developments.

A network of national GMES coordinators has been created. Each Member State is nominating a single contact point (in many cases participating to the GMES Advisory Council), who is charged among others to mobilise the country's stakeholders' communities when needed and to convey messages to the Commission.

Within the context of the European Space Policy and a High-level Space Policy Group was set up in 2004 analysing GMES aspects more relevant to the implementation of the European Space Policy. This Group has regularly prepared the four Space Councils which have adopted orientations and a resolution also on GMES.

Moreover, expert groups of GMES users' representatives (Implementation Groups) have been set up in order to define the scope and the implementation plan of the first GMES services. More IGs will be created when new services are set up or specific issues are raised.

A High-level Coordination Group whose members include heads of the main European space agencies has been set up jointly with ESA to elaborate on issues related to space infrastructure for GMES.

Dedicated workshops have been organised. For instance, specific workshops were held for the launching of GMES services and for the implementation of FP7. Specific events on governance have been regularly organised by the Presidencies of the EU (e.g. in Graz by Austrian Presidency resulting in the adoption of the "Graz Dialogue", in Munich by German Presidency resulting in the adoption of the "Munich Roadmap" etc.)

A Eurobarometer on GMES is an open option.

ROADMAP

Title of the proposal: **Communication and Action Plan on Towards a Sustainable Industrial Policy. An industrial policy for a competitive low carbon economy**

Expected date of adoption: **March 2008**

A. Initial impact assessment screening

- (6) What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

There are four main reasons for acting at European level.

First, the challenge is European. GHG emissions are a clear example of environmental externalities. The impacts of Climate Change are supported by everyone and they do not respect borders.

Second, innovation support for low Carbon technologies, products and services varies among Member States, resulting in some countries improving rapidly their Carbon profile, while some others continue lagging behind in their production processes. Critical mass for research requires action at EU level.

Third, internal markets for more energy efficient, low carbon products and services in particular for environmental industries hardly exist. In some Member States, the market penetration for these products is quite extensive, in some others quasi inexistent. Common minimum requirement and best performance benchmarks in terms of energy and environmental efficiency would facilitate the free circulation of products, provide the adequate uniformed information for consumers, create an internal market for this type of products and rewarding front-runners. Existing companies with a lead position in providing environmental services could play an important role in controlling environmental damage if the internal market was to function adequately.

Fourth, international negotiations to facilitate level playing field for the different EU industries requires a common front to convince the partners from the rest of the world and achieve reduction of GHG emissions.

Independent actions by Member States in these four areas would not only be less efficient but also would very partially contribute to the ambitious targets in GHG reduction, renewable energy and energy efficiency set by the EU 2007 Spring Council to respond to the worsening of the climate change situation. There is a need to complete the EU Climate Change and Energy package with a strong third pillar, the Sustainable Industrial Policy.

- (7) What are the main policy objectives?

This initiative aims at encouraging industry to attain the highest environmental profile through development and deployment of European low carbon, energy efficient technologies, products and services by removing obstacles, tackling market failures and furthering internal and external demand. It will comprise the following components: Innovation for low carbon, energy efficient technologies –Make use of the internal market instruments to create a critical, dynamic mass of demand for low carbon and energy efficient technologies, goods and services, thereby reducing their cost through economies of scale–
- Exploit first mover advantages to export EU know-how in a low-carbon economy to external markets and create a level playing field for industry through global sectoral agreements.

It will be complemented by the Action Plan on “Sustainable Consumption and Production”. This action plan will extend the scope of SIP to cover most environmental impacts. It will comprise activities in the field of leaner and cleaner production and smarter consumption.

There is a strong synergy between both Action Plans. It is clear that the objective of a Low Carbon economy will not be achievable if there are no changes in terms of production and consumption patterns. On the other hand, the latter will not be reachable without innovation and a stronger market for better products. Actions in the international arena are essential for the rightly valorisation of the EU effort in all these fields.

(8) What are the policy options? What regulatory or non-regulatory instruments could be considered?

The initiative will be launched through an Action Plan in the form of a Communication. No regulatory legal act will be included at this stage although proposals for amending existing Directives such as the EUP Directive might be proposed. To promote the most energy efficient, low carbon technologies, products and services, several options have already been identified: market based instruments, use of minimum performance standards coupled with advanced performance benchmarks and labels, facilitation of the emergence of key markets for advanced performing products, promotion of sectoral agreements, risk sharing funding facility for innovation, enhanced use of CIP and FP7, use of IPR.

(9) What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

The Communication is geared mainly to national and Community authorities and enterprises, depending on the actions foreseen (for instance, public procurement, IPR, minimum performance requirements and advanced performance benchmarks, innovation and export framework conditions to be dealt by public authorities whereas enterprises would need to act in the deployment of technologies). In terms of impacts, it will be necessary to analyse the economic and environmental effects of the Communication and its Action Programme.

In the case of putting forward an amending Directive for the EUP Directive (scope, dynamism, incentives), a full impact assessment will be carried out.

B. Planning of further impact assessment work

(10) What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The Communication is based on the results of the mid term review of the industrial policy due in July 2007. Further information will be necessary to cover the sectors not included in the screening of the last industrial policy Communication. Information will also be drawn from the work of the High Level Group on Competitiveness Energy and the Environment. The analysis will focus on the aspects to be covered by the Communication (see question 2 above). Studies have been launched to identify main barriers for innovation and options to overcome them. The impact assessment will include their outcome as well as the results from inter-service consultations.

(11) Which stakeholders & experts will be consulted, how and at what stage?

Two consultations were organized:

The first one was business oriented: the questionnaire was sent to around 4000 companies participating in the European Business Test Panel, of which 354 responded. This consultation took place from the 15th of September to the 15th of October 2007. Participants agreed on the need for SIP (89%) and SCP (86%). Leveraging innovation and Product policy were identified as the two most important challenges. The results will be published in the website early November.

The second consultation was done jointly with DG ENV and concerned the SIP as well as the Sustainable Consumption and Production Action plans. The Internet consultation on the basis of the questionnaire and a 10 pages Background document was launched on "Your voice in Europe", and took place between the 27th of July and the 23rd of September. It addressed both stakeholders (national ministries, industries, associations, NGOs) and general public. Participants to the consultation were also invited to provide position papers. The 479 answers indicate a strong consensus (97%) on the necessity to act in these fields. Improving consumption patterns, innovation and product policy appear to be the most relevant areas of intervention for stakeholders.

(7) Will an inter-service steering group be set up for the IA? Yes

ROADMAP

Title of the initiative: **Sustainable Consumption and Production (SCP) Action Plan**

Expected date of adoption of the initiative: **February 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The decision to develop an SCP-Action Plan was taken by the Commission in its Proposal for a reviewed Sustainable Development Strategy (in Dec 2005). Furthermore, in June 2006, the Council adopted the renewed Sustainable Development Strategy and identified sustainable consumption and production as one of the seven key challenges, inviting the Commission to draw up an Action Plan on sustainable consumption and production. Finally, the Environmental Council in its conclusions on the Thematic Strategy on the Sustainable Use of Natural Resources in October 2006 drew particular attention to the forthcoming SCP-Action Plan.

The forthcoming SCP-Action Plan would help to identify and overcome barriers for SCP and to ensure better coherence between the different related policy areas, and to raise awareness among citizens and change unsustainable consumption habits. This Action Plan will be presented as a package including also the revisions of the Eco-label and EMAS Regulations, and a communication on Green Public Procurement. The SCP Action Plan builds further on existing SCP-related policies such as the Integrated Product Policy (IPP) Communication and the Thematic Strategies on Sustainable Use of natural Resource and Waste Prevention and Recycling.

What are the main problems identified?

European and global consumption and production patterns exceed the carrying capacity of ecosystems, causing environmental degradation. Actions have to be taken at all levels, including the European level, according to their specific competencies.

Is EU action justified on grounds of subsidiarity?

As a result of intra-Community and global trade, the environmental impacts related to consumption and production are likely to affect more than one country. Coordinated actions on SCP are thus needed at EU level in addition to initiatives at the international, national and local levels. This coordination will ensure policy coherence and synergies, and allow ensuring single market issues and simplification.

B. Objectives of EU initiative

What are the main policy objectives?

The main policy objective is to promote sustainable consumption and production by addressing social and economic development within the carrying capacity of ecosystems and decoupling economic growth from environmental degradation.

Specific objectives of an EU policy on sustainable consumption and production should encourage to design or promote policies which lead to:

- products that use less materials and energy and generate less emissions
- production processes with material and energy efficient, low pollution technologies
- consumption of eco-efficient products within the environment's carrying capacity

Does the objective imply developing EU policy in new areas or of strategic importance?

Yes, developing an EU initiative on sustainable consumption and production is an initiative of strategic importance as it covers the three pillars of sustainability: environment, economic and society.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- Policy options: Nothing, a strategic document (with vision but no concrete actions), an action plan
- Instrument options: Communication, white paper, green paper, opinion

Complementary remark: Various more concrete regulatory or non-regulatory actions are under present thinking considered to be included in the SCP-Action Plan. For instance, a framework on eco-design of products, reinforcement of existing instruments such as Ecolabel, EMAS, ETAP, GPP, and improvement of the coherence between existing policy instruments. Note that for each legislative action announced by the plan, a specific IA will be done when the action in question is being developed

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, on industrial policy particularly (planned Action Plan on Sustainable Industrial Policy).

Do the options respect the proportionality principle? Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- No action: Impact is that there is no coordinated EU-policy answer to tackle the unsustainable consumption and production patterns that affected the environmental of the European and world citizen.
- Strategic document: the renewed SDS is already a strategic document. Impact of another strategic document would be that there is no operational EU-policy answer to tackle the unsustainable consumption and production patterns that affected the environmental of the European and world citizen, in spite of the fact that a need for action is politically recognised, in particular in the renewed SDS.
- Action plan: Impact is that there is a coordinated and operational EU-policy answer to tackle focused aspects of unsustainable consumption and production patterns that affect the environment.

Complementary remark: Impact of specific actions of the SCP-Action Plan should be further analysed. A general EU eco-design framework should be an impetus for environmental protection and future competitiveness through innovation and anticipating trends. Green Private Procurement, as well as the reinforcement of Ecolabel, EMAS, ETAP, ... should combine better environmental protection with enhanced marked development of greener products, processes and services. Better coherence in the existing policy tools should improve policy efficiency and effectiveness, and work towards simplification and reduction of administrative burdens.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Yes towards simplification.

Who is affected?

Enterprises, consumers, Member States and public administrations

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this

be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

- Needed information is a feasibility analysis and impact assessments of a number of relevant future actions identified by the actions plan underdevelopment. Study on the eco-design framework launched in 2007, and later for other specific actions of the action plan in development.
- Available information is the 2004-inventory of existing EU and national SCP policy.
- EIPRO-IMPRO studies to identify priority products and potential for environmental improvement.
- EEA Report 11/2005 on Household Consumption and the Environment.
- Background document for the conference 'Time for Action' 27-29/09/2007
- Various other sources of information, figures, etc.
- Needed information is a feasibility analysis and impact assessments of a number of relevant future actions identified by the actions plan underdevelopment. Study on the eco-design framework launched in 2007, and later for other specific actions of the action plan in development.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Member States and stakeholders representatives were consulted by workshops and meetings in 2007 during the elaboration stage. An on-line public consultation took place in the summer of 2007.

ROADMAP

Title of the initiative: **Revision of Regulation (EC) No 761/2001 of the European Parliament and of the Council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)**

Expected date of adoption of the initiative: **February 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

On 29 June 1993, the Council adopted Regulation (EEC) No 1836/93 allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit scheme. This Regulation - known as the EMAS Regulation - entered into force on 13 July 1993 and was opened to industrial participation since April 1995.

On 19 March 2001, the European Parliament and the Council adopted Regulation (EEC) No 761/2001, which revised and expanded the scope of EMAS by allowing voluntary participation by any type of organisation (not just industrial companies) in the scheme.

The scheme represented when it entered into force, and still represents, a direct response to some of the key principles embodied in the 5th and 6th environmental Action Programme, in particular the concept of broadening the range of instruments and of promoting an approach of shared responsibility in the area of environmental protection.

EMAS is part of the overall objective to promote sustainable production and consumption patterns by providing a framework for the effective management of environmental effects and for the promotion of continuous improvements in the environmental performance of all organisations (small or large, from the private or public sector) in Europe. The scheme is a market-based instrument which provides for voluntary participation. This means that rather than relying on traditional enforcement measures through national regulators it is intended to generate peer pressure and supply chain pressure to encourage organisations to participate. All participating organisations in EMAS must however comply with all the requirements of the Regulation. This ensures a credible and rigorous approach to environmental management.

The scheme reconciles both economic and environmental concerns by allowing organisations to set their own environmental objectives as a result of examining their environmental performance. Participating organisations can thus address environmental issues within the framework of their economic considerations. EMAS also embodies the qualities of credibility and transparency. The implementation of the scheme in organisations is independently verified by an accredited environmental verifier. This verifier also checks the reliability of the data and information in the environmental statement which is used by participating organisations to communicate information about its environmental performance to stakeholders and the public.

EMAS represents an alternative approach to environmental protection through the use of market mechanisms and the integration of environmental considerations into the core of company management. At the same time the scheme is complementary to the traditional command-and-control approach.

What are the main problems identified?

Article 15 of the Regulation provides for the revision of the Regulation not more than five years after its entry into force.

The Commission shall review EMAS in the light of experience gained during its operation and international developments no later than five years after the entry into force of this Regulation, and shall, if necessary, propose to the European Parliament and Council the appropriate amendments.

This provision reflects the dynamic nature of the scheme which, as a market instrument, needs to improve on the basis of findings related to its practical implementation and in conjunction with the evolving views of its stakeholders.

It is in that context that a large-scale evaluation study of the EMAS scheme was carried out in 2005. This review identified the strengths and weaknesses of the scheme and proposed options to improve the effectiveness of the Regulation.

The review shows that at micro-level, EMAS has achieved its objectives as it significantly improves the environmental performances of participating organisations. It is therefore, in theory, an instrument that enables the EU to take forward its environmental agenda, leading to environmentally beneficial changes in production and consumption patterns.

However, the review also shows that at macro-level, the scheme has not reached its full potential in terms of diffusion. Even though EMAS registrations continue to grow steadily with more than 4,700 registered organisations in Europe, this still represents only a very small proportion of the number of organisations that could potentially use the scheme. The scheme has also been criticised because the international standard for environmental management systems ISO14001, a 'competitor' scheme which is less demanding in terms of environmental achievements, has developed more rapidly than EMAS, with now some 30,000 certifications in Europe.

Given the current political context, with the renewed Lisbon strategy focusing on improving and simplifying the regulatory framework for business, voluntary instruments such as EMAS remain attractive tools in the EU environmental policy mix in order to achieve our overall environmental objectives, particularly towards more sustainable production and consumption.

We therefore propose to fundamentally revise EMAS scheme in order to significantly increase its functionality and up-take, and make it become what it should always have been: a true, sizeable support to traditional "command-and-control"-type legislation, which is business-friendly and helps the EU achieve its overall environmental objectives.

Is EU action justified on grounds of subsidiarity?

The adoption of the scheme at Community level is necessary to propose a level playing field within the Single Market and avoid the establishment of national schemes which could potentially be incompatible. This Proposal does not alter the current situation with regard to the internal market and continues to respect the principles of subsidiarity by leaving the technical implementation of the Regulation to the Member States through the functioning of the competent bodies and accreditation bodies. The effectiveness of the scheme in contributing to better environmental performance of European companies is thus ensured whilst the measures that can be adequately performed at national level are left to the Member States.

B. Objectives of EU initiative

What are the main policy objectives?

The objective is to revise the EMAS scheme, as required by Article 15 of the EMAS Regulation, in order to best encourage continuous improvement in the environmental performance of all organisations. To achieve this objective, the revision of the EMAS Regulation aims at substantially enhancing the political profile and hence the number of organisations applying the scheme, especially SMEs. The fundamental changes proposed will focus on the substance with special attention for the needs of SMEs, the institutional set up and the links to other policy instruments in particular Green Public Procurement.

Does the objective imply developing EU policy in new areas or of strategic importance?

The EMAS revision is part of the package of measures accompanying the Communication on a Sustainable Consumption and Production Action Plan, which is to be adopted in February 2008. The Action Plan seeks to substantially change consumers and producers behaviours towards better products, a leaner and cleaner production and a smarter consumption. It will encompass together with the EMAS revision, a revision of the Ecolabel Regulation and a Communication on green Public Procurement

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Based on the results of several studies and the feedback from stakeholders, 3 options have been analysed for the revision of the scheme, ranging from substantially modifying the EMAS scheme in order to significantly improve its take-up, to terminating the scheme. Based on a risk analysis of all options (see question 4 below), we recommend option 1: substantially modifying EMAS.

1. Option 1 – Substantial modification

Revise fundamentally the scheme to:

- Make it the best indication towards external stakeholders and national enforcement authorities that EMAS organisations comply with all applicable legal requirements relating to the environment and continuously improve their environmental performances.
- Increase its user-friendliness, particularly for SMEs, by reducing procedural requirements, by re-writing the text of the Regulation in a more logical, easier-to-understand way, and by increasing the consistency of the implementation of EMAS across the Member States.
- Raise its attractiveness for participating organisations, by reducing the administrative burden for participating companies at EU and national level, and by increasing the visibility of participation in EMAS.
- Raise its attractiveness for participating organisations, by extending the scope of EMAS to outside EU organisations.

Rationale:

Several studies confirm that there is evidence that EMAS leads to better site environmental management activities than other existing environmental management systems and that EMAS requires full compliance with all applicable legal requirements relating to the environment and continuous improvement of an organisations' environmental performance. However, even though its uptake is steadily rising, EMAS has not reached its market penetration potential. In industrial sector, the global scheme ISO14001 with about 30,000 certificates in the EU has overtaken in numbers EMAS. On contrary, the use of EMAS is steadily increasing in institutions and local governments. Geographically the scheme has gained a good position in countries such as Germany, Austria, Italy and Spain while it is less recognised and used in UK, Ireland and also France.

As the obstacles for a higher up-take of EMAS are now well understood, this option offers the chance to substantially modify and turn the scheme into the best instrument on the market, complementing and supporting the implementation of EU environmental legislation.

Possible ways forward:

Make the scheme the best indication towards external stakeholders and national enforcement authorities that EMAS organisations comply with all relevant environmental legislation and continuously improve their environmental performances.

- Strengthen and clarify the existing requirements for EMAS organisations to comply with all relevant environmental legislation in order to offer EMAS as a true tool for Member States regulators to reduce the administrative burden of registered organisations.
- Strengthen and clarify existing environmental reporting requirements for EMAS organisations with the use of core performance indicators in order to better focus the scheme on the current EU political priorities (e.g. emission to air, etc), and enable better benchmarking between participating organisations.
- Develop reference documents for best practice in environmental management, covering specific sectors and focussing on direct environmental aspects of production operations as well as indirect aspects. Where applicable, performance benchmarks set by other instruments, e.g. Eco-label will be used. Green private purchasing will be encouraged.
- improve consistency in the implementation of the scheme throughout Europe by aligning and harmonising the requirements applicable to accreditation and verification procedures for different types of EMAS organisations across all countries by setting the rules out more clearly in the Regulation.

Raise the attractiveness of the scheme for participating organisations, by reducing the administrative burden for participating companies at EU and national level, and by increasing the visibility of participation in EMAS.

- Continue to maintain and clarify the link between EMAS and the ISO14001 environmental management system for organisations that wish to opt for the latter as well as for EMAS.
- clarify the links and complementarities with other (national) environmental management systems so that registration in these schemes can be taken into account when an organisation applies for registration under EMAS and *vice versa*.
- Create closer operational links between EMAS and other EU legislation e.g. Green Public Procurement, Emission Trading Scheme, Integrated Pollution Prevention Control (cost-savings, lower permit renewal frequency).
- Intensify Member States efforts to reduce the administrative burden for EMAS registered organisations and to provide financial, fiscal, market related incentives for registered organisations.
- Improve the use of the EMAS logo and the environmental report as more attractive communication and marketing tools for participating organisations.
- Create yearly European EMAS award event to reward frontrunners.
- Open EMAS registration to organisations outside the EU, in order to enhance the visibility of the scheme outside of the EU and raise the attractiveness of the scheme for organisations that wish to use EMAS as a communication tool to their international customers.
- Improve and intensify EMAS promotion / explanation efforts made by Member States; establish an EU-wide communication program in order to better explain and promote the scheme, as well as give more recognition and visibility to registered organisations.

Increase the user-friendliness of the scheme, particularly for SMEs, by reducing procedural requirements to EMAS organisations, by re-writing the text of the Regulation in a more logical, easier-to-understand way, and by increasing the consistency of the implementation of the scheme across the Member States.

- Re-write the text of the Regulation in a more logical and easier-to-understand way to make it easier for candidate organisations to apply
- Integrate the main elements of the existing non-binding EMAS guidelines in the regulation to improve legal certainty

2. Option 2 – Continue with the present approach

Option two aims at continuing with the current approach, i.e. not bring any major changes to the scheme's content and level of ambition. No substantive changes to the scheme's content and level of ambition will be introduced. Changes considered could only be of administrative / institutional nature, in order to just make the current scheme run better.

Rationale:

Some Member States and interested parties have expressed their preferences for continuing with the present approach. The rationale is that after several changes in the scheme since its inception –EMAS was introduced in 1995 and revised in 2001- it may be better to leave potential and current participants some time to accustom to EMAS II, especially as the number of registrations is rising again and EMAS has high political support in several Member States. In addition, the pace of new registrations in institutions and local governments is encouraging.

Possible ways forward:

This option foresees:

- Rewriting of the text of the Regulation and the guidelines in a more logical and easier to understand way.

3. Option 3 – Gradually phase out the scheme

Option three aims at abolishing EMAS in the long run and instead at doing nothing or promoting other existing voluntary tools.

Rationale:

The rationale for this option would be, as a few stakeholders argued, that since the scheme missed some of its targets (i.e.: broad diffusion), it should be phased out and other initiatives should be encouraged.

It is however to be noted that the vast majority of Member States, stakeholders and interested parties consulted do not share this view and confirmed that EMAS is a useful policy tool that brings added value and that they do not want the scheme to disappear.

Possible ways forward:

- the easiest way to phase out EMAS would be to slowly reduce all resources allocated to the scheme; with no further public support, the number of EMAS registrations is likely to shrink and the more difficult legal abolition of the scheme can be transferred to a later moment.

In practical terms, the Commission could start by reducing its own staff and abandoning any actions on EMAS (no further promotion, pilot projects, helpdesk, etc).

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

1. Option 1 – Substantial modification

Pros As the obstacles for a higher uptake of EMAS are now well understood, this option to substantially modify of the scheme offers an opportunity to correct the weak points identified by the studies that have been carried out and confirmed by stakeholders. Through introduction of a number of substantive changes, EMAS can become what it was originally designed to be: a sizeable voluntary alternative to traditional command and control legislation, which addresses all types of organisations, which is business friendly and which helps the EU achieve its overall environmental objectives and priorities.

Cons It might be difficult to reach agreement on some of the suggested changes, particularly related to providing incentives to EMAS organisations. A number of radical changes will also require some upfront investment by the Commission and/or the Member States. It is however felt that, even where the measures have budgetary implications for Commission or Member States, the benefits of the measures proposed outweigh these negative cost-aspects. Thus, negative impacts on member state tax revenues might be compensated for example by an increase of taxes on the most polluting companies.

To mitigate the budgetary implications, a smooth transition is needed towards the revised Regulation.

2. Option 2 – continuing with the present approach

Pros This option would provide stability for New Member States which just started implementing the scheme and current users. No significant effort will be required by the Commission or by the Member States at the different organisational and co-ordination levels.

Cons This option will only improve slightly the “weak points” of the scheme and will not provide a chance for substantial modifications aiming at its much wider diffusion, especially towards SMEs. Slightly expanding EMAS expenditures will still require a management effort by the Commission and the Member States. Without some bigger 'push', the continued low take-up of the scheme in many Member States will undermine its credibility and its overall impact will remain low. The visibility of the scheme will not increase and uneven distribution between the Member States is likely to prevail. Member States would criticise the Commission for not taking positive action to support the scheme in the future.

3. Option 3 – Gradually phase out the scheme

Pros Gradual phase-out means a less evident loss of credibility for the Commission and lower level of conflict with some Member States than if it just terminated the scheme. Financial and personnel resources would be set free for new initiatives in the field of the environment.

Cons This option will have negative environmental and economic impacts. It also entails the risk of having significant negative indirect impacts on the overall perception of EU environmental policy, as phasing out the scheme would send the signal that the Commission is downgrading its environmental policy. The Community would lose an environmental instrument in its policy mix. It would also lose an opportunity to influence and raise the level-playing field for private similar voluntary initiatives to deliver meaningful environmental improvements to participating organisations.

Terminating EMAS, one of the two EU voluntary instruments (EMAS and Eco-label) might also be interpreted as a move towards more command-and-control policies. Several Member States and other EU institutions would likely criticise the Commission heavily and relevant communities which have been involved with the implementation of the scheme and want it to continue would also likely attack the Commission for letting them down.

Finally, there would also be a loss of opportunity to turn EMAS into a successful instrument.

Do the options respect the proportionality principle? Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

1. Option 1 – Substantial modification

Pros Option 1 would improve the visibility, impact and political profile of the EMAS scheme, which would lead into a significantly wider diffusion, especially towards SMEs. This option would also enable the EU to deliver better and more focused environmental benefits, both directly and indirectly. It would also improve the economic situation and reduce the administrative burden of environmental management in participating organisations.

Cons Some of the suggested changes, particularly related to providing incentives to EMAS organisations, may be difficult to agree on, both within the Commission, and at Council level. Member States may also resist substantial changes, as they will require some up-front investment both by the Commission and the Member States. To mitigate this risk, a smooth transition is needed towards the revised Regulation.

2. Option 2 – Reinforce the present scheme

Pros This option would provide stability for New Member States which just started implementing the scheme and current users. No significant effort will be required by the Commission or by the Member States at the different organisational and co-ordination levels.

Cons This option will only improve slightly the “weak points” of the scheme and will not provide a chance for its much wider diffusion, especially towards SMEs. Slightly expanding EMAS expenditures will still require a management effort by the Commission and the Member States. Without some bigger ‘push’, the continued low take-up of the scheme in many Member States will undermine its credibility and its overall impact will remain low. The visibility of the scheme will not increase and uneven distribution between the Member States is likely to prevail. Member States would criticise the Commission for not taking positive action to support the scheme in the future.

3. Option 3 – Gradually phase out the scheme

Pros Gradual phase-out means a less evident loss of credibility for the Commission and lower level of conflict with some Member States than if it just terminated the scheme. Financial and personnel resources would be set free for new initiatives in the field of the environment.

Cons This option would bring the risk of having significant negative indirect impacts on the overall perception of EU environmental policy, as phasing out the scheme would send the signal that the Commission is downgrading its environmental policy. The Community would lose an environmental instrument in its policy mix. It would also lose an opportunity to influence and raise the level-playing field for private similar voluntary initiatives to deliver meaningful environmental improvements to participating organisations.

Terminating the two EU voluntary instruments (EMAS and Eco-label) might also be interpreted as a move towards more command-and-control policies. Several Member States and other EU institutions would likely criticise the Commission heavily and relevant communities which have been involved with the implementation of the scheme and want it to continue would also likely attack the Commission for letting them down. Finally, there would also be a loss of opportunity to turn EMAS into a really successful instrument.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Yes, this initiative is part of the Simplification Rolling Programme 2005.

Who is affected?

Organisations willing to join the scheme, organisations already part of the scheme.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The revision process began around two years ago, with the launching of a large-scale evaluation study on EMAS and Eco-label carried out by a consortium of consultants led by Bocconi University, known as the 'EVER' study.

This study included, as well as a major literature review, a number of workshops and in depth interviews with participants and non-participants in the schemes as well as other interested parties.

Concurrently the Member States bodies running the EMAS and Eco-label schemes organised a number of stakeholder meetings and seminars on the future of the schemes, producing recommendations for their revision in the future.

Since the publication of the EVER study results in January the consultation process has intensified further with the Commission organising 4 working group meetings with selected EMAS experts and visiting selected Member States to gather their opinion on the revision of the Regulation, and Member States and other interested parties putting forward their ideas for the future of the scheme.

In parallel, the REMAS project -a three-year project funded by the EU LIFE Environment Fund, the UK Environment Agency, the Scottish Environment Protection Agency, the UK Institute of Environmental Management and Assessment and the Environmental Protection Agency in Ireland- was concluded in May 2006. The objectives of the REMAS project were to determine the influence of different types of EMS on site environmental management activities, and their subsequent impact on compliance with legislation and performance against best available techniques. The project concluded that EMAS leads to better site environmental management activities than any other existing EMS.

No additional external contracts are planned at this stage. At this stage in the process, it is felt that enough information has been collected through the above-mentioned studies conducted so far.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Commission services maintain a continuing dialogue with representatives of the Member States and with the different stakeholders of the EMAS process, in order to follow the practical implementation of the Scheme. This makes it possible to monitor its strengths and weaknesses.

A formal round of consultation with EMAS stakeholders was nevertheless felt to be necessary to provide the Commission with good grounds to conduct an effective revision process.

Apart from the above-mentioned EVER study (see question 5 above) which included a major literature review and a number of workshops and in depth interviews with participants and non-participants in the schemes as well as other interested parties, further consultation took place and is planned in order to gather recommendations from the main EMAS stakeholders.

These include representatives from the business community, including SMEs, and public organisations community, EMAS verifiers, EMAS consultants, accreditation bodies, competent bodies, NGOs, national EMAS experts.

The Commission gathered four working groups comprised of EMAS verifiers, consultants, accreditation bodies and competent bodies on May 17, June 06, July 20 and July 27 2006 to analyse in details the pros and cons of specific changes proposed to the EMAS Regulation.

A further workshop took place on December 11 and 12 2006 with around 100 EMAS experts and stakeholders to receive feedback on the final draft of the revised EMAS Regulation.

Member States representatives to the Article 14 comitology meeting of the EMAS regulation have also been consulted and have provided input into the revision work of the Commission on the following dates: June 20 2005 – Brussels, November 22 2005 – Turin, June 29-30 2006 – Luxembourg – Athens, November 13-14 2006 and Warsaw, June 26-27 2007.

As part of the Impact Assessment, a public stakeholder consultation using the IPM internet consultation tool has been launched at the end of December 2006. The consultation was opened to all interested parties and provided a useful feedback on the main options proposed to revise the EMAS Regulation.

ROADMAP

Title of the initiative: **Revision of Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme**

Expected date of adoption of the initiative: **February 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In the beginning of the 90's, voluntary instruments were created as alternative policy tools to traditional "command-and-control" legislation. The 5th and 6th Environment Action Programmes advocate strongly the use of voluntary instruments as part of the EU environmental policy mix. Some 10 years later, in the current political context, with the renewed Lisbon strategy focusing on improving and simplifying the regulatory framework in which business operates, voluntary instruments such as EMAS or the Eco-label can still prove useful additional tools for achieving our environmental objectives.

The EU Eco-label is the only Europe-wide label of its kind. It is supposed to set the standard for other labels to follow, taking forward the European environmental agenda. It can give EU consumers an environmental certification they can trust, when there are many other labels that are simply self-claims, and it can give businesses the opportunity to use one label for all their pan-European or global marketing.

The Eco-label is, in theory therefore, an instrument that enables the EU to take forward its environmental agenda, leading to environmentally beneficial changes in production and consumption patterns.

What are the main problems identified?

Article 20 of the Ecolabel Regulation stipulates that *"...the Commission shall review the Scheme in light of the experience gained during its operation. The Commission shall propose any appropriate amendments to the Regulation."*

The revision process began around two years ago, with the launching of a large-scale evaluation study on EMAS and Eco-label carried out by a consortium of consultants led by Bocconi University. This study included, as well as a major literature review, a number of workshops and in depth interviews with participants and non-participants in the schemes as well as other interested parties. Concurrently the bodies running the EMAS and Eco-label schemes organised a number of stakeholder meetings and seminars on the future of the schemes, producing recommendations for their revision in the future.

The study leads us to the following conclusions:

- Companies participating in the EU scheme use the Eco-label in their marketing campaigns
- It has contributed to them setting targets for better product environmental performance
- It influenced their demand on suppliers concerning the environmental performance
- 80% of the non-Eco-label participants use the Eco-label criteria as benchmarks for the environmental performance of their products
- Neither users or non-users of the Eco-label want to see the label abolished
- The EU Eco-label is preferred to national labels.

However the main problems identified are:

- Low awareness and uneven geographic coverage
- Insufficient product group categories
- Procedural and organisational problems – i.e. bureaucracy
- Fees and cost of getting the label are perceived as barriers
- Lack of perceived public purchasing benefits

Basically, the scheme has not nearly reached its potential. While those using the scheme point out the positive environmental benefits they have brought, and while the scheme continues to grow steadily with around €700million of sales of Eco-labelled products, it still commands very small market shares in relative terms.

The Eco-label needs to aim for a much higher awareness, understanding and respect along with a higher participation if it is to meet its aim. It needs to be well integrated with other schemes and with other Community instruments such as green public procurement

Is EU action justified on the grounds of subsidiarity?

The Ecolabel certification is a Community-wide certification. Any revision of this scheme should therefore be made at EU level.

B. Objectives of EU initiative

What are the main policy objectives?

According to Article 1 of the current Regulation:

“The objective of the Community eco-label award scheme is to promote products which have the potential to reduce negative environmental impacts, as compared with the other products in the same product group, thus contributing to the efficient use of resources and a high level of environmental protection.”

This aim still seems valid and relevant. It is precise, easy to understand and to use, and it should, therefore, be kept as the cornerstone of reference for the discussions on the future of The Flower. This means that at all times during the revision process we should ask ourselves how best to meet this aim.

It is also necessary to envisage how an EU Eco-label scheme that is best meeting this aim would look. What is the ‘vision’ for The Flower to maximise its environmental benefits?

Vision for the EU Eco-label

An Eco-label with:

- High awareness, understanding and respect in the EU25 and around the world;
- Criteria for all products and services where the Eco-label can provide benefits;
- Many more Eco-label products on the shelves for consumers to choose from;
- A much more influential Eco-label in terms of setting benchmarks for companies and educating the public;
- An EU label very well harmonised with other labels, globally and nationally;
- A business friendly Flower;
- A GPP friendly Flower;
- A Flower that is self marketing to a much greater extent;
- An Eco-label that can be a useful tool for driving the environmental agenda.

Leading to:

- Much higher direct and indirect benefits coming from the Flower.

It is on the basis of the Eco-label aim, and the vision for The Flower, that the discussion and consultation process on the revision of the scheme are based.

Does the objective imply developing EU policy in new areas or of strategic importance?

The EMAS revision is part of the package of measures accompanying the Communication on a Sustainable Consumption and Production Action Plan, which is to be adopted in February 2008. The Action Plan seeks to radically change consumers and producers behaviours towards better products, a leaner and cleaner production and a smarter consumption. It will encompass together with the EMAS revision, a revision of the Ecolabel Regulation and a Communication on green Public Procurement

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option 1 – Radical overhaul

Give the Eco-label a fundamental reappraisal from the ground up with the aim of rapidly expanding the number of product groups covered and the number of companies involved in the scheme.

Changes required:

- Change institutional set-up, outsource day-to-day business to office/agency.
- Major restructuring of the scheme – remove the bureaucracy, cut red tape.
- Commission keep overall control and political steer
- Complete change in the way criteria are developed and agreed – allowing for the development of more product groups.
- Involvement of all stakeholders in decision making, more business orientated criteria.
- Major rethink of the nature of criteria themselves – stringency, number of criteria, environmental focus.
- Legislation enabling convergence with national schemes.
- Big marketing push to increase the knowledge of the label.
- Introduce legislation linking to the use of green claims, where product in areas covered by the Eco-label cannot make green claims unless then meet the criteria.
- Change to the public procurement regime to encourage use of Eco-labelled criteria.

Option 2 – Reinforce the current scheme

Look at, and address, some key problems with the current scheme to promote its continuing growth and make changes appropriate for the next five to ten years of its operation.

Changes required:

- Make some minor modifications to the management of the scheme to remove some bureaucracy in decision making processes
- Modify the rules on how criteria are developed in order speed up the process
- Ensure criteria documents are easier to use and are more accessible for public purchasers.
- Improve synergy with national labels
- Develop new marketing strategy

Option 3 – Continue with the present approach

Leave the scheme alone, giving it stability, and allow the slow but steady growth to continue.

Changes required:

None – the current regulation would remain in force

Option 4 – Gradually phase out the scheme

Give up on the idea of an EU Eco-label, phase out the scheme and help to support the development of national labels.

Changes required:

- Stop Commission funding for development of new product groups and marketing.
- Slow down and eventually stop having Eco-label meetings.
- Stop taking on new Eco-label customers

Finally withdraw the Regulation

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, industrial policy and consumer protection

Do the options respect the proportionality principle? Yes.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Option 1 –Radical overhaul

Potential impacts:

- Pros These changes could significantly increase the number of Eco-labelled products on the market, the knowledge of the label and its influence as a driver of the environmental agenda within the next five to ten years. Under such conditions the Eco-label could provide significant environmental benefits, directly and indirectly.
- Cons Some of the changes might be difficult to reach agreement on. Need to be careful not to change only for change's sake - need to ensure that the good base on which the Eco-label is currently growing steadily is maintained and that there would be a smooth transition between the old and new Regulations for companies that have invested to get the label.

Option 2 – Reinforce the current scheme

Potential impacts:

- Pros This approach could tidy up some of the most obvious problems with the current Eco-label and build on the promising recent growth that has been witnessed. These changes would be easy to agree and implement and would allow the new Member States to get used to the scheme they have only recently implemented.
- Cons While growing steadily, the Eco-label would be unlikely to achieve a significant mass or become a very well known label within the next five to ten years. It would continue to be just another label alongside the national labels and, although it might survive, it would be unlikely to have significant impact.

Option 3 – Continue with the present approach

Potential impacts:

- Pros No action required. Stability for New Member States and current scheme users.
- Cons Very unlikely that the Eco-label will grow significantly. Scheme will remain marginalised and relatively unknown. Negative feeling could develop for not taking positive action to support the label in the future.

Option 4 – Gradually phase out the scheme

Potential impacts:

- Pros The scheme has not been very successful in terms of its diffusion; there are potential cost savings; national labels already exist and that time energy could be better focused on them
- Cons Abandoning the scheme would be unpopular with many stakeholders including Member States; it would mean that opportunities for improving the scheme and benefits currently coming from the scheme would also be lost.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

This is a simplification included in the Simplification Rolling Programme 2005.

Who is affected?

Business awarded with the Ecolabel and potentially interested business.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

As described earlier, the revision process began around two years ago, with the launching of the large-scale evaluation study on EMAS and Eco-label carried out by a consortium of consultants led by Bocconi University, known as the 'EVER' study.

This study included, as well as a major literature review, a number of workshops and in depth interviews with participants and non-participants in the schemes as well as other interested parties.

Concurrently the Member States bodies running the EMAS and Eco-label schemes organised a number of stakeholder meetings and seminars on the future of the schemes, producing recommendations for their revision in the future.

Since then informal discussion on options for the revision of the Eco-label scheme have been ongoing. The results of the EVER study itself were the basis of a two day Eco-label Presidency meeting in Vienna in February 2006 and a detailed informal discussion paper on the revision was then produced by the Commission and presented to the Eco-labelling board in February 2006.

Wider stakeholder consultation is now required but no additional external contracts are planned at this stage.

Which stakeholders & experts have been/will be consulted, how and at what stage?

A Commission open consultation is envisaged for the end of 2006 as part of the impact assessment. This will use the Interactive Policy Making tool in the form of a questionnaire published on the Your Voice in Europe web pages.

The consultation will be targeted at all interested stakeholders, including:

participating and non-participating companies
SMEs
NGOs
trade unions
competent bodies
market experts
retailers

ROADMAP

Title of the initiative: **Mid-term report on the Implementation of the Biodiversity Action Plan**

Expected date of adoption of the initiative: **November 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In 2006, the Commission published a Communication entitled- "Halting Biodiversity Loss by 2010 and Beyond. Annexed to this Communication was an Action Plan setting out the measures (154 in total) which should be taken by the EU and within the Member States in order to achieve the 2010 target. The report of progress for 2008 will provide a basis for the Commission and the other institutions to assess overall progress towards the 2010 target and to determine whether the efforts need to be reinforced. The 2008 report will also provide a platform to revisit the issue of Biodiversity protection at the highest political level.

What are the main problems identified?

Together with Climate Change, conserving and protecting biodiversity is the main environmental challenge at both the global and EU level. By conserving biodiversity we also guarantee the continuing flow of the ecosystem goods and services upon which our society depends. If we do not ensure the health and integrity of our ecosystems we will not be able to deliver sustainable development.

Is EU action justified on grounds of subsidiarity?

The motivation for EU actions in the area of biodiversity protection were set out in the initial Communication – Halting Biodiversity Loss by 2010 and Beyond.

The subject of the present screening relates to the report on the delivery of the already agreed Biodiversity Action Plan attached to this previous communication.

B. Objectives of EU initiative

What are the main policy objectives?

The report does not imply new policy objectives. It will simply be a mid-term check-up on the progress towards the achievement of the 2010 target identified in the 2010 Communication.

Does the objective imply developing EU policy in new areas or of strategic importance?

The publication of the report will not imply the development of new EU policy in areas of strategic importance.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The document under consideration is a report. The question of the most appropriate policy option is not relevant.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The publication of the report will inform the development of EU policy and actions in other policy areas. If EU level actions that were already foreseen among the 154 actions included in the 2006 Action plan have not yet been taken this may create pressure for these non-completed actions to be carried out.

Do the options respect the proportionality principle?

Not relevant (see answers to previous questions)

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

As explained above, the report in question will not imply the development of new policy options and therefore it is not relevant to refer to the impacts of such policy options.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The report will not imply new policy options or initiatives and therefore there will not be an impact on the EU budget.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

There will be no additional cost/burden for third countries.

Who is affected?

No parties will be affected.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Information for the completion of the report will come from within the Commission, from the Member States and other stakeholders.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Member States have already been consulted regarding the need and the mechanism for providing information for the completion of the report. Other stakeholders will be addressed within the coming months.

ROADMAP

Title of the initiative: **Communication on policy options to tackle invasive alien species**

Expected date of adoption of the initiative: **September 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Invasive Alien Species has been identified as an environmental concern in the 6th EAP and in the 2006 Communication on Halting the Loss of Biodiversity.

The threat of IAS has been recognised at the global level. The Convention on Biological Diversity (CBD) adopted Guiding Principles for the prevention, introduction and mitigation of impacts of alien species that threaten ecosystems, habitats or species. IAS will be subject to in-depth review at coming COP9 in 2008. IAS issue is also addressed by the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE) or the International Maritime Organisation (IMO). In 2003, the 'European Strategy on Invasive Alien Species' was adopted under the Bern Convention at Pan-European level.

Ongoing EU activities concerning IAS include the recently adopted Regulation concerning the use of alien and locally absent species in aquaculture (708/2007 of 11 June 2007), research projects e.g. DAISIE (Delivering Alien Invasive Species Inventories for Europe) and ALARM (Assessing Large-scale Risks for biodiversity with tested Methods) or SEBI 2010 process (Streamlining European 2010 Biodiversity Indicators).

The legal framework addressing IAS at EU level is very incomplete and covers only specific groups of organisms (e.g. plant pests, 4 species covered under the Wildlife Trade Regulations, aquaculture organisms). Addressing IAS issue at Member States level varies between MS. There is no consistent horizontal coordination at EU level.

What are the main problems identified?

Invasive Alien Species – i.e. species that are not native to Europe and which threaten the survival of native species of fauna and flora- are one the biggest threats to Biodiversity. The proliferation of invasive alien species has been exacerbated by the increased transportation of goods across the globe and is likely to intensify as global trade increases. Climate Change is also contributing to this phenomenon e.g. where species experience difficulties in adapting to changes in local climatic conditions they migrate to more suitable climates.

Is EU action justified on grounds of subsidiarity?

Because of the lack of internal border controls between Member States, a co-ordinated approach is necessary at the outer borders of the EU to stop the introduction of alien species in the European territory. Once an alien species is present it can be very difficult for one Member State to control its subsequent dispersal; plant pollen can be carried great distances on the wind, while animals and birds can also spread very quickly. Co-ordinated actions across the EU are therefore needed to detect and report on invasive alien species and also for eradication programmes.

B. Objectives of EU initiative

What are the main policy objectives?

To minimize the impact of Invasive Alien Species on EU biodiversity.

Does the objective imply developing EU policy in new areas or of strategic importance?

The objective has already been agreed by the Commission as part of the 2006 Communication on "Halting Biodiversity Loss by 2010 and Beyond". Furthermore, any measures to be undertaken would fall within the framework of existing policy on environment, trade, plant and animal health and research.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

First of all, the purpose of the Communication would be to explore and examine the various policy options which are available. Therefore it is not possible to be specific as to exactly what combination of policy options are going to be recommended. However, the types of options under consideration will be:

- i) A 'business as usual' option with no additional initiatives at EU level;
- ii) An EU Action Plan involving greater research and information exchange but no regulatory actions;
- iii) An EU Action Plan comprised of amendments to existing legislation dealing with Animal and Plant Health combined with greater research and information exchange.
- iv) The same as "iii" but with a specific piece of dedicated legislation to ensure co-ordinated responses from the Member States and to fill any legislative gaps.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Transport, trade, phyto and zoo sanitary policy, agriculture, fishery and development policies are potentially concerned.

Do the options respect the proportionality principle?

Given the potential economic damage associated with Invasive Alien Species it would seem appropriate for the EU to strengthen its current arrangements. The graded nature of the options to be explored will allow a transparent debate on the additional costs that Member States and Stakeholders consider appropriate to dedicate to tackling this problem.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The negative economic and biological impacts of IAS are enormous. The majority of such costs will be for the national administrations in terms of tighter controls (more border inspections with trained, specialised staff), monitoring (systematic monitoring of environmental media in order to detect invasive species quickly) and eradication programmes (removing, trapping etc of invasive species), while at the same time they will also be the main beneficiaries of a tighter control of invasive alien species (alien species have been estimated to cost our economies hundreds of billions of euros.)

There may be some additional costs imposed on importers of species or materials which are identified as Invasive Alien Species or which may risk to bring IAS with them into the EU. Such additional costs could include greater administrative costs for getting authorisations for importation and in some cases the loss of income resulting from restrictions being placed on imports (e.g. ornamental plants)

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Not at this stage.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

This initiative will not result in a simplification of the 'acquis'.

It may have impacts on our relations to third countries as it may entail a reinforcement of controls at the EU external borders with regard to the import of species which may constitute a risk. However, any measures which are taken would need to be compatible with WTO rules.

Who is affected?

Member States' administrations that will have to implement future policy. If further legislation is adopted, impacts can be foreseen on importers of products from Third countries, shippers and professionals of the transport sector.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

DG ENV has already done a preliminary assessment of the gaps in current legislation and the potential policy options in 2006. A call for tender (€250K) has been launched on the 2007 budget in order to generate information on the costs of various policy options.

Which stakeholders & experts have been/will be consulted, how and at what stage?

All Member States, experts, business representatives, NGOs and other members of civil society. Meetings and conferences will be held as well as an inter-net consultation.

ROADMAP

Title of the initiative: **Green Paper on Agricultural Product Quality Policy**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Farmers and producers of agricultural products face increasing competition in the marketplace, (in general) downward pressure on farm-gate prices, and increasing demand from consumers for quality products. Those who can respond by improving quality and supplying quality markets should be able to better valorise production and improve their economic performance and prospects.

The Green Paper is a first step towards a possible revision of policy. It will build on the conclusions to the Food Quality Certification Conference (Brussels, 5-6.2.2007) and will cover development of existing EU marketing standards and quality instruments for protected geographical indications, protected denominations of origin and traditional specialities guaranteed, as well as the increasing number of private and national schemes and initiatives. The Green Paper will seek views of stakeholders on any developments needed in the legal framework, such as labelling, as well as measures to assist farmers and producers both pre- and post-farm gate to improve quality production and successfully market product on the basis of quality characteristics.

What are the main problems identified?

- increased competition and, in general, downward pressure on prices;
- difficulties in communication by farmers about the quality attributes of products to final consumers through the food chain;
- difficulties for farmers (usually small businesses) to make improvements in quality production and secure access to markets for quality products;
- need to ensure consumer confidence in the increasing number and variety of claims concerning farm production qualities of products and foodstuffs;
- need to ensure the smooth operation of quality schemes in the single market.

Is EU action justified on grounds of subsidiarity?

- EU action is justified as measures and the legal framework applicable to farmers fall within the Common Agricultural Policy and to ensure the functioning of the single market
- However, much action should take place at the level of private operators, representative organisations, or regional and national authorities.

B. Objectives of EU initiative

What are the main policy objectives?

The objectives of the Green Paper are:

- to seek views on the development of existing EU quality schemes;
- to consult stakeholders on the challenge of improving quality production and marketing of agricultural product and foodstuffs.
- to hear views on possible options for the evolution of agricultural product quality policy, marketing rules, and initiatives for development of measures and the legal framework.

Does the objective imply developing EU policy in new areas or of strategic importance? No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Building on the operation of current EC quality policy instruments, the conclusions of the Food Quality Certification Conference, Brussels February 2007, and studies on food quality assurance and certification schemes, the Green Paper will examine a range of policy ideas and options, including possible developments in existing instruments and measures available for farmers and producers to improve their production quality and marketing.

The Green Paper will not, however, consider changes to the recently-adopted organic farming regulation (Regulation (EC) No 834/2007), nor will it cover issues of safety and hygiene of agricultural product and foodstuffs.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Agricultural policy instruments concerning the marketing of agricultural products and foodstuffs involve internal market policy, competition of product in the single market, and product labelling policy. These policy areas concern also DGs Internal Market, Enterprise, Competition, and Health and Consumer Affairs (Sanco). The marketing of agricultural product having environmental quality attributes concerns also environmental policy (DG Environment). Trade implications and WTO compatibility is an issue also of interest to DG Trade. Enforcement of EC quality schemes, such as that for protected geographical indications, falls under general food law enforcement, under DG Sanco competence.

Do the options respect the proportionality principle?

Options are not yet defined and any such will be elaborated respecting proportionality.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Not applicable. An impact assessment will accompany any proposals that come forward after the consultation on the Green Paper.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

IA is not applicable to a Green Paper.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Not applicable for a Green Paper.

Who is affected?

Farmers and first-stage producers of agricultural products and foodstuffs; consumers; other stakeholders in the supply chain for agricultural products and foodstuffs.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Available information comes, *inter alia*, from studies completed in preparation for the Food Quality Certification Conference, February 2007; an evaluation of the geographical indications quality instrument is in train (due to report in June 2008); other work is ongoing under the 7FP. No additional specific studies are foreseen for the Green Paper, but that does not exclude identification of research needs as a result of the exercise.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The aim of the Green Paper is to consult stakeholders, including academics and other experts.

ROADMAP

Title of the initiative: **Review of the method to delimit Less Favoured Areas (Article 37 of Council Regulation (EC) No 1698/2005**

Expected date of adoption of the initiative: **December 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Support for Less Favoured Areas (LFAs) is granted with the objective to contribute through the continued use of agricultural land to maintaining the countryside, as well as to maintaining and promoting sustainable farming systems. In accordance with Article 93 of Council Regulation (EC) No 1698/2005 the current provisions with regard to the delimitation of LFAs shall be repealed with effect from 1 January 2010, subject to an act of the Council.

There are doubts as to whether the criteria used to delimit LFAs are still justified. There seems to be a risk that criteria applied at present do not result in an optimal LFA delimitation which could have consequences for the success of the policy objective to maintain the countryside and to promote sustainable farming systems

What are the main problems identified?

Support for LFAs has been in place since 1975. Over time the precise criteria to delimit LFAs has evolved. The Commission has been requested to update indicators used to delimit LFAs with a view to ensure the coherent application of delimitation criteria.

Is EU action justified on grounds of subsidiarity?

Support for LFAs is common policy and is (partly) community financed. Therefore, the establishment of common rules is justified.

B. Objectives of EU initiative

What are the main policy objectives?

The initiative is necessary to evaluate the delimitation criteria used in the Member States. If and to adjust them with a view to ensure a coherent delimitation of LFAs.

Does the objective imply developing EU policy in new areas or of strategic importance?

No, it is the adaptation of an existing policy.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Options:

1. Maintain status quo
2. Empower Member States to delimit LFAs according to national criteria
3. Application of a single set of Community criteria to delimit LFAs.

The legislation currently in place imposes a Council Act (see Art 93 of Council Regulation (EC) No 1698/2005).

Any (possible) amendment is not a routine update of delimitation criteria. It may have a direct influence on the economics of rural areas.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes. The proposed action is part of the Rural Development Policy, a key policy area of DG Agriculture and Rural Development that also has an impact on environmental policy and regional policy.

Do the options respect the proportionality principle?

Yes. The problem is the exact delimitation of LFAs and thus the area benefiting from a specific kind of support. The policy options chosen focus on the exact delimitation logic.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

1. If status quo is maintained, there is a risk that LFA delimitations no longer reflect the actual handicaps of the land with the risk that support is targeted at areas that are not restricted by natural handicaps.
2. If Member States are empowered to delimit LFAs according to national criteria there is a risk of a non coherent community wide delimitation which could lead to distortion between farmers.
3. If a single set of Community criteria is applied to delimit LFAs, there is a risk that the criteria will be too rigid, not allowing for specific treatment of particular circumstances.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No impact on budget. The total budget for rural development is fixed per Member State.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No impact on administrative burden for beneficiaries. Support for LFAs has no impact on relations with third countries.

Who is affected?

Farmers.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A study being conducted by DG Joint Research Centre is ongoing. This study focuses on the selection of objective criteria.
The Institute for European Environmental Policy (IEEP) evaluated the application of LFA policy in some Member States.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Consultations will take place at various levels with Member States, farming organisations and other stakeholders concerned.

ROADMAP

Title of the proposal: **Communication from the Commission to the Council and the European Parliament on Sustainable Development of Community Aquaculture.**

Expected date of adoption of the proposal: **December 2008**

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

Seafood is an important and healthy source of proteins all over the world. Increasing consumption of fish in the context of over-fished wild stocks creates an opportunity for the aquaculture sector to help bridge the growing gap between demand and supply of fishery products.

In 2002, the Commission presented a Communication on a Strategy for the sustainable development of European aquaculture (COM(2002)511 final), which gave a ten-year vision of aquaculture aimed at reaching the status of a stable industry guaranteeing long-term secure employment, which was able to cope with the main problems identified, ensuring health and environmental protection.

At EU level, this strategy identified several actions which aimed at:

- providing support to sustainable development of aquaculture (notably through structural funds), promoting integrated coastal zone management,
- assuring the availability of healthy and good quality products to consumers, as well as promoting high animal health and welfare standards,
- ensuring an environmentally sound industry (reducing the impact of waste, tackling the problem of alien species, preventing pollution, conducting environmental impact assessments, protecting biodiversity),
- promoting research.

Aquaculture in the EU appears to be well placed to seize opportunities created by the increasing demand in fish and seafood (strong market for such food, a long tradition of fish and shellfish cultivation, dynamic and advanced research, modern technology, qualified and trained entrepreneurs and fish farmers, suitable climatic conditions and sites for the species currently farmed).

However, our aquaculture sector also faces a number of challenges which have an important impact on production and development. These include limitation of space, limits on access to water of good quality and measures to protect public health and the environment. The high Community standards put European aquaculture at the forefront of sustainable development in the world, both in terms of social and environmental impacts but make it more difficult to compete price-wise with third-country producers, especially in Asia and in South-America where aquaculture production growth is the highest in the world. While worldwide production shows steady overall yearly growth rates close to 9 % between 1995 and 2004, total EU aquaculture production grew at only 3 to 4 % until 1999. This trend served as a basis to set a comparable growth prospect in the 2002 Strategy. However, since the beginning of the millennium, total EU production has been stagnating (data available for the 2000 to 2004 period).

Six years after the adoption of the 2002 Strategy, time has come to take stock of progress made so far and to open a debate with all stakeholders with the view to update it to evolving circumstances allowing the further development of sustainable aquaculture in the EU.

The economic, environmental and social dimensions of aquaculture make EU action fully justified in the different areas of Community competence. However, an important part of the responsibilities in terms of aquaculture development also falls under the subsidiarity principle. Issues such as access to water, allocation of space (e.g. local opposition, competition with other activities such tourism), allocation or renewal of licenses to run an aquaculture farm or setting stricter environmental rules remains fully within the remit of national or local authorities, and their stance is crucial as regards the economic prospects for the overall aquaculture production at EU level.

2. What are the main policy objectives?

At this stage, most of the actions listed in the 2002 Strategy falling under the EU responsibility have been launched: a number are already finalised (such as the adoption of the new European Fisheries Fund or the new fish health legislation) and some are under-way or ongoing actions (e.g. implementing regulations on "organic aquaculture" or "aliens species in aquaculture", support to research). Considering the time lag between the date of EU decisions, their translation into concrete actions, and the delay in access to data collected, it is not yet possible to assess accurately their effect.

However, considering the evolving circumstances and the slowing down of aquaculture growth in Europe in comparison to other parts of the world, the objective of this Communication would be to identify in which ways the European Community, but also others players, could help in providing favourable conditions for the sustainable growth of aquaculture, ensuring both adequate supplies of seafood to our citizens and adequate protection of the environment.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

The first Policy option would be not taking any specific initiative on aquaculture from the Commission and to continue "business as usual" on the basis of the actions identified in the 2002 strategy (i.e. no change until 2012).

The second Policy option is to note that the growth objectives of the 2002 strategy have not been met as foreseen, while the environment and health ones have been generally better addressed. The aim would therefore be to identify the main constraints and challenges hampering sustainable growth and to assess which role should be played by public authorities in contributing to establish the most transparent and predictable business and legal environment which is needed by entrepreneurs to invest and develop.

This second policy option is not of legislative nature. The Communication, to be built upon the 2002 strategy, would identify challenges and further possible actions and their actors (including some further legislative action if needed and appropriate), based on a wide consultation held on the present situation with all stakeholders.

The third policy option could be to develop a specific sectoral "Common Aquaculture Policy", parallel to, or as a specific part of, the Common Fisheries Policy. Considering that fish farming activity may be in some aspects much closer to farming of other animal species than to exploiting wild fish by capture fisheries, a "Common Aquaculture Policy" might also be seen in parallel to the Common Agriculture Policy.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

Public authorities (all EU, national, and local level), all stakeholders, and EU citizens may all be concerned. For the first option, the impact would be essentially of an economic dimension when looking at recent developments of this sector. No specific initiative on aquaculture could probably be seen as leaving European aquaculture facing its present constraints and possibly adding new ones, without allowing it to benefit as much as possible from the global growth prospects for this economic sector.

The second option would aim at identifying ways to set the best framework to increase the importance of the economic pillar of sustainable development of Community aquaculture (while keeping a right environmental dimension).

The direct impact of such Communication will be of political nature. It would act as strong "political" support from the Commission to aquaculture development, helping also in particular the aquaculture sector in its contacts with private investors or national / local authorities. Any important political or legislative action that may be identified in this Communication would be based only on some general impact assessment. A more detailed and comprehensive IA would have to be developed later, when such legislative action would be subsequently developed and proposed.

The third option could lead in proposing to develop a new basic legal framework specific to community aquaculture (which would cover aspects of this economic activity, including for example controls, etc) and to built upon it for the further management of this activity in a more horizontal manner all Community level. This option could lead also to envisaging some important changes in the management of EU aquaculture and its organisation, and were this option retained for consideration, it should be more logical to develop it in parallel to a review of the Common Fisheries Policy.

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when?

What type and level of analysis will be carried out (cf. principle of proportionate analysis)? Information and data available on recent trends in aquaculture and the challenges faced by this sector have been summarised by DG FISH to serve as a basis for a wide stakeholder consultation on the opportunities for the development of community aquaculture that began in May 2007¹⁷. Contributions received are being presently assessed. In addition, the on-going study on the definition of data collection needs for aquaculture will provide information to be used in the analysis and impact assessment. The consultation process should serve as the basis to prepare the Commission communication. Considering the non-legislative nature of this Communication, the analysis should remain at a rather general level

6. Which stakeholders & experts will be consulted, how and at what stage?

In parallel to the consultation launched on the internet (see point 5 above), specific consultation meetings have being organised with each of the main stakeholder groups (fish producers, shellfish producers, feed industry, NGOs, social partners).

A conference will also be organised in November 2007 with the main stakeholders to discuss in particular the role of public authorities in contributing to the sustainable growth of Community aquaculture.

7. Will an inter-service steering group be set up for the IA?

Health, Environment or Trade aspects are among the policy areas with significant importance to aquaculture. The development of the EU Maritime Policy should also integrate aspects of interest to marine aquaculture.

An inter-service steering group, involving other concerned DGs (in particular SANCO, ENV, RTD, TRADE, ENTR and the SG) should be set up in November 2007. An inter-service meeting was already held at the time of the launching of the consultation exercise.

¹⁷ See http://ec.europa.eu/fisheries/cfp/governance/consultations/consultation_100507_en.htm

ROADMAP

Title of the proposal: "**Regulation establishing rules for the monitoring and control of the fisheries activities within the context of the CFP**"

Expected date of adoption of the proposal: **October 2008**

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

The level of compliance with Community Fisheries Policy ("CFP") rules throughout the European Union is far from being satisfactory.

The quality of the data notified by Member States is highly variable and more than once data have proved to be unreliable.

Sanctions imposed for breaches of CFP rules have not a deterrent effect.

Moreover, existing provisions are often incomplete, insufficient and scattered over different legal texts, sometimes obsolete or incoherent.

The proposal concerns a field of exclusive competence for the European Community.

2. What are the main policy objectives?

General objective:

To converge the different quality levels of monitoring and control of the fisheries activities by Member States within the context of the CFP and to strengthen the current regulatory framework in order to ensure a level playing field and to develop a culture of compliance within the fisheries sector across the European Union.

Specific objectives:

- 1) To gather in a single text all relevant legislation in this field, in a comprehensive and coherent manner, avoiding repetition and useless obligations for national administrations and the fisheries sector.
- 2) There is also a need to introduce new provisions by taking in due account recent pieces of control legislation, such as those relating to electronic reporting, the fight against Illegal, Unreported and Unregulated ("IUU") fishing and the management of fishing activity in non-EU waters.
- 3) Furthermore, it is important to set a harmonised catalogue of sanctions for the most serious infringements to the CFP rules and to increase the powers of the Commission's agents.
- 4) To obtain a high level of compliance through simplification and better streamlining of the obligations.
- 5) To obtain high quality data through simplification and harmonization of communication procedures, leading to a more efficient data transfer and leaving more time for cross-checks.
- 6) Finally, it is essential to favour the simplification of the rules and procedures. Simplification will facilitate enforcement by control authorities and will increase ownership of CFP rules by fishermen.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

The following options will be considered:

- 1) "No action" option.
- 2) Non-regulatory instrument, like a code of good conduct, guidelines, best practices.
- 3) Regulatory instrument, like a binding text at Community level. As it concerns a field of exclusive competence for the Community and given the need for rules to be applied directly and similarly by all actors concerned, the legislation is proposed in the form of a Regulation.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

The first option would have, at least indirectly, a negative environmental impact, in the sense that the continuation of the current shortcomings will weaken our conservation policy. The maintenance of current provisions will also continue to have, at least indirectly, a negative economic impact in the sense that stakeholders and administrations will continue to suffer from administrative burden created by unnecessary reporting obligations and lack of coordination.

The second option would bring some clarity to the current situation and would allow a step-wise approach whereby an active participation and feed-back of Member States would gradually improve the situation. Such an approach however would take considerable time and given its non-binding nature, it will not change the situation dramatically in the mid-term.

The third option, carefully applied around simplification, harmonization and by focusing on the main issues, will bring about a positive indirect economic and environmental impact through the reduction of administrative burden and the strengthening the enforcement of conservation measures respectively.

The main objectives of the modernization of the present CFP control system are the strengthening, harmonisation and simplification of existing rules in the fisheries control area.

The strengthening and modernisation of the procedures will facilitate a better enforcement by alleviating the burden and constraints for the sector and public administrations, including an increased use of IT tools to reduce reporting obligations.

As to the *Commission's services*, they will have extended investigation powers and means to increase compliance and transparency; these will also bring more efficiency in the collection and cross-checking of the data so that the Commission will obtain more accurate data.

As to *national administrations*, they will benefit from a set of less numerous rules which will be clearer, easier to enforce and better tailored to needs of ensuring compliance by operators.

As to *the operators*, they will see their administrative burden reduced to the maximum possible extent, especially thanks to a broader use of modern ITC means. The lessening of the burden will be measured in accordance with the Impact Assessment Guidelines of the SG. It is worth remembering that the recast of Regulation (EC) N° 2847/93 ("control Regulation") is listed in the "Action plan for reducing administrative burden" (COM(2007)23).

As to *NGOs*, they will appreciate the effort of EU to put in place clearer and more stringent provisions to be applied throughout EU and in the international waters.

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Many documents and data are already available in DG FISH, such as:

- tri-annual control reports;
- annual reports from Member States on behaviours which seriously infringed the CFP rules;
- minutes of the meetings of the Expert Group on Fisheries Control;
- minutes of internal meetings on control strategy, and
- the upcoming Special Report from the Court of Auditors.

Part of the Impact Assessment work can be carried out internally using this information.

An external contractor will work on the impacts of the different options on stakeholders and national administrations. This analysis should be ready by end March 2008 to be used in the Impact Assessment.

6. Which stakeholders & experts will be consulted, how and at what stage?

National control experts will be consulted as from the onset.

In parallel, stakeholders, NGO representatives will also be consulted, namely through the Advisory Committee for Fisheries and Aquaculture ("ACFA"), and through the Regional Advisory Councils ("RACs").

7. Will an inter-service steering group be set up for the IA?

Yes.

The following DGs/Services will be invited to participate in the inter-service steering group managed by DG FISH: JLS, LS, SG, BUDG, ENV, SANCO, COM, OLAF, ENTR, DEV, AIDCO, RELEX, TAXUD, AGRI, EUROSTAT and the Community Fisheries Control Agency.

ROADMAP

Title of the initiative: **Communication on the EU Maritime Transport Policy in the 2008-2018 horizon**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The initiative aims to update the policy guidelines of the EU maritime transport policy, assessing in particular:

- the ability of the maritime transport to provide cost-efficient maritime transport services of adequate quality for the needs of the sustainable economic growth of the EU as a whole (including environmental protection).
- the long-term competitiveness of the EU shipping sector, enhancing its capacity to generate value and employment in the EU, both directly (shipping sector) and indirectly (clusters of maritime industries including ports sector).

The political context of the initiative flows from:

- the 2006 mid-term review of the Transport White Paper (action announced for 2008)
- the Commission's "Blue Paper" on a new integrated maritime policy (maritime package to be approved on 10 October 2007)

What are the main problems identified?

In the framework of the transport policy, the Commission's views on maritime transport strategy were explained in 1996 for the last time.

An update of the EU policy guidelines is justified in view of the significant developments in the sector since then. All implications resulting from the intensification of the globalisation process, the growth in trade, energy and climate change constraints, security factors, sustainable development, human factor, competitiveness and emerging logistics trends will be examined. The new Communication will address all the questions raised in connection with the role and contribution of maritime transport to the European economic system as a whole (new logistic requirements).

Is EU action justified on grounds of subsidiarity?

The proposed Communication will examine the situation in the maritime transport industry in the Community and examine matters of common interest for all the EU Member States. This is an exercise that cannot be carried out by the individual Member States alone.

Building on the basis of the likely scenarios affecting the Community as a whole, the Communication will propose an EU policy line and explain the possible actions that could be undertaken at the different levels of decision in conformity with the subsidiarity principle.

B. Objectives of EU initiative

What are the main policy objectives?

Maritime transport and ports make a significant contribution to the EU economy, both as industrial sectors contributing to GDP growth and employment and as an essential part of the overall transport chain. European shipping plays a prominent role in the global supply chain and has a vital importance for maritime connections between EU Member States, between EU Member States and commercial partners all over the world and in cross trades between different continents.

The European Union has a key interest in ensuring that the maritime transport and port industries continue to play such prominent roles in the future. A strategic vision looking at the development of shipping, ports and

related sectors for the short, medium and long terms is essential for the making of the EU maritime policy. Today's trends and signals of change have to be examined in order to enable all relevant EU stakeholders to be better informed when making the long term, strategic decisions.

The objective of the proposed initiative would be to offer an updated framework of reference for individual policy initiatives. Such a framework of reference will benefit of the effort of an in-depth reflexion about how the maritime transport industry will look like in the next decade, what are the most important challenges for the EU in terms of integrated maritime and transport policies and what are the possible options to address those challenges.

Does the objective imply developing EU policy in new areas or of strategic importance?

The objective is linked to the development of both the Transport Policy and the New integrated maritime policy announced by the Commission. The Communication will look after update and further development of those EU policies.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The proposed initiative entails a strategic review of sectoral policy guidelines that were updated by the last time in 1996.

There are two main options: the "do nothing" option, that would entail to continue with the 1996 Maritime Transport Communication as the main framework of reference text for the EU Maritime Transport Policy and the proposed options that would entail the update of that framework.

The purpose of the proposed initiative (Communication) is to examine possible policy options for the future maritime transport strategy. They will be established and examined within the Impact Assessment exercise.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes. This action has to be seen in the context of the new integrated maritime policy proposed by the Commission. Among other areas of work of the Commission, the action proposed will cut across economic, employment, RTD, Environment, Trade, External Relationships and Industrial competitiveness aspects.

Do the options respect the proportionality principle?

Yes. The options are limited to what it is strictly necessary to further develop / update EU policy options.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The likely impact of the "do-nothing" option is that the framework of reference for the EU policy guidelines in the maritime transport sector becomes senseless, as the situation of the maritime transport sector has completely changed since the last time (1996) it was assessed. Community actions in this field could not be properly assessed in an integrated manner. Ensuring coherence and consistency with other EU policies would be much more difficult to achieve.

The impact of each policy option will be assessed. In particular, it will be analysed how possible options can help address the challenges the maritime transport sector is facing.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The options would not have an impact on the EU-Budget above 5 Mio €. The IA would not serve as an ex-ante evaluation within the meaning of the Financial Regulation.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Prima facie, the options would not have impacts on simplification/administrative burden.

Third countries would have a keen interest in being associated to the policy examination exercise proposed by the Commission.

Who is affected?

The EU maritime transport related industries
The EU maritime & transport administrations
The Users of maritime transport services
Seafarers and maritime professionals

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

In the framework of the transport policy, there is significant information and data concerning maritime transport issues, both at world and EU levels.

In the framework of the new integrated maritime policy, the public consultation carried out by the Commission between July 2006 and June 2007 has provided a significant number of contributions, both from stakeholders at large and from EU and national institutions.

For the purposes of drafting conclusions and recommendations on possible policy choices panel of high level experts with relevant experience in the shipping sectors will be established.

The panel of high level experts will have as a mission the supervision of the quality of the study at each different stage of the research and assessment of the points covered in the study. The panel of high level experts will be in charge of drafting policy conclusions and recommendations.

The members of the panel of high level experts will be appointed with the approval of the Commission who will chair the panel. The rules of procedure and the working plan of the panel will be proposed by the Commission and approved by the panel itself.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The EU maritime transport related industries
The EU maritime & transport administrations
The Users of maritime transport services
Seafarers and maritime professionals

All interested parties will be informed of the launching of the study and invited to submit comments.

The preliminary results of the study will be presented and discussed in a European conference gathering the relevant experts of the EU Member States, main stakeholders associations and interested academic personalities.

The final report would take account, when appropriate, of the contributions received at that conference. An ad-hoc Internet site and a dedicated blog for the purposes of facilitating the work and discussions of the panel of high level experts will be established. All documents and contributions will be properly managed and posted in the internet site.

ROADMAP

Title of the initiative: **Revision of Regulation 1406/2002 establishing a European Maritime Safety Agency**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The European Maritime Safety Agency (EMSA) was created in 2002 as part of the EU's response to different maritime accidents (second maritime safety package).

What are the main problems identified?

The maritime legislation of the EU has considerably evolved since the creation of EMSA as witnessed by the three modifications already adopted of the founding regulation. The third maritime safety package proposed by the Commission in 2005 will further enhance EMSA's tasks.

There is currently a mismatch between the EMSA-founding regulation and the other legislative texts in the area of maritime safety, which leads to uncertainties and a lack of visibility (better regulation context).

Furthermore, the EMSA regulation foresees an independent external evaluation organised by EMSA's Administrative Board. This evaluation, which is due to be completed in early 2008 and which will include recommendations from EMSA's Administrative Board, will provide valuable input to the revision exercise by the Commission.

Is EU action justified on grounds of subsidiarity?

The principle of subsidiarity has been respected throughout all the previous legal acts in the area of maritime safety and will be examined again regarding further extensions of EMSA's tasks.

B. Objectives of EU initiative

What are the main policy objectives?

The main objective is to improve maritime safety, maritime security and prevention from and response to pollution by vessels (the underlying general objective is the safety of citizens) and to ensure better regulation between the different elements of EU maritime legislation.

Does the objective imply developing EU policy in new areas or of strategic importance?

No, the EU has a well developed policy in the area of maritime safety.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- Option 1: "do nothing" (i.e. leave regulation 1406/2002 unchanged despite the changes in EU maritime law)
- Option 2: "minimal" revision limited to tasks arising from existing and proposed EU-legislation in the area of maritime safety;
- Option 3: "medium" revision encompassing option 2 plus taking over a large part of the activities of the Paris Memorandum of Understanding in the area of Port State Control;

- Option 4: "large" revision encompassing option 3 plus new tasks in the areas of security, research and general maritime policy.

'Soft-law'-instruments are not possible, as the EU-agencies are created by EU-legislation.

The initiative will go beyond routine up-date of existing legislation.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, in particular regarding DG Environment's activities in protecting the marine environment.

Do the options respect the proportionality principle?

Yes, as far as known today (July 2007), otherwise they will have to be modified or disregarded.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The main impact will be administrative and financial. However, the changes under examination will also imply a certain environmental and social impact.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The IA should also serve as the ex-ante evaluation.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Some elements under consideration could have a limited impact on simplification/administrative burden to the extent that central action by an EU-agency proves to be more efficient than actions by different national administrations.

It is also foreseen to consider the participation of selected third countries (in particular European Neighbourhood Partner countries and other maritime partners) in some activities of the Agency.

Who is affected?

EMSA, Commission, national maritime administrations and to a lesser extent other maritime stakeholders.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Information on international maritime safety and on EU maritime safety legislation is available. The external contractor will analyse the data according to the tasks specifications.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Commission, EMSA, national administrations after familiarisation phase for the external contractor.

ROADMAP

Title of the initiative: **Proposal for a Regulation on a European Maritime Transport Space without Barriers**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In its Mid-term Review White paper on Transport Policy¹⁸ the Commission announced the creation of a European Maritime Transport Space where the maritime transport of Community goods between Community ports should be simplified and facilitated in the light of experience acquired from land transport.

In its Conclusions on the promotion of on Short Sea Shipping of 11 December 2006, the (Transport) Council stressed upon the necessity to simplify the administrative procedures imposed to Short Sea Shipping. The demand was repeated in the (General affairs) Council Conclusions concerning the Lisbon Strategy of 12 February 2007.

The creation of a European Maritime Transport Space without barriers is also an important initiative described in the action of the European Maritime Policy adopted on 10 October 2007.

It is an anachronism that, 14 years after the achievement of the Internal Market for land transport, maritime transport within the EU is still subject to complex administrative procedures. The equipment of vessels with new communication and tracking technologies which permit to trace them permit to envisage extending the benefit of the Internal Market to maritime transport.

What are the main problems identified?

European goods transported by sea between two ports located in the European Union are treated as imported goods according customs and other legislation even if the ship has no contact with foreign ports or vessels en route.

Maritime transport between two Member States is thus subject to complex administrative procedures, which induce a distortion with other transport modes, notably road transport, and is an obstacle for its development. These administrative procedures shall be cancelled in view to build an effective Internal Market for short sea shipping as well as reducing the burden on congestion, environment, energy consumption, safety and public finances which are the consequence of increased road traffic.

Solving this problem will require a change in the existing legislation and administrative framework

New regulations requiring positioning on vessels as AIS (Automatic Identification Systems) and LRIT (Long Range Identification and Tracking) can certify the ship route allowing authorities to ascertain that it is an "internal" transport. New technologies for the transmission of reliable administrative data, and facilitating controls by the authorities, will further contribute to a better and more automatic administrative environment for short sea shipping

Is EU action justified on grounds of subsidiarity?

EU action is justified on grounds of subsidiarity as most of these procedures result from EU legislations. Some measures (as specific implementation measures for customs procedures) fall on the responsibility of Member States. The EU will assess the different options to address these measures. As the European Maritime Transport Space without barriers aims at facilitating the transport of goods between Member States, it is however

¹⁸ Commission Communication: "Keep Europe moving - Sustainable mobility for our continent - Mid-term review of the European Commission's 2001 Transport White Paper" (COM (2006)314 final of 22 June 2006)

The Communication will highlight measures permitting to differentiate international and intra-European maritime transport in view to treat the latter in the same way as land transport. Most of the measures will be incumbent to the EU, as for other transport modes.

B. Objectives of EU initiative

What are the main policy objectives?

In view to establish an effective Internal Market for short sea shipping, the administrative procedures imposed to short sea shipping shall be identical to those applying to land transport. The expected benefits will be a shift from road to maritime transport and thus a reduction of transport congestion, better environment and energy consumption, increased safety. In addition the European Maritime Transport Space without barriers will induce a reduction of need for public funding in expensive land infrastructure.

Establishment of an effective Internal Market for short sea shipping is important in view to facing the future growth in transport demand.

Does the objective imply developing EU policy in new areas or of strategic importance?

No. The objective is to extend the Internal Market which is a basic area of competence of the European Union.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

To do nothing:

The responsibility to adapt administrative procedures to the future needs of the maritime transport activity falls on the Member States and the economic operators. However, most of the procedures results from EU law. In addition, recent trends showed an increase in legislative requirement, for instance to address new challenges in the field security, illegal immigration.

To act on a case-by-case basis (e.g. reforming customs, health, veterinary... procedures independently):

It could be necessary to keep some procedures which targets particularly important issues.

Capturing new cargo by maritime transport, as foreseen by the EU transport policy, will necessitate the involvement of a range of stakeholders from shipbuilders to port authorities, and of course shippers and ship-owners. Will a more discrete case-by case approach provide a sufficiently strong signal to them, in order to promote a better use of maritime transport for internal EU transport?

To propose a Regulation abolishing administrative formalities, possibly accompanied by recommendations for measures falling under Member States competence:

The problem can be addressed simultaneously in several legislative domains which involve both legal and technical aspects. This option could be realized through a single initiative for the simplification, facilitation or, if possible, the abolishment of administrative procedures.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes. One of the main difficulties in view to building an effective Internal Market for Short Sea Shipping is the necessity to co-ordinate various national authorities and Commission services involved in all these procedures: customs, trade, sanitary, veterinary, phytosanitary, safety, security, immigration authorities in charge of the application of the relevant legislations.

Do the options respect the proportionality principle?

Yes, as the initiative will reduce administrative cost for the citizen without extra cost for public authorities.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The potential impacts will be:

- saving corresponding to the administrative costs and delays for short sea shipping operators as well as for public administrations;
- reduction of the congestion in certain seaports;
- modal shift from road to short sea shipping, if it becomes more attractive;
- reduction of environmental impacts, energy consumption and accident casualties in the transport sector induced by a modal shift from land to seaborne transport;
- possibility to redeploy administrative staff rendered available by the initiative;
- impact on the risk of frauds (and thus a loss of revenues for Member States and the EU) which shall be assessed taking into account the implementation of new communication and positioning technologies on vessels, and of electronic data interchange between Member States administrations, based on the revision of Directive 2002/59.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The options will not have any overall impact on the EU budget.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The simplification of administrative burdens is the main objective of the initiative.

Who is affected?

Short sea shipping operators, ports and to a lesser extent shippers and customers will be the primary beneficiaries.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The research project called "MarNIS" launched in 2004 until November 2008 will contribute to identify technical measures supporting the initiative.

An inventory of all existing legislation has been done by an interservice group on internal market and maritime transport.

To this respect a workshop with operators was organised on 26 March 2007.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Commission launched a Consultation based on a staff working document on 18 October 2007, until 20th December 2007. A stakeholders' workshop will be organised beginning 2008.

ROADMAP

Title of the initiative: **Ciel Unique (2ème Paquet)**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

La législation sur le "Ciel Unique" a été adoptée en 2004. Elle vise à améliorer l'efficacité de la gestion du trafic aérien (augmentation de la capacité et de la sécurité, réduction des coûts) en réduisant la fragmentation.

La Commission a fait état des résultats acquis par rapport à cette législation. Ce rapport recommande de prendre de nouvelles mesures pour renforcer la mise en œuvre de la réglementation et mieux atteindre ces objectifs.

What are the main problems identified?

1. La fragmentation importante du système et des prestataires de service n'a pu se résorber de manière significative depuis 2004. Des plaintes importantes sont exprimées par les compagnies aériennes. Le coût des services de gestion de trafic aérien reste trop important à cause de la fragmentation. Des calculs démontrent un gain possible d'un ordre de grandeur de €2 milliards dans une industrie avec un chiffre d'affaires de €8 milliards.
2. L'impact de l'aviation sur le climat requiert des mesures pour améliorer la circulation du trafic aérien. Le 'International Panel on Climate Change' a identifié la circulation du trafic aérien comme un outil efficace de réduire les nuisances environnementales par vol.

Is EU action justified on grounds of subsidiarity?

Le marché intérieur mis en place pour le transport aérien requiert des mesures à prendre au niveau communautaire. Le paquet Ciel unique établit déjà une compétence communautaire, mais les Etats membres restent responsables de la mise en œuvre des éléments critiques. D'autre part, une définition transeuropéenne du réseau de gestion du trafic aérien est compatible avec les règlements RTE.

B. Objectives of EU initiative

What are the main policy objectives?

La proposition vise essentiellement à:

- Augmenter la performance de la gestion du trafic aérien.
- A rendre compatible l'infrastructure avec les prévisions de croissance du trafic aérien.
- Favoriser l'émergence de nouvelles technologies (en cohérence avec les objectifs de e Lisbonne).
- Renforcer l'efficacité de la réglementation du trafic aérien y compris pour faire face au défi nouveau que représente la réduction des émissions par vol.

Does the objective imply developing EU policy in new areas or of strategic importance?

La proposition sera principalement motivée par les besoins d'une politique du transport aérien durable: La gestion du trafic aérien relève déjà de la compétence de la Communauté, mais la politique environnementale de la CE devrait y être intégrée. Actuellement, l'environnement n'est pas encore un objectif explicite de cette politique.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Trois options existent, avec des modalités différentes:

- Option 1: Status quo
Sans modifier la législation Ciel Unique de 2004, meilleure utilisation de l'acquis existant en appliquant la législation par comitologie; maintien des relations avec Eurocontrol, sans modifier la relation avec cette organisation internationale. Création des blocs fonctionnels d'espace soumise à l'approche actuelle 'bottom up' relevant des Etats membres.
- Option 2: Changement total d'approche ('top down')
Création des blocs fonctionnels par le 'haut' ('top down') au niveau communautaire au lieu de l'approche actuelle; Transfert des activités d'Eurocontrol à une agence communautaire; Renforcement de la législation dans le domaine de la performance.
- Option 3: Evolution
Modification de la législation pour accélérer la création des blocs fonctionnels d'espace via des critères de performance et de convergence vers le Ciel unique; Activités d'Eurocontrol encadrées à travers un partenariat avec la Communauté; Compétences de l'Agence européenne de la sécurité aérienne sont étendues à la gestion du trafic aérien.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Essentiellement la politique du transport aérien, environnementale, de l'emploi et de la recherche.

Do the options respect the proportionality principle?

Les mesures proposées sont en adéquation avec les attentes des usagers de l'espace aérien de l'UE.
Un groupe à haut niveau mis en place par VP Barrot a confirmé la pertinence de l'approche.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Les propositions envisagées résultent de deux analyses substantielles qui ont été menées de manière indépendante. Celles-ci confirment toutes deux que la méthode communautaire représente la seule approche possible pour l'organisation de la gestion du trafic aérien en Europe, selon des modalités à définir.
De plus, l'impact de l'aviation sur l'environnement requiert des mesures urgentes qui doivent aller au-delà de simples actions opérationnelles. Les études démontrent toutes deux qu'un changement de gouvernance est également indispensable.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Il n'y a pas d'impact budgétaire prévisible à ce stade.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

L'approche proposée doit très probablement permettre aux pays tiers d'avoir accès aux infrastructures de gestion de trafic aérien de manière plus conviviale: une approche unique, normalisée et centralisée est source de simplification

Who is affected?

La société pourra bénéficier d'une aviation plus durable. Les nuisances (bruit et émissions) provoquées par les avions pourront être réduites par vol.

Les compagnies aériennes pourront bénéficier d'un réseau plus performant et d'une réduction considérable des coûts pour les services du trafic aérien.

Le changement demande une participation des partenaires sociaux qui seront concernés par la modernisation et la redéfinition de l'ATM au niveau européen.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Beaucoup d'information sur l'impact se trouve dans les études:

- Evaluation of the impact of the Single European Sky initiative on ATM performance (21/12/2006).
- Performance review report 2006 (mai 2007).
- Rapport du groupe à haut niveau sur le cadre réglementaire pour l'aviation.

Les services considèrent la nécessité de faire appel à un contractant externe.

Which stakeholders & experts have been/will be consulted, how and at what stage?

L'ensemble du secteur est consulté sur une base permanente entre autre grâce à l'Industry Consultation Body qui réunit les représentants du personnel, les équipementiers, les prestataires de service, les pilotes, Eurocontrol, les compagnies aériennes, l'aviation générale, les militaires etc.

Un dialogue social, dans lequel des représentants des travailleurs et des employeurs de l'industrie sont présents, est également systématiquement associé afin d'anticiper les effets du changement industriel.

Contacts avec les syndicats d'Eurocontrol ont été établis.

ROADMAP

Title of the initiative:

Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1592/2002 of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (extension of the Agency's tasks to airports and air traffic management)

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

En Europe, le trafic aérien croît rapidement : il a plus que doublé au cours des 15 dernières années. Cependant la sécurité aérienne doit encore être améliorée. Les passagers européens doivent avoir la certitude que les appareils à bord desquels ils embarquent pour se rendre en Europe ou pour la quitter répondent aux niveaux de sécurité équivalents, qu'ils soient exploités ou non par des compagnies aériennes de l'UE.

L'Agence européenne de la sécurité aérienne a été créée en 2002 mais son mandat est actuellement limité à la sécurité des aéronefs eux-mêmes et à leurs incidences sur l'environnement. En novembre 2005, la Commission a proposé au Conseil et au PE d'étendre les règles communes aux équipages de conduite et de cabine, aux opérations aériennes et à la sécurité des aéronefs. Elle a également annoncé l'initiative sous objet pour la future extension des règles communes (services de la navigation aérienne, gestion du trafic aérien et aéroports).

What are the main problems identified?

Avant la création de l'AESA, chaque Etat membre de l'UE adoptait une législation nationale en matière de sécurité aérienne qui s'inspirait de normes internationales minimales. Or ces normes ne sont pas contraignantes, et leur mise en œuvre varie largement d'un Etat membre à l'autre.

Aujourd'hui, le transfert d'un certain nombre de responsabilités à l'AESA – notamment en matière de navigabilité et d'entretien des aéronefs par l'adoption du règlement 1592/2002 – n'a que partiellement remédié à cette situation insatisfaisante. Il reste beaucoup à faire : un grand nombre de règles de sécurité aérienne européennes sont encore élaborées au sein de diverses instances, telles que la Conférence européenne de l'aviation civile (CEAC) et ses organes techniques, les Autorités conjointes de l'aviation civile (JAA), et le groupe des régulateurs de la sécurité aéroportuaires (GASR) et l'Agence Européenne EUROCONTROL. Ces instances élaborent des règles non contraignantes qui viennent compléter celles qui sont définies au niveau mondial par l'Organisation de l'aviation civile internationale (OACI). Cependant, procédant de la simple coopération intergouvernementale, ces règles ne sont appliquées que dans la mesure où les Etats concernés le veulent bien. Il s'ensuit de grandes disparités nationales et parfois, malheureusement, ce ne sont pas les normes les plus exigeantes qui sont appliquées. Cette absence d'uniformité en Europe a également des répercussions sur le bon fonctionnement du marché intérieur.

Le 15 novembre 2005, la Commission a adopté une communication COM(2005)578, *'l'extension des missions de l'Agence européenne de la sécurité aérienne : un Agenda pour 2010'* proposant de renforcer progressivement le cadre communautaire en matière de sécurité aérienne en étapes successives:

- l'extension des règles communes, et donc des compétences de l'AESA, aux opérations aériennes, aux licences des pilotes et à la sécurité des aéronefs des pays tiers : cette proposition de modification du règlement 1592/2002 est actuellement débattue par le Parlement européen et le Conseil ;
- l'extension progressive des règles communes à la sécurité et à l'interopérabilité des services de la navigation aérienne, de la gestion du trafic aérien et aux aéroports, objet de la présente initiative.

Is EU action justified on grounds of subsidiarity?

Comme mentionné ci-dessus, il y a des grandes disparités nationales dans l'application des règles de sécurité aérienne élaborées au sein de diverses instances et parfois, malheureusement, ce ne sont pas les normes les plus exigeantes qui sont appliquées. Seule une action au niveau communautaire peut donner des garanties en termes d'uniformité et d'efficacité.

B. Objectives of EU initiative

What are the main policy objectives?

L'objectif politique principal consiste à continuer dans l'action d'amélioration de la sécurité aérienne moyennement l'extension progressive des règles communes à la sécurité et à l'interopérabilité des services de la navigation aérienne, de la gestion du trafic aérien et aux aéroports.

Does the objective imply developing EU policy in new areas or of strategic importance?

Il s'agit de continuer une action déjà entamée avec l'adoption du règlement 1592/2002 et la création de l'Agence.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- Option 1 : Ne rien faire, c'est-à-dire limiter les règles communautaires de sécurité aérienne à l'entretien et à la maintenance des aéronefs, aux licences des pilotes, aux opérations aériennes et aux aéronefs des pays tiers, en laissant au niveau national et intergouvernemental la responsabilité de la sécurité pour les services de la navigation aérienne, la gestion du trafic aérien et la sécurité des opérations aéroportuaires ;
- Option 2 : Renforcer au niveau communautaire le cadre de la sécurité aérienne, selon des modalités à préciser quant au rôle des différents organes existants.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

L'action proposée relève de la politique de sécurité aérienne exclusivement.

Do the options respect the proportionality principle?

Le principe de proportionnalité est parfaitement respecté par la proposition : En adoptant le règlement 1592/2002, le législateur reconnaissait qu'un niveau optimal de sécurité et d'uniformité ne pourrait être atteint qu'en étendant son champ d'application aux opérations aériennes et aux licences des équipages de conduite, en même temps qu'il souhaitait voir ce texte viser aussi les aéronefs des pays tiers. Par suite, la nécessité d'une action communautaire pour atteindre l'objectif poursuivi, soit l'établissement et l'application uniforme de règles communes sur les licences des pilotes, les opérations aériennes et les aéronefs des pays tiers, ainsi que à la sécurité et à l'interopérabilité des services de la navigation aérienne, de la gestion du trafic aérien et aux aéroports, apparaît clairement admise. La proposition réglementaire n'ira pas au-delà de ce qui est nécessaire pour atteindre cet objectif. Elle répondra donc aux principes de subsidiarité et de proportionnalité établis par l'article 5 du Traité instituant la Communauté européenne.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- Pour l'option no 1, continuation des difficultés identifiées plus haut et risque pour la sécurité aérienne ;
- Pour l'option 2, renforcement de la sécurité aérienne par des règles communes uniformément appliquées et contraignantes.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

L'extension des tâches de l'Agence aura un impact en terme budgétaires : les effectifs de l'Agence seront augmentés afin d'assurer à l'AESA les ressources nécessaires à exécuter convenablement les nouvelles fonctions. Le nombre exact sera déterminé lors de l'IA mais sur base d'une première estimation le montant pourrait dépasser le 5 Mio €

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Identifying EASA as the single EU instrument for aviation safety regulation including airports and ATM will positively impact on simplification of procedures for applicants, including third countries.

Who is affected?

All airports and ATM operators, aviation authorities in general.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

- Une analyse préliminaire d'impact sur l'extension de règles communes pour la gestion du trafic aérien, les services de navigation aérienne et les aéroports a été conduite par un consultant extérieur et finalisée en septembre 2005 (disponible sur le web). Ce consultant a impliqué plus de 50 acteurs-clefs dans la réalisation de ce travail.
- L'Agence européenne de la sécurité aérienne a publié sur son site internet une 'notice of proposed amendment' le 16 mai 2006 pour consulter les parties intéressées sur des règles communes en matière aéroportuaires. EASA should publish the result of this consultation, in the form of 'Comments Response Document'. On the basis of this consultation, EASA will submit to the Commission its formal opinion on the extension of EASA Regulation to aerodromes, accompanied by a draft legislative proposal and a Regulatory IA.
- In parallel, F3 has prepared, with the assistance of the Interservice steering group (IS SG) dedicated to the IA in object, a detailed analysis of expected administrative costs linked to the present legislative proposal.

Which stakeholders & experts have been/will be consulted, how and at what stage?

- Consultation des parties intéressées dans le cadre de l'analyse d'impact, du processus de consultation de l'AESA, dans le cadre d'un groupe de travail d'Eurocontrol et lors de la réunion du 20 septembre 2006 intitulée The Future of Aviation Regulation in Europe.
- Parties intéressées : compagnies aériennes, prestataires de services de navigation aérienne ; équipementiers ; gestionnaires des aéroports ; acteurs sociaux (syndicats) ; AESA, Eurocontrol. Les Etats membres et les Etats associés, ainsi que l'agence de la sécurité aérienne aux Etats-Unis ont également été consultés dans le cadre de l'analyse d'impact.

ROADMAP

Title of the initiative: **Rapport d'avancement sur SESAR**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

L'entreprise commune SESAR a été créée par règlement du conseil (CE) n°219/2007. Lors de sa session du 9 juin 2007, le Conseil a adopté une résolution demandant à la Commission de lui faire un rapport lui permettant d'endosser le résultat de la phase de définition (ATM Master Plan), lui proposant les modalités de transition entre la phase de développement et la phase de déploiement de SESAR, et lui proposant une politique de coopération avec les Etats tiers.

Il s'agit donc avant tout de faire un rapport permettant de discuter avec le Conseil les principes de mesures d'accompagnement du programme SESAR, et qui ne représente donc pas d'engagement supplémentaire de la Communauté.

What are the main problems identified?

L'initiative SESAR comprend trois phases:

- La phase de définition, débutée en 2005 et qui se terminera en 2008 par la livraison de "l'ATM Master Plan"
- La phase de développement (2007-2013), qui fait la Recherche et Développement basée sur les résultats de la phase de définition et pour la gestion de laquelle une entreprise commune a été créée par le Conseil
- La phase de déploiement (2013-2020), qui mettra en service opérationnel les nouvelles technologies et systèmes issus de la phase précédente.

Le Conseil souhaite être régulièrement informé de l'avancement de SESAR, et c'est la raison pour laquelle il a demandé à ce que la Commission lui présente en juin 2008 le résultat de la phase de définition. Le Conseil a par ailleurs souhaité que la Commission fasse un point sur la politique de participation des pays tiers à SESAR, ainsi que sur l'articulation entre la phase de développement et celle de déploiement.

La Communication objet de cette roadmap ne constitue donc pas en une nouvelle initiative de la Commission, mais en un état d'avancement sur le projet SESAR.

Is EU action justified on grounds of subsidiarity?

C'est le Conseil qui a demandé à la Commission de lui faire rapport sur les points sus-cités.

B. Objectives of EU initiative

What are the main policy objectives?

Il ne s'agit pas d'une nouvelle politique mais d'un état d'avancement sur une politique déjà lancée.

Does the objective imply developing EU policy in new areas or of strategic importance?

Non.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Il ne s'agit pas d'une nouvelle politique mais d'un état d'avancement sur une politique déjà lancée

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Il ne s'agit pas d'une nouvelle politique mais d'un état d'avancement sur une politique déjà lancée

Do the options respect the proportionality principle?

Il ne s'agit pas d'une nouvelle politique mais d'un état d'avancement sur une politique déjà lancée

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Il ne s'agit pas d'une nouvelle politique mais d'un état d'avancement sur une politique déjà lancée. Dès lors, une analyse d'impact spécifique n'est pas nécessaire.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

N/A

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

N/A

Who is affected?

N/A

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

L'analyse d'impact faite lors de l'adoption par la Commission de la Communication COM (2005) 602 et du projet de règlement du conseil sur SESAR est toujours valide.

Which stakeholders & experts have been/will be consulted, how and at what stage?

N/A

ROADMAP

Title of the initiative: **proposal for a directive on the conditions of entry and residence of seasonal workers (provisional title)**

Expected date of adoption of the initiative: **November 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In November 2004, the European Council asked the Commission to present a policy plan on legal migration by the end of 2005 that would build on the result of the public consultation that was about to be launched with the publication of a Green Paper on an EU approach to managing economic migration of third-country nationals (COM(2004)811 final of 11 January 2005). On the basis of this consultation, the Commission has published a Policy Plan on Legal Migration (COM(2005)669 final of 21 December 2005). This proposal is part of the comprehensive package of legislative measures the Commission has presented in this Communication: i.e. a proposal for a general framework directive stating – among other things – a minimum set of rights for third-country workers (scheduled for September 2007) and proposals for directives on the conditions of admission of highly skilled workers (also for 2007), of seasonal workers and remunerated trainees (2008) and of intra-corporate transferees (2009). The first legislative measures (the admission of highly skilled third-country workers and proposal for a directive on the rights of third-country workers and single permit, "framework directive") will be presented by the Commission at the end of October 2007.

Furthermore, besides the Policy Plan, other important Commission documents, endorsed by the Council and/or by the European Council, and notably the Communication on Migration and Development: Some concrete orientations (COM (2005)390 final of 1.9.2005) and the Communication The Global Approach to Migration one year on: Towards a comprehensive European migration policy (COM(2006)735 final of 30.11.2006) highlighted the need for the EU to adopt policies apt to effectively sustain and encourage temporary and circular migration. Following the mandate of the December 2006 European Council, the Commission explored ways to facilitate circular migration in its Communication on circular migration and mobility partnerships between the European Union and third countries (COM(2007)248 of 16.05.2007). Seasonal work and internships in EU companies are among the types of immigration that can – with appropriate features – be characterised as circular migration.

The proposal is also relevant in the fight against illegal work, as seasonal work is one of the most important pools of illegal employment in the EU, especially for third-country nationals. In this respect, the Commission has presented in May 2007 a proposal for a directive on sanctions for EU employers employing illegally staying third-country nationals, which – although not limited to seasonal work – will be another important tool to fight illegality in this sector. This proposal could also be strictly connected to the setting up of "an automated entry/exit tracking system for third country nationals at the external borders of the Member States of the European Union and introducing a border crossing facilitation mechanism for *bona fide* travellers (Registered Traveller Programme)", for which an impact assessment is presently being carried out and a Communication on this subject is foreseen to be adopted by the Commission in February 2008.

This initiative will need to be developed in close connection and in Complementarity with other EU policies. In the context of the Lisbon strategy, for example, the initiatives to be proposed in the area of economic immigration are seen as complementary to the broader framework identified by the integrated guidelines for growth and jobs – where both macro and micro economic policies are clearly identified to foster the competitiveness of the EU. In the area of employment policy in particular, the initiatives relating to economic migration from third countries are to be placed in the broader objectives to attract more people into employment, improve the adaptability of workers and enterprises, as well as the flexibility of labour markets, and increase investment in human capital. However, when it comes to seasonal workers, even in a period of high unemployment, this category of workers is needed in the EU economy and rarely conflict with EU resident manpower: few EU citizens and residents are willing to engage in seasonal activities in their own country of residence (with the only exception of some occupations in tourism) and therefore the issue of defending local workers is not really at stake. Furthermore, Member States already must give priority to seasonal workers from new Member States (preferential treatment clause in the Acts of Accession of 2003 and 2006).

Making reference to another overarching and long term goal of the European Union, i.e. the Sustainable Development Strategy agreed at the European Council in Göteborg in 2001, the reviewed Strategy focuses on some key issues, among which "Social exclusion, demography and migration". In this context, it is clearly recognised that the effective management of migration flows, should form part of the response needed to "prepare Europe's economy and society for the onset of ageing". This should also include filling in seasonal needs in the labour markets of the Member States, taking into account that already now these are sectors employing mostly third-country nationals, with the important exception of workers from the "new Member States" employed in seasonal work in Member States different from the one of nationality; this is however most likely a temporary situation, as the availability of seasonal workers from these Member States will be inversely proportional to the growth of their home economies.

Finally, this initiative will need to be developed in the broader framework of the EC development policy and of the relations with third-countries, as highlighted above in respect of circular migration policies.

What are the main problems identified?

The Policy Plan on legal migration, including admission procedures for third-country nationals seeking work in the EU, represents the necessary and comprehensive response to a number of interrelated and complex issues which – despite the steady developments in this policy field, remain open, particularly in the field of economic migration. Since the entry into force of the Treaty of Amsterdam in 1999, a number of common measures have been adopted in the areas of immigration. Despite such important steps forward in the creation of a common policy on legal migration, no common measures yet exist to admit third-country nationals entering the EU territory for employment, even though the admission of economic migrants represents the cornerstone of any immigration policy.

Evidence from consultation and preliminary analysis highlighted a common need for seasonal workers in all Member States, need that cannot be fully fulfilled neither by recurring to the national labour market nor to seasonal workers from other Member States of the EU. The reasons for proposing an EU policy on labour migration have been explored in SEC(2005)1680, annexed to the Policy Plan on Legal Migration, where the Commission has examined whether and for which reasons a common policy in this field would be necessary, by evaluating the following elements:

- interrelation of national immigration policies: at the current state of the *acquis*, it is acknowledged that admission of economic immigrants in a Member State can have an impact on other Member States and/or on the Community as a whole. Indeed, the absence of border checks in the Schengen area, the common visa policy, the tight economic and social relations between EU Member States and the development of the common immigration policy in recent years have as an indirect consequence the fact that immigration measures taken by one Member State are more likely to have an impact on other Member States. For instance, a very restrictive migratory policy in one Member State may deviate migration flows to its neighbours; and a regularisation procedure may attract illegal immigration into one Member State, from which regularised migrants could afterwards move easily to other Member States. In the case of seasonal workers, this factor is less important than for the other workers, as seasonal workers are by definition temporary immigrants and should not be entitled to any form of intra-EU mobility (nor will they fulfil the conditions to be regularised by Member States). However, as other third-country nationals admitted in the EU, they could overstay and move to other Member States to work illegally.
- the EU labour market and demographic change: Eurostat projections concerning demographic ageing and its impact on the labour market indicate that there will be a fall in the EU working age population by 2011, with an estimated fall of 52 million between 2004 and 2050 (STAT/05/48). While this situation will have to be addressed primarily with measures such as these foreseen by the Lisbon Strategy, immigration has been recognised as one of the available tools – within a broader policy mix – necessary to tackle the negative effects of the demographic change. While such trends will not affect all the Member States at the same time and at the same degree, this is a common trend that must be addressed coherently. Present analysis already shows gaps in the labour markets, at all level of skills and qualifications. As concerns seasonal workers, there is already a strong need throughout the EU for this category of temporary workers, especially in the agriculture, tourist and building sectors. Member States are presently filling in these needs with both EU (mainly from the new Member States) and non-EU manpower: this will not change with an EU instrument (priority must continue to be given to EU nationals), although it is very likely that needs for third-country seasonal workers will increase proportionally to the economic growth and relative increase in wages in the present countries of origin of EU-national seasonal workers, as it happened in the past in other EU Member States.
- the outcome of the public consultation on the Green Paper on managing economic migration (around 130 written contributions received from a vast variety of stakeholders): some clear elements emerged, i.e. the need

for EU common rules regulating at least the conditions of admission for some key categories of economic immigrants (highly skilled and seasonal workers), coupled with the request to ensure a secure legal position to all immigrants in employment.

Finally, it must be recalled that the above is a general assessment of the necessity of EU action in the field of economic immigration, in particular of immigration of seasonal workers. A throughout assessment of the need or not for such common rules will be done in the context of the impact assessment that will be done prior to the possible drafting of this legislative measure.

Is EU action justified on grounds of subsidiarity?

In line with the principle of subsidiary, the volumes of third-country nationals seeking entry to the EU for employment reasons will remain under the competence of the Member States. Please see also the previous point. A throughout analysis of the respect of the subsidiarity principle will be carried out in the context of the impact assessment exercise, when assessing the concrete options and the preferred one.

B. Objectives of EU initiative

What are the main policy objectives?

According to The Hague Programme, adopted by the European Council on 4/5 November 2004, "*legal migration will play an important role in enhancing the knowledge-based economy in Europe, in advancing economic development, and thus contributing to the implementation of the Lisbon strategy. It could also play a role in partnerships with third countries.*" For this reason, the European Council has asked the Commission to prepare before the end of 2005 a policy plan on legal migration, "*including admission procedures, capable of responding promptly to fluctuating demands for migrant labour in the labour market*". The overall aim of the different measures proposed in the Policy Plan on legal migration is to respond to this clear objective by developing a number of instruments that will support the effective management of future economic migration flows towards the European Union. Furthermore, the European Council of 14-15 December 2006 stated that: "*while respecting the competences of Member States in this area, consideration will be given to how legal migration opportunities can be incorporated into the Union's external policies in order to develop a balanced partnership with third countries adapted to specific EU Member States' labour market needs; ways and means to facilitate circular and temporary migration will be explored [...]*". Seasonal immigration is one of the forms of temporary and/or circular forms of immigration that have been addressed in the 2007 Communication on circular migration.

A more specific objective is to devise "*admission procedures, capable of responding promptly to fluctuating demands for migrant labour in the labour market*", i.e. capable of effectively and quickly filling in labour market gaps, also with a view to addressing the consequences of the demographic trends in Europe.

Further specific objectives are:

1. Pursue the coherent further development of the EU immigration policy: no immigration policy can be coherent and effective without addressing the immigration for employment purposes. The absence of almost any common policy concerning immigration for employment represents therefore a big gap in the EU policy, as well as a potential source of disturbances in the EU labour market.
2. Complement the set of policies and measures aimed at enhancing the competitiveness of the EU economy, as well as at addressing the negative consequences of demographic ageing, and respond to existing and future demands for seasonal migrant labour: evidence shows that there are already important gaps in the labour markets of the Member States, for various skills and sectors, and projections indicate that such gaps will increase in the next decades, due to a fall in the active population. In particular, most Member States do already need seasonal workers, especially – but not exclusively – for the agriculture, forestry and building sectors. These are needs to which the EU labour force is not and cannot respond in a sufficient way (also in view of the fact that these jobs are quite often discarded by EU nationals) and for which Member States are already recurring to non-national manpower. These needs will most likely increase in the future, with the ageing of the population and the economic growth of the new Member States, from where most of the seasonal EU workers come at present;
3. To ensure a secure legal status and a reinforced protection against exploitation to a particularly weak category of third-country workers, such as seasonal workers. Seasonal workers are often subject to exploitation in the EU, also in cases when they work legally. It is therefore necessary to ensure that there are legal avenues for such workers in the EU and that their rights are recognised and respected.

The achievement of the objectives will be pursued within the broader objective of developing coherent and complementary initiatives, in close connection with existing policies and legislation (see section A).

Does the objective imply developing EU policy in new areas or of strategic importance?

Yes, as the initiative falls within the development of the common immigration policy and has close links with the implementation of the Lisbon Strategy and with the external relations and development policy.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Indicative policy options (to be further developed in the impact assessment analysis) could be:

- 1) To maintain the status quo;
- 2) To put forward a comprehensive directive dealing with the entry and stay of all third-country immigrants in employment;
- 3) To put forward a proposal for directives dealing with the conditions of entry and residence of targeted categories of immigrants, including seasonal workers.
- 4) To foster communication, coordination, and cooperation among Member States on this issues, including the open method of coordination.

The legislative initiatives would therefore go clearly beyond routine up-date of existing legislation, especially because there is not yet EC legislation in this area.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

As this initiative will address immigration for employment reasons, it clearly cuts across several policy areas, such as: immigration, border controls, employment, development, external relations.

The options should support both employment (Lisbon Strategy) and development policies, striking the balance between the aims of the three policies involved (immigration management, employment and development). However, a sensible analysis of the impacts of the policy options can only be carried out in the context of the impact assessment exercise.

Do the options respect the proportionality principle?

In principle they should, but a sensible analysis of the respect of the proportionality principle by the policy options can only be carried out in the context of the impact assessment exercise.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Policy option 1: Admission procedures and management of legal migration for economic reasons would remain under the competence of the Member States. This would undermine the development of the EU immigration policy and migrants seeking access to the EU labour market would not have one set of common definitions, criteria and procedures to refer to, but 27 different systems. Since the immigration policies of one Member State do affect the others, this situation could have a negative impact on the other Member States and in particular undermine their labour market policies, as well as create pull factors for immigration. As a way of example, the *acquis* provides for a right to settle for work purposes in another Member State than the one of first admission for all third-country citizens having acquired the long-term resident status under the terms of Council Directive 2003/109/EC. This means that all concerned third-country workers will enjoy intra-EU mobility, even though they have been admitted in the EU according to different national rules. In respect of seasonal workers, in case of non effective systems and controls being put in place, there could be growth in the number of overstayers, with spill-over effects. All economic immigrants would be affected by this option.

Policy option 2: This option would introduce common rules for all economic immigrants seeking entry in the EU for work purposes. In this case as well, all economic immigrants would be affected by this option. From the point of view of policy development, such a proposal would represent a major step forward in the common policy for

legal immigration. From the point of view of the economy, though, such an approach could result into an unwanted stiffening of the national EU labour markets because of the differences in labour market gaps, structures and needs, as well as in demographic projections. Furthermore, Member States need specific schemes to admit specific categories of economic immigrants, either to respect international obligations or to quickly react to gaps in their labour markets: such a scheme would therefore need to be really flexible and include the possibility of derogating to the normal procedures, its EU added value being therefore to be closely examined as it risks to be minimal under these conditions.

Policy option 3: The EU could limit its common action to certain key categories of immigrants: the public consultation – and above all the analysis of the economic and labour market situation in the EU – highlighted a common need and interest for highly skilled third-country nationals, to fill in already existing and future labour gaps and needs, and for seasonal workers. As concerns the first category, the Commission will put forward end of October 2007 a proposal for a directive on the conditions of admission of highly skilled workers.

As concerns seasonal workers, it is necessary to ensure that this particularly weak category of workers is protected as much as possible from discrimination and exploitation. This can be done by granting them fair and transparent admission procedures, as well as rights. Since the needs for seasonal workers do not change dramatically year after year, the idea of having a “multi-seasonal” work/residence permit is important to encourage these workers not to fall into illegality at the end of their yearly period of legal work in the EU, because they are already in the EU territory and they are aware of the difficulties of obtaining new permits. The hoped impact on the Member States’ labour markets in the sectors making more use of – or even living on – seasonal work (mainly agriculture, building and tourism) of the proposed common rules would therefore be to ensure a pool of seasonal workers and to contribute to the fight against illegal employment and illegal migration. The impact on illegality would most likely be limited, but such a directive would at least help tackle some of the most important pools of illegal work in the EU. As for the impact on the host society, such workers are admitted for a very limited period (usually 3-6 months a year) and are not given the possibility to modify their permits in order to reside and work in a more permanent way in a Member State. Moreover, as already underlined, immigrants admitted to carry out seasonal work rarely “take the jobs” of EU nationals and residents. On the contrary, it is likely that the EU will have to recur more and more to third-country nationals in the near future because of the economic growth and relative impact on salaries in the Member States of origin of present EU seasonal workers. The impact of admission of third-country seasonal workers in terms of new immigrants on the EU territory appears therefore quite limited (and anyhow numbers are decided by Member States), while the positive impact of regulating in the proposed way the entry and residence of such workers should be important. Such scheme will also contribute to the development of countries of origin by the salaries that the workers will be sure to gain for a certain number of years. From the point of view of the impact on policy development, addressing this key category of temporary immigrants as a priority would have the advantage of reaching more easily a political consensus, in a sector where unanimity of Member States is the rule. On the other hand, the clear disadvantage of this option is that it would leave outside the scope of any EU rule the bulk of economic immigrants entering the EU each year.

Policy option 4: Actions would be developed within the existing legal framework, without new legislative intervention but using a comprehensive programme of communication and cooperation with all parties and coordination of Member States’ legal and policy initiatives to achieve a greater approximation. Possible elements of this option could be the exchange of best practices, setting up networks, etc. The policy option might however be too weak to reach the objectives. As concerns the open method of coordination, this has already been unsuccessfully proposed by the Commission in July 2001. With its Communication on "Communication from the Commission to the Council and the European Parliament on an open method of coordination for the community immigration policy" (COM(2001)387), the Commission proposed the adoption of an open method of coordination for the Community immigration policy, to encourage the exchange of information between the Member States on the implementation of the common policy. The procedure comprised reaching agreement on a number of European objectives or guidelines which Member States would then incorporate into national action plans which would be reviewed on a regular basis. This proposal was not supported by the MS and was therefore abandoned.

Other impacts that will have to be examined for all options are the impacts on labour markets, enterprises, third countries and fundamental rights (the latter are to be examined in accordance with the Communication of the Commission of 27 April 2005).

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

NA, as there should be no impacts on the EU budget.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The options should aim at cutting down red tape for immigrant workers and their employers, therefore simplifying administrative burdens. It will most likely impact on relations with third-countries as seasonal work is an important source of income for many neighbouring countries or countries with whom Member States still maintain historical ties. It will also impact on development of the countries of origin of seasonal workers in terms different from remittances/salaries, for example by means of possible skills/competences acquired while working in the EU. Immigration is becoming more and more important in the EU and international agenda, therefore the IA will have to analyse in details the impact on third-countries concerned.

Who is affected?

EU Member States' administrations, labour markets and employers (and, to a lesser degree, EU workers).
Third-country workers and their countries of origin.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A public consultation has been carried out with the Green Paper on an EU approach to managing economic migration (COM(2004)881 final of 11 January 2005). The Commission has received more than 130 contributions from Member States, the other EU institutions, social partners, NGOs, third countries, academia, etc: such written contributions can be consulted on the Commission's web-site at: http://ec.europa.eu/justice_home/news/consulting_public/economic_migration/news_contributions_economic_migration_en.htm.

An extended impact assessment based on a report by an external contractor will be launched before the end of 2007, so as to assess whether to present such a legislative proposal and, if so, which should be its exact contents.

Which stakeholders & experts have been/will be consulted, how and at what stage?

All interested stakeholders have been already consulted (see the previous point). Moreover, the Commission has already stated in its policy plan on legal migration that it will discuss with all the interested stakeholders before putting forward legislative proposals, even though this consultation will not take the form of public events, but of ad hoc meetings whenever considered necessary. These further consultations will also take place in the framework of the study to inform the Commission impact assessment.

ROADMAP

Title of the initiative: **Proposal for a directive on the procedures regulating the entry into, the temporary stay and residence of Intra-Corporate Transferees (ICT) and on the conditions of entry and residence of remunerated trainees (provisional title)**

Expected date of adoption of the initiative: **November 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In November 2004, the European Council asked the Commission to present a policy plan on legal migration by the end of 2005 that would build on the result of the public consultation that was about to be launched with the publication of a Green Paper on an EU approach to managing economic migration of third-country nationals (COM(2004)811 final of 11 January 2005). On the basis of this consultation, the Commission has published a Policy Plan on Legal Migration (COM(2005)669 final of 21 December 2005). This proposal is part of the comprehensive package of legislative measures the Commission has presented in this Communication, i.e. a proposal for a general framework directive stating – among other things – a minimum set of rights for third-country workers (scheduled for September 2007) and proposals for directives on the conditions of admission of highly skilled workers (also for 2007), of seasonal workers and remunerated trainees (2008) and of intra-corporate transferees (2009). The first legislative measures (the admission of highly skilled third-country workers and proposal for a directive on the rights of third-country workers and single permit, "framework directive") will be presented by the Commission at the end of October 2007.

Furthermore, besides the Policy Plan, other important Commission documents, endorsed by the Council and/or by the European Council, and notably the Communication on Migration and Development: Some concrete orientations (COM (2005)390 final of 1.9.2005) and the Communication The Global Approach to Migration one year on: Towards a comprehensive European migration policy (COM(2006)735 final of 30.11.2006) highlighted the need for the EU to adopt policies apt to effectively sustain and encourage temporary and circular migration. Following the mandate of the December 2006 European Council, the Commission explored ways to facilitate circular migration in its Communication on circular migration and mobility partnerships between the European Union and third countries (COM(2007)248 of 16.05.2007). Seasonal work and internships in EU companies are among the types of immigration that can – with appropriate features – be characterised as circular migration. Such a policy is therefore strictly linked with the EC developments and external relations policies.

Another relevant aspect relates to international obligations contracted by the EC in the framework of trade and investment agreements. Since the creation of the WTO in 1995, the EC has gradually entered into negotiations on the temporary movement of natural persons linked to international trade in services ('Mode 4'). The EC approach to such negotiations focuses on four broad categories of natural services suppliers, namely intra-corporate transferees, business visitors, contractual services suppliers and independent professionals. International commitments taken by the EC in the framework of the WTO or bilateral agreements on trade and investment typically provide for specific conditions and duration of stay for each of those categories.

As regards ICT, EC obligations under international agreements liberalize the possibility to supply their services to EC-based subsidiaries of multinational companies having their headquarters in the territory of a third country partner, without the application of an economic needs test. Natural persons falling under the definition applying to the sub-categories of managers and specialists are in most cases allowed to stay for a period of 3 years, provided they meet a number of requirements such as a prior employment period of 1 year. The sub-category of graduate trainees, which was introduced for the first time in the context of ongoing negotiations on the Doha Development Agenda, will allow services suppliers with less experience to reside in the EC for a period of 1 year

What are the main problems identified?

The Policy Plan on legal migration, including admission procedures for third-country nationals seeking work in the EU, represents the necessary and comprehensive response to a number of interrelated and complex issues which – despite the steady developments in this policy field, remain open, particularly in the field of economic migration. Since the entry into force of the Treaty of Amsterdam in 1999, a number of common measures have been adopted in the areas of immigration. Despite such important steps forward in the creation of a common policy on legal migration, no common measures yet exist to admit third-country nationals entering the EU territory for employment, even though the admission of economic migrants represents the cornerstone of any immigration

policy.

Remunerated trainees and intra-corporate transferees are a particular categories of immigrants for which no common rules exist in the immigration field, unlike for unremunerated trainees, whose conditions for admission are regulated by Council directive 2004/114/EC.

Allowing third-country nationals to acquire skills and knowledge through a period of training in Europe can be a way to encourage brain circulation, beneficial for both the sending and receiving country, and to implement effective policies for co-development. It should be recalled that a particular sub-category of these trainees ("graduate trainees" as sub-category of intra-corporate transferees) may fall under the GATS mode 4 negotiations, therefore under the provision of services negotiated in the context of the common commercial policy and would not be addressed by this proposal.

In the case of ICT, the procedures for entry and the conditions of residence should be compatible and complementary to the international commitments entered into by the EC or by the EC and its Member States in the framework of international provision of services (GATS and bilateral Free Trade Agreements).

These common systems should be designed within and be fully compatible with the existing EU immigration policy, the Lisbon Strategy's objectives and measures and other long term goals of the EU, such as the Sustainable Development Strategy (II), the common Trade policy (WTO, GATS) and the development policy of the EU and of its Member States. It has to be recalled that the determination of the volumes of third-country workers admitted in the EU for employment remains under the competence of the Member States (except for possible numerical ceilings agreed to in the context of GATS mode 4 negotiations).

The reasons for proposing an EU policy on labour migration have been explored in SEC(2005)1680, annexed to the Policy Plan on Legal Migration, where the Commission has examined whether and for which reasons a common policy in this field would be necessary, by evaluating the following elements:

- *interrelation of national immigration policies*: at the current state of the acquis, it is acknowledged that admission of economic immigrants in a Member State can have an impact on other Member States and/or on the Community as a whole. For instance, a very restrictive migratory policy in one Member State may deviate migration flows to its neighbours; and a regularisation procedure may attract illegal immigration into one Member State, from which regularised migrants could afterwards move easily to other Member States. In the case of third-country trainees, this factor is less important than for the other categories of workers, as they should be temporary immigrants by definition (unless a Member State provides in its national legislation for the possibility of changing status while still in its territory) and must not be entitled to any form of intra-EU mobility (nor would they normally fulfil the conditions to be regularised by Member States). However, as other third-country nationals admitted in the EU, they could overstay and move to other Member States to work illegally;
- *the EU labour market and demographic change*: Eurostat projections concerning demographic ageing and its impact on the labour market indicate that there will be a fall in the EU working age population by 2011, with an estimated fall of 52 million between 2004 and 2050 (STAT/05/48). Already existing needs in the high qualifications' segment of the labour market will become more and more evident in the years to come and will have to be addressed if Europe wants to remain competitive on the global market. Even though the contribution of trainees and ICTs to tackling such negative effects on the labour markets will be most likely limited, their input in skills and new ideas could be yet another contribution to the broader objectives of the Lisbon Strategy in terms of enhancing the EU competitiveness;
- *the outcome of the public consultation on the Green Paper on managing economic migration* (around 130 written contributions received from a vast variety of stakeholders): some elements clearly emerged, i.e. the need for EU common rules regulating admission for employment, including temporary work, coupled with the request to ensure a secure legal position to all immigrants in employment.

Finally, it must be recalled that the above is a general assessment of the necessity of EU action in the field of economic immigration. A throughout assessment of the need or not for common rules for remunerated trainees will be done in the context of the impact assessment that will be prepared prior to the drafting of this possible legislative measure.

Is EU action justified on grounds of subsidiarity?

In line with the principle of subsidiarity, the volumes of third-country nationals seeking entry to the EU for employment reasons will remain under the competence of the Member States. Please see also the previous point for reasons for proposing an EU policy on labour migration, in particular as regards remunerated trainees and ICTs.

A thorough analysis of the respect of the subsidiarity principle will be carried out in the context of the impact assessment exercise, when assessing the concrete options and the preferred one.

B. Objectives of EU initiative

What are the main policy objectives?

According to The Hague Programme, adopted by the European Council on 4/5 November 2004, "*legal migration will play an important role in enhancing the knowledge-based economy in Europe, in advancing economic development, and thus contributing to the implementation of the Lisbon strategy. It could also play a role in partnerships with third countries.*" For this reason, the European Council has asked the Commission to prepare before the end of 2005 a policy plan on legal migration, "*including admission procedures, capable of responding promptly to fluctuating demands for migrant labour in the labour market*". The overall aim of the different measures proposed in the Policy Plan on legal migration is to respond to this clear objective by developing a number of instruments that will support the effective management of future economic migration flows towards the European Union. Furthermore, the European Council of 14-15 December 2006 stated that: "*while respecting the competences of Member States in this area, consideration will be given to how legal migration opportunities can be incorporated into the Union's external policies in order to develop a balanced partnership with third countries adapted to specific EU Member States' labour market needs; ways and means to facilitate circular and temporary migration will be explored [...]*". Seasonal immigration is one of the forms of temporary and/or circular forms of immigration that have been addressed in the 2007 Communication on circular migration.

This instrument should not however be viewed primarily as an instrument to manage economic migration. The main objective would rather be to facilitate a form of migration related to professional training, with a view to improving the pool of skills available in particular in developing countries. In this perspective, such a regime could strongly contribute to supporting the development policies of the EU and Member States. However, care would need to be taken to limit the risk of brain drain.

Specific objectives are:

1. Pursue the coherent further development of the EU immigration policy, including more efficient migration management through facilitation of temporary and circular immigration. .
2. Complement the set of policies and measures aimed at enhancing the competitiveness of the EU economy: the input of trainees coming from outside the EU could represent yet another measure to enhance the EU competitiveness and capacity of innovation.
3. Facilitate admission procedures for ICT and provide them with favourable residence conditions. Even though the conditions under which ICT can perform their economic activity broadly fall under the common commercial policy, the non-harmonisation of entry procedures and of (temporary) residency rights – which fall under the immigration policy – contribute to the existence of important differences between Member States, which may in turn impede the uniform application of international commitments entered into by the EC and its Member States. Therefore, it could be in the interest of the Member States, of the Commission and of the countries of origin to ensure a uniform application of those elements that do not fall under the common commercial policy.
4. Contribute to the EU policies aimed at supporting co-development and addressing the issue of brain drain: a well regulated temporary admission scheme for such usually young and qualified workers will allow the EU economy in the broader sense to benefit from their skills and competences. On the other hand, remunerated trainees will in fact be able to acquire further skills and knowledge through their period of training, which can then benefit to the development and economic/social/cultural growth of their country of origin once they return there after the expiry of their permit.

5. Need to maximise the 'circular' nature of the proposed policy and the benefits for trainees' countries of origin (in the case of developing countries).

The achievement of the objectives will be pursued within the broader objective of developing coherent and complementary initiatives, in close connection with existing policies and legislation (see section A).

Does the objective imply developing EU policy in new areas or of strategic importance?

Yes, as the initiative falls within the development of the common immigration policy and has close links with the external relations and development policy.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Indicative policy options (to be further developed in the impact assessment analysis) could be:

- 1) To maintain the status quo;
- 2) To put forward a comprehensive directive dealing with the entry and stay of all third-country immigrants in employment;
- 3) To put forward proposals for directives dealing with the conditions of entry and residence of targeted categories of immigrants, including remunerated trainees and ICT.
- 4) To foster communication, coordination, and cooperation among Member States on this issues, including the open method of coordination.

The legislative initiatives would therefore go clearly beyond routine up-date of existing legislation, especially because there is not yet EC legislation in this area.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

This initiative clearly cuts across several policy areas, such as: immigration, border controls, employment, development, external relations.

The options should support the Lisbon Strategy and above all development policies, striking the balance between the aims of the three policies involved (immigration management, employment and development). However, a sensible analysis of the impacts of the policy options can only be carried out in the context of the impact assessment exercise.

Do the options respect the proportionality principle?

In principle they should, but a sensible analysis of the respect of the proportionality principle by the policy options can only be carried out in the context of the impact assessment exercise.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Policy option 1: Admission procedures and management of legal migration for economic reasons would remain under the competence of the Member States. This would undermine the development of the EU immigration policy and migrants seeking entrance to the EU labour market would not have one set of common definitions, criteria and procedures to refer to, but 27 different systems. Since the immigration policies of one Member State do affect the others, this situation could have a negative impact on the other Member States and in particular undermine their labour market policies, as well as create pull factors for immigration. As a way of example, the *acquis* provides for a right to settle for work purposes in another Member State than the one of first admission for all third-country citizens having acquired the long-term resident status under the terms of Council Directive 2003/109/EC. This means that all concerned third-country workers will enjoy intra-EU mobility, even though they have been admitted

in the EU according to different national rules. All economic immigrants would be affected by this option.

Policy option 2: This option would introduce common rules for all economic immigrants seeking entry in the EU for work purposes. In this case as well, all economic immigrants would be affected by this option. From the point of view of policy development, such a proposal would represent a major step forward in the common policy for legal immigration. From the point of view of the economy, though, such an approach could result into an unwanted stiffening of the national EU labour markets because of the differences in labour market gaps, structures and needs, as well as in demographic projections. Furthermore, Member States need specific schemes to admit specific categories of economic immigrants, either to respect international obligations or to quickly react to gaps in their labour markets: such a scheme would therefore need to be really flexible and include the possibility of derogating to the normal procedures, its EU added value being therefore to be closely examined as it risks to be minimal under these conditions.

Policy option 3: The EU could limit its common action to certain key categories of immigrants: the public consultation – and above all the analysis of the economic and labour market situation in the EU – highlighted a common need and interest for highly skilled third-country nationals, to fill in already existing and future labour gaps and needs, and for seasonal workers. As concerns the first category, the Commission will put forward a proposal for a directive on the conditions of admission of highly skilled workers end of October 2007 and a similar exercise will be launched in the second semester 2007 for the proposal on seasonal workers. Other important categories that emerged from the debate are the intra-corporate transferees and the remunerated trainees. A proposal on the first category has been scheduled for 2009, while for the second proposal, it seemed opportune to anticipate its drafting and presentation to 2008. As a matter of fact, since 12 January 2007 admission of unremunerated trainees is being regulated at EU level according to a common procedure, while rules applicable to remunerated trainees still remain at national level, creating a sort of distortion between the two categories of trainees. Furthermore, since the adoption of the Policy Plan on Legal Migration, the EU has been engaging in deeper discussions with its partners and neighbours on how to better organise and facilitate temporary and circular migration. The conclusions of the European Council of 14-15 December 2006 have also underlined the need to engage in exploring further modalities for temporary migration. The proposal on remunerated trainees and ICTs should reply to these new priorities of the EU in respect of better managing migration for the benefit of all the parties involved. A well regulated temporary admission scheme for such usually young and qualified workers will allow the EU economy in the broader sense to benefit from their skills and competences. On the other hand, remunerated trainees will in fact be able to acquire further skills and knowledge through their period of training, which can then benefit to the development and economic/social/cultural growth of their country of origin once they return after their experience in the EU. However, clear limits and safeguards will most likely have to be put in place to combat abuses having perverse impacts on the EU labour market, for example to avoid that an EU company could keep on employing trainees who would in reality be used as low-cost temporary manpower, therefore lowering wage levels and social standards. From the point of view of the impact on policy development, addressing such category of temporary immigrants would have the advantage of reaching more easily a political consensus, in a sector where unanimity of Member States is the rule. On the other hand, the clear disadvantage of this option is that it would leave outside the scope of any EU rule the bulk of economic immigrants entering the EU each year.

Policy option 4: Actions would be developed within the existing legal framework, without new legislative intervention but using a comprehensive programme of communication and cooperation with all parties and coordination of Member States' legal and policy initiatives to achieve a greater approximation. Possible elements of this option could be the exchange of best practices, setting up networks, etc. The policy option might however be too weak to reach the objectives. As concerns the open method of coordination, this has already been unsuccessfully proposed by the Commission in July 2001. With its Communication on "Communication from the Commission to the Council and the European Parliament on an open method of coordination for the community immigration policy" (COM(2001)387), the Commission proposed the adoption of an open method of coordination for the Community immigration policy, to encourage the exchange of information between the Member States on the implementation of the common policy. The procedure comprised reaching agreement on a number of European objectives or guidelines which Member States would then incorporate into national action plans which would be reviewed on a regular basis. This proposal was not supported by the MS and was therefore abandoned.

Other impacts that will have to be examined for all options are the impacts on labour markets, enterprises, third countries and fundamental rights (the latter are to be examined in accordance with the Communication of the Commission of 27 April 2005).

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

NA, as there should be no impacts on the EU budget.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The aim should be to simplify admission procedures for remunerated trainees and ICTs, as well as try to enhance circular migration (possibility to come back for further retraining, for example).

According to the options that will be elaborated and assessed during the impact assessment analysis, the instrument will clearly have an impact on relations with third countries. As a matter of fact, the options selected must – among other things – aim at facilitating a form of migration related to professional training, with a view to improving the pool of skills available in particular in developing countries. In this perspective, such a regime could strongly contribute to supporting the development policies of the EU and Member States. However, care would need to be taken to limit the risk of brain drain. Such an instrument could also make a strong contribution to the creation and functioning of networks (of academics, of business people, of officials, of NGOs...) or twinning arrangements, thereby promoting people to people contacts, which is an important objective of EU external relations policy, notably in the framework of the European Neighbourhood policy, the future EU-Africa strategy or relations with other third countries, including in the developed world.

Who is affected?

EU Member States' administrations, enterprises (and, to a lesser degree, EU trainees). Third-country trainees, ICTs and their countries (and/or institutions) of origin.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A public consultation has been carried out with the Green Paper on an EU approach to managing economic migration (COM(2004)881 final of 11 January 2005). The Commission has received more than 130 contributions from Member States, the other EU institutions, social partners, NGOs, third countries, academia, etc: such written contributions can be consulted on the Commission's web-site at: http://ec.europa.eu/justice_home/news/consulting_public/economic_migration/news_contributions_economic_migration_en.htm.

An extended impact assessment based on a report by an external contractor **will be** launched before the end of 2007, so as to assess whether to present such a legislative proposal and, if so, which should be its exact contents.

Which stakeholders & experts have been/will be consulted, how and at what stage?

All interested stakeholders have been already consulted (see the previous point). Moreover, the Commission has already stated in its policy plan on legal migration that it will discuss with all the interested stakeholders before putting forward legislative proposals, even though this consultation will not take the form of public events, but of ad hoc meetings whenever considered necessary. These further consultations will also take place in the framework of the study to inform the Commission impact assessment.

ROADMAP

Title of the initiative: **Green paper on Education and migration**

Expected date of adoption of the initiative: **April/2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The Common Basic Principles for Integration issued in the framework of the Hague programme¹⁹ underline that education is a central building block of integration policies. Also the Council of Europe recently adopted a recommendation focusing on the key importance of education to integration, and encouraging governments to facilitate the integration of migrant children into the educational system²⁰.

Migration is posing a significant challenge to education systems. Education policies need to take adequate account of needs emerging from migration, and to be equipped to cope with the new challenges, in order not to hinder the overall equity and efficiency of the education systems. Within the context of migration the considerations outlined in the Communication on Efficiency and Equity of education systems and the Communication on the quality of teacher education become even more relevant. Also the European Council of 21-22 June 2007 focused on migration and integration issues and emphasised "the importance of further initiatives to facilitate the exchange of experiences on integration policies of the Member States".

What are the main problems identified?

The surveys carried out in the framework of OECD's Programme for international student assessment (PISA) shows that pupils of immigrant origin still face significant educational difficulties and specific problems in Europe. Children from minorities tend thus to have lower scores than majority children, and the disadvantage persists in the second generation and beyond. They are also more frequently subject to early school leaving. Besides, they tend to find themselves more often in less prestigious school pathways.

At the same time, the increasing presence of pupils of immigrant origin changes the educational panorama. The phenomenon of white flight is increasingly conspicuous and its reasons deserve to be analysed in depth, as do the possible countermeasures.

Is EU action justified on grounds of subsidiarity?

According to art. 149, the role of the Community is to contribute to the development of quality education by encouraging cooperation between Member States. This should be done inter alia by developing exchanges of information and experience on issues common to the education systems of the Member States.

In this context the effects of migration on the education systems in Europe are closely linked to the rights and opportunities of individuals and it becomes crucial that common ground is explored and possible solutions are shared between the Member States. In addition, the detailed work programme for Education and Training 2010 decided by the Council includes clear reference to both "improving the quality and effectiveness of education" as well as "facilitating the access of all to education and training systems". It is thus fully justified to envisage action on the level of the EU in order to tackle the above outlined issues

¹⁹ See also the recent Third report on Migration and Integration

²⁰ CoE, CDMG (2007)11 Recommendation on Strengthening the Integration of Children of Migrants and of Immigrant Origin

B. Objectives of EU initiative

What are the main policy objectives?

The general objectives are:

To explore further the relation between education and training systems and their specific role for the migrant population of Europe

To initiate EU-level reflection on policies to promote school integration of migrants on the basis of existing data thereby focusing on what constitutes good national/local policy approaches and the value-added of EU policies and programmes.

Specific objectives are :

To underline the central role of education in integration policies: Education could thus be considered and budgeted for both in immigration policies and in economic analysis on immigration.

To outline the specific problems the migrant pupils may face and draw on the results of existing research to outline possible solutions and good practices.

To explore the effect the results on problems and solutions affecting migrants also affect natives with low SES, draw out wider messages on inclusive education.

In addition a possible review of the 1977 directive (77/486/EEC) could be explored.

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

1. No-policy option: no particular attention would be given to the relation between education and migration at the level of the EU and issues arising in this context as documented by PISA would need local, regional and national attention. No consideration for general equality issues on the EU level would be granted.

2. Regulatory policy: not possible in relation to the definition of education and training systems at the EU level as the Treaty defines the role of the EU to be additional with the exclusive competence for education and trainings systems at the national level.

3. Policy with argumentative measures: Analysis of state of play and indication of possible measures to enable developments of education results in the desired direction.

In addition and following this action it could be envisaged to revise or repeal the Directive (77/486/EEC) from 1977. This would however be done in a separate action.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The document focuses on an area which is of direct interest to integration policies (JLS) and to social inclusion (EMPL)

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

1 No policy option: the inequality for migrant children mentioned above would need to be addressed by the individual Member states. Thereby, other inequalities between the various Member states could be produced and additional negative economical effects on both the social policies as well as labour market disparities are predictable.

2. Regulatory policy option: could be possible in relation to certain aspects of the labour market that would thus not treat the root causes but merely work on remedy the negative effects.

3. Policy with argumentative **measures**: This is the preferred option and it is envisaged to establish a Green Paper that would enable exchange and discussion and allow for best practices to be fully explored on the basis of common understanding. A general framework needs to be created in order to better assess the various impacts of possible policy solutions. This would allow for informed and adequate policies to be developed in respect of both the individuals concerned as well as the needs for the development of the European society and economy.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

no

Who is affected?

Direct interlocutors are education authorities, both at the national and at the local/institutional level. Indirectly affected is in a second step the migrant population in Europe and therefore there is in a third step an impact on the future European societies.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Existing data will be used, in particular the PISA results and the Eurydice studies on the subject as well as Eurostat data and the Education and Training 2010 Progress reports as well as other relevant national sources.

A very significant amount of European and international (mainly American) research has been conducted on the issue. Analysis of available data and research results is being done both internally and with the support of external consultants organised in the network for experts in social science education and training (NESSE)

Which stakeholders & experts have been/will be consulted, how and at what stage?

Exchange of views with colleagues in DG Employment and JLS, with representatives of national Ministries of Education through the Cluster on Social inclusion as well as with academics (NESSE network, academics at EUI etc).

The NESSE network of experts of social sciences of education was asked to provide an extensive report on the

issue, which will feed in the Green Paper the annex. The King Baudouin Foundation and the EUI gave their availability to organise informal high level policy seminars to assess the validity and possible political impact of the findings.

ROADMAP

Title of the initiative: **(provisional) Communication of the Commission to the European Parliament and the Council on the further development of the EU as an area of freedom, security and justice (Post the Hague Multiannual Programme)**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

As a follow-up to the first "Tampere" multi annual JLS programme (1999-2004), The Hague programme was adopted for a new period of five years in December 2004. Following the Commission Communication of 10 May 2005 "The Hague Programme: Ten Priorities for the next five years. The Partnership for European renewal in the field of Freedom, Security and Justice" (COM(2005)184), The Hague Action Plan was adopted in June 2005 and set priorities in JLS areas until 2010 in order to further develop the EU as an area of freedom, security and justice.

Several circumstances suggest that there is a need for anticipating the adoption of a new multi-annual programme for the area of freedom, security and justice, namely:

- most of the initiatives foreseen under The Hague Action Plan are concentrated in the first three years of the plan, leaving only few ones left for 2009 and 2010;
- the mid-term review of the Programme carried out under the Finnish Presidency in the second half of 2006 has clearly showed the need for a new impetus in the area of Freedom, Security and Justice (see Presidency Conclusions of the Brussels European Council dated 14/15 December 2006, adopted on the basis of the Commission Communication "Implementing the Hague Programme. The way forward" (COM (2006)331 final)
- the ongoing reflection on the future of JLS policies within the so-called "High Level Future Groups" – one on Interior issues and a second one on Justice-related policies. These are high-level advisory groups on the future of European home affairs and Justice policies, to which Vice-President Frattini is part, where reflection is ongoing on how to further develop policies at EU level in the area of justice and home affairs. The aim of these Groups is to conclude their work by producing a report by the end of the Slovenian Presidency (first half 2008).
- France is keen to adopt the new multi-annual programme under their Presidency (second half 2008) and to label it as "**Paris Programme**".
- finally the foreseen Reform Treaty currently discussed in the ongoing IGC, which should enter into force before the European Parliament elections of June 2009, may need to be considered as it will have a substantial impact on the further development of JLS policies – in particular in terms of decision-making.

What are the main problems identified?

In order to develop further the EU as an area of freedom, security and justice in a coherent and consistent way, as well as to ensure an harmonious development of all policies within this area, there is a need to plan well ahead and have a strategic vision of the future. This proved to be efficient and successful through the last The Hague Programme and its action plan. The lack of such a strategic plan would lead to a lack of coordination within and between the different policy areas.

Is EU action justified on grounds of subsidiarity?

The development of the EU as an area of freedom, security and justice and thus the definition of common priorities needs to be defined and planned at EU level. Leaving it to every single Member State to define priorities in this area would seriously undermine the coherence and consistency of policies - such as immigration, fight against organized crime etc – which have a transnational and cross-border nature. The need for a European approach in these matters is underlined by the ongoing work between Member States on suggestions for future European action in the area of Freedom, Security and Justice Policies with the context of the Future Groups mentioned above

B. Objectives of EU initiative

What are the main policy objectives?

The main aim of this initiative is to define over a certain number of years the priorities and objectives for the future development of the EU as an area of freedom, security and justice, and to determine the means and initiatives to best achieve them. This initiative would include a global pact on migration, e-justice and action plan on drugs.

Does the objective imply developing EU policy in new areas or of strategic importance?

The envisaged action (together with the changes to the current Treaties which will follow the entry into force of the Reform Treaty) could encourage and accelerate the further development of areas of strategic importance such as the development of a common policy on migration or the creation of a truly "European judicial area".

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- 1) To maintain the status quo, i.e. having solely an annual planning (CLWP Commission programme building up its WP partially on the multi-annual programming adopted by the Council).
- 2) To ensure a follow-up to the strategic multi-annual planning at EU level to further develop JLS policies following a Commission proposal, the duration of the planning period could range from 2 to 10 years. The previous 2 multi-annual programmes (Tampere and the Hague) lasted for 5 years each.
- 3) To leave to Member States / a group of Member States the responsibility to define future developments in EU JLS areas

A regulatory instrument does not seem appropriate given the nature of the initiative (multi-annual and strategic planning). Leaving to presidencies/Member States the lead on defining future developments in this strategic area would undermine the strategic focus on JLS issues at EU/Commission level. Option 2) would moreover naturally constitute a follow up to the two previous JLS multi-annual programmes adopted by the Commission.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, other Commission departments than DG JLS could be concerned, namely DG RELEX, DG EMPL, DG TREN, DG SANCO, the Legal Service

Do the options respect the proportionality principle?

The options do not go beyond what is necessary to reach the policy objectives, in so far as in order to ensure multi-annual planning, the appropriate initiative needs to be a planning document. As was the case for the previous multi-annual programmes, the adoption of a multi-annual programme would not hamper the flexibility of the Commission, European Parliament and Council to react to changing circumstances. Reconsidering the implementation of initiatives or adding additional ones would be foreseen. Also, the degree of concreteness of initiatives included in such a programme would depend on the available knowledge basis. Where further studies of a matter would be necessary prior to the decision if a concrete initiative should be taken, this would be clearly indicated in the planning.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

1) option 1) would not allow to have a strategic vision of the development of JLS policies, but would leave a certain flexibility of action;

2) option 2) would ensure that JLS policies are developed in a more coherent and consistent manner, with an EU perspective

3) option 3) would not allow to have a strategic vision of the development of JLS policies and would not allow for proper EU perspective to be taken into account

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Not immediately. Certain individual actions which could flow from the multi-annual planning are expected to have an impact on the EU budget and will be assessed separately before actual implementation.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

They could have an impact on relations with third countries (for example, the further development of legal migration policies).

Who is affected?

EU Institutions and Member States will be directly affected by the envisaged initiative. Indirectly and in the longer term, EU citizens would also benefit from it. The initiatives contained in such a multi-annual planning would have impacts on the different stakeholders in this field. They include citizens in general, migrants, civil and criminal justice practitioners, law enforcement authorities, third countries concerned by measures in the area of migration and terrorism. Further detailed assessment of the impacts of individual initiatives would be carried out at later stages of policy development.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The assessment of multi-annual planning of JLS policies in the past (Tampere and The Hague programmes) is already available. As regards the Hague Programme, in particular, the Communication "Implementing the Hague Programme. The way forward" (COM (2006)331 final) is to be taken into account. Moreover, the impact of the new Treaty will have to be assessed and it should be considered whether it is appropriate to take it into account as well.

The impact assessment of this initiative will be done internally. Given the vast field of activities which would be touched by the initiative, the assessment will remain on a high level of aggregation. The detailed assessment of individual initiatives will be carried out at later stages of policy development.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Consultations will involve Member States (outcomes of work of the Future Groups will be taken into account in this framework) and the European Parliament (, which will be consulted before the drafting of the Communication.

ROADMAP

Title of the initiative: **Communication sur l'anticipation et la gestion du changement (2ème phase de consultation des partenaires sociaux)**

Expected date of adoption of the initiative: **Juillet 2008**

A. Context and problem definition

What is the political context of the initiative?

Différents facteurs tant internes (politiques communautaires) qu'externes (progrès technique, évolution de la demande, globalisation,...) créent le besoin d'adaptations rapides des entreprises européennes. Ces adaptations entraînent des restructurations ou des réorganisations au sein des entreprises dont certaines peuvent avoir des effets non négligeables dans certaines régions, secteurs ou catégories de travailleurs. Ce type de répercussions peut se traduire par un sentiment de rejet des adaptations à réaliser freinant d'autant les nécessaires changements de l'industrie européenne et dans bien des cas par une perte de capital humain. Il apparaît donc opportun de compléter les actions précédemment mises en œuvre au niveau européen.

How does this initiative relate to past and possible future initiatives, and to other EU policies?

Plusieurs actions passées de la Commission sont en relation avec la présente initiative. On peut citer la mise en œuvre du Fonds européen d'ajustement à la mondialisation, la nouvelle période de programmation des Fonds structurels, la politique industrielle et bien évidemment la stratégie de Lisbonne. Plusieurs autres débats actuels peuvent également s'inscrire dans le cadre de la présente initiative comme celui sur la flexicurité. Concernant directement le sujet traité par cette initiative, la Commission a lancé en janvier 2002 une première phase de consultation des partenaires sociaux qui leur demandait de définir et de mettre en œuvre des bonnes pratiques en matière d'anticipation, de préparation et de gestion des restructurations.

En 2003, les partenaires sociaux ont présenté des orientations de référence dans ce domaine, toutefois sans mécanisme de mise en œuvre et de suivi. En mars 2005, la Commission a adopté une Communication qui présentait une série d'actions permettant notamment de renforcer la coordination de nos politiques et de favoriser l'anticipation et l'établissement de partenariats en insistant auprès des partenaires sociaux qu'ils développent et mettent en œuvre les orientations de référence 2003.

What are the main problems identified?

Les principaux problèmes identifiés résident dans la nécessité de réaliser des adaptations et de la peur que ces dernières peuvent générer, compte tenu des conséquences sociales qu'elles peuvent entraîner quand elles sont mal anticipées, préparées et gérées. Il est donc essentiel de pouvoir offrir un climat et des outils aptes à faciliter les nécessaires adaptations et de réduire les pertes en capital humain. Cette problématique a tout récemment été rappelée dans plusieurs études et documents émanant par exemple de l'OCDE, du FMI ainsi que de la Commission.

Plus particulièrement, il importe de renforcer l'implication des partenaires sociaux au niveau européen sur cette question. A cet égard, on se doit de constater que les orientations de référence présentées par les partenaires sociaux en 2003 n'ont pas pu être adoptées formellement par l'ensemble de ces derniers par manque de mécanismes de mise en œuvre et de suivi.

En second lieu, l'anticipation, la préparation et la gestion des restructurations nécessitent une pleine coopération et coordination de l'ensemble des acteurs concernés (les entreprises, les travailleurs, leurs représentants et les autorités publiques (locales, régionales, nationales et européennes)) si l'on désire qu'elles soient socialement acceptables. Or, on constate que trop souvent la coordination entre les différents acteurs est insuffisante lors de restructurations. L'établissement de partenariats ayant pour objet de favoriser la coopération, tel qu'en discussion dans le secteur automobile au niveau européen, constitue donc un autre besoin.

Is EU action justified on grounds of subsidiarity?

Les enjeux, les facteurs déclencheurs et les moyens de traitement dépassent les cadres nationaux. Plusieurs politiques communautaires mises en œuvre depuis longtemps entraînent elles mêmes des restructurations (marché intérieur, politique commerciale, politique de concurrence,...). Tandis que d'autres permettent à la fois d'exploiter le potentiel positif des changements en cours (politiques industrielle, d'innovation et de R&D,...) ou de pallier à leurs impacts problématiques (politiques structurelle et d'emploi). La poursuite de l'action dans ce domaine respecte donc le principe de subsidiarité.

B. Objectives of EU initiative

What are the main policy objectives?

Les principaux objectifs de cette initiative sont :

- de faciliter les changements dans un contexte socialement acceptable et permettant de préserver le capital humain;
- de faire le bilan des actions développées depuis la Communication de mars 2005;
- de renforcer ou de mieux cibler les instruments précédemment mis en place.

Does the objective imply developing EU policy in new areas or of strategic importance?

Cette initiative permettra de renforcer des domaines stratégiques existants compte tenu du fait que l'objectif principal est de faciliter l'introduction des changements.

C. Options

What are the policy options?

La première option consiste en un statu quo. L'Union est d'ores et déjà dotée d'une série d'instruments qui permettent d'anticiper, de préparer et de gérer les restructurations. Toutefois, et comme peuvent en témoigner de nombreuses demandes du Parlement européen mais également les conclusions de plusieurs Forums sur les restructurations ainsi que des réactions de la société civile, des actions complémentaires pourraient utilement faciliter le changement tout en préservant le capital humain.

La seconde option tend à renforcer les instruments de soutien existants (activités de coordination, d'anticipation et d'intervention des Fonds européens) ainsi qu'à développer les échanges d'expériences et la diffusion des meilleures pratiques. Elle pêche cependant par manque d'un encadrement plus global donnant un sens et une visibilité à toutes ces actions.

La troisième option intègre les éléments de l'option précédente mais la complète par la demande d'établir des partenariats entre tous les acteurs concernés par les processus de restructurations et par la mise en place d'un cadre européen pour l'anticipation, la préparation et la gestion de mutations socialement responsables.

What legislative or 'soft law' instruments could be considered?

Ce cadre européen pour une anticipation, une préparation et une gestion des mutations socialement responsables peut être mis en œuvre suivant plusieurs options.

La première pourrait prendre la forme d'une initiative législative qui bien que difficilement envisageable en termes politiques (différences dans la manière de gérer la sphère sociale) ne peut pas être en théorie exclue.

La seconde pourrait consister en une "soft law" qui prendrait la forme d'un code de conduite à définir et à mettre en œuvre par les partenaires sociaux (ceci constitue l'objet même de cette seconde phase de consultation).

En l'absence d'une réponse adéquate des partenaires sociaux européens, une Recommandation du Conseil (non contraignante par nature) apporterait un message politique fort aux différents acteurs.

Would any legislative initiatives go beyond routine up-date of existing legislation?

Toutefois à ce stade et comme indiqué précédemment une initiative législative traditionnelle n'est pas envisagée.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Cette initiative pourrait avoir des impacts positifs pour plusieurs autres services de la Commission. En effet, toute action facilitant l'adaptation aux changements et la préservation du capital humain ne peuvent que favoriser les évolutions exigées par d'autres services (MARKT, COMP, ENTR, TRADE,...)

Do the options respect the proportionality principle?

L'action est nécessaire et se tient à l'indispensable pour permettre que l'action communautaire soit efficace.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

L'absence d'action aurait des coûts politiques dans la mesure où la Communication de 2005, qui a lancé une stratégie coordonnée d'anticipation et de bonne gestion des restructurations resterait sans suite.

L'option consistant à se limiter à renforcer ou mieux cibler les moyens de coordination politique et de soutien, financier et d'autre type, à des mécanismes d'anticipation n'aurait pas d'impact majeur en dehors de la Commission (tout en exigeant un effort de coordination accru au sein de celle-ci). Elle risquerait en revanche d'être perçue comme insuffisante par les partenaires extérieurs (Parlement européen, partenaires sociaux, autorités nationales et régionales, etc.), qui ont répondu positivement à l'appel qui leur a été lancé par la Commission en 2005 de mieux se mobiliser au tour des principes centraux définis dans la Communication (anticipation, partenariat, coordination accrue des politiques, renforcement des moyens de soutien).

La troisième option, qui renforce et élargit la coordination, le partenariat et le soutien existant à travers le lancement d'un partenariat européen élargi pour l'anticipation et la gestion des restructurations et la promotion d'un code de conduite européen (ou d'une charte) correspond aux attentes de la plupart des différentes parties prenantes. Elle supposerait la création d'une dynamique externe à la Commission, soutenue par celle-ci, dont l'impact ne peut pas être mesuré à ce stade dans la mesure où il dépendrait de l'ambition et des moyens à affecter.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Non

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

L'un des domaines horizontaux à développer dans la nouvelle Communication concerne la simplification du cadre réglementaire (l'un des objectifs de la politique industrielle, par exemple). La politique commerciale est également concernée dans la mesure où elle est à l'origine de beaucoup de restructurations. Cependant, aucun changement majeur dans les orientations actuelles n'est envisagé.

Who is affected? Sans pertinence

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

L'essentiel de l'information requise est disponible (documents de la Task Force "Restructurations", travaux du Forum "Restructurations", information accumulée par les services de la Commission les plus concernés (EMPL, ENTR, TRADE, REGIO, ECFIN et autres) dans le cadre de la coordination menée jusqu'à présent.

Des analyses plus poussées sont nécessaires pour ce qui concerne la création d'un cadre européen non contraignant (code de conduite, charte, autre) sur l'anticipation et la gestion socialement responsable des restructurations, notamment sur des dispositifs similaires existant au niveau international (OCDE), national (dans certains Etats membres) ou au niveau des entreprises (Accords-Cadres Internationaux). Ces analyses seront réalisées par les services de la Commission sans recours à l'expertise externe.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Les idées de base de la Communication font l'objet de débats approfondis depuis deux ans, dans le cadre du Forum "Restructurations" qui regroupe toutes les parties prenantes (institutions communautaires, gouvernements, autorités régionales et locales, partenaires sociaux, experts, etc.), ainsi que par les services concernés de la Commission pour la partie concernant la coordination interne et le développement cohérent des différentes politiques.

ROADMAP

Title of the initiative: **Proposal for a Revision of the European Works Councils' directive (94/45/EC)**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

European works councils play a major role in the anticipation and the proper treatment of the social dimension of change and in developing European partnership at corporate level. Their development contributes to enhance competitiveness and safeguard social cohesion. The initiative to adapt their governing directive – Council Directive 94/45 of 22 September 1994 on the establishment of a European Works Council - follows the conclusions of an implementing report in 2000. Consultations of the social partners were carried out in 2004, 2005 (first consultation on the basis of Article 137.2) and forthcoming end 2007 second consultation on the basis of Article 137.3).

What are the main problems identified?

Transnational information and consultation needs to become more effective, notably in anticipating and managing change, in a higher proportion of European works councils. The Directive 94/45/EC needs to be adapted to the major evolution of the legislative, economic and social context. Problems and legal uncertainties encountered in its application need to be resolved, notably as regards the relation between national and transnational levels of information and consultation and the consequences of mergers and acquisitions. In addition, the forthcoming second stage consultation of the social partners may raise further aspects to be modified in the directive.

Is EU action justified on grounds of subsidiarity?

The objectives of the proposed initiative cannot be sufficiently achieved by the Member States in that the object is to revise a directive establishing a set of rules on transnational workers' information and consultation

B. Objectives of EU initiative

What are the main policy objectives?

The objectives of the revision of the legislation governing European works councils are: to ensure the effectiveness of transnational information and consultation rights, to resolve the problems and legal uncertainties encountered in its application and to ensure coherence between Community legal instruments relating to workers' information and consultation

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Three main options are identified: No action; Non regulatory approach: promotion of best practices; Review of existing legislation

1-No action; This is the preferred option expressed so far by the employers' organisations. It would nevertheless not address the problems identified, in particular that, according to research findings, rights to transnational

information and consultation are not properly ensured in half of the existing European works councils in case of restructuring.

2-Non regulatory approach - promotion of best practices; After the Commission's consultation on European Works Councils in 2004, the social partners have made a substantive step by dealing jointly with this issue. The best practices identified in 2005 after common seminars identify a number of important points in relation to positive, anticipative and socially acceptable corporate restructuring as well as effective transnational information and consultation. They nevertheless fell short of giving clear and precise indications to companies and workers in Europe and addressing the issue of how they will be developed and implemented throughout the EU. The 2005 joint consultation on best practices in corporate restructuring and European Works Councils included in the 2005 Communication "restructuring and employment" invited therefore the social partners to negotiate an agreement on monitoring and follow-up mechanisms to their common text. The social partners have included the promotion and evaluation of their lessons learned on European works councils in their work programme 2006-2008. The promotion of best practices is therefore underway by the social partners themselves and is supported by existing Community financing (Budget line 04.03.03.03) and by the Commission's follow-up of the Communication "restructuring and employment". Further action of the Commission in this area through "soft law" instruments may presently interfere with the action of the social partners and would not address some major problems identified in the application of the 1994 directive, in particular the legal uncertainties in mergers and acquisitions and the need for effectiveness and coherence in the Community legislation.

3- Review of existing legislation: This is the preferred option expressed so far by the trade unions and the European Parliament. The Commission will launch a second stage consultation in order to adapt and reinforce Directive 94/45/EC in late 2007. The social partners may undergo a negotiation as an answer to this consultation; A legislative proposal may be adopted by the Commission in the absence of such a successful negotiation. The review of existing legislation would aim at addressing the problems identified in the operation of European works councils and listed in the 2000 report of the Commission, in the 2004 first stage consultation of the social partners and in the forthcoming 2007 second stage consultation. Part of the proposed revision would be a routine update of the 1994 directive while the other part would go beyond this updated by reinforcing European Works Councils' activity.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The proposed action cuts notably across Commission's policies on social dialogue, corporate restructuring, industrial policy and better regulation.

Do the options respect the proportionality principle?

The options identified do not go beyond what is necessary to achieve more effective transnational workers' information and consultation rights and more coherent Community legislation. In particular, the adaptation to the particular need of each situation covered is being made possible through the priority given to negotiated solutions and the proposed legislative review would focus on resolving actual identified problems and reinforcing effectiveness, while avoiding unnecessary burden on business and providing flexible solutions.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

1- Impact of no action: continuing legal uncertainties for companies and workers the cost of which may be very high (example of the failure of the GDF-Suez merger due to uncertainty on GDF European works council's consultation end 2006) ; social unrest in cases of corporate restructuring and mergers & acquisitions without effective information and consultation (example of VW-Forest restructuring plan) ; higher economic and social costs of corporate restructuring in the absence of anticipation and negotiated accompanying measures

2- Impact of best practice promotion : No immediate and direct consequences follows from the promotion of best practices, but depending on how transnational information and consultation are implemented and developed, they

could impact on business (short term costs against long term benefits), on workers (increased protection in restructuring times against acceptance of change, increased mobility and adaptability) and on the social dialogue between them.

3- Impact of Directive's revision: Part of the impact would be the same as promotion of best practices. Proponents of strengthening information-consultation procedures would see it as contributing positively to the competitiveness of enterprises and to social cohesion while opponents would see it as imposing additional costs. However, it is difficult to envisage that any likely outcome, whether resulting from social partner agreement or otherwise, would be such as would entail significant additional cost for companies already complying with the requirements of the existing Directives. Thus a preferred way would be for the social partners themselves to reach an agreed solution on the issue they are best placed to strike a balance between perceived positive and negative effects. The information and consultation of workers is also addressed by a set of directives; The initiative will thus contribute to make the existing instruments more coherent (same definitions, interplay between national and transnational rules,..).

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No significant impact, save the registering of the agreements establishing European works councils that may form part of the legislative proposal

Who is affected?

The present 94/45/EC directive covers Community-level undertakings and groups of undertakings with over 1000 employees in the Member states including 150 employees in two different Member States. About 2200 companies are covered. 820 European works councils, representing 14,5 millions workers are presently operating.

E. Planning of further impact assessment work

What information and data is already available?

Results of the first stage consultations, EP and EESC opinion, implementation report of the Directive 94/45/EC, different studies, results of the seminars held by the social partners

What further information needs to be gathered?

Update of data; detailed assessment of some costs and impacts

How will this be done (e.g. internally or by an external contractor) and by when?

Internally and by a specific study on an impact assessment, using Commission's framework contract – to be launched 4th quarter 2007.

What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

As the initiative deals with existing legislation, the analysis will focus on considering the changes in need and context since the adoption of the 94/45/EC Directive. It will build on the 2000 application report of the Directive and the existing numerous studies on European works councils will be used. The Commission needs however additional input to its own resources and work in assessing some costs and impacts.

Which stakeholders & experts have been/will be consulted, how and at what stage?

First phase of consultation of the social partners under article 138(2) of the treaty on the orientation of the initiative in April 2004; Second phase of consultation of the social partners under article 138(3) of the treaty on the promotion of best practices in the framework of the Communication "restructuring and employment" COM (2005)120 in March 2005; Forthcoming second phase of consultation of the social partners under article 138(3) of the treaty on the content of the envisaged proposal in late 2007.

ROADMAP

Title of the initiative: **Completion of the EU anti-discrimination legal framework**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Since 1997, the protection of fundamental rights has been a specific objective of the European Union with Article 13 EC providing the basis for measures to combat discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation. Important progress has been made in developing measures to underpin these rights but a significant gap remains in the scope of the legal protection as regards religion or belief, age, disability and sexual orientation. This initiative seeks to close that gap.

Under the current EC legal framework, racial discrimination is prohibited in the areas of employment, training, education, social protection, social advantages and access to goods and services (Directive 2000/43/EC). The scope of protection against discrimination on grounds of religion or belief, age, disability and sexual orientation is limited to employment, occupation and vocational training (2000/78/EC). Directive 2004/113/EC extends protection against sex discrimination to the area of goods and services.

Responding to concerns expressed by civil society and the EP on this 'hierarchy of grounds', the Commission committed itself in 2005²¹ to undertake an in-depth study into the relevance and feasibility of possible new measures to complement the current legal framework and then, on the basis of this material, to assess the feasibility of possible new initiatives to complement the current legal framework.

The results of the study were received in late 2006²² and revealed that there is a considerable variety in national situations with respect to protection against discrimination on grounds of religion or belief, age, disability and sexual orientation, regarding notably the type of legal rule in question and its material and personal scope of application.

The European Year of Equal Opportunities for All, which addresses all discrimination grounds under Article 13, has helped to highlight existing rights under EU law. It has also allowed for a greater focus on multiple discrimination. A wide-ranging Eurobarometer survey on Discrimination in the European Union²³ showed that a high proportion of the EU population considers that discrimination exists in all the areas covered by Article 13.

In the light of these factors, the European Commission announced in its Annual Policy Strategy for 2008 that it *'As a follow-up measure to the European Year of Equal Opportunities for All (2007), the Commission will extend and reinforce its equal opportunities policy. It will, in particular, propose new initiatives designed to prevent and combat discrimination outside the labour market – based on gender, religion, belief, disability, age or sexual orientation..'*

What are the main problems identified?

People across the EU suffer discrimination on grounds of religion & belief, sexual orientation, age and disability in areas outside of employment. The level of protection against discrimination provided under existing EU law on the grounds of religion & belief, sexual orientation, age and disability varies depending where the discrimination takes place (work, access to goods & services, education etc), leaving people subject to discrimination in certain areas with no legal protection and no guaranteed redress. This differing level of protection also makes it more difficult to tackle multiple discrimination.

²¹ COM (2005) 224 Non-discrimination and equal opportunities : a framework strategy

²² http://ec.europa.eu/employment_social/fundamental_rights/pdf/pubst/stud/mapstrand1_en.pdf

²³ http://ec.europa.eu/employment_social/eyeq/uploaded_files/documents/Eurobarometer_report_en_2007.pdf

Is EU action justified on grounds of subsidiarity?

Yes: action is considered necessary at EU level in order to achieve a uniform minimum level of protection against discrimination, completing the EU framework is the only option. Creating the same level of protection across the Member States will increase the likelihood of cross-border service provision, as well as free movement for certain groups.

B. Objectives of EU initiative

What are the main policy objectives?

The main policy objective is to improve the level of protection against discrimination on the grounds covered by article 13 EC, and to provide a uniform level of protection.

Does the objective imply developing EU policy in new areas or of strategic importance?

No, inasmuch as non-discrimination instruments have already been adopted under Article 13 but, as noted above, their coverage is incomplete.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

If, at the end of the Impact Assessment a legislative instrument was considered the most appropriate way forward, a directive rather than a regulation would be appropriate as it allows Member States to go beyond the minimum requirements. The options could, subject to the outcome of the impact assessment, include amending existing directives or proposing a new directive or directives, although the most efficient and effective approach would appear to be a new Directive prohibiting discrimination on grounds of religion & belief, sexual orientation, age and disability outside of the employment sphere (for example social protection, health care, education, access to goods and services).

Experience of the existing legislation in the field of anti-discrimination and individual rights shows that legislation alone is not sufficient: accompanying measures are required to achieve the effective application of the law, such as actions to raise awareness about rights, information campaigns fighting stereotypes and prejudices, and training for public and private providers, NGOs & lawyers. In addition, it is necessary to increase the expertise and capacity of national authorities and in particular the bodies at national level responsible for promoting equality and helping the victims of discrimination. This can be achieved by, for example, the promotion of mechanisms for an EU-level exchange of information and good practice between the national equality bodies.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, education, service provision, social protection.

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Social: extending protection against discrimination on grounds of age, disability, religion and sexual orientation would be likely to have a positive impact, in terms of improved education possibilities (leading to better employment chances), ability to participate in social/cultural activities, and social cohesion/integration in general

Environmental: extending protection against discrimination on grounds of disability might imply physical alterations to premises and goods and services for accessibility, which could contribute to their sustainability, particularly in an ageing society. Nevertheless, it would be subject to a "reasonableness" or undue burden consideration.

Economic: the above mentioned physical alterations are likely to cost money to business and public authorities in some cases, but in general these costs are neglectable if they are considered in the early stages of design. This should be balanced against the fact that extending protection against discrimination to access to goods and services will increase customer base and will improve economic activation of people with disabilities.

The costs and benefits of each option will be assessed in the IA.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries? No

Who is affected?

EU citizens and other people present in the EU; public and private suppliers of goods and services, law and policy makers in the Member States.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A study on the anti-discrimination legal instruments in all the Member States has been concluded, and a study on the evidence of discrimination outside the labour market has been commissioned. This latter study will also look at the possible options to resolve the problem identified and the costs and benefits of the options that will be proposed

Which stakeholders & experts have been/will be consulted, how and at what stage?

1. Public on-line consultation (July 4 – Oct 15): http://ec.europa.eu/yourvoice/consultations/index_en.htm

Public consultation widely publicised – in the context of the European Year of Equal Opportunities for All through a Commission press release, speeches by the Commissioner and Commission officials, newsletters, and a mailing to the main stakeholders including via the DG EMPL anti-discrimination database of more than 6000 subscribers as well as.

2. The European Business Test Panel is being consulted via an on-line questionnaire, the result will be known in autumn 2007

3. NGOs & social partners have been consulted in writing, with a follow-up meeting planned for October 2007

ROADMAP

Title of the initiative: **Proposal for a Directive amending Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast-feeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)**

Expected date of adoption of the initiative: **September 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

In its Roadmap for equality between women and men 2006-2010, the Commission has announced its intention to review the existing EU gender equality legislation not included in the 2005 recast exercise with a view to updating, modernising and recasting where necessary. In addition, reconciliation of professional, private and family life has been identified, in the Roadmap, as one of the priority areas for action in the period 2006-2010.

The European Parliament has consistently called for improvements to the existing legislation in relation to protection of pregnant workers and for measures to improve reconciliation of professional, private and family life (see for example European Parliament resolution on the report on the implementation of Directive 92/85/EEC (A5-0155/2000)).

On 12 October 2006, the Commission decided to launch the first stage of the formal consultation of European social partners on reconciliation of professional, private and family life in accordance with Article 138 of the EC Treaty. Based on the responses to the first stage consultation, the Commission identified a number of options for amendments to Directive 92/85/EEC. Options for new types of leave which could better meet the needs of workers in reconciling professional, private and family life, namely paternity leave (a short period of leave for fathers around the time of the birth or adoption of a child), adoption leave (leave similar to maternity leave around the time of the adoption of a child) and 'filial leave' (leave to care for dependent family members) as well as a number of options for possible amendments to the framework agreement on parental leave annexed to Directive 96/34/EC were also identified (separate Roadmaps are provided). The Commission therefore launched the second stage consultation of the social partners on 30 May 2007.

In response to the second stage consultation, ETUC, BUSINESSEUROPE, CEEP and UEAPME have decided to set up a joint working group within the context of the European social dialogue to carry out a review of the framework agreement on parental leave, in connection with other arrangement supporting parents and work-life balance. . They have also indicated that they will furnish a progress report to the Commission and the Tripartite Social Summit of March 2008.

Without prejudice to the information that European social partners will provide in their March progress report, the Commission considers that new legislation is needed.

What are the main problems identified?

Available statistics show that there still is an important gender gap in the participation in the labour market, and in particular that the participation of women decreases dramatically after they give birth. There is also evidence that Member States with effective reconciliation policies have not only higher fertility rates but also a higher female labour force participation rate.

The Directive 92/85/EEC provides for a minimum period of maternity leave (14 weeks) which is inferior to the minimal period of maternity leave applied in most Member States. Indeed, the duration of maternity leave varies from 14 weeks in a small number of Member States to 28 weeks in other Member States (e.g. the Czech Republic and Slovakia)²⁴ and in certain circumstances up to 52 weeks.

²⁴ The references to individual Member States are by way of example only and are not intended to provide exhaustive lists.

Is EU action justified on grounds of subsidiarity?

Yes.

Action is considered necessary at EU level in order to achieve a minimum level of legal protection. An existing Directive has to be amended and this can be done only at EU level.

A European Directive would establish a minimal level of protection in Europe, leaving Member States free to adapt their legislation to their national context, provided the minimal standard is respected.

B. Objectives of EU initiative

What are the main policy objectives?

The main policy objectives are (i) to increase the level of protection of the health and safety of women who recently gave birth, (ii) to increase the rate of participation of women in the labour market, and (iii) to enhance the reconciliation of professional, private and family life in Europe. The achievement of these objectives is likely to bring economic benefits and contribute to meet the challenges of the Lisbon agenda for growth and jobs.

In this framework, it appears in particular necessary to increase the minimum period of leave and the minimum level of payment during maternity leave (not less than what the worker would receive during sick leave).

Does the objective imply developing EU policy in new areas or of strategic importance?

Maternity leave is already covered by a Directive. The initiative will increase the protection of pregnant workers.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Depending on the outcome of the consultation of social partners and of the conclusions of the IA, as this area is covered by a Community Directive, the review of the Directive could be the only way forward.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No.

Do the options respect the proportionality principle?

Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Social: The proposals will facilitate greater participation by pregnant workers in the labour market. The proposals will also contribute to facing the demographic challenge by enabling women and men to have as many children as they would like.

Environmental: no likely impact.

Economic: improved maternity protection will facilitate increased participation by women in the labour market; and will have economic benefits for businesses e.g. lower staff turnover, reduced absenteeism, etc. Improved maternity leave rights will also have costs for Member States and individual businesses e.g. the State may have to bear the cost of any increase in the level of payment during maternity leave; businesses will have to facilitate longer absences by pregnant women, etc.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No

Who is affected?

Pregnant women, employers and Member States.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Some studies are available, notably reports by the Commission's network of independent legal experts in the fields of employment, social affairs and equality between women and men and the expert group on gender, social inclusion and employment. A new external study on the costs and benefits of options to improve legislation in the area of reconciliation of professional, private and family life is being prepared.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The European social partners have been formally consulted in accordance with the procedure laid down in Article 138 of the EC Treaty.

ROADMAP

Title of the proposal: **High Level Reflection Process on Health Professionals in Europe**

Expected date of adoption of the proposal: **4th Quarter 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Political context

The primary responsibility of the organisation and delivery of health services and medical care lies with the Member States. However, the introduction of the free movement of health professionals in the EU has changed the political climate in Europe. The free movement requires changes in national health policies and planning of the health workforce.

Mobility of health professionals can ensure that health professionals go where they are most needed. But on the other hand, it can, together with other factors such as the overall ageing of the healthcare workforce combined with the ageing of EU population, also leave challenges for some regions and some specialities effecting in health professionals shortages and regional disparities in the EU. If the overall numbers and specialisations of health professionals are not adequate, this still represents a serious risk for health systems across the Union, with the impact being felt hardest in the poorest Member States and regional disparities being exacerbated.

In order to ensure high quality care and patient safety it is necessary to have appropriately trained and skilled health professionals distributed throughout the Union and to facilitate their mobility. In this context, it will be difficult for any one country to invest in training health professionals without knowing that other countries will do likewise. Policy makers recognise increasingly that there is a need for a common European strategy. In order to be able to plan an efficient and high quality health workforce for Europe we need to know what the migration patterns are and what the real needs are. The enlargement of the European Union made this even more important, since the diversity in health care systems across an enlarged Europe provides greater impetus for mobility of health care professionals. This creates particular challenges for acceding countries in safeguarding accessibility, quality and sustainability of healthcare systems.

The environment in which health services are delivered is changing constantly. The major challenge which policy makers are facing is to adapt health care system to demographic, technological, economic and institutional changes. Health services are extremely labour intensive. Health workers constitute one of the most significant sectors of the EU economy, providing employment for 9.7% of the EU workforce (European Commission 2002). While healthcare consumes between 7% and 11% of the GDP in Western European Countries, approximately 70% of the European budgets are allocated to salaries and other charges related directly to employment.²⁵ It places health workforce on the top of political agenda.

The issue of health professionals is of great importance also because of the aging of the EU population. People live longer in better health and have higher expectations from the health services. It is combined with the aging of the health workforce. Between 1995 and 2000, the number of physicians under the age of 45 across Europe dropped by 20%, whilst the number aged over 45 went up by over 50%. For nurses as well, average ages are rising; in five Member States nearly half of nurses are aged over 45. Moreover, the participation of women in health workforce is increasing. It has an implication on the capacity of health workforce as women tend to work fewer hours, to have career breaks and to work part-time. Furthermore, health workers both man and women would like to have more time for their families and are reluctant to work long hours. The working time directive helps to ensure both the health and safety of health professionals and their patients, but also has an impact on the working hours of health professionals. If these trends continue, shortages will become critical across the whole Union in the coming decades.

Technological innovations have also an impact on the health workforce. New technology requires health professionals to acquire new skills. The use of eHealth applications, telemedicine is increasing and some patient treatment has moved outside the hospital.

²⁵ Human Resources for Health in Europe, European Observatory on Health Systems and Policies Series, 2006, Chapter 2, p. 15

Links to other initiatives and EU policies

The impact of health professionals mobility has been discussed by Member States and key stakeholders through the Health Professional Working Group of the High Level Group on Health Services and Medical Care (see COM(2004)301 of 26 April 2004) which was established in 2004.

The consultation on the Community Action on Health Services has recently ended and its outcome has been analysed. The issue of the mobility of healthcare professionals was explicitly mentioned in the consultation document. The responses received touch upon several problems which should be tackled at the EU level.

The initiative on health professionals will follow and complement the proposal for the framework directive on health services. Health professionals are essential for the quality of health services, patient information and patient safety.

Without prejudice to the Directive 2005/36/EC on mutual recognition of professional qualifications, which comes into force in October 2007, the initiative on health professionals will address issues linked to managing the impact of professional mobility and continuous professional development which go beyond the scope of this directive. Any follow-up action related directly to mutual recognition of qualifications would be taken forward within that framework.

This initiative will also take into account the External Council conclusions on the international crises in human resources for health of April 2006. We will also work closely on the issue of ethical recruitment with DEV which adopted the European Programme for Action to tackle the critical shortage of health workers in developing countries (2007-2013) on December 2006.

The planned proposals on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment will inevitably have an impact on the recruitment of the health professionals from third countries. It aims at improving the EU ability to attract and retain third-country highly skilled workers so to increase the contribution of legal immigration to enhance the competitiveness of the EU economy and to address the consequences of demographic ageing. It will facilitate the third-country health workers mobility and employability within the EU and will attract more health professionals from outside the EU. It could have serious consequences on the developing countries ('brain drain'). The proposal sets out additional measures which should be taken by the EU to counter-balance the negative effects.

What are the main problems identified?

- Lack of coherent European approach to health professionals

There is a lack of a coherent approach to health workers in Europe, which therefore undermines the effectiveness of Member States in addressing challenges arising from the impact of the health professionals' mobility. The lack of policy coordination and limited exchange of best practices might cause in the near future insufficiencies and loss of resources in various EU regions.

- Lack of comparable data on health professionals

The lack of comparable data on health professionals impedes the development of evidence based policies. Given the potential for shortages in one part of Europe to have an impact elsewhere, Europe-wide information on the number of health professionals, their specialisations, and their distribution is key for planning and providing health services for all health authorities throughout the EU.

- Issue of ethical recruitment of health professionals from developing countries

Lack of health professionals within the Union also creates demand for health professionals from outside the Union, which can have the effect of depriving less developed countries of the health professionals that are vital to ensure the effective provision of their own health systems. EU wide approach is needed to address this issue.

- Differences between Member States in health professional training, recruitment standards, retention, ongoing professional development, and monitoring and other barriers to free movement of health professionals

Differences between Member States in health professional education, training, recruitment standards, retention, ongoing professional development, and monitoring can make the comparison of health workers' professional abilities and qualities beyond those covered by the existing directives on mutual recognition of professional

qualification difficult and have given rise to concerns about the quality and safety of care that different health professionals provide – and this in turn creates barriers for free movement of health professionals and their expertise within the EU.

- Other issues identified in the course of the forthcoming high level reflection process (please see section B on objectives)

Is EU action justified on grounds of subsidiarity?

As mentioned before, the primary responsibility of the organisation and delivery of health services and medical care lies with the Member States. However, the internal market provides for the free movement of health professionals in the EU. The mobility of health professionals has therefore a European dimension. Policy coordination and exchange of best practices at the EU level would be an added value to the national health policies, which cannot themselves effectively address the issues identified above

In order to be able to plan the health workforce in Europe effectively, there is an urgent need for the comparable data at the EU level which would only be developed with the cooperation of all Member States

.Differences between Member States in health professional education, training, recruitment standards, retention, ongoing professional development, and monitoring can only be addressed through the cooperation and benchmarking at the European level.

Cooperation on training and mobility can help to bring up-to-date expertise to patients throughout the Union, rather than patients having to travel to centres of expertise. It will also help to ensure that health systems are better prepared for the coming pressure of demographic ageing of the population in general and the health workforce in particular.

There is an urgent need for structured discussion and coherent approach to health workforce in Europe which would help to identify the needs and plan effectively the European health workforce.

B. Objectives of EU initiative

What are the main policy objectives?

On the basis of the identified problems the Commission would like to develop a strategic approach to human resources in health in order to ensure that Member States would see a return on their investment in health professionals and that the Union as a whole will be able to meet its objectives of providing high-quality healthcare and maintaining a healthy workforce, without undermining health systems in developing countries. This work will need to be developed in collaboration with relevant stakeholders including the health professions, and supported by better information in the future on the number of health professionals, their specialisations, and their distribution, in order to improve planning and providing health services throughout Europe and to strengthen economic and social cohesion both within the health sector and through its contribution to the wider economy and maintaining a healthy workforce.

Given the primary responsibility of the Member States for the organisation and delivery of health services and medical care, the complexity of issues related to health professionals and the large resources at stake, in the first instance, the Commission would like to provide a mechanism for dialogue and collective reflection on the identified problems and proposes to convene a high level reflection process which would develop specific policy recommendations. Any future Commission proposals would only follow at a later stage and will be based on the reflection process recommendations.

The High Level Reflection Process

The high level reflection process on health professionals will build on the work of the High Level Group on health services and medical care and its working group on health professionals and on the outcome of the recent consultation on the Community Action on Health Services. Contrary to the working group which was more technical, the reflection process will take the discussion to a higher political level and will widen the membership to include representatives from all Member States, different health professions and health NGOs (around 40-50 members). The Forum will investigate further already recognised problems, help to clarify issues and identify issues which should be addressed at the EU level and areas of collaboration between Member States. It would develop, in a certain period of time (in 2 years), recommendations and benchmarks where useful and appropriate.

Does the objective imply developing EU policy in new areas or of strategic importance?

The new initiative is the reaction to the implications of the free movement of health professionals in the internal market. It aims to address the consequences of this movement and the recognition of professional qualifications within the EU.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

1. Do nothing

As the primary responsibility for the organisation and delivery of health services and medical care lays in the Member States any EU action in the field of health professionals would be politically very sensitive. However, 'do nothing option' would almost certainly result in little or no action in some Member States and an overlap of activities and an ineffective use of resources in Europe as a whole. It is likely that without the efficient cooperation at the European level and a common strategic approach current trends would continue, ie: increasing shortages of certain types or specialisations of health professionals in specific parts of the Union, affecting particularly the most remote and poorest parts of Member States within the Union, and the least developed countries outside it. The lack of the coordinated policy on health professionals would also have a negative impact on patient safety.

2. Non – binding instruments

The high level reflection process on health professionals would launch a discussion on the impacts of the health workers mobility within the EU. It will help to manage human resources in health more efficiently throughout the EU and address national barriers for health professional mobility. Cooperation at the European level would give substantial support to Member States policies. It would provide opportunity to develop best practices and data-sharing mechanisms. The outcome of the work of the high level process will be taken forward by the Commission.

3. Binding legislation

The upcoming Commission initiative on health services will provide a legal framework for health professionals. The binding legislation on the recognition of the professional qualifications already exists. Therefore, at this stage, there is no need for more legislation in this area. However, further work may be required on specific issues and their practical implementation.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The work of the high level process will relate to the framework Directive on health services, the future Communication on Patient Safety, MARKT's Directive on the recognition of the professionals qualifications, DEV's Programme for Action to tackle the critical shortage of health workers in developing countries (2007-2013) and the future JLS's Directive on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment.

Do the options respect the proportionality principle?

As it is a proposal for a Communication the policy options suggest possible approaches to be taken rather than setting detailed policy actions. The aim of the proposal is to give a support and facilitate coordination of national policies concerning health workers rather than setting out binding requirements. The proportionality principle is therefore observed.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option, even if these impacts would materialise only after subsequent Commission initiatives?

The proportionality principle shows that the impacts envisaged will be limited and evaluated in a rather qualitative way.

At this stage of the process the Commission, through its coordinative role, would focus on bringing on new impetus and targeted discussions between all the Member States. Possible subsequent actions will be led through other initiatives and individual efforts of Member States

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No

Who is affected?

Health professionals, health services, health care system

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Some information about the problems linked to the health workforce is already available as set out above, and is being further developed in particular through the health professionals working group of the High Level Group on health services and medical care. For more information, see:http://ec.europa.eu/health/ph_information/dissemination/hsis/hsis_12_en.htm

The Commission is collaborating with the Organisation for Economic Cooperation and Development (OECD) to further develop information on this issue, and will work with health professionals and their regulators, as well as other international organisations such as the World Health Organisation (WHO). Commission is also going to fund projects on health professionals under the FP7.

Further information will be gathered in the course of the work of the high level reflection process. The recommendations of the reflection process will be taken forward in any future Commission proposal on health professionals.

Which stakeholders & experts will be consulted, how and at what stage?

Member States and representatives of health professionals are already involved in discussions through the health professionals working group of the High Level Group on health services and medical care. The public consultation will be organised in 1st semester 2008 to help establish the range of issues and priorities

ROADMAP

Title of the proposal: **Commission Communication on a European Union action in the field of rare diseases (including genetic diseases)**

Expected date of adoption of the proposal: **November 2008**

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

1. The need of a recognition of rare diseases as a main EU problem

The future Commission Communication on an European action in the field of rare diseases (including genetic diseases) pretends to improve the chance for patients to get appropriate care and information on rare diseases and to reverse the current situation of uncertainty and invisibility for people suffering from a rare disease. Health professionals and public health authorities have insufficient knowledge of the majority of rare diseases. This lack of knowledge underlies diagnostic error - a great source of suffering for patients and their families - and delayed care provision, which can sometimes be prejudicial. This will in turn contribute to the over arching goals - an improvement in health outcomes, and therefore a growth in Healthy Life Years, a key Lisbon Strategy indicator.

Rare diseases, including those of genetic origin, are life-threatening or chronically debilitating diseases which are of such low prevalence that special combined efforts are needed to address them so as to prevent significant morbidity or perinatal or early mortality or a considerable reduction in an individual's quality of life or socio-economic potential.

- A [Community action programme on rare diseases](#), including genetic diseases, was adopted for the period 1 January 1999 to 31 December 2003. This programme defined the low prevalence of a disease (the rarity) as less than 5 per 10 000 persons in the European Union.
- While this number seems small, it translates, per disease, into approximately 246 000 persons in the EU with 27 Member States. Most of the people represented by these statistics suffer from less frequently-occurring diseases affecting one in 100 000 people or less.
- It is estimated that between 5 000 and 8 000 distinct rare diseases exist today, affecting between 6% and 8% of the population in total.
- In other words, between 27 and 36 million people in the European Union (with 27 Member States) are affected by a rare disease.
- The majority of rare diseases are caused by variations (unusual forms) or mutations (alterations) in genes and are called genetic diseases. These variations or mutations (called anomalies) sometimes increase a person's chances of developing certain diseases. There are three types of genetic diseases: Monogenic (involving an anomaly in one specific gene out of thousands), Multifactorial (involving the interactions of numerous genes in the body often in combination with environmental factors) and Chromosomal (resulting from an excess or deficiency in a package of genes called a chromosome or in a segment of chromosome).
- Rarity has certainly not the same meaning as unknown [e.g. Haemophilia or Thalassemia (which according to its prevalence belongs to the rare diseases) are very well known bleeding disorders]. Hundred different kinds of cancer (mostly paediatric) are also considered as rare diseases. The rarity or the frequency of a disease plays a role when one should define the European strategy to provide adequate information, treatment or drugs to everybody.
- The definition of the rarity of a disease should not mask the importance of the challenge that rare diseases represent for public health. A large number of these pathologies are also called "orphan diseases" because the affected populations do not have access to any therapeutic treatment.

2. Necessity of a EU action

- There is probably no other area in public health in which **27 national approaches could be considered to be so inefficient and ineffective as it happens with rare diseases**. The reduced number of patients for these diseases and the need to mobilise resources could be only efficient if done in a coordinated European way.
- The focus on rare diseases is a relatively new phenomenon in most EU Member States. Until recently, public health authorities and policy makers largely ignored these challenges. The reasons why rare diseases in general have been so long ignored are better understood today. Clearly, it is impossible and would be unjustified to develop a public health policy specific to each rare disease. But a global rather than a piecemeal approach could provide some solutions. A global approach to rare diseases means that individual diseases do not fall through the net and real public health policies can be established in the areas of scientific and biomedical research, drug research and development, industry policy, information and training, social benefits, hospitalisation and outpatient treatment.
 - National Reference Networks for rare diseases exists in the majority of Member States. However it's not imaginable that a centre for every disease could exist in every Member State. The idea is that the expertise, rather than the patients, should travel - although patients should also be able to travel to the centres if they need to.
- There are a number of competences at EU level that could impact on rare diseases. For example, Community competence in the areas of orphan drugs, research, and environmental factors. With the EU data protection directive, a tool for dealing with data resulting from research and diagnosis of rare diseases is given. Further EC competences are found with regard to the freedom of service providers and the single market for medical devices (e.g. provision of diagnostics over the internet).
- However, many interventions that could have an impact in this field are in settings that are either fully outside the competence of the Community or need a shared management with national authorities (reference networks) or with the WHO (classification and codification).

2. What are the main policy objectives?

This proposal for a Commission Communication is intended to cover all the necessary elements to strengthen the cooperation between the [EU Public Health Programme 2003-2008](#) and the new Public Health Programme, the FP7 Programme ...-2013, the Orphan Drugs strategy, the advanced therapies strategy, the EU Statistical Programme and any other EU existing action.

The priorities in the Communication will be to provide EU consensus methods of action according to the following principles:

1. Common definition of rare diseases in the EU.
2. To strengthen the necessity of national plans for rare diseases in the EU Member States;
3. To recommend European guidelines for the elaboration of such national plans for rare diseases;
4. To set up a common system of databases and medical protocols for the identification of rare and genetic diseases;
5. To establish a common approach for a better codification and classification of rare diseases in the process of revision of the International Classification of Diseases;
6. The creation of the EU Forum on Rare Diseases as an EU advisory body for the EU policy on rare diseases;
7. The biannual organisation of the European Conference on Rare Diseases;
8. A common approach and framework to the support of rare diseases patient's organisations;
9. The creation of the EU Rare Diseases Portal as a part of the EU Health Portal and as common tool for share of information and knowledge on rare diseases;
10. To improve the use of the e-health facilities for information and treatment;
11. The creation of networks of action for rare diseases supported by the Public Health Programme in order to network stakeholders and to support the creation of EU registers of rare diseases;
12. A better integration of the EU rare diseases public health action with other rare diseases policies (research, orphan drugs, advanced therapies, etc);

13. An EU procedure for the creation and recognition of the EU networks of reference for rare diseases in order to share knowledge and facilitate the mobility of patients;
14. To support a genetic testing common system for the identification of genetic rare diseases assuring equal access to everybody in the EU to quality laboratory testing
15. To network Bio Banks in the EU with all the necessary data protection measures;

16. The training of rare diseases researchers and professionals;
17. Intensifying Therapeutic Research, toward a Public–Private Partnership
18. A systematic report on the situation of rare diseases in the EU

A monitoring for the future with the possible creation of an European Office for Rare Diseases in the next Public Health Programme 2014-2020.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

- Option A: Do nothing
- Option B: Adoption of the Commission Communication

Option A

- a) **Option A:** Do nothing/no change. No further attempt to develop or provide further framework to Community level actions.
 - Continue to finance projects and networks as a part of the Public Health Programme
 - Continue to support research via the FP7 Programme
 - Continue to facilitate best practice in the creation of Reference Networks for rare diseases without EU framework
 - Continue to facilitate Orphan Drugs designation without an integrated approach
 - Continue to collect and disseminate information on epidemiology of rare diseases via ORPHANET
 - Continue with meetings of the Task Force on Rare Diseases and to improve the commitment from its members

Instruments: no specific new instruments to be used. Continue to use the [EU Public Health Programme 2003-2008](#) which not contains specific actions for rare diseases.

Option B

- b) **Option B:** A strategy at Community level along traditional lines, i.e. which seeks to further develop, and identify the actions from different DG's without a clear framework. Community level actions in the field of rare diseases could include, inter alia:
 - Bring coherence as far as possible to existing Community actions in the field of rare diseases. Here there are already encouraging initiatives: ENTR and EMEA in the field of orphan drugs, RTD for research on rare diseases, SANCO for the networks of action, databases and reference networks, EMPL for equal rights and ESTAT for classification and codification.

Instruments: White Paper, Action plan, Coordination and partnership mechanisms including with DG RTD, DG ENTR and EMEA.

Option C

- c) **Option C:** A comprehensive EC rare diseases strategy (including a Recommendation from the Council) including a wider Public Health Genomics perspective, that not only seeks to identify and develop actions at Community level but which also aims to galvanise action at national and regional level (by the adoption of National or Regional Plans on Rare Diseases) within Member States, and through new channels that are not normally responsive or reachable. In this way, it would respond to the limited Community competence in this field. This option would require stronger subsidiarity agreements with Member States.

This option comprises Option B + actions and develops new mechanisms to influence activity at national and regional level, for example:

- Encourage the development and implementation of the Communication objectives via the adoption of National or Regional Plans on Rare Diseases adopting the necessary guidelines for that purpose;
- Develop new forms of partnership with the most relevant patient's organisations, e.g. (EURORDIS);
- Develop a new and objectives complementary partnership with the FP7 Programme in the area of research on rare diseases;
- Develop new forms of partnership with the COMP (Committee of Orphan Medicinal Products) in the EMEA (European Medicines Agency);
- A new initiative, a "EU Forum on Rare Diseases" which would bring together Member States, NGO's and experts to support and monitor the EU Rare Diseases Agenda

Instruments: Commission Communication.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the enclosed guide)?

Option 1: No Action

There will be no additional impact on health. Choosing this option would mean accepting the lack of a coherent approach to the EU's work in the field of rare diseases. It would mean continuing work on a fragmented, ad hoc basis and without guidance. It would mean accepting a level of cooperation with international institutions that is not optimal as well as an approach to global health information serving EU policies that is heterogeneous, fragmented and sometimes contradictory. Ultimately this option represents a failure to optimize Community added value in addressing the main health problems.

Option 2: Develop a more comprehensive and coherent approach to key issues for health at the EU level, Health in all Policies, and the EU's role in global health

There is probably no other area in public health in which 27 national approaches could be considered to be so inefficient and ineffective as it happens with rare diseases. The reduced number of patients for these diseases and the need to mobilise resources could be only efficient if done in a coordinated European way.

- Given the strong capacity of the EU to coordinate a policy in the Community and to coordinate this approach with actions at national level in terms of policies that could have an impact on treatment, information and share of knowledge, this approach addresses the need for joined up action at these levels. Accordingly the EC shall strive for coherent best practice recommendations from a comprehensive framework's point of view – such as the Public Health Genomics framework.
- In developing new ways of linking Community, Member State and sub-national action it would be innovative and could trail blaze for other Community initiatives
- Would signal to citizens that Europe is working for them by bringing an initiative to all the levels
- Would take advantage of upcoming interest from future presidencies (e.g. Slovenian and, especially, French).

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this the basis be done (e.g. internally or by an external contractor) and by when?

The availability of data is very large. The scientific knowledge on rare diseases At present stage, the identification and the list of rare diseases it's possible in the EU using for that the database ORPHANET²⁶ supported by the European Commission. This database for rare diseases lists by categories and contains information about more than 4 280 rare diseases. ORPHANET is the most important database in the EU for rare diseases and orphan drugs for the general public. It offers to health-care professionals, scientists, health authorities, patients and their relatives, the media and the community at large reliable, up-to-date, relevant information on rare diseases and orphan drugs. Other important databases for the identification of rare diseases are: the database of the [US Office of Rare Diseases \(ORD\)](#)²⁷, the database on rare diseases of the [Swedish National Board of Health and Welfare](#)²⁸, the database of the Spanish Institute for Research on Rare Diseases²⁹, and other thematic databases for rare diseases as OMIM (for the Mendelian inheritance diseases)³⁰ and Geneclinics (for some genetic diseases)³¹.

The rare diseases web site of DG SANCO provides a large overview on the existing registers and network initiatives. However it's obvious that the most part of the 6 000/8 000 rare diseases are not covered by these actions.

6. Which stakeholders & experts will be consulted, how and at what stage?

During the development of the White Paper, a formal discussion has started in the EU Task Force on Rare Diseases. A specific Drafting Group with some of the most relevant experts in rare diseases in the EU has been set up. The relevant specialised bodies to be consulted in the elaboration of the White Paper are: the EU Task Force on Rare Diseases, the Working Group on Reference Networks for Rare Diseases from the High Level Groupon Health Services, the Committee on Orphan Medicinal Products from the EMEA (European Medicines Agency) and EURORDIS (European Organisation on Rare Diseases) as the most representative patient's organisation. A first draft of the White Paper will be presented in the European Conference on Rare Diseases (Lisbon, November 2007).

The direct consultation with Member States will take place through the Network of Competent Authorities on Health Information and the existing EU Task Force on Rare Diseases.

A document will also be placed on the web, so that other external stakeholders including the general public will also have the opportunity to comment on the Communication, in particular in how to identify key overarching objectives and means to implement them.

7. Will an inter-service steering group be set up for the IA?

A sub-group of the existing Inter-service Group on Health could be proposed since September 2007. They will assist in developing the Impact Assessment.

²⁶ See <http://www.orpha.net/>

²⁷ See http://rarediseases.info.nih.gov/asp/resources/rardis_info.asp

²⁸ See <http://www.sos.se/smkh/indexe.htm>

²⁹ See <http://www.sos.se/smkh/indexe.htm>

³⁰ See <http://www.ncbi.nlm.nih.gov/sites/entrez?db=OMIM>

³¹ See <http://www.geneclinics.org/>

ROADMAP

Title of the initiative: **Communication of the Commission to the Council and the European Parliament: Action plan on strengthened cooperation between Member States on organ donation and transplantation and proposal for a Directive of the European Parliament and of the Council on standards of quality and safety for the donation, procurement, testing, preservation, transport and characterisation of human organs**

Expected date of adoption of the initiative: **November 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

From 1999 onwards, with the adoption of the Treaty of Amsterdam, Article 152 has explicitly enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted Directives of the Parliament and the Council on blood³² in 2003 and on tissues and cells³³ in 2004. The third step in this process would be to ensure the quality and safety of human organs. However, it was already recognized during the discussions of the Tissues and cells Directive that Organs needs a different approach³⁴. Such an approach in the current situation characterised by shortage of organs has to balance two factors: the need for organs' transplantation which is usually a matter of life and death with the need to ensure high standards of quality and safety.

In order to response to these problems the Commission adopted a Communication on organ donation and transplantation³⁵ on 31 May 2007. This Communication and the Impact Assessment³⁶ attached to it identified the main problems in the area of organ transplantation and proposed two mechanisms of action in the field of organ donation and transplantation: a legal instrument containing the basic quality and safety principles in organ donation and transplantation and an action plan for a strengthened cooperation between Member States. The initiative presented today is the natural follow up of the previous communication.

What are the main problems identified?

Over the past 50 years organ transplantation has become established worldwide, bringing immense benefits to hundreds of thousands of patients. Organ donation and transplantation are sensitive and complex issues, with important ethical dimension, which require the full participation of the societies for their development. Several aspects are dealt with differently in different Member States depending on cultural, legal, administrative and organisational issues.

The use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart, it is the only available treatment. The excellent results of transplants, in terms of life years gained and improvement in quality of life, have multiplied the indications of these therapies. Transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs.

The use of organs in therapy however poses a risk of transmission of diseases. Every year, a number of organs are exchanged between EU Member States. Cross-border exchanges mean that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions.

³² OJ L 33, 8.2.2003, p. 30–40

³³ OJ L 102, 7.4.2004, p. 48–58

³⁴ COM/2004/0080 final - COD 2002/0128 */

³⁵ SEC(2007) 704 – SEC(2007) 705

³⁶ Impact Assessment of the Communication from the Commission to the European Parliament and the Council. Organ donation and transplantation: Policy actions at EU level
http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

On the other hand, the shortage of organs is a major factor affecting transplantation programmes. Nearly 40 000 patients are now on waiting lists in Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. There are large differences in the deceased and living organ donor rate within the EU. These differences cannot be easily explained. Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models are performing better than others.

One of the potential consequences of the scarcity of organs is the trafficking of human organs carried out by organised criminal groups, who track down and remove organs in developing countries and hand them on to recipients within the European Union.

Is EU action justified on grounds of subsidiarity?

The Treaty itself in its art. 152.4 a) provides expressly the possibility for the EC to adopt harmonising measures to ensure Organ safety and quality of organs. National legislations differ between Member States. A national approach could not ensure the same minimum standard of quality and safety for organs.

Organ interchange is already taken place in Europe. In the Eurotransplant area the average exchange rate of kidneys between partners countries was around 20% over the last five years. The Eurotransplant region covers 118 million inhabitants. Common quality and safety rules are needed in this context.

The example of Eurotransplant shows that once a common organisation and common rules are in place, the number of organ exchange increases and contributes to maximize the opportunity for patients to obtain the best possible organ. It also contributes to avoid that potential donors are not considered because the lack of suitable recipient at that moment in the national waiting list.

There was identified the need to develop systems for offering exchange of organs for urgent patients and difficult recipients (e.g. children, highly sensitized patients). These patients can not be adequately treated in small member states with limited donor pool, and can clearly benefit from an EU initiative. In order to establish such a system common quality and safety standards should be in place.

Also the movement of donors should be considered (e.g. In Spain close to 10 % of the donors last year were foreigners (more than 50% of these were Europeans) and this tendency has steadily increased in the last years from 2 % in 2000. Cooperation to introduce initiatives that facilitate information to citizens about the different donation systems in Europe and facilitate these donations of foreign citizens will have an added value.

The exchange of organs is not the only "European issues" that justifies a common set of basic standards, also the movement of patients. Having common binding standards of quality and safety will be the only mechanism to ensure a high level of health protection all along the EU.

It is also important to consider the link with the quality and safety requirements for tissues and cells. Many times an organ donor is also a tissue donor. Currently the Directive on quality and safety covers the traceability and the Tissue and cells adverse event/reaction reporting but not the organ side. These systems should be linked, even if organs are not largely cross border exchanged, tissues and cells are. An adverse reaction in an organ donor recipient should be traced and reported on the tissue vigilance system (already foreseen under the tissues and cells directive) if needed.

This is in close relation to the fact that organ shortage is a common dilemma in all European countries, and that sharing of best practices, best models and expertise across the EU members has already proved useful in increasing organ donor rates in some countries.

This is of particular interest because the experience shows how some organisational models are performing clearly better than others. Identifying those elements in the different systems (appropriate legal framework, good technical approach or organizational support) that could be promoted at community level will bring a clear European added value, in particular for those member states with less developed systems.

In addition European cooperation is imperative on the evaluation of measures intended to increase organ donation such the use of the so call expanded donors. Again, published experience is not enough to establish safety limits in this practice. Same can be said for other hundreds of donors with pathological findings genetic or congenital disorders, or very rare diseases or conditions. Cooperation between countries will give bigger number of recorded charts to be on the way of defining quality and safety practice guidelines for those cases. This is linked to the need of develop of consensus guidelines and professional standards to ensure good medical practices or the evaluation of post transplant results “organovigilance” to lead to a safer and more effective use of organ donors. This can be addressed more efficiently with a community perspective

B. Objectives of EU initiative

What are the main policy objectives?

This initiative intends to respond to these challenges based on the mandate in Article 152 a) of the Treaty, which enables the European Parliament and Council to adopt harmonised health measures on the basis of the codecision procedure pursuant to art. 251 EC, by setting high standards of quality and safety of human organs.

It sets out the actions the Commission is planning to take to respond to the main policy challenges in relation to organ donation and transplantation, as reflected in the adopted communication: ensure quality and safety of organs, increase organ availability and making transplantation systems more efficient and accessible.

Does the objective imply developing EU policy in new areas or of strategic importance?

Strengthen the cooperation between Member states, specifically adapted to this concrete field, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The Commission is proposing a combination of legislative and 'soft law' mechanisms oriented to respond to the identified problems. Strengthen the cooperation between Member states through the action plan combined with a legal framework introducing the basic principles and the technical requirements on donation, procurement, testing preservation, transport and distribution, for human organs that will complement the approach taken under the strength cooperation method.

For the action plan three options are to be considered: Level one “coordination of existing programmes” would mean strengthening coordination between the projects which are already in place. The second level consists of an EU action plan. The third level suggests the establishment of an Open Method of Coordination in the field of organ donation and transplantation.

For the quality and safety framework there are also three levels of possible intervention. Level one "minimal intervention" would mean that national legal frameworks at their current level of development would be sufficient to ensure the quality and safety aspects, these frameworks could be supported by European cooperation through European Guidelines. A further level would consist of implementing a European legal instrument incorporating the basic quality and safety principles based on a "risk assessment approach"; the third option would be to reproduce the tissues and cells and the blood model based on a "precautionary approach".

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The action plan aims also to coordinate the work that several DGs have done during the last years in the area of organ donation and transplantation. Already in 2005, DG SANCO has identified all projects related with organ transplantation. All relevant DGs were contacted. As a result the Commission (DG INFSO, RTD and SANCO) organised a Workshop in December 2005 on organ transplantation with the objective of promoting EU cooperation on organ donation and transplantation on the basis of the existing projects. Project coordinators, member states experts and transplantation organisations participated. One of the main conclusions of the workshop was the need for these projects to be better coordinated and become operational in a more strategic.

Do the options respect the proportionality principle?

The combination of an action plan with common objectives for which it is agreed that a Community response is necessary with a an appropriate and flexible European legal framework that takes into account the specificities of organ donation will be adequate in terms of proportionality.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Social/Health impacts

Generally, actions aiming at increasing organ availability will have a positive impact on the number of life-saving transplantations carried out. Organ transplantations can improve the quality of life, increase healthy life years and reduce suffering for many patients and their families. It can furthermore improve integration into the working and family life of the patient.

The combination of an efficient system for organ donor identification and detection and procurement has been identified as a key element in increasing the cadaver donation rate in those countries that have not reached their full potential, this should be achieved measures that have prove efficacy in different Member States such the promotion of the role of transplant coordinator and the implementation of quality improvement programmes, the efficacy of this measures could be quantified.

Donation from alive people has been growing strongly in recent years, thanks to the advances in the field of organ transplantation and its success as a treatment to procure quality-adjusted life years for many patients with end-stage diseases.

Public awareness and opinion also has an important role to play in increasing organ donation. Continued education should form an essential element of any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens have discussed organ donation within the family³⁷. There is an important positive correlation between having discussed it within the family and willingness to donate organs.

The proposed measures aiming at enhancing the efficiency and accessibility of transplantation systems will have a positive impact on transplantation activity. An increased interchange of organs between MS for children, urgent and difficult to treat patients will have a significant (and immediate) life-saving effect for those patients. Support and guidance for Member States with less developed transplant systems can lead to a huge improvement in terms of donation rates; number of organ transplantations carried out; and post-transplant results. Training of professionals, cooperation in the field of research, an EU-wide agreement on transplantation medicine and the collection of transplantation activity data will have a medium to long-term positive impact on transplantation activity and the success of organ transplantations.

Improving quality and safety of organ donation and transplantation will have an impact on risk reduction and consequently on reduction of co-mortality and co-morbidity of patients. The introduction of the new standards

³⁷ Eurobarometer survey 2006

and regulations is designed, ultimately, to improve procedures related to organ transplants. The process of defining standards should impact the procurement, handling and the subsequent use of human organs for transplantation. Benefits are concentrated in the provision of better service to patients through extension of their lives and the quality of life.

Adverse medical events are relatively rare, however for various reasons, their occurrence are likely under-reported. The adoption of quality and safety standards is expected to prevent a considerable percentage of these events, to improve their occurrence and to react promptly to minimize their effects.

One of the primary arguments for adopting quality and safety standards is to maximize the safety and efficacy of the use of human organs in the health system. Benefits from implementing quality and safety standards would accrue in the form of avoid cost to healthcare institutions and individuals from fewer adverse medical events/reactions, shorter hospital stays, etc. The compilation of sufficient information in form of registers can facilitate the evaluation of post-transplant results and contribute to the development of good medical practices in organ donation and transplantation. The data can furthermore assist in determining the acceptable levels of risk in the use of expanded donors and facilitate the exchange of best practices on living donor protection.

It is often not straightforward to measure the impact of the proposal in a quantitative way. However the qualitative evidence is also important. The methodology based on the capability approach (multi-dimensional approach inspired that aims to assess human well-being with a special emphasis on freedom and distribution) shows that the proposal could have impact on five of the nine categories; 1) health; 2) safety; 3) standard of living; 4) social cohesion; and 5) employment.

Economic impact

The most important benefit for the grafted patients is measured in terms of survival and improvement of perceived quality of life, and consequently integration to the working and family life and productivity, taking into account that the opportunity cost of labour applied to both patients and home care members of the family.

Organ transplantation is the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such as liver, lung and heart, it is the only available treatment. Diseases that can be cured by transplantation usually carry a significant burden of morbidity and mortality, and therefore have a significant impact on the national health care budget. It is estimated that, at present, more than 3% of health care budgets of European Member States are dedicated to patients waiting for a transplant.

Organ transplantation provides the possibility of saving lives and also has the best cost/benefit ratio in terms of economic gains as well as quality of life. It has been calculated that each 10,000 renal patients living with a functioning kidney graft are saving to health systems (when comparing costs of transplantation versus costs of dialysis treatments) over 200 million € annually. Saving lives and improving quality of life of patients will have, furthermore, a positive effect on the employment prospects and the productivity of patients.

Several studies have shown that investing in organ procurement and transplantation is clearly a good health investment. It is highly likely that obtaining additional donors will be cost effective even at a much higher average cost per donor. Actions aiming at increasing the effectiveness of transplantation systems and upgrading the organisational structures can multiply the positive net effects of transplantations. Quality analysis and cost/benefit studies programmed for large samples and in different countries identified the need of investment in the organ donor promotion activities.

This proposal will have an impact on the activities carried out within the Organ transplantation process. The establishments directly concerned by the provision of this proposal vary from hospitals or health centres where procurement is carried out, to third parties which can be responsible for some step of the process. The adoption of the standards will mean in some cases the need of hiring and training personnel, and upgrade the equipment.

Adverse medical events/reactions are costly to the health care system due to prolonged hospital stays, repeat procedures and extended days in recovery facilities and extra follow-up health care systems. They can also be costly for families in additional time-off work and requirements for home-care.

Establishing a notification system as well as an inspection and control system may introduce an administrative burden on those Member States where such systems are not already in place. On the other hand, common high standards for the quality and safety of human organs may help to reduce costs associated with adverse events and

effects related to transplantation, facilitate the circulation of human organs across the borders, and encourage advancement of the goal of Community self-sufficiency, and lead to positive economic effects.

Environmental impact

No environmental impacts are foreseen.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The action plan will be covered by health programme 2008-2013. (Action 1.2.2)

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No, with the exception that the proposal will establish the relevant safeguards to ensure the quality and safety of organs imported to the EU from third countries

Who is affected?

Patients, professionals, national administrations, organ exchange organisations, procurement organisations, hospitals and related health care bodies.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The Impact Assessment³⁸ attached to the communication on organ donation and transplantation already provided with basic information and identified future sources of information. The future gathering of information will be focused on analysing the current situation of the organ transplant systems, the description of the systems and quality and safety standards in place and the Impact of the different policy measures in terms of cost and benefits. An external contractor will be hired to help in carrying out these data collection and analysis.

Which stakeholders & experts have been/will be consulted, how and at what stage?

For the adopted communication DG SANCO launched an open consultation in the public health web site from June to September 2006. The objectives of the consultation process have been to gather the opinions and views of the stakeholders on issues to be included in the Communication. All contributions received provided valuable information for the Commission's further action in this field. The summary report and the contributions could be found at:

http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/oc_organ_en.htm

This consultation has also facilitated to identify the key stakeholders in the field. A group of key European stakeholders will be created for regular consultations. At the same time a working group of national experts have been created in July 2007 to collaborate with the Commission in the design of the future initiatives.

³⁸Impact Assessment of the Communication from the Commission to the European Parliament and the Council. Organ donation and transplantation: Policy actions at EU level
http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

ROADMAP

Title of the key initiative: **Critical communication and information infrastructure protection (CIIP)**

Foreseen Adoption date:

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

Communication and information infrastructures are rapidly becoming the nervous system of our modern information society. Many services and processes in our economy and society become increasingly dependent on the well functioning of our communication and information infrastructures. As a consequence, the failure of a single network or sub-system could potentially propagate very widely and affect many other sectors such as energy supply, transport, health and financial services.

The complexity of communication and information infrastructures and their interdependencies with other infrastructures stretches out well beyond national borders. The interconnectedness and interdependence makes these infrastructures more vulnerable to disruption or destruction. Problems can cascade through these interdependent infrastructures, beyond national borders, causing unexpected and increasingly more serious failures. As a consequence, in our modern technological society, infrastructures and systems become ever more fragile and may fall faster than ever before because of a major technological collapse of a communication or information network.

Because of the trans-national interconnectedness of information infrastructures, the action of Member States in investigating the weaknesses and vulnerabilities of information infrastructures and identifying protective measures might not suffice when problems cascade beyond Member States borders. Indeed, the level of security and resilience of the communication and information infrastructures in any Member State heavily depends on the security and protection provided outside its national borders. In addition, many of the challenges and the issues faced by Member States will be common and thus a coordinated approach will benefit all. Lastly, private stakeholders want and support a European or even global market approach.

An integrated EU-wide approach would not only add value but also be necessary in order to complement national programmes for critical infrastructure protection in place in the Member States as well as bilateral and multilateral Critical Infrastructure Protection (CIP) cooperation schemes between Member States. It would also add important value to the continued viability and wealth creation capabilities of the European single market.

2. What are the main policy objectives?

The objective of the proposed European policy initiative on Critical Information Infrastructure Protection (CIIP) is to enhance the level of CIIP preparedness and response across the EU. To this end, a policy framework and an action plan will be proposed, as the ICT sector specific approach under the broader and evolving framework of the European Programme on Critical Infrastructure Protection (EPCIP)³⁹. The initiative, which will build on National and private sector activities, will engage relevant public and private stakeholders in ensuring that adequate and consistent levels of preventive, detection, emergency and recovery measures are put in operation to ensure the high level of resilience of critical communication networks and information infrastructure (like Internet) and guarantee continuity of services. Another important element of the initiative will be the process to define the (most likely functional) criteria to identify the European Critical communication networks and information infrastructures as foreseen by the current Commission's proposal on EPCIP.

³⁹ COM(2006) 786, 12.12.2006; See also the proposal for a directive: COM(2006) 787 of 12.12.2006

This initiative will constitute a significant step forward in the implementation of the Commission strategy for a Secure Information Society⁴⁰, whose main elements were endorsed by the Council in its Resolution 2007/C 68/0141.

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

The contributions to the Green Paper on EPCIP suggested that the EU approach should fully involve the private sector, taking into account sector characteristics and should be built on existing sector-based protection measures. Full involvement of the private sector is important as most critical infrastructure is privately owned and operated. In addition, critical infrastructure owners and operators possess particular experience, expertise and are knowledgeable of specific requirements concerning the protection of their critical infrastructures.

If at some future point in time the dialogue with stakeholders would result in wider consensus agreements between Member States and private sector players on how to act in this area, the need may be felt to capture such agreements and put them into common rules or regulations. This could include legislative measures. Whereas the policy framework would normally take the form of a Communication, more options are considered for the action plan including that of a Council Decision.

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

The most affected sector will be the European electronic communications networks and services industry. Member States will also be impacted in terms of requirements for enhanced cooperation and coordination. The Communication would investigate the available options that would stimulate and support the implementation of prevention and protection measures as well as of continuity and recovery plans.

As some 90 % of the responsibility for CIIP falls with the commercial players in the private sector, solutions need to come from the commercial field.

A constructive dialogue and a close cooperation with Member States and private sector players is needed to move forward step-by-step in an atmosphere of trust and confidentiality. Tabling legislative measures too early may disrupt the trust environment that is needed for a constructive dialogue. If, however, at some future point in time the dialogue would result in wider consensus agreements between Member States and private sector players on how to act in this area, the need may be felt to capture such agreements and put them into common rules or regulations. In such case, Member States will need to rewrite current national rules.

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

We are in the very first stages of development of this new policy area for the EU. Although data exists in Member States, a very limited amount of information is available on the issues at the EU level. The study which have been concluded and others which will be launched in the course of 2008, in cooperation with DG JLS, will add important new information. This may include important data made available by Member States.

⁴⁰ Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions on A strategy for a secure Information Society – " Dialogue, partnership and empowerment", COM(2006) 251 final of 31.05.2006.

⁴¹ Council Resolution of 22 March 2007 on a Strategy for a secure Information Society in Europe, (2007/C 68/01), 24.03.2007

6. Which stakeholders & experts will be consulted, how and at what stage?

Representatives of Member States involved in the field of network and information security
National Regulatory Authorities in the field of electronic communications networks and services
Telecommunications operators and Internet Service Providers and related sector associations (ETNO, ECTA, EuroISPA, CSIA...)

Manufacturers of hardware and software components for electronic communications networks and services and related associations (BSA, ESA...)

Public organisms involved in the field of network and information security such as CERTs

Major corporate users of information infrastructures from financial world, the electricity and transport sector. The consultation process has already started. Further to the study on the Availability and Robustness of Electronic Communication Infrastructures (ARECI) 42, the Commission invited comments on the study's recommendations as well as held an informal meeting on 19th of January 2007 with Member States' experts. A second meeting was convened on 18th of June with representatives from Member States and the industry. Lastly, specific aspects relevant to the stability of Internet were discussed in a workshop on business continuity of country code Top Level Domain (ccTLD) that was held on 19th September 2007.

A workshop on lessons learnt from recent large scale attacks on the Internet and relevant policy options is planned for 12th of December with delegates from Member States and representatives from organisations involved in ensuring network and information security. The discussions would contribute to identify key priorities and elements for actions at the EU level. More workshops will be convened beginning of 2008 to complement the analysis.

7. Will an inter-service steering group be set up for the IA?

An inter service steering group will be set up for the IA with the key involvement of JLS, TREN, ENTR and MARKT.

⁴² See http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=3334

Telemedicine tools for chronic disease managementForeseen adoption date: **October 2008****A. Context and problem definition**

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The initiative on telemedicine tools for chronic disease management is based on the i2010 policy priorities⁴³, in particular the ICT flagship in support of caring for people in an ageing society. It has been foreseen in the Communication 'e-Health - making healthcare better for European citizens

An action plan for a European e-Health Area' ([COM\(2004\) 356](#)) which *inter alia* identified an action that, by the end of 2008, the majority of European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare.

The initiative is largely in response to the [Communication on Ageing Well](#) (COM/2007/0332 final) and the Communication on innovation '[Putting knowledge into practice: A broad-based innovation strategy for the EU](#)' adopted on 13.09.2006 (COM(2006)502) in particular action 9 "Lead Markets" from the Roadmap which is of high political priority as part of the Lisbon strategy for growth and jobs. The action, which was also highly recommended by the report on '[Creating an Innovative Europe](#)' (Aho, Hampton Court Summit, 2005), will contribute to current Commission innovation and industrial policy such as the 'Lead Market Initiative' being led by DG Enterprise, where telemedicine was identified as one of the key focus areas.

The Communication would build on DG SANCO's new Public Health Strategy (The White Paper), which defined new technology as one the most urgent challenges, and the planned Health Services Initiative, as well as DG MARKET' initiatives in e-Commerce, DG JLS' initiatives in personal data protection and DG EMPL's activity regarding the Health Insurance Card, among other relevant Commission policy activities.

What are the main problems identified?

It is estimated that 70% of care expenditure is dedicated to chronic disease management, with 3 out of 4 elderly experiencing cancer, cardiovascular diseases, mental health problems, diabetes and chronic respiratory disease. By 2030, the World Health Organisation estimates that the incidence of chronic disease in the over 65s will more than double due to the ageing demographic.

Telemedicine can contribute to alleviating the pressure on Health systems, while allowing elderly citizens to enjoy a healthier, longer life, while maintaining a high degree of independence, autonomy and dignity. Moreover there is particularly strong growth forecast in the European Medical Records⁴⁴ and remote home health monitoring markets⁴⁵.

Implementing 'smart ageing' through telemedicine only requires a small step. For example the architecture of an intelligent house can be enriched with sensors and technology to gather medical information that could be vital for people who live alone. Handicapped citizens and those experiencing chronic obstructive pulmonary disease, congestive heart failure, diabetes, and dementia could benefit from such technology. New technologies can complement traditional care, while increasing comfort for patients and carers alike. Encouraging home care instead of hospitalisation will alleviate some of society's financial burdens as a result of our rapidly ageing population. Telemedicine can also be the only healthcare solution for those citizens who are living in rural or remote areas of the EU.

⁴³Communication " i2010 - A European Information Society for growth and employment" ([COM \(2005\) 229](#))

⁴⁴The Frost & Sullivan report, European Electronic Medical Records Markets, values the European EMR market currently to be worth €349.6m and will reach €1.15bn by 2013.

http://www.ehealthurope.net/news/strong_growth_predicted_in_european_emr_market

⁴⁵With the blessing of government payers in Western Europe and Canada, the market for remote home health monitoring is expected to generate \$225 million revenue in 2011, up from less than \$70 million in 2006 (Five-Year Annualized Growth Rate over26%), according to Parks Associates' upcoming report Digital Health in Western Europe and Canada. <http://www.sys-con.com/read/420161.htm>

However, the proven cost-effective solutions that improve quality of care and outcomes cannot find their way to benefit EU citizens and health delivery systems due to barriers to successful deployment. These include a lack of standardised systems and methodologies that ensure reliability and safety; lack of validated business models; legal and regulatory barriers that hamper a growing and transparent eHealth market including personal data protection issues, reimbursement issues and concerns regarding health professionals (accreditation, registration, right for establishment, liability); the need to learn from past mistakes of early innovators. In the interests of the subsidiarity principle the focus will be on aspects of problems that are common to all Member States, or that involve cross-border healthcare in the framework of free circulation of persons within the EU single market.

A consultation conference will take place in December 2007, aiming to identify more precisely the nature of the obstacles hindering full deployment of telemedicine solutions, and to discuss how the aforementioned problems can be addressed at an EU level.

Is EU action justified on grounds of subsidiarity?

The initiative does NOT address any health issues that can be addressed at national level according to the Art. 152 of the EC Treaty. It is an action supporting cooperation among Member States and focuses only on development of an innovation friendly market, as identified in the Lead Market Initiative and support to cross-border health care where needed. It will support technological development in information and communication technologies (ICT), which is based on Articles 163 to 172 (research and development) of the EC Treaty and will contribute to creating the necessary conditions for the competitiveness of the Community's industry, in line with Article 157 of the EC Treaty. The actions include identification of barriers to development of telemedicine tools, providing coordination and dissemination of lessons learnt, technological know-how and support to legal and organisational issues for large scale deployment of such telemedicine services. EC can provide real added value by facilitating the creation and growth of these new innovative systems and services.

B. Objectives of EU initiative

What are the main policy objectives?

Policy objectives are five-fold: to bring the benefits of eHealth faster to EU citizens by improving the research and development take-up in this sensitive and large service of public interest; to facilitate growth, innovation and sustainability in eHealth market; to contribute to economic and social cohesion; to address challenges resulting from globalisation; and to provide valuable feedback for new orientations in eHealth research

Does the objective imply developing EU policy in new areas of strategic importance?

For the time being all activity will be conducted as an extension of existing policy, building on DG SANCO's new Public Health Strategy (The White Paper), which defined new technology as one the most urgent challenges, and the planned Health Services Initiative, as well as DG MARKT's initiatives in e-Commerce, DG JLS' initiatives in personal data protection and DG EMPL's activity regarding the Health Insurance Card, among other relevant Commission policy activities

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Option 1: No action

Option 2: Legislative proposal

Option 3: Communication

A communication is planned in 2008 examining possible regulatory instruments for the eHealth market.

Following the adoption of the Recommendation on Interoperability in eHealth (March 2008) it could be used as a basis to introduce an initiative regarding Electronic health record systems basic functionality (e.g. audit trail

and security) and content (Minimum data sets for supporting mobility of patients).

One proposed action is the support to EU wide eHealth technology assessment and accreditation mechanism to tackle the issues of market fragmentation and transparency, safety of patients. The focus in 2008 will be on proposing EU-level certification of eHealth Information systems following deep analysis of existing certifications in EU, US and Canada

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

As with the eHealth Action Plan of 2004, 'e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area' ([COM\(2004\) 356](#)), there will be overlap with other policy areas. The objective is to identify methods for developing ICT tools for telemedicine for chronic disease care which will contribute to current innovation policy being carried out by DG ENTR; on Patient mobility and Health Services initiatives of DG SANCO; and the aims of International cooperation (DG INFSO, DG DEV, DG RELEX).

Do the options respect the proportionality principle?

Respect has been paid to the proportionality principle in that the approach leaves the greatest freedom to the Member States and individuals. The initiative will not go beyond what can be expected from ensuring development of quality eHealth products and free movement of eHealth goods and services in support of the internal market.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

A Communication is likely to result in an ongoing mechanism to create a coherent and continuous feedback loop among European industrialists, European research representatives, and European policy-makers.

Could the options have impacts on the EU-Budget (above 5 M €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

It is not expected that there are such larger EU budget impacts.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Application of information and communication technologies in general contributes to minimizing of administrative burden. ICT services are in principle faster, more innovative and price competitive. International cooperation is already in place for research activities, e. g. The T@lemed project which introduced an eHealth model for the provision of health services in strongly underserved regions in Colombia and Brazil⁴⁶, conclusions from the EU-US summit held in Brussels in May 2007

Who is affected?

All main stakeholders, namely, the ICT for Health industry, health authorities and health professionals. Of course ultimately the impact will be on European citizens, especially elderly patients and health professionals through new working procedures.

⁴⁶ The cooperation was carried out under the @LIS programme which is a programme of the European Commission aiming to reinforce the partnership between the European Union and Latin America in the field of the Information Society.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Current available information includes:

- the original Hampton Court Report (Aho report) and its follow up, DG INFSO (July 2006)
- In some Member States (the UK is a prime example) responses have been drafted by national governments and alternatives proposed by political parties in opposition.
- many reports from EU projects and global consultancies such as Gartner's group

Further information (both quantitative and qualitative) would ideally be gathered through a specific impact assessment study to be carried out in the first quarter of 2008, in addition relevant Integrated projects, CIP Pilots, and external reports from industry and authorities will provide additional relevant information

Which stakeholders & experts have been/will be consulted, how and at what stage?

- Member States have been approached *via* the i2010 subgroup on eHealth and the general concept has been presented; stakeholders reporting to the i2010 group have been informed *via* an electronic mail mechanism (and not *via* formal meetings);
- awareness raising of the need for this approach is already under way through events such as the Personal Health Systems conference (February 12-13, 2007), and the eHealth Conference 2007 (April 2007). Furthermore proactive relationships have been built with industrial organisations and their representative associations, e.g., Intellect; BITKOM.

The following organisations should be kept informed and consulted at regular intervals:

- Regional authorities through institutions such as Committee of Regions and organisations such as European Assembly of Regions
- Industrialists and associations dealing with telemedicine and chronic disease management such as:
 - The Continua Health Alliance (a consortium of 100 companies)
 - COCIR (the European Coordination Committee of the Radiological, Electromedical and Healthcare-IT Industry, a consortium of 30 enterprises and national industry associations)
 - IHE (Integrating the Healthcare Enterprise)
 - EHTEL (European Health Telematics Association).
 - the Brussels Round Table
 - European and national SME associations
- All affected users groups, for example:
 - AIM Association internationale de la Mutualité
 - CPME (Comité Permanent des Médecins Européens) /Standing Committee of European Doctors
 - EHMA (European Health Management Association)
 - HOPE (European Hospital and Healthcare Federation)
 - PGEU Pharmaceutical Group of the European Union
 - Standing Committee of Nurses of the European Union (EFN, formerly PCN)
 - European Union of Medical Specialists/Union Européenne des Médecins Spécialistes
 - WMA (The World Medical Association)
 - AGORIA (the federation for the technology industry)

research representatives – notably in the European Technology Platforms – will be approached through the IST and ISTC committees already in existence.

ROADMAP

Title of the initiative: **Protecting children using the Internet and new media (2009 – 2013)**

Expected date of adoption of the initiative: **December 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The overall aim of the initiative is to promote safer use of Internet and other communication technologies, especially by children. The Commission has been successful in placing the issues of developing a safer Internet firmly on the agenda of the EU and the Member States via policy work which started in 1996 with the Communication on illegal and harmful content on the Internet. This was followed by two successive programmes, the Safer Internet Action Plan (1999-2004) and the Safer Internet plus programme (2005 – 2008). The foresight of the European Commission in identifying issues related to risks to children in the online environment early on in the development of the Internet has been widely recognised.

Risks for and negative impacts on the child can result from being exposed to illegal content and conduct or to legal, but harmful, content and conduct. The EU (and the Council of Europe) has set certain Europe-wide standards, clarifying legal issues through various recommendations and directives concerning the protection of minors and human dignity, electronic commerce, privacy and electronic communications and child sexual abuse images.

The initiative will complement and not duplicate what has already been decided through the above instruments. The above instruments are largely legislative instruments while the envisaged initiative is action-oriented.

What are the main problems identified?

The risks children can encounter when they go online or use mobile phones depend on the kind of activities which they deploy. The most evident and potentially most harmful risks are:

Exposure to harmful content (it can range from pornography and violence to racism, xenophobia, hate speech and music, self-mutilation, anorexia, and suicide sites) can cause psychological trauma to children and lead to physical harm if a child is motivated to inflict harm on other children or on him/herself.

Children are often interacting in the online environment and generating content. When generating content, they tend to disclose personal information. This material is in some cases used by offenders or it may cause financial and security risks.

Active harassment (Cyber-bullying) takes place on the Internet and through mobile phones.

This can be particularly distressing, as often there is no escape for the victim as the bullying has a potentially enormous audience.

"Happy slapping" stands for people, including children, being beaten up for the sake of filming, which can be posted online or sent through mobile phones.

The process by which a person befriends a child with the intent to abuse him/her is called "grooming". Abusers sometimes target children through the relative privacy of the Internet and mobile phones by pretending to be children themselves, or by befriending vulnerable children in the online environment. Grooming has severe consequences on children. Even in the cases where the contact is stopped before the abuse has taken place, sexual encounters/conversations online can be very disturbing for the child. If abuse takes place, the effect on the child is very serious and deeply traumatizing.

The Internet has become one of the main distribution channels for material depicting sexual abuse of children. Despite increased efforts in the international community aimed at reducing the sexual abuse material, the amount

of material distributed does not seem to decrease. Latest figures show the severity of online child abuse content is strongly increasing depicting for example penetrative and sadistic sexual activity. There is also a decrease in the age of abused children and an increase in the number of new abused children.

More and more children are using mobile phones. The mobile phones are becoming more sophisticated, most of them carry cameras, and some allow for accessing Internet. The risks concerning mobile phone use are the same as for use of other online technologies like the Internet. However, the risks might become even more pronounced as the mobile phones is seen as even more private than Internet use.

The excessive use of mobile phones and the Internet can also cause addiction to these activities.

Is EU action justified on grounds of subsidiarity?

Illegal or harmful content may be produced in one country, hosted in a second, but accessed and downloaded all over the world. Commercial payment systems operating worldwide may be used to fund sale and purchase of the images. Actions are required on all levels (global EU level / national / regional / local) in order to be effective. They are not alternatives but show their best effectiveness when working together complementarily.

Action at Member State level is essential; however in the area of child safety the protection level varies between the countries: there are more activities in some Member States than in others, in varying degrees of intensity. The initiative aims at maximising synergy with national activities.

The evaluations of the preceding Community activities have shown that there exist a significant number of activities which would not have been taken at all without the intervention of the previous Community programmes. In other cases, activities would not have benefited from the exchange of best practice with other European countries as the European networks would not have been set up. If Commission funding ceased, many of the activities would close down and the pan-European coverage of the child safety activities would not be ensured any more. The Community action enhances furthermore the cost-efficiency and the quality of operation of actors on the Member State level via the re-use of tested tools, methods and strategies, the promotion of the best performing technologies (like parental control tools) or access to updated investigation data on European level.

Action in this field will be taken by the Commission only if, and insofar as, the objectives of the proposed action can rather be better achieved at Union level: Networking and access to good practise, spreading and generation of knowledge, co-ordination of activities (e.g. Safer Internet Day), cross-cutting co-operation between different public bodies, ministries on national and regional levels, NGOs, law-enforcement and industry are issues where the initiative will give the necessary impetus.

B. Objectives of EU initiative

What are the main policy objectives?

The overall aim is to promote safer use of Internet and other communication technologies, especially by children. The main objectives are:

1. Reducing illegal content and tackling harmful conduct online
2. Promoting a safer online environment
3. Ensuring public awareness

Establishing a knowledge base

Does the objective imply developing EU policy in new areas or of strategic importance?

The envisaged initiative is a follow-up to two preceding programmes. It therefore does not develop EU policy in new areas.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The initiative is not a legislative instrument but it is action-oriented. Commission services have considered four options. Options 1 to 3 differ insofar as the possible range of actions is of different intensity and nature.

- **Option 1:** Make no change - continue activities in this area as set out in the Safer Internet plus programme 2005 – 2008 without any modification

The option aims at ensuring continuity of the *acquis* achieved under the preceding programmes. This would include continuing funding for network co-ordination and for individual hotlines, awareness nodes and helplines to fight illegal content and to raise awareness, continuing promotion of a safer environment (self-regulatory actions) and of rating systems, quality labels and technological measures with a view to tackling harmful content.

- **Option 2:** Modify - adjust the scope of current activities and add new activities to deal with new risks and to enhance effectiveness

This option would mean to further develop a coherent strategy for the fight against harmful effects of online technologies at EU-level. It would consist of two basic elements: to continue with the activities developed (the *acquis*), while strengthening and reinforcing them, and to enhance a set of new actions which are envisaged to meet new challenges due to developing technologies (such as ongoing technological convergence) and societal developments (such as the increase in the use of social networking sites).

Actions which would improve their effectiveness by being reinforced are for example:

- Reducing illegal content by enhancing efficiency and effectiveness of the existing networks; enlarging their coverage (EU-27)
- Initiating the creation of new self-regulatory systems, as for example for ISPs, in view of a safer online environment
- Improving awareness-raising methods and tools by identifying, enhancing and disseminating effective and cost-efficient awareness-raising methods
- Enhancing global international cooperation, particularly by making existing international instruments more efficient and by stimulating the development and implementation of actions in the relevant fields.

New features under this option would namely be:

- Tackling harmful *conduct* online, especially grooming (adults befriending children online in order to abuse them sexually), cyber-bullying
- Stimulating the involvement of children and young people in creating a safer online environment
- Establishing a knowledge base which would allow a better understanding on how actually children use online technologies and how risk situations develop - continuously updated in order to keep pace with fast changing technologies and services. It would open European-wide access to aggregated data and include a EU-level coordination of investigation activities
- Developing strategies to protect children better in evolving environments such as social networking sites and chatrooms.

- **Option 3:** Slow down - reduce the scale of activities

This option would imply that a core set of activities which have been developed in the past and proved to be successful will be maintained. However, the scale of activities would be reduced. The core issues for the preceding programmes has been to build up networks of reporting facilities for the public (hotlines) and for coordinating awareness raising activities (with subsequent national awareness nodes) including the promotion of Internet safety on political level. In comparison to Option 1 and the preceding Safer Internet *plus* programme a reduction of the budgetary impact would be expected (estimated at 40%, i.e. an annual decrease of 4.5 million Euros).

- **Option 4:** Stop - cease activities completely

The Commission would not take any further general horizontal action in this field; no pro-active related policy would be carried out on EU level. The Commission would however assess the need for possible targeted legislation or policy action at a regular basis and take appropriate action when needed possibly at later stage. The Commission would follow existing international projects and activities but neither support nor initiate such projects. The option would imply to stop funding activities.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

In order to avoid overlapping with the competences and activities of other Directorate Generals and services, certain risks for children related to activities in the online environment are not taken into account. These are namely health risk due to radiation (DG SANCO) and Internet security issues (DG INFSO A.03). In the area of law enforcement it will be ensured that no interference will happen with the actions under the Cyber Crime Communication (DG JLS).

Do the options respect the proportionality principle?

Yes, none of the options is excessive in range or in correlated budgets.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Option 1 will, based on past experience, generate a considerable number of impacts, especially of a social nature as it would be an important ongoing instrument to reduce the risks for children online. However, it would also imply shortcomings when dealing with changing and emerging uses and behaviours which will lead to new risks and which would need specific and more intensive efforts to be taken.

Option 2 will allow to efficiently combating also those harmful effects of online technologies which are due to the changing landscape. Online technologies and their uses are in continuous progress. Due to the changing features of communication technologies and to changing societal patterns of behaviour the challenge of reducing the risks for children is not static but dynamic. To be truly effective, the future policy must be of a multi-faceted nature combining instruments which ensure the continuity of the structures and actions which have been built up successfully in the preceding programmes with new counterstrategies which in a flexible way respond to emerging phenomena and risk scenarios. New approaches and additional efforts which are not foreseen in the current programme are needed.

Option 3 would generate impacts on operational level with high probability, such as it has been proven in the past. It would help to reduce the risks for children online by allowing for mechanisms where the public can report illegal online content, and for increasing public awareness concerning online risks and the way to deal with them. But it is a minimal solution only. It aims at safeguarding core infrastructures of the preceding programmes which have been gaining visibility in the perception of the European public and internationally. It would not cope with any new challenges, and not reduce any related risk situations for children. It can be anticipated that the distribution of illegal content will increasingly take place through peer-to-peer communication, 3G mobile phones etc. This will certainly require new counterstrategies, which Option 3 cannot deliver.

Option 4 (no action at all in this field) would be likely to result in negative impact on the dimension of risks children are confronted with when using online technologies. Any draw-back in dealing with these risks will lead to a situation where the door would be left open to harmful and illegal activities. The potential long-term negative impact of a "no action" scenario is very high, taking into account the current and growing importance of the types of crime which are linked to illegal content and conduct.

The building of public awareness is a long-lasting task which requires continuity in the activities. Under the current Safer Internet *plus* programme, this public awareness has grown further and the Safer Internet Day 2007 had very impressive media coverage. If these actions were stopped, also the momentum created would be lost and the efforts of the past years would be jeopardized.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Options 1 to 3 would have an impact above 5 M€ For this reason the IA includes the ex-ante evaluation required by the Financial Regulation.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No, any possible impacts will not be significant on administrative level.

Who is affected?

The main target group are children and young people. But it is not only the children who need to be addressed. Further affected groups are:

- a) Parents, carers, teachers and other adults responsible for children
- b) State authorities with responsibility for industry, education, consumer protection, families, children's rights and child welfare; law enforcement authorities and regulators
- c) Industry, as for example content providers, technical intermediaries, mobile network operators, industry self-regulatory bodies
- d) Non-governmental organisations working on issues related to child safety online
- e) Universities and research institutes broadening the knowledge base, as for example understanding better how children use online technologies

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

In addition to the legislative and policy instruments information and data is already available, stemming from the implementation and evaluations of the previous programmes (Safer Internet Action Plan (1999 to 2004), Safer Internet plus programme (2005-2008)), from the Eurobarometer surveys and from surveys at the national level, from research results (funded by the Commission and by national sources) and from public consultations on EU level.

In addition to this and in view of complementing and updating the available information and data for the impact assessment work, information is gathered via the Eurobarometer Qualitative Study 2007 (carried out within a framework contract concluded between an external contractor and DG COMM; delivered in May 2007) and a public consultation on Safer Internet and online technologies for children (carried out by the responsible service of DG INFSO).

Sources for the impact assessment work therefore include:

- Several Programme evaluations (Safer Internet Action Plan (1999 to 2004), Safer Internet plus programme (2005-2008))
- Several Eurobarometer surveys on Safer Internet

- Public consultations on Safer Internet and online technologies for children (2007), Child safety and Mobile phone services (2006)
- Research results ("The Appropriation of New Media by Youth" research project and national studies)
- Media Literacy website (DG INFSO)

Which stakeholders & experts have been/will be consulted, how and at what stage?

In order to complement and update the available information the Commission launched a consultation of interested parties consisting of an online Public Consultation (open from 12 April 2007 until 7 June 2007) and of the "Safer Internet Forum 2007" (Luxembourg, 20-21 June 2007).

The online Public Consultation was structured around three topics:

- Fighting illegal content
- Fighting harmful content
- User-generated content and online communication

The online Public Consultation focused on specific risk situations for children and dealt with a broad variety of possible measures. 93 contributions were received, from industry actors and associations, a variety of associations, hotlines and awareness nodes, a variety of public administration bodies, researchers, universities and individuals.

The **Safer Internet Forum** is a European discussion forum for representatives of industry, law enforcement authorities, child welfare organisations and policy makers to exchange experience and knowledge on creating a safer online environment for children. The Forum 2007 focused on specific risks for children related to the use of the Internet and online technologies. It was composed of three workshops and a plenary session for discussing relevant issues with 125 participants / stakeholders, who had the opportunity to give input to the public consultation in advance to the possible follow-up programme.

The three workshops dealt with:

- Online-related sexual abuse of children, in particular grooming
- Assessing the need for awareness-raising for creating a safe online environment for children
- The impact and consequences of convergence of online technologies for online safety.

ROADMAP

Title of the Proposal: **Communication concerning the review of the functioning of Regulation (EC) No 717/2007 on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC**

Expected date of adoption of the initiative: **December 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The European Parliament and the Council adopted on 27 June 2007 a Regulation on roaming on public mobile telephone networks within the Community and amending Directive 2002/21/EC⁴⁷. The regulation addresses the high level of prices payable by users of mobile voice services while travelling abroad within the Community through three main measures, namely: wholesale price regulation, retail price regulation and transparency measures. The regulation complements and supports the rules provided for by the 2002 regulatory framework for electronic communications⁴⁸. It expires on 30 June 2010.

The Regulation requires the Commission to review and report to the European Parliament on the functioning of the Regulation by 30 December 2008, and in particular to evaluate whether its objectives have been achieved, taking account of developments in wholesale and retail charges for roamed voice and data services, including SMS (text messaging) and MMS (multimedia messaging).

The Commission is also required under the Regulation to assess whether, in the light of developments in the market and with regard both to competition and consumer protection, there is a need to

- extend the Regulation beyond 30 June 2010, or
- amend it, taking account of developments in charges for mobile voice and data communications services at national level and the effects of the Regulation on the competitive situation of smaller, independent or newly started operators.

What are the main problems identified?

The review of the Regulation will need to examine whether the measures taken have corrected, on a sustainable basis, the phenomenon of persistently high roaming prices, in the light of market and technological trends. As regards the latter, account will have to be taken of new technologies which may have a significant impact on the markets concerned.

Further, during the legislative process for this Regulation, members of the European Parliament and consumer groups raised concerns that the markets for roamed data communications, including SMS and MMS, may demonstrate some of the same characteristics as those of the roamed voice market. The review of the regulation will need to examine whether roamed SMS, MMS and/or general data services require corrective measures similar to those for voice.

⁴⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007R0717:EN:NOT>

⁴⁸ http://ec.europa.eu/information_society/policy/ecomms/info_centre/documentation/legislation/index_en.htm

Is EU action justified on grounds of subsidiarity?

The Regulation adopted in June 2007 constitutes a measure designed to introduce price discipline and transparency into a market where national regulatory authorities were unable to act under the existing Community legal framework in view of the fact that the retail market is situated in a Member State other than the Member State in which the wholesale service is provided. This fact has led to both the absence of a meaningful relationship between retail prices for roaming services and underlying costs of production on the one hand, and between retail prices for roaming services and retail prices for like services in a domestic setting on the other. The resulting discrepancy in the internal market was addressed by the Regulation

B. Objectives of EU initiative

What are the main policy objectives?

The objectives of the general regulatory framework are to encourage innovation and stimulate new investment in communication networks and services, by both new entrants and existing operators; to create a competitive single market for electronic communications services and networks in Europe, providing users with choice, quality and value for money, to keep regulation to the minimum necessary to achieve these objectives. This review will have to be seen in the context of the contribution which it makes to the implementation of the regulatory framework for telecommunications and the smooth functioning of the internal market.

In addition to the questions of possible extension of the duration and scope of the Regulation, the Commission's review will also address the following specific issues, as required by the Regulation:

- 'involuntary' roaming in border regions;
- developments in charges for mobile voice and data communications services at national level;
- whether traffic steering is being used by operators to the disadvantage of consumers;
- developments in wholesale and retail charges for roamed voice and data communications services in the outermost regions of the Community.

The impact of this Regulation on smaller, independent or newly started mobile telephony providers in the Community and their position in the Community-wide roaming market will also need to be assessed, as required by the Regulation.

Does the objective imply developing EU policy in new areas or of strategic importance? No

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The Regulation provides a number of regulatory options, which will need to be viewed in the light of other possible approaches, including soft law measures and exhortatory pressure on the industry. Additional options may arise in the course of the review of the regulation.

Roamed voice services

- Allow the Regulation to expire on 30 June 2010

This option could be accompanied by a soft law benchmarking exercise to maintain residual pressure in regard to pricing and transparency.

- Extend elements of the Regulation

As stated, the current Regulation has three major pillars: wholesale and retail price regulation and transparency. An assessment could be made of the elements of the regulation that could be allowed to expire and those which

might still be necessary to ensure that consumers continue to benefit from the intended effects of the regulation. One option could be to retain either wholesale or retail regulation only, with or without transparency measures.

- Extend the duration of the Regulation in its entirety

Another scenario could be the retention for one or more years of the main elements of the Regulation using the price ceilings applicable at the date currently set for the expiry of the Regulation, or with ceilings reducing over the extended lifetime of the Regulation.

Roamed data services

In assessing whether regulation of roamed data services might be necessary, account will need to be taken of the fact that the market and technical characteristics of SMS, MMS and other data services are potentially disparate.

- No regulation

If analysis indicates that there are indeed pricing and transparency problems in the roamed data markets, continued political pressure, not only from the Commission but from other sources including the European Parliament and national governments and regulators, coupled with market and technological advance, could obviate the need for regulation.

- Self regulation/soft-law options

In the light of such pressure, the industry might come forward with suitable proposals, such as codes of conduct, for self regulation for SMS, MMS and/or data services. Benchmarking at EU level may also be considered.

- Regulation of SMS and MMS prices

Price regulation could take the form of wholesale, retail, or wholesale and retail regulation, possibly combined with transparency measures.

- Regulation of other data services

A combination of measures similar to that for SMS/MMS services could be envisaged.

Finally, the policy options envisaged for roamed data services may need to be combined with measures relating to roamed voice services.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No. Nevertheless DG INFSO intends to set up an inter-service steering group comprising relevant DGs to advise in relation to the preparation of an impact assessment.

Do the options respect the proportionality principle?

Yes. Regulatory intervention to extend the duration or scope of the current Roaming Regulation will only be considered if justified in light of market and technological developments and if other options, such as soft law or self regulation, are considered insufficient to address any underlying problems. As with the current Regulation, any amendments will respect the principle of proportionality.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Changing the regime of price regulation provided for by the current Regulation would have substantial – primarily economic - consequences. The precise nature of these would have to emerge from a detailed economic assessment. The principal parties concerned, however, would be mobile operators and consumers within the Community. Equally, extending the duration of the Regulation or indeed allowing it to expire could have similar effects.

The main impacts to be expected would include:

- Changes to the economic welfare of mobile customers through higher or lower prices for mobile roaming services
- Changes to the economic welfare of mobile customers through different patterns and levels of consumption of mobile roaming services
- Changes to profits of the European mobile industry through higher or lower prices for mobile roaming services
- Changes to the relative competitive position of individual mobile operators through higher or lower prices for mobile roaming services
- Changes to the overall costs of doing business in the Community for industries other than the mobile industry
- Second-order consequences of changes in prices for mobile roaming services, e.g. spill-over effects on neighbouring markets or changes in firms' investment behaviour

Clearly, further dimensions to such an impact assessment could be conceived, for instance social, economic or cultural.

Further, the impact of any amendment of the Regulation would have to be assessed in terms of the Community's relationships with third countries, either via obligations contained in the GATS or via changes in the relative price level for mobile roaming services for countries sharing common borders with the EU not yet subject to the roaming regulation.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No.

Who is affected?

Primarily consumers and operators of mobile roaming phone services.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Commission is working closely with the European Regulators Group (ERG) to gather data for the Review and the Communication.

In addition to the Commission's own data sources (including the annual reports on the implementation of the e-communications regulatory framework) the ERG is expected to provide *inter alia* data of considerable granularity in the following two areas:

- Price information for the EU27 on a per-operator basis for voice roaming calls, SMS/MMS roaming and GPRS/UMTS data roaming
- Volume information for the EU27 on a per-operator basis for voice roaming calls, SMS/MMS roaming and GPRS/UMTS data roaming

Furthermore, it is envisaged that external consultants will be retained to carry out two analytical studies relating respectively to the market and production characteristics of SMS/MMS on the one hand and data roaming on the other.

Finally, it is envisaged that an extensive public consultation during the first half of 2008, will give all stakeholders the opportunity to participate in the process.

ROADMAP

Title of the initiative: **Legislative proposal on strengthening Eurojust**

Expected date of adoption of the initiative: **July 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The Hague Programme invites the Council to consider the 'further development of Eurojust', on the basis of a Commission proposal. Furthermore, under the Action Plan for the Hague Programme, the Commission should have presented a proposal for a 'European law' (on the basis of the Constitution) on Eurojust in 2006. In view of the developments regarding the Constitution, the Commission decided to first adopt a Communication on the future of Eurojust and the EJN as a preparation for further legislative proposals.

The Communication, to be adopted end October 2007, contains Commission's suggestions for strengthening Eurojust and revising the Eurojust Decision of 2002. It will be discussed during a High-level conference, organised by the PT Presidency (29 and 30 October in Lisbon) on the future of Eurojust and the EJN. In parallel, an Impact Assessment Study is being prepared and a report will be available by end of February 2008. On the basis of the outcome of the High Level Conference and the Impact Assessment Study, the Commission may present a proposal to amend the Eurojust Decision on the basis of Article 31 TEU by July 2008.

What are the main problems identified?

The fight against transnational organised crime requires coordination and cooperation between national authorities of the MS. Eurojust's objective is to stimulate and improve such coordination and cooperation. However, the present powers of Eurojust are limited. By strengthening the powers of Eurojust and rethinking relationships between Eurojust and the EJN, Eurojust will be able better to contribute to the fight against transnational organised crime.

Is EU action justified on grounds of subsidiarity?

Yes. Eurojust is an agency and its National Members (representing all 27 Member States) act on the basis of a Decision of 2002. Amendment of this Decision is necessary in order to enforce the role of Eurojust and strengthen the powers of the National Members.

B. Objectives of EU initiative

What are the main policy objectives?

Eurojust plays an important role in the coordination and cooperation between national authorities of the MS in the fight against transnational organised crime. At present, the powers of the national members of Eurojust are limited and focus on the coordination of investigations and prosecutions. In order to improve the fight against transnational organised crime, the powers of Eurojust should be increased and relationships between Eurojust and the EJN should be restructured. If this is done, Eurojust will be able to contribute more substantially to the fight against transnational organised crime.

Does the objective imply developing EU policy in new areas or of strategic importance?

Eurojust already has powers to coordinate national prosecutions between Member States in order to better fight against transnational organised crime. This is however not enough and it could be considered to give additional powers to both national members of Eurojust and the College.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

There are several options including:

- a) maintaining status quo: this would mean no amendments of the Decision of 2002 and continuing with the situation as it is.
- b) improvement of the existing coordinating role of Eurojust. Closer liaison between Eurojust and EJM is one of the options. Furthermore, the information position of Eurojust can be improved (e.g. early warning of the possible setting up of JITs).
- c) enforcing the role of Eurojust and its National Members by providing them with more powers for example concerning the initiation of investigations or the execution of requests for judicial cooperation. This may not be possible under the TEU.

The impact assessment will further analyse the different options.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes. OLAF.

Do the options respect the proportionality principle?

Yes. Will be detailed in the IA.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The option of maintaining the status quo will not contribute to any improvements of Eurojust' role in the fight against transnational organised crime. On the other hand, providing the national members e.g. with the possibility to suggest executing specific investigative measures related to transnational organised crime could facilitate and speed-up the investigation and prosecution of transnational crime considerably. To be further detailed in the IA.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Yes to some extent if the idea of offering a common platform within the Secretariat of Eurojust to various criminal law related networks is kept.

Who is affected?

Prosecutors and Member States.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Documents available: annual reports of Eurojust, reports of conferences etc. Data to be collected: a questionnaire has been sent to all the MSs. Replies need to be analysed. Furthermore interviews shall be held with stakeholders. The outcome of the Lisbon Conference (29-30 October) will be part of the study as well.

The study will be conducted by an external contractor.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Prosecutors and Member States have received already a questionnaire sent by the PRES PT beginning of July 2007. A high-level group conference is organised on 29 and 30 October in Lisbon. Contractors preparing the IA will participate to this conference.

ROADMAP

Title of the initiative: **Communication on e-Justice**

Expected date of adoption of the initiative: **June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Several presidencies have put e-justice on the top of their agendas and the Council has recently adopted conclusions calling for a broader development of e-justice at EU level. E-justice also appears among Commission's priorities in the framework of e-government and has been included among DG Infso research priorities. DG JLS wants to focus mainly on concrete achievements in order to facilitate access to justice for citizens and business in the European Union. In this regard, it will improve the visibility of the European area of justice and it is directly linked with the general policy of better transparency in a "Europe of results".

What are the main problems identified?

There are already achievements related to e-justice at national level but good practice have to be shared. At European level, several initiatives have already been developed (European judicial network in civil and commercial matters, European judicial atlas in civil and in criminal matters) or are on the way (interconnexion of criminal records) but should gain more visibility. . Moreover new technologies offer a wide range of possibilities to facilitate the circulation of information between professions, between citizens and the judiciary, and also to provide for access to information (business register, land registers...). In general, there is a need for more coordination and coherence in this area.

Is EU action justified on grounds of subsidiarity?

The priority for this file is non legislative action. Member states are responsible to develop e-justice at national level, but the EU should favour interoperability and develop practical tools to exchange information in cross border cases. .

B. Objectives of EU initiative

What are the main policy objectives?

The development of e-justice will contribute significantly to the development of the European area of justice, freedom and security, by granting a better access to justice for the citizens and an increased effectiveness of judicial proceedings.

The first objectives have been defined in the Council conclusions:

- the setting up of a EU justice portal
- the intercommunion of national registers (criminal records, insolvency register, business and commercial register, land register...)
- the development of the use of video conference in justice
- the development of specific EU procedures (ie European payment order).

More generally the Communication will focus on the one hand on the practical needs both for professionals and for the citizens, and on the other hand will insist on the necessity for interoperability and coherence between the various initiatives related to e-justice.

Does the objective imply developing EU policy in new areas or of strategic importance?

The objective does not imply developing EU policy in new areas - the use of e-justice will facilitate the operation of legislation already in place (such as the European Payment Order). However the proposal is of significant importance to improve the visibility of EU action regarding the European judicial area. It will also improve the efficiency of judicial cooperation by facilitating cross border access to information

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- a) Status quo: The Council has already decided that e-justice is an important issue to facilitate exchange of information and access to justice at EU level
- b) non legislative action: The Council has adopted a resolution in June 2007 insisting on the fact that e-justice should be developed as a tool for the implementation of EU legislation but should not lead in principle to the adoption of new legislation. Member States are not obliged to participate in all aspects of E-Justice. The Commission shares this approach. And e-justice will mainly be developed through non legislative instruments.
- c) Regulation or Directive: Taking into account what has been explained under b, it could appear that in some specific cases the development of e-justice will imply new legislation. The interconnection of criminal records is an example of such situation.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

.E-justice also relates to the e-government project (DIGIT), and might have some connection with some projects ruled by DG MARKT (EBR project).

Do the options respect the proportionality principle?

Yes, given that the non-compulsory nature of the action.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- a) Maintaining the status quo would not improve the present situation whereas e-justice appears an area where more European action could bring real added value.
- b) Non-legislative initiative. The development of an e-justice portal in particular would lead to more information sharing between Member States and would facilitate access to justice for citizens.
- c) Some legislation might be necessary for specific areas (interconnection of criminal records in particular).

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Yes, in 2007-2008 a budget of 14 million Euro has been devoted to the modernization and interconnection of the criminal records in the Member States under the criminal justice program, the creation of an EU E-justice portal will also have financial consequences. The credits foreseen under the Civil Justice Program and the Criminal Justice Program will be used in this regard..

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Certainly, the creation of e-justice portal, an interface where the informatics resources of the 27 Member States will be available will simply the administrative burden, facilitate access to information for citizens, and improve the efficiency of justice within Europe.

Who is affected? The Member States

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

To assure sound implementation of the Regulation on the European Payment Order the Commission will launch in 2007 a study on the feasibility of the electronic application and processing of this procedure.

The Commission will also launch an external feasibility study on the European portal in 2008 and continue to make proposals regarding interconnection of criminal records.

A study made by Germany last year could be reused when making the impact assessment. In general, the IA will have to take stock of all initiatives or existing projects on e-justice in particular when they have been developed at EU level.

The IA will be externalized.

The analysis will in particular concern the needs, and a first overview of technical feasibility of e-justice projects.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Member States have been consulted by the Working Party on Legal Data Processing which has submitted a report to the JAI Council in June 2007. The Commission shares the broad guidelines of this report on the e-justice.

ROADMAP

Title of the initiative: **Legislative initiative on applicable law, jurisdiction, recognition and enforcement of decisions and cooperation in matters relating to succession and wills and on the creation of a European system for register of wills.**

Expected date of adoption of the initiative: **November 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

This initiative is based on Article 65 of the Treaty establishing the European Community. The adoption of a European instrument relating to successions was among the priorities of the 1998 Vienna Action Plan⁴⁹. The Programme of measures for implementation of the principle of mutual recognition of decisions in civil and commercial matters⁵⁰ adopted by the Council and the Commission at the end of 2000 provides for an instrument to be drafted on succession. Finally, The Hague Programme⁵¹ of 4-5 November 2004, called on the Commission to present a Green Paper covering the whole range of issues – applicable law, jurisdiction and recognition, administrative measures (certificates of inheritance, registration of wills).

What are the main problems identified?

In order to fulfill these different mandates, a Green Paper *on Succession and wills* (COM(2005) 65 final) was adopted on the 1st of March 2005, launching a wide public debate on intestate and testate succession where there is an international dimension. Following the conclusions of a Study on Conflict of Law of Succession in the European Union commissioned by the Deutsches Notarinstitut (Institut Notarial Allemand) in November 2002, by the European Commission, the Green paper revealed that the increasing frequency of unions between nationals of different Member States, often entailing the acquisition of property in the territory of several Union countries, are a major source of complication in succession to estates. It stressed that the difficulties facing those involved in a transnational succession mostly flow from the divergence in substantive rules, procedural rules and conflict rules in the Member States. The study evaluates the number of transnational successions in the EU each year to be around 50 000 to 100 000. The great majority of contributions to the Green Paper clearly highlighted that there is a general wish in order to fulfil the political mandate given in The Hague Programme in the field of succession and wills.

Is EU action justified on grounds of subsidiarity?

The matters of conflict of laws and conflicts of jurisdiction between EU courts and recognition of decisions in the field of succession and wills are excluded from Community rules of private international law adopted so far. The objectives of the action cannot be accomplished by the Member States but require action at Community level in the form of common rules on jurisdiction and applicable law. Jurisdiction rules as well as conflict-of-law rules must be identical to ensure the objective of legal certainty and predictability for the citizens and legal practitioners. Unilateral action by Member States would therefore run counter this objective. There is no international convention in force between all Member States on the question of succession and wills. The Hague Convention of 1989 on applicable law to succession and has been ratified only by one State and is not in force. The public consultation has demonstrated that the scale of the problems addressed in this proposal is significant and that it concerns dozen of thousands of citizens and their heirs each year. In light of the nature and the scale of the problem, the objectives can only be achieved at Community level.

⁴⁹ OJ C 19, 23.1.1999.

⁵⁰ OJ C 12, 15.1.2001.

⁵¹ See Presidency conclusions, Brussels European Council, 4 and 5 November 2004.

B. Objectives of EU initiative

What are the main policy objectives?

The main objective of this initiative will be to simplify matters for those involved in a transnational succession and to provide an effective response to the practical problems of individuals involved in a transnational succession as raised by the Study.

Any future instrument should create the ways and means of removing the administrative and practical obstacles facing citizens wishing to have their status as heir, for instance, recognised abroad. As full harmonization of the rules of substantive law in the Member States is inconceivable, action will have to focus on the conflict rules.

After all the consultation process and in particular the hearing of November 2006, it was revealed that there can be no progress on succession at the Community level without the question of the applicable law being settled as a matter of priority. For facilitating the concrete life of citizens, the following specific problems should also be tackled: how to establish a "European certificate of inheritance" and a European scheme for registration of wills as a matter of priority.

Does the objective imply developing EU policy in new areas or of strategic importance?

No, the objective implies to create a genuine European Judicial Area in the matter of succession law.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

1. Status quo;
2. legislative proposal(s) in the field of applicable law and jurisdiction for the matters concerned ; in this regard several sub-options will be considered relating to the rules to the scope and the rules of ant future instrument;
3. Ratification by the Member States of the Basel Convention of 16/05/1972 as regards the question of the register of wills or Community instrument like a directive or non-regulatory options.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No, the action applies to civil law only.

Do the options respect the proportionality principle?

Yes, the options may be the *status quo*, the adoption of soft law, or creation of one or several new Community instruments, e.g. a regulation and a directive.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The adoption of one or several Community instruments would reduce the administrative burdens and practical difficulties in the frame of the administration of an international succession for citizens.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No impact.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The creation of a "European Inheritance Certificate" or a "European Successions and Wills Register" would substantially simplify the administration of international successions for citizens including those living in third countries and also for third countries' citizens living in the EU.

Who is affected?

All citizens, their potential heirs and relatives, the legal practitioners acting in the field of succession and wills, like the notaries (*notaires*) or solicitors or bodies performing the same functions and the States.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The report of the Study published in 2004 (and its annexes State by State), the Green paper and its annex of 2005 and the contributions to the Green paper received and their resumé, the documents related to the hearing of November 2006 are already available on the web site of the Commission (DG JLS). An expert Group on succession and wills, composed by independent Member States' experts has been set-up in 2006 that meets regularly to provide help to the Commission to prepare the project. The information on the legislation of the Member States which acceded to the EC after the publication of the Study is being gathered. An impact assessment will be launched before the end of 2007 with the help of an external contractor.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Study of 2004 has been prepared by some of the best experts in the field in Europe. The stakeholders have been consulted through the consultations launched by the Green Paper of 2005 followed by the hearing of 2006. The Commission is being assisted since February 2006 in its task by a high level expert group composed in particular of legal practitioners in the field of succession and wills coming from different legal traditions.

ROADMAP

Title of the initiative: **Policy on violent radicalisation, based on the results of the expert group report and other expertise and knowledge gained during 2006 and 2007**

Expected date of adoption of the initiative: **30 June 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies.

The positive contribution that the EU could provide to this policy area has been acknowledged by the Strategy and the Action Plan on Radicalisation and Recruitment which imposes on both Member States and European institutions certain actions to be taken in the fight against violent radicalisation.

In September 2005 the Commission issued a Communication entitled *Terrorist recruitment: addressing the factors contributing to violent radicalisation* which was the Commission's contribution to the Strategy and Action Plan adopted by the Council in December 2005 and updated in December 2006.

The implementation of the Strategy and Action Plan on Radicalisation and Recruitment requires a strong commitment by the Member States and EU Institutions in order to be successful. The Commission is committed to continue delivering upon the actions under its responsibility. It adopted a decision setting up an Expert Group on Violent Radicalisation which will advise on policy-making in this field and which is to produce a report on the state of play of research on radicalisation foreseen for November 2007. It also issued a call for tenders in March 2006 for three studies on violent radicalisation that encourage the research community to invest in this field and to adopt multi-disciplinary as well as comparative approaches towards the analysis of the subject. Contracts for the studies have been awarded and the results are expected by December 2007. The studies concern the following issues:

- the factors that may possibly trigger or affect violent radicalisation processes, particularly among youth;
- the beliefs, ideologies and narrative of violent radicals;
- the methods through which violent radicals mobilise support for terrorism and find new recruits.

Another open call for tenders was published on 10 January 2007 for a study on best practices in cooperation between authorities and civil society with a view to the prevention of and response to violent radicalisation. The general objective of the study is to identify cooperation initiatives for such two key actors in countering violent radicalisation which will assist in identifying new ways in which they can be supported by the Commission. The study will therefore guide and support the Commission's policy-making. The contract was awarded in July 2007.

Furthermore, the Commission has sent a questionnaire to the Member States on policies to address violent radicalisation the aim of which is to compile good or the most salient practices of the MS in the field. The deadline for answering the questionnaire has been set at 30 September 2007.

In October 2007, the Commission is organising a conference on the role of education in the prevention of violent radicalisation.

Following the knowledge and expertise to be gained from the above initiatives, the Commission will be in a position to produce a policy document (probably in the form of a Communication) that outlines a number of initiatives for the prevention of violent radicalisation.

What are the main problems identified?

Addressing violent radicalisation is a very complex area that requires a well-considered approach. The factors that might contribute to violent radicalisation are multiple and different variables might operate in different scenarios. Shortcuts in policy-making cannot be made and investment in research has been and is currently high on the Commission's list of priorities.

Is EU action justified on grounds of subsidiarity?

The measures undertaken through this action cannot be achieved by any single EU Member State alone and must therefore be addressed at EU level. Although it is the Member States who set the social, education, and economic policies that can foster equality and inclusion within mainstream society, working at the pan-European level can provide an important framework. Member States should be able to co-ordinate their policies at the European level; share information about responses developed at national level; determine good practice; and work together to come up with new ideas.

B. Objectives of EU initiative

What are the main policy objectives?

The policy objectives are to develop initiatives in the field of the fight against violent radicalisation based on the studies, the questionnaire and the education conference. The studies are based on field research and the collection of new empirical data and adopt comparative and inter-disciplinary approaches. This should ensure that the policy document in 2008 will be based on sound data.

The objectives will focus mainly on sharing knowledge on the analysis of the phenomenon of violent radicalisation including offering a comparative analysis of how radicalisation processes are happening in Europe in order to identify similar factors and undercurrents that are contributing to radicalisation of individuals and groups within Europe; spreading best or good practices that are identified following the initiatives being currently undertaken; provide concrete recommendations to the Member States based upon the knowledge being accumulated in order to ensure a coordinated approach towards tackling the phenomenon.

Does the objective imply developing EU policy in new areas or of strategic importance?

The Commission has already issued a Communication on the subject for the first time in 2005. Since then, the threat from violent radicalisation has been growing across Europe. The 2008 policy document will build upon the 2005 Communication which had highlighted the need to conduct reliable research in terms of future policy-making. The studies and reports commissioned in 2006 and 2007 as well as the questionnaire and the conference on education will allow the Commission to come up with new ideas in addressing the factors contributing towards violent radicalisation from a policy perspective.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The policy options can be various. The Commission could produce a Communication in which future policy developments in the field, probably cutting across various EU policies, could be suggested. Recommendations and examples of good practice in the MS could be made too. The Communication could serve as a very valuable instrument for suggesting amendments to the EU Strategy and Action Plan on Radicalisation and Recruitment that is currently in place.

The Communication is unlikely to contain legislative measures although it cannot be entirely excluded.

The current stage of the ongoing external studies does not allow drafting possible policy options on their basis yet. Their results should be known at the end of 2007 and the beginning of 2008.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

As mentioned, the Commission could produce a Communication in which future policy developments in the field, probably cutting across various EU policies, could be suggested. Such EU policies are likely to involve education and youth; culture; employment, social affairs and equal opportunities, research, media, external relations, integration policies.

Do the options respect the proportionality principle?

This proposal will not go beyond what is necessary in order to achieve the underlying objectives of Member States co-operation in the field. The possible Communication is unlikely to contain legislative measures, but will probably suggest future policy developments in the field.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

No action: would deprive the EU of the possibility to reinforce the current ongoing initiatives in the field within a coherent framework if considered necessary to respond to increasing threats.

Although a Communication does not have any legally binding force, member States authorities which in some way deal with the problem of violent radicalisation would be affected. These could be prison authorities, educational and religious institutions, social welfare institutions, media, government public relations bodies.

The 2008 Communication will provide the opportunity for discussion within Council and EP fora and it is hoped that the proposals contained within it become part of the Action Plan on Radicalisation and Recruitment which MS and EU institutions are responsible for implementing.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Yes, the 2008 Communication could have a significant impact on relations with third countries since the fight against violent radicalisation has a crucial external relations dimension. Furthermore violent radicalisation is a global phenomenon and addressing its factors will always involve third countries.

Who is affected?

Education establishments, Government administrations, youth organisations, research institutes, media.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Three studies have already been contracted, the results of which are expected to be delivered to the Commission by the end of 2007.

A further study on cooperation initiatives between civil society and public authorities should be ready by the first months of 2008 and therefore in time to feed into the policy document of 2008.

Furthermore, the Expert Group on Violent Radicalisation will continue helping the Commission with policy advice in the area, particularly with a report expected before year's end.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The contractors of the 3 studies are expected to deliver policy suggestions in the conclusions to their studies in line with the terms of reference. The Expert Group mentioned above would also be consulted.

Title of the proposal: **Framework Directive on Consumer Contractual Rights.**

Expected date of adoption of the proposal: **December 2008**

A. Initial impact assessment screening

1. What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

The rationale for the consumer acquis review⁵² stems from a number of factors and problem areas.

Fragmentation of rules and markets: the existing EU consumer protection rules are fragmented in two ways. Firstly, the current directives allow Member States to adopt more stringent consumer protection rules in their national laws (minimum harmonisation) and many Member States have made use of this possibility. Secondly, many issues are regulated inconsistently between directives or have been left open. During the preliminary phase of the Review, business and consumer stakeholders pointed out a number of examples of regulatory fragmentation which create problems. The differences usually trigger extra compliance costs for businesses, including costs of acquiring relevant legal advice, changing information and marketing material or contracts, and litigation costs. Compliance costs are often cited by enterprises as one reason among others for not conducting business cross-border. Different rules resulting from minimum harmonisation may generate confusion for consumers and undermine their confidence in the internal market.

Market Developments: Most directives that are part of the Consumer Acquis are prescriptive rather than principle-based. Most of them no longer meet fully the requirements of today's rapidly evolving markets, particularly as technological developments are creating new channels for transactions between businesses and consumers. This is particularly important in the face of the growing importance of digital technology and digital services, which raise controversial issues relating to user rights, as compared to the sale of physical goods.

Better regulation: the overlaps and inconsistencies between different consumer protection Directives provide for a patchy regulatory environment which is not conducive to consumer and business confidence, and can act as a barrier to growth and competitiveness. The consumer acquis provides for different contractual requirements, often at once. The different requirements may imply a degree of uncertainty in the regulatory framework. For example, if a timeshare contract is concluded in a doorstep selling situation both the Doorstep Selling Directive and the Timeshare Directive would apply. These two Directives grant consumers a right of withdrawal, but with different time periods during which the consumer can exercise this right.

In particular the review examines the following questions:

Is the overall level of consumer protection required by the directives appropriate to ensure consumer confidence?

Is the level of harmonisation sufficient to eliminate possible internal market barriers and distortions of competition for business and consumers?

Does the level of regulation keep burdens on business to a minimum and facilitate competition to the benefit of consumers?

Are the directives implemented effectively?

As a whole, are there any significant gaps, inconsistencies or overlaps between the eight⁵³ directives?

Is the scope of the directives appropriate?

Are the pre-contractual information requirements appropriate?

⁵² The eight consumer directives under review are: Directives 85/577, 90/314, 93/13, 94/47, 97/7, 98/6; 98/27, 99/44.

⁵³ See footnote 1

Is there scope for a further rationalisation and simplification of the consumer acquis? If so, which means are the most appropriate to achieve better regulation objectives?

2. What are the main policy objectives?

The Commission's key goals remain to enhance consumer and business confidence in the internal market through a high common level of consumer protection, the elimination of internal market barriers and regulatory simplification.

The review will evaluate to what extent the current directives, as a whole and individually, have in practice met the Commission's consumer protection and internal market goals. That implies looking not only at the directives themselves but the way they are applied and the markets within which they operate (i.e. national transposition laws; jurisprudence; self-regulation; enforcement; levels of compliance in practice; and developments in business practice, technology and consumer expectations).

Improving the consistency and coherence of EU consumer law acquis is very much inspired by the Better Regulation agenda. In fact, the consumer acquis review project can be seen as an implementation of the 2003 Interinstitutional Agreement on better lawmaking, by which the Commission, the Council and the EP committed to "promote simplicity, clarity and consistency in the drafting of laws and the utmost transparency of the legislative process".

3. What are the policy options? What regulatory or non-regulatory instruments could be considered?

Five general policy approaches were identified in the Green Paper on the Review of the Consumer Acquis, and they will form the basis of the thinking to develop policy options during the impact assessment process

a) No action – baseline scenario;

b) A vertical approach consisting of the individual revision of existing directives (e.g. revision of the Timeshare Directive);

c) A more horizontal approach, adopting a framework, horizontal instrument to regulate common features of the acquis. This framework instrument would provide common definitions and regulate the main consumer contractual rights and remedies. In addition, this instrument would regulate consistently the contractual aspects of sale, which are currently scattered in several directives (e.g. Directives on the Sale of Consumer Goods, Unfair Contract terms, Distance Selling and Doorstep Selling). In accordance with Better Regulation principles, this instrument would rationalise the regulatory framework considerably since all the relevant provisions of the relevant existing directives would be systematised into the new piece of legislation. The parts of existing Directives covering marketing techniques (e.g. restrictions on the use of certain means of distance communication) and services would remain in force. The horizontal approach would not exclude vertical solutions if need be.

d) A combination of the vertical and horizontal approaches (the 'mixed' approach), combining the revision of sectoral directives where necessary, and the introduction of a framework instrument regulating common features of the consumer acquis.

e) A self-regulatory approach (in selected areas, subject to applicability)

4. What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

Economic impacts

Eliminating any inconsistencies in EU consumer protection legislation will increase legal certainty and thus reduce the necessity for legal advice when conducting business cross-border. The consequence of reduced costs for legal advice and reduced litigation costs will be strong incentives to EU enterprises to venture beyond

national borders and consider expanding their scale of operations to more than one EU Member State. Increased competition across EU borders, enhanced competitiveness for European enterprises and general economic growth are the likely results of these developments..

The economic impacts will be particularly favourable for SMEs since the legal advice costs are proportionately higher for them. Reducing legal inconsistencies will therefore make it easier for SMEs to carry out cross-border activities, and higher cross-border investment flows are likely to be stimulated. Their competitive disadvantage compared to domestic operators or to large businesses will be reduced, with further positive impacts for the general competitiveness of the EU.

The same impact should be expected for larger enterprises, as the streamlining of consumer protection legislation will remove uncertainty resulting from legal lacunae, and will encourage a greater volume of cross-border activity. While some additional adjustment and/or compliance costs might be imposed on businesses by the review of the consumer protection legislation, these will not be disproportionate to benefits that will incur, and are unlikely to offset the advantages of the exercise.

Increased consistency will likewise be favourable to consumers, who are even less likely than SMEs to be able to afford costly legal advice. The better protection offered to consumers will increase confidence and encourage cross-border spending, enhancing their ability to benefit from the internal market. The elimination of consumer protection lacunae, as well as possible enhancements in the amount of information consumers receive will foster more empowered and better-informed consumers that can make better purchasing decisions, and yield more power in the internal market. Further, the expected growth in cross-border business activity, is likely to foster more competitive market conditions, leading to consumers being exposed to more and better cross-border offers, better prices and higher quality products.

All of the above-mentioned economic impacts will be analysed during the impact assessment process.

Social Impacts

The rationalisation of the acquis will make it easier to inform consumers better about their rights. In addition, the rationalised and simplified legal environment is likely to result in better enforcement of consumer rights in cases of disputes with traders, creating incentives for consumers to feel more confident when shopping cross-border

B. Planning of further impact assessment work

5. What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Available data:

1. Green Paper responses: the Green Paper on the review of the consumer acquis has received more than 300 responses from various stakeholders and Member States. These responses will be analysed as part of the impact assessment process, and will closely inform the final impact assessment report.
2. Two surveys on business and consumer attitudes to consumer protection and cross-border shopping – 2002.
3. Consumer protection Eurobarometer – 2003.
4. Consumer protection Eurobarometer – 2006
5. Business attitudes toward cross boarder trade – Flash Eurobarometer 2006
6. Results of a SME Panel survey conducted by the EuroInfo Centers
7. Responses to separate public consultations on the application of and possible problems arising from individual directives covered by the Review of the acquis. Consultations on the Distance Selling Directive ending 21 November 2006, the Unit Prices Directive ending 1 September 2006, and the Package Travel Directive ending 1 October 2007.
8. The European Consumer Center Network (ECC-Net) has in the past provided valuable information by conducting cross-border comparisons on issues such as prices, legislation and number and reasons for complaints. This could prove to be a useful source of data and evidence
9. Comparative analysis of how the existing Directives are applied in the Member States, including case-law and administrative practice. The study also focuses on the use of minimum harmonization clauses in consumer protection Directives and analyse national provisions aiming at making use of such clauses.
10. Consumer complaints received directly or via MEPs

Information to be gathered:

1. Input from CFR-net workshops and researchers' reports
2. Stakeholders input gathered through formal consultations and bilateral contacts.
3. Public consultation until end November 2007 on the application of and possible problems arising from the Doorstep Selling Directive.
4. A big conference gathering a large number of stakeholders will be organized by SANCO in November as a follow up to the consultation on the Green Paper. Issues arising from the consultation on the Green Paper will be discussed and stakeholders will have the opportunity of developing their reasoning and tell about their experiences.
5. Surveys of Member States, business and consumer stakeholders, and European Consumer Centres; to be conducted by an external contractor, by Spring 2008.

Formation of an expert group to advise on the issues under review; consultation of the expert group to be conducted by an external contractor, by Spring 2008.

6. Which stakeholders & experts will be consulted, how and at what stage?

Stakeholder consultation has been ongoing, and culminated in the publication of the Green Paper on the review of the consumer acquis in February 2007. The consultation exercise through the Green Paper closed in May 2007. Overall, more than 300 responses were submitted, from the majority of Member States, as well as a variety of stakeholders and academics.

A number of stakeholders, academics and Member States have also provided/will provide replies to the consultations made on the SANCO webpage regarding the individual directives covered by the Review of the acquis: The Distance Selling Directive, the Unit Prices Directive, the Package Travel Directive and the Doorstep Selling Directive.

A big conference gathering a large number of stakeholders will be organized by SANCO in November as a follow up to the consultation on the Green Paper.

There have also been ongoing contacts with various stakeholders interested in the acquis review project, including in the context of the CFR-net workshops.

A working group of Member States experts' was set up pursuant to the Commission Communication of 2004. On the 1st of December 2005 the first meeting was held. Separate meetings followed for specific directives and/or horizontal issues.

7. Will an inter-service steering group be set up for the IA?

An interservice group has already been set up, and has met twice, in July 2007 and September 2007. A series of further meetings are envisaged for the rest of 2007 and the first half of 2008.

The following DGs participate in the inter-service steering group: JLS; ENTR; MARKT; INFOS; ENV; COMP; and SG.

ROADMAP

Title of the initiative: **Communication Promoting multilingualism: a shared strategy**
 Expected date of adoption of the proposal: **September 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

To ensure their contribution to the Lisbon strategy, Ministers of Education adopted in 2001 a report on *the Concrete Future Objectives of Education and Training Systems* (5680/01), agreeing for the first time on shared objectives to be achieved by 2010. A year later, the Education Council and the Commission endorsed a 10-year *Work Programme* (OJ C 142, 14.6.2002) to be implemented through the open method of coordination. In these documents the improvement of language skills was identified as one of the key objectives in the modernisation process of education and training systems.

Furthermore, the Barcelona European Council in 2002 called for further action "to improve the mastery of basic skills, in particular by teaching at least two foreign languages from a very early age" (Barcelona European Council, 15-16 March 2002, Presidency Conclusions, part I, 43.1)

In 2003 the Commission adopted a Communication on "*Promoting Language Learning and Linguistic Diversity: an Action Plan 2004-2006*". (COM(2003) 449 final) proposing 47 actions to be undertaken from 2004 to 2006 in three strategic areas: lifelong language learning, better language teaching and building a language-friendly environment.

In 2004 multilingualism became part of Commissioner Figel's portfolio, encompassing both internal and external action. This was reflected in the Commission Communication "*A new Framework Strategy for Multilingualism*" (COM(2005) 596 final).

Both communications called for presenting, on the basis of the results of the actions recommended, a further Communication to the Parliament and the Council proposing a comprehensive approach to multilingualism in the European Union.

In September 2007 two substantial documents on the implementation of the above-mentioned communications will be made available: a Commission Working Paper *on the implementation of the Action Plan "Promoting language learning and linguistic diversity"*, including national contributions and the *Final Report of the High Level Group for Multilingualism* advising on further action to promote multilingualism.

In the context of the relaunched Lisbon strategy for Growth and Job, the improvement of language skills plays not only a role in improving employability and competitiveness but also links up to intercultural dialogue and social cohesion through a broader vision of multilingualism targeting all languages spoken in Europe.

The new Communication will provide orientations for a better synergy between EU and Member States policies to promote multilingualism, notably through the Open Method of Coordination and by making better use of existing European programmes and initiatives.

What are the main problems identified?

Despite the target of the Barcelona Council of teaching two foreign languages at school, only little progress in the number and variety of foreign languages taught has been achieved: an average of 1.3 and 1.6 foreign languages was taught per student in general lower- and upper-secondary education respectively in 2003 (Progress towards the Lisbon objectives in education and training – 2006 Report).

Linguistic competence has direct and indirect effects on a number of key policy areas:

- **Growth and Jobs:**

Insufficient language skills are among the reasons for insufficient growth performance in Europe hindering, inter alia, international business relations, as pointed out in the study: *Effects on the European Economy of Shortages of Foreign Language Skills in Enterprise (ELAN)*

(http://ec.europa.eu/education/policies/lang/key/studies_en.html).

Limited language skills make increased mobility on the European labour market difficult, failing to counteract uneven employment rates. The percentage of Europeans residing in an EU country other than their country of

origin has remained stable at around 1.5% over the last 30 years.

- Social cohesion:

According to the 2004 Eurydice survey: *Integrating Immigrant Children into Schools in Europe* (<http://www.eurydice.org/portal/page/portal/Eurydice/showPresentation>), "Language is often the first barrier to integration encountered by immigrant pupils when they enter school" (p.30). In 2006, the proportion of pupils in the total school population, whose first language was not the language of instruction represented around one-fifth of all pupils in Luxembourg and Liechtenstein and 6-8% in Denmark, Germany, Austria and Sweden.

- Dialogue with Citizens:

The rejection of the European Constitution by French and Dutch voters in June 2005 mirrored a shaken confidence in the EU in certain countries and called for a concentration on how to involve citizens in European issues. The European Commission adopted the White Paper on a European Communication Policy in February 2006 with the aim of strengthening the EU's emphasis on communication work and propose a new, more citizen-centred and decentralised approach.

Surveys have shown that 97% of citizens in the Union agree with one of the fundamental aims of the White Paper: information about the EU should be widely available, accessible in the citizens' own language and readily understandable. Six out of 10 Europeans feel that it is difficult to communicate with the EU for language reasons, this constituting a barrier towards a more direct participation in EU-level politics for them (Eurobarometer: EU Communication and the citizens - General Public Survey 2006).

Is EU action justified on grounds of subsidiarity?

The issue identified is relevant for all Member States and possible solutions envisage collaboration and coordination between them. It is therefore relevant for the EU to be active in the field. Moreover is the proposed action in accordance with the EU's role of supporting and supplementing Member States' activities, that bear primary responsibility for the content and the organisation of education systems (according to Article 149 of the Treaty), of which language teaching is an integral part. Also the Report on the Concrete Objectives of Education and Training Systems of 2001 identified the improvement of language skills as one of the key objectives in the modernisation process of education and training systems to be carried out through the Open Method of Coordination.

B. Objectives of EU initiative

What are the main policy objectives?

General objective: to prepare a strategy shared between the Commission and the Member States for the promotion of multilingualism, in particular to improve citizens' employability, the competitiveness of European enterprises, intercultural dialogue and social inclusion as well as to create a European space for dialogue with the citizens.

Specific objectives:

- To raise awareness of the advantages of language skills, in particular for economic growth and competitiveness as well as for better mutual comprehension of cultures and peoples within Europe;
- To contribute to improving the formal and non-formal education systems with respect to quality language teaching and the supply of an appropriate choice of languages taught, matching local needs (border regions, areas of regional and minority languages, migrant communities, areas with important relations with third countries, etc.);
- to encourage companies to take languages into account and set language strategies to become more competitive;
- to raise awareness of linguistic diversity and foster informal language learning through the media, culture, youth and other activities involving the civil society;
- To make the best use of the financial support available under the Lifelong Learning Programme and other existing European programmes and initiatives to promote multilingualism;
- To ensure that all Commission services apply multilingualism policy in a coherent way through mainstreaming language issues across different policy areas in the Commission.

Does the objective imply developing EU policy in new areas or of strategic importance?

The proposal reinforces the various Community initiatives in the field of intercultural dialogue and contributes to the realisation of the objectives defined in the Strategy for Growth and Jobs.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

Three policy options can be considered:

1. Do nothing
2. Use regulatory instruments
3. Use the Open Method of Coordination: issuing a Commission Communication setting the ground for cooperation with Member States and have it endorsed by the other European Institutions

1. Do nothing:

In 2002 Member States committed themselves "to improve the mastery of basic skills, in particular by teaching at least two foreign languages from a very early age". As far educational systems are concerned, the recent Report on the implementation of the Action Plan "Promoting Language learning and linguistic diversity" (COM(2007)554) shows that, although steps forward have been taken especially in initial education (for instance by introducing early language learning and increasing the offer of languages at secondary level), vocational and adult education have been mobilised to a lesser extent, let alone promoting informal ways of learning languages (through the media, leisure activities, travels..).

This findings are supported by the statistical assessment of the 2006 Eurobarometer "Europeans and their languages" (http://ec.europa.eu/public_opinion/archives/ebs/ebs_243_sum_en.pdf), showing that: 56% of citizens in the EU Member States are able to hold a conversation in one language apart from their mother tongue and 28% of the respondents state that they speak two foreign languages well enough to have a conversation.

From the socio-economic point of view, the Eurobarometer found that a "multilingual" European is likely to be young, well-educated or still studying, born in a country other than the country of residence, who uses foreign languages for professional reasons and is motivated to learn. Consequently, it seems that a large part of European society is not enjoying the advantages of multilingualism. The adults, those no longer in education, the low-skilled workers and/or unemployed are the ones who are less likely to master the basic language skills.

In the light of the above a Commission decision of non - intervention would not be justified, as Member States in Lisbon (2001) and in Barcelona (2002) called on to the Commission to help to reach their commitment, by ensuring a coordinated approach and by making good practices circulate.

2. Use regulatory instruments

Regulatory instruments could be of valuable help, especially by adjusting the educational systems so to teach two languages in an efficient way and by providing incentives to adults to take up languages.

Nevertheless the Commission action should only complement Member States policies, as stated in Art.149 of the EU Treaty "The Community shall contribute to the development of quality education by encouraging cooperation between Member states and, if necessary, by supporting and supplementing their action, while fully respecting the responsibility of the Member States for the content of teaching and the organisation of education systems and their cultural and linguistic diversity.

Community action shall be aimed at: developing the European dimension in education, particularly through the teaching and dissemination of the languages of the Member States".

Art 150 and 151, concerning vocational training and culture and relevant to languages go along the same line.

In the light of the above mentioned articles a regulatory approach is out of the Commission scope

3. Use the Open Method of Coordination: issuing a Commission Communication setting the ground for cooperation with Member States and have it endorsed by the other European Institutions

As already mentioned, Member States called in Lisbon and in Barcelona for the Commission to help them to reach their commitment of improving the citizen's basic skills, where languages are included. The Commission should, among other things ensure a coordinated approach and make good practices circulate. Furthermore, as already quoted under option B Art.149 of the Treaty gives the Commission mandate to intervene in such a way.

In order to set a coordination framework and areas for intervention at European and national level, a Commission Communication seems to be the adequate instrument. Furthermore, the Communication will take into account the feedback of a wide consultation process, thus securing a broad endorsement of the actions proposed.

In the framework of the Open Method of Coordination, already in use for language policy as part of the Education & Training 2010 Process, the Communication should be endorsed by the Council and the Parliament through autonomous or joint statements.

As for multilingualism issues internal to the Commission services: a coordinated approach set via the Inter-Service Group on Multilingualism seems the adequate answer to reach all services concerned. The Inter-Service Group will also be used to mainstream multilingualism in existing European programmes and initiatives, through interventions at programme level (thematic priorities, budget for linguistic preparation and linguistic activities, adequate monitoring, etc.).

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The action has an impact on all services; therefore an Inter-service Group on Multilingualism has been set up.

Do the options respect the proportionality principle?

The action enhances co-operation among Member States without additional budgetary implications.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Policy

Policy option 1: Do nothing.

This option is likely to have a negative impact, caused by the absence of a European framework and guidelines which will increase the gap between countries investing on strong language skills and countries lagging behind. It is likely to have a negative economic impact on the individual employability and European competitiveness at large. As for social impact it might increase the lack of communication and comprehension about the European project and the other cultures living in Europe.

Policy option 2. Use regulatory instruments.

This is a theoretical option of policy making, but it is not applicable because the Treaty binds the Commission not to use regulatory instruments in the area of Education, Vocational Training and Culture. Therefore it is not possible to forecast its impact.

Policy option 3. Use the Open Method of Coordination: issuing a Commission Communication setting the ground for cooperation with Member States and have it endorsed by the other European Institutions

Economic impacts: by way of the role of language skills in citizens' employability and competitiveness, the new strategy defined in the Communication is likely to have an impact on international trade and cross-border investments; technological development and innovation; the number and quality of jobs; third countries and overseas relations.

Social impacts: the strategy is likely to have an impact on social inclusion, as well as governance and participation as language skills are a prerequisite to intercultural dialogue and European political dialogue with citizens.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Not applicable.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Not applicable.

Who is affected?

EU citizens and enterprises; education systems of Member States.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

In September 2007 two substantial documents providing information on the past three years and ways forward will be made available: the *Report on the implementation of the Action Plan "Promoting language learning and linguistic diversity"*, including national contributions, will be adopted as Commission Working Paper and the *Final Report of the High Level Group for Multilingualism* advising on further action to promote multilingualism will be published.

Member States have already reported on the implementation of the Action Plan at national level. Information on the way Member States have implemented the recommendations of the Communication *A New Framework Strategy for Multilingualism* of 2005 are expected by October 2007.

Thematic input is expected from a wide range of stakeholders consulted through meetings and open consultation as listed under the following point. When needed, specific expertise will be provided by the results of the studies mentioned under point F.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The Commission regularly consults/will consult the following groups of experts in the field of multilingualism:

- a Working Group on Languages composed by officials in charge of language policy in the Member States. The aim of group is to cooperate with the Commission in achieving the objectives stated in the Education and Training 2010 Process as far languages are concerned and to assist the Commission in developing and following up the Action Plan for language learning and linguistic diversity. The group meets around three times a year or more. Next two meetings are foreseen in October and December 2007. Other meetings will be scheduled in 2008;

- a High Level Group to provide independent, non-political recommendations to the Commissioner for Multilingualism on the development of initiatives to promote and support multilingualism. The Group met seven times in 2007 and will release its final report in September 2007;

- a Group of Intellectuals for Intercultural Dialogue to provide independent recommendations to the Commissioner for Multilingualism on concrete contributions of multilingualism to intercultural dialogue. The Group will meet three times in 2007 and provide its recommendations;

- a European Network of Inspectors of Foreign Language Education and Training in which inspectors exchange good practice and learn from each other's experience. The Network meets around three times a year;

- a Business Forum to foster a structured dialogue and partnership with European business. Two/ three meetings are foreseen between the last months of 2007 and spring 2008;

- Member States High Representatives involved in multilingualism policies will be invited for a meeting in January 2008;

- Member States will be invited to discuss the future orientations for multilingualism during a Ministerial Conference in February 2008;

- An open public consultation will take place in September-November 2007, where all citizens and stakeholders will have the opportunity to contribute to the shaping of the new strategy. Information about the consultation will be diffused especially to interest groups and experts in the field of education and training;

- A public hearing presenting the results of the on-line consultation and discussing themes for the Communication is planned for mid-March.

ROADMAP

Title of the initiative: **Communication "EU Development assistance: Doing more, better and faster – Delivering on our commitments"**

This communication will be supported by four documents respectively on:

1. The EU contribution to the UN follow-up conference on Financing for Development (Doha, late 2008)
2. the EU contribution to the 3rd High Level Forum on Aid Effectiveness (Accra, September 2008)
3. EU commitments on Policy Coherence
4. State of play regarding the EU contribution on Aid for Trade (monitoring report)

Expected date of adoption of the initiative: March 2008

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

Following the adoption of the European Consensus for Development at the end of 2005, the EU has taken on several commitments to deliver its aid better, faster and continued to implement its pledge to provide higher ODA volumes.

1/ The EU has to determine its contribution to the Follow-Up Conference on Financing for Development to Review the Implementation of the Monterrey Consensus (Doha, December 2008).

Doha will provide the framework for taking stock of the state of implementation of existing international and related EU commitments (Monterrey Consensus; EU commitments on financing for development of 2002 and 2005).

Based on the Council mandate to the Commission to monitor EU progress and provide annual reports and to propose ways to improve delivery on EU commitments, the Commission has, since 2003, presented five progress reports. The Commission proposes preparing its sixth annual report, taking account of the contribution of the EU Member States to the annual "Monterrey survey" of autumn 2007. The report shall also facilitate the preparation of a shared EU position in the UN preparatory process for the Doha conference on financing for development.

2/ The EU has to determine its contribution to the Third High Level Forum on Aid Effectiveness (Accra, September 2008)

Accra will provide the framework for driving the aid effectiveness processes forward at global level by introducing recent and new EU initiatives into the international debate (e.g. Code of Conduct on Division of Labour in Development).

3/ EU's enhanced efforts for development lie in improving policy coherence. In 2005 the EU agreed on Policy Coherence for Development (PCD) commitments in 12 policy areas and gave a mandate to the Commission to monitor progress towards PCD through a biennial report. On 20 September the Commission adopted the European Union's first report on PCD covering both Member States and Community actions. The proposed communication will draw the lessons from the debate on the PCD report and propose further actions to increase coherence of EU policies with development objectives.

4/ In 2006/2007 the EU developed a strong input on aid for trade. It is essential to monitor the implementation of these commitments that are a parallel essential tool linked to the ongoing negotiations on Economic Partnership Agreements.

What are the main problems identified?

(1) To remain a driving force in the international debate the EU needs to speak with a single voice at the international fora, based on agreed shared commitments and a joint position.

(2) EU has to demonstrate it has followed through commitments taken at European or international level.

(3) Other partners, including new and emerging powers have to also contribute to progress in financing for development and aid effectiveness.

(4) To increase the contribution policies other than development cooperation can make to achieve development objectives.

Is EU action justified on grounds of subsidiarity?

The annual progress report on financing for development belongs to the Commission's regular report obligations. In its Conclusions of May 2007 the Council has also asked the Commission to report on progress and lessons learned from the implementation of the Code of Conduct on Complementarity and Division of Labour in Development Policy.

Some of the policy areas covered by the PCD commitments are exclusive EU competence, e.g. trade and agriculture. Ensuring coherence is a legal obligation of the Community enshrined in article 178 of the EC Treaty. Furthermore the policy proposals will build on the findings of the EU Report on PCD for which the Commission had an explicit mandate from the Council.

B. Objectives of EU initiative

What are the main policy objectives?

To ensure that the EU remains a driving force for progress in the international debate on financing for development and aid effectiveness.

To provide proposals enabling the EU to adopt a common position and contribution for Accra and Doha. The Communication will also put forward concrete steps to be taken with a view of increasing the coherence of selected EU policies with development objectives.

Does the objective imply developing EU policy in new areas or of strategic importance?

No

C. Options

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The proposals will build on and impact on ongoing work of Commission departments. It will cut across several policy areas in all its segments (financing for development, aid effectiveness, aid for trade and policy coherence for development).

Do the options respect the proportionality principle? Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

The Communication will propose changes to certain EU policies with a view of making them more development friendly.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

NO

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

(1) Contribute to achieving the Millennium Development Goals and other internationally agreed development objectives in developing countries.

(2) Better "value for money" and better development results through improved aid effectiveness, including through division of labour between EU and international donors.

(3) The positive impact of other EU policies on developing countries should be maximised and incoherence corrected.

Who is affected?

EC, EU Member States, other international donors, and developing countries.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

A proportionate IA will be required for the part on Policy Coherence for Development. An IA will not be required for the other parts of the initiative which relate to an annual Commission report, to internationally agreed development objectives and to existing EU commitments.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Regarding the EU commitments on financing for development and aid effectiveness the annual survey based on a detailed questionnaire is under preparation and will be sent to all EU MS (in the autumn replies expected by December 2007). Based on the feedback of EU Member States on the different thematic EU commitments the Commission will draft the Communication and additional Staff Working Papers.

The EU PCD report was drafted on the basis of contributions from Member States and the Commission services concerned. Civil society was consulted, too. The proposed communication will draw the lessons from the discussion of this report with Member States, the EP, civil society and developing countries.

ROADMAP

Title of the initiative: **The EU, Africa and China: Towards trilateral dialogue and cooperation on Africa's peace, stability and sustainable development**

Expected date of adoption of the initiative: **September/October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

- China's policy in Africa has substantial repercussions on the EU's Africa policy and on African development. The main challenge is political, in terms of development policies and outcomes for Africans as China is perceived as an alternative by many African elites in terms of access to finance and a development model. In economic or trade terms China is less of a threat to EU interests, except regarding some minerals. Even in the oft-cited area of energy security China's impact on EU energy security is limited. China's impact on African interests is more profound, politically and economically. The diversity of African countries and the relatively recent developments forbid rash conclusions, but demand more research.
- The EU's current strategy on China includes dialogue and cooperation on this topic because China's rise in Africa has important repercussions on EU relations with Africa. To some extent the envisaged cooperation is a test case for the strategic aspects of the EU-China partnership and the EU-Africa partnership respectively, as both include a focus on global challenges, in this case Africa's peace, stability and sustainable development.
- the envisaged cooperation also aims at progress on MDG 8 (global development partnership) and on the Paris Declaration on aid effectiveness in a step by step approach
- Since 2005 Commission (DEV) and Council Secretariat have had an informal dialogue, in 2007 there was the first official dialogue of Africa Directors which agreed on enhanced cooperation as did a first trilateral conference with representatives from Africa, China and the EU.
- There is a need to define a common EU position to agree on the objectives and to make cooperation among EU MS on this topic more effective (e.g. through planning and sharing analysis and research, agreed messages etc.)
- This issue is linked to the EC policies to untie aid and make development aid more effective, more coherent and more efficient.

What are the main problems identified?

- lack of information and mutual understanding of development policies between EU, China and Africa
- lack of evidence and research on impact of the different policies and activities for Africa's peace, stability and sustainable development
- lack of coordination on implementation of China's development aid and economic cooperation
- different underlying values and principles notably regarding governance issues, democracy and human rights
- potential for cooperation nevertheless clearly exists, common interests needs to be brought out as a basis for dialogue and cooperation: peace, stability, governance and legal certainty in African countries, MDG, sustainable economic growth. There is a need for structured exchange of good practice notably in the methods of aid delivery and coordination among donors.

Is EU action justified on grounds of subsidiarity?

Yes. It concerns an EU wide strategy towards both Africa and China. Collective EU action is more efficient than actions by individual member states and they can complement each other. The choice of an EU framework for trilateral cooperation is in line with the choice of a European framework for action by the MS in the cases of the European Consensus and the EU's Africa strategy.

A recent study by the German Development Institute concludes that in most cases, and specifically regarding China, triangular cooperation should be pursued at EU level and not bilaterally from Germany.

The Chinese side has also called for a collective EU dialogue with China.

B. Objectives of EU initiative

What are the main policy objectives?

The EU's strategy on China includes dialogue and cooperation on Africa because China's rise in Africa has important repercussions on EU relations with Africa. The envisaged cooperation also aims at progress on MDG 8 - global development partnership - and on the Paris Declaration on aid effectiveness in a step by step approach.

- The main policy objective is to foster an innovative, step by step process of dialogue and cooperation to promote mutual understanding, allow better coordination and cooperation in specific cases including on multilateral initiatives with the long-term objective of improved coordination on security issues in Africa and better aid effectiveness. This has to be embedded in a trilateral framework with ownership by our African partners. Ultimately, such trilateral cooperation should contribute to the promotion of the values, principles and objectives of the European Consensus and the EU's Africa strategy (including the joint strategy to be adopted at the EU-Africa summit)

- initially the cooperation could focus on promotion of security and stability, political dialogue and cooperation in sectors such as health, capacity building, infrastructure, rural development with others to be envisaged as trilateral cooperation makes headway. An interesting aspect is the exchange of views and good practice of China's own development experiences.

Does the objective imply developing EU policy in new areas or of strategic importance?

- yes. Adding a triangular dimension to ongoing bilateral dialogues and partnerships and aiming at policy coherence between the EU policy on Africa and on China.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- this initiative cannot be based on EC legislative initiatives or soft law, no regulation is required

- the most promising policy option seems to engage in dialogue as a first step which is the most suitable means to achieve the objectives of better mutual understanding and of promoting our objectives

- the second step would then be policy dialogue and cooperation in concrete sectors as specified above

- a second policy option is to pursue cooperation with financial instruments. This is not excluded in principle for the future, but seems premature at this stage, except for modest operations (financing of conferences, studies, dialogue and coordination events, pilot cooperation projects etc.). For these no new funds are required.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Main policy areas concerned are development policy, CFSP. To a smaller extent trade, environment, energy, transport, fisheries are concerned.

Yes, DG DEV and RELEX as lead departments respectively on Africa and China, DG AIDCO as potential implementer of concrete cooperation in the future, some thematic DGs may be concerned by specific initiatives such as DG ENV on issues related to forestry (FLEGT), TREN/TRADE on EITI and eventually others.

Do the options respect the proportionality principle?

Yes.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- no measurable social, economic or environmental impact, however it is expected that by enhanced cooperation on sector wide approaches, on initiatives such as EITI, FLEGT, on the promotion of the rule of law and governance, currently negative impacts of China's policy may be mitigated and positive impacts such as economic growth may be enhanced. The cooperation envisaged would promote sustainable development as compared to the current Chinese focus on economic cooperation. According to the current state of analysis, impact on energy security and trade is limited and this initiative consequently will focus on these issues only to the extent that cooperation improves the governance framework or level-playing field for competition in trade related areas. However, major impacts on Africa's trade relations will be conditioned by other processes such as the conclusion of the EPAs and the WTO Development Round. This initiative may contribute somewhat to facilitate these processes in as far China is a factor in these. Trade volumes of both the EU's and China's trade with Africa are very small, notably when compared to EU-China trade.
- aim is to have a broadly defined political impact on improved political relations in the EU-Africa-China triangle

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

- no, some of the planned follow-up can be covered by existing programmes or through administrative credits for conferences, studies and the like, in any case less than €5 million.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

- perhaps in the medium-term need for additional staff resources in the Beijing Delegation or in DG DEV
- relations with third countries: the objective is to improve relations with China and with African countries. The already mentioned initial steps have already had some impact on relations with the US and Japan. The China-Africa issue features in the strategic dialogue with the US and Japan seems to have come to the conclusion that on Africa issues it should – like the EU – engage with China constructively. The EU may envisage developing a similar approach with other emerging powers such as India or Brazil. The strategy will also influence the G8 Heiligendamm process.

Who is affected?

Policy makers in EU, Africa and China.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

- there is a body of literature on the problems and opportunities of China's engagement in Africa and since the EC has launched the dialogue with China there is also literature on how the EU should position itself. Many recent studies, including some produced by NGOs, advocate a cooperative or even a triangular approach. The impact assessment will largely draw on this literature plus the results of official and informal meetings.
- in principle the impact assessment work will be done internally, but will require attending conferences, perhaps organising a stakeholder conference and missions to Africa/China to gather further evidence and discuss policy options

Which stakeholders & experts have been/will be consulted, how and at what stage?

- a first stakeholder consultation was organised through the conference on EU-China-Africa on 28 June which involved a broad selection of stakeholders from governments, international organisations, academia, think-tanks and civil society from the three regions
- a second conference could be envisaged in spring 2008, provided sufficient budget resources are available
- regular meetings with individual stakeholders or groups are envisaged
- an internet based consultation is a possibility, but needs to be assessed in terms of cost-effectiveness criteria (given the broad range of issues there could simply be an overwhelming flow of individual opinions, while the topic warrants a consultation of organised stakeholders with knowledge of the subject in government, academia, international organisations and groups of NGO such as CONCORD or African networks).

ROADMAP

Title of the initiative: **Communication on Economic Development and Regional Integration in African, Caribbean and Pacific countries**

Expected date of adoption of the initiative: **October 2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

A number of recent EU initiatives and policies have had an impact on regional integration in African, Caribbean and Pacific (ACP) countries, in particular the EU Aid for Trade Strategy (due for adoption in October), the negotiations of Economic Partnership Agreements, the programming of the 10th EDF (in particular the Regional Indicative Programmes), the adoption of regional strategies for the Caribbean and the Pacific, and the drafting of the EU-Africa Strategy (due for adoption in December).

In parallel, concerning Africa, a rationalisation exercise of the Regional Economic Communities is being undertaken by the African Union.

At the same time, there is a growing recognition that support to the development of the private sector is essential to foster growth in developing countries.

What are the main problems identified?

In the European Consensus for Development, regional integration has been identified as a key intermediate objective for the EU's development policy.

Given the profound changes in the context for regional integration in ACP countries, it is appropriate to review the tools existing both at national and Community level, in particular with a view to enhancing their complementarity and efficiency in a post-EPA context, where private sector development will be a key tool to achieve trade development and growth in ACP countries. This is even more needed since the latest policy orientations on private sector development (A European Community strategy for Private Sector Development in ACP countries, COM (1998) 667) date back from 1998 and therefore need updating anyway.

Is EU action justified on grounds of subsidiarity?

Yes. Development policy is a joint responsibility of the Community and its Member States. In the context of the European consensus for development, support to regional integration was identified as a key priority for the Community, which should also promote co-ordination and harmonisation, in particular among its Member States.

B. Objectives of EU initiative

What are the main policy objectives?

- to take stock of regional integration in ACP countries;
- to re-define how best to support existing integration processes and economic development in a new regional context;
- to ensure complementarity of actions and instruments existing at EU and Member States level, in particular in relation to private sector development.

Does the objective imply developing EU policy in new areas or of strategic importance?

In new areas: most probably no.

In areas of strategic importance: yes – the issue is key for EU-ACP relations and the emergence of strong ACP regions.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

- a) The Commission takes the initiative to produce a Communication aiming at reviewing the regional integration tools existing both at national and Community level, possibly leading to the redefinition of financial instruments.
- b) The Commission undertakes a routine update of the tools for regional integration and private sector development on a base-by-case basis (i.e. not in the context of a wider review).
- c) No EU action.
- d) Making use of legislative instruments: in the context of the redefinition of financial instruments, this possibility should not be excluded. In such case, legislative initiatives may indeed go beyond routine updating.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

The communication will deal with the formulation of development policy in the ACP countries. However, it will relate to the activities of other policy areas such as trade, customs, agriculture, enterprise, environment, health protection, consumer protection.

Do the options respect the proportionality principle?

Yes.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- a) The communication will:
 - update Commission policies to the changing environment in the ACP;
 - enhance the coherence of policies to strengthen regional approaches in EU relations with ACP countries;
 - foster the complementarity and efficiency of instruments.
- b) This approach could lead to significant improvement in the efficiency / effectiveness of policies but it would fail to maximise complementarity between the various instruments, favour business-as-usual solutions or minimal reforms – and, probably, eat up more resources than a joined-up policy-making exercise.
- c) This is not advisable given the context characterised by the implementation of EPAs and of the Strategy for Africa that emphasises regional integration, the importance of the business climate and the rationalisation of instruments. Not updating a strategy that will be 10 years old in 2008 entails the risk of sticking to instruments that are no longer performing adequately.
- d) Not advisable as legislative instruments may not be adequate for the policy objectives pursued. Yet, the communication itself could be a first step towards the adoption of new legislative proposals, in particular in the context of the redefinition of financial instruments. The impact of these proposals would be considered when they are eventually proposed.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No. The communication will be based on the existing allocations for the European Development Funds and the budget (financial perspectives 2007-2013). The communication may, however, propose changes concerning the financial instruments.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Former: potentially, yes, through the eventual simplification of instruments. The benefits of increased efficiency and effectiveness would accrue both to the Commission and Member States, and to the economic operators concerned by these instruments.

Latter: yes, this is the very object of the communication.

Who is affected?

EU Member States; all ACP countries and their Regional Economic Communities; existing and potential economic operators in ACP countries.

Potentially: multilateral donors.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The necessary information is already available internally. It will be collected in the course of the first semester of 2008. This information concerns in particular policy orientations as well as current financial and other instruments at EC and Member States level. The emphasis of the work will be on the analysis of this information with a view to formulate a new strategy.

Which stakeholders & experts have been/will be consulted, how and at what stage?

No consultation has taken place at this early stage.

All stakeholders, in particular EU Member States, ACP governments, ACP regional organisations, the private sector in the ACP and in the EU as well as relevant NGOs, will be consulted during the first quarter of 2008.

Extensive consultation will include face-to-face meetings (general ones on the full scope of the communication and others dedicated to more specific aspects) with the various stakeholders. Online consultation tools are also likely to be used.

ROADMAP

Title of the proposal: **Green Paper on Deforestation and Climate Change**

Expected date of adoption of the proposal: **July 2008**

A. Initial impact assessment screening

What are the main problems identified? Are they unlikely to be solved satisfactorily by the sole action of Member States? (principle of subsidiarity – necessity test)

This Green Paper aims at encouraging discussion on different policy options to combat deforestation. Deforestation accounts for 20% of global CO₂ emissions – more than the transport sector. Emissions from deforestation were not included in the Kyoto Agreement but appear likely to be included in the successor regime. Tackling deforestation would bring a number of other benefits apart from reduced CO₂ emissions, notably in terms of biodiversity conservation. There are a number of technical and policy choices to be made and ultimately a political decision on whether the EU should provide substantial financial resources as an incentive for countries to reduce deforestation and conserve forest cover.

While several Member States are active in this field a common EU position will need to be developed for the UNFCCC negotiations. Furthermore the scale of resources that may be required will require a concerted initiative involving both the Commission and Member States, possibly involving a link to the EU emissions trading scheme. The Commission therefore must take the initiative to coordinate an EU policy on this topic.

What are the main policy objectives?

Reduce greenhouse gas emissions from deforestation; conserve biodiversity in forest areas, particularly tropical forests; develop a mechanism which will secure commitments from key developing countries to contribute to global efforts to reduce greenhouse gas emissions.

Does this initiative contribute to the simplification of the environmental acquis? How? (Recast, revision, repeal)

No

What are the policy options? What regulatory or non-regulatory instruments could be considered?

Given the complexity of the drivers of deforestation, the Green Paper will outline a mix of possible policy responses in fields such as environment and development cooperation as well as policy coherence with fields such as EU agricultural and energy policies.

The major policy decisions to be made relate to the amount of funding that should be provided by the EU, the source of such funds (public/ private), mechanisms for such funding and the conditions under which it should be provided. In addition policy decisions will need to be made on potential linkages of any such finance with EU carbon trading schemes and with the post-Kyoto climate change regime.

What are the impacts likely to result from each policy option and who is affected? Which impacts are likely to warrant further analysis (cf. list of impacts in the impact assessment guidelines)?

The policy options have potential impacts on public funding provisions by the Commission and Member States as well as on a future carbon trading regime. The potential impacts on climate change mitigation that could arise from addressing deforestation will need to be compared to other options to achieve similar levels of climate change mitigation. Potential impacts in related areas such as environment and poverty reduction will need to be considered.

B. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

No formal impact assessment is foreseen for the Green Paper. However, there is a considerable amount of information and data available on deforestation and the drivers of deforestation. The further information that will need to be gathered will mainly concern potential financial and institutional mechanisms. Analysis will need to include consideration of political factors as any initiative will require the active involvement of tropical forest countries.

Which stakeholders & experts will be consulted, how and at what stage?

Member State experts (eg. members of the Council “sinks expert group”); World Bank Forest Carbon Partnership technical experts; environmental NGOs; carbon trading companies; forestry development experts. Limited consultation through a meeting prior to publication of the Green Paper – most of the feedback will be after publication of the Green Paper.

Will an inter-service steering group be set up for the IA?

No formal impact assessment is foreseen for the Green Paper. However an inter-service group will be established to provide inputs for the Paper and review it.

ROADMAP

Title of the initiative: **Communication and Legislative proposal to prevent the placing on the market in the EU of timber or timber products derived from illegally harvested trees**

Expected date of adoption of the initiative: **May/2008**

A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The Communication and the legislative proposal to prevent the placing on the EU market of timber and timber products from illegally harvested trees is a logical step forward from the bilateral approach which constitutes the main element of the FLEGT initiative (Forest Law Enforcement, Governance and Trade). They will constitute a milestone for the protection of forests.

A FLEGT Action Plan was adopted in 2003 outlining a series of measures to address illegal logging both in the countries concerned and within the EU as a timber importer. In 2005 the Council adopted a proposal for a Regulation and negotiating directives for the negotiation by the Commission of Voluntary FLEGT Partnerships with exporting countries. These voluntary partnership agreements avoid the import of illegal timber into the EU from countries with which the EU has signed an agreement. Voluntary partnership negotiations are underway with Ghana, Indonesia and Malaysia.

What are the main problems identified?

The bilateral nature of the FLEGT voluntary partnership agreements means that they constitute an incomplete framework since illegally harvested timber from countries with which the EU does not have an agreement can continue to enter the EU without effective control. Such measures are likely to affect the internal market for timber products as well as international trade in such products and should thus be introduced at Community level.

Is EU action justified on grounds of subsidiarity?

It is necessary to have an EU approach on the trade of timber and on the strategies to stop imports and the sale of illegal timber. Because of the free movement of goods within the EU, MS individual action would not ensure the achievement of the objective.

B. Objectives of EU initiative

What are the main policy objectives?

Ensuring that illegally harvested timber or products derived from such timber does not enter the EU market, with direct benefits to EU environment and development policies as well as more generally to strengthening the rule of law, particularly in developing countries with high levels of illegal logging.

Does the objective imply developing EU policy in new areas or of strategic importance?

This initiative is a development of the existing EU FLEGT policy so in that sense is not new, however there could be implications for some aspects of forest policy within the EU which have not previously been directly affected by Community legislation.

C. Options

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

The policy options considered are:

- further development of the existing bilateral FLEGT approach;
- enhanced use of private sector voluntary measures;
- legislation preventing the importation of illegally harvested timber;
- legislation on the placing of the market of illegally harvested timber products.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Trade and Development policies are particularly concerned.

Do the options respect the proportionality principle? Yes

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

In all cases the policy options will require an increased use of systems to trace timber and timber product flows from source. The impacts from the first two options are relatively easy to identify as they represent extensions of existing initiatives. More intensive analysis will be necessary to determine the impacts of potential legislation. The main types of impact to be examined will be the economic impacts on forest management and on forest industry and the environmental and social impacts, especially in countries affected by illegal logging. Particular attention will need to be paid to differential impacts on small and medium enterprises.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

No simplification implications. Some increased administration possible.

The proposal is likely to be welcomed by some timber exporting third countries but not by others.

Who is affected?

The forest sector within and outside the EU would be affected as well as downstream industries such as furniture and paper.

E. Planning of further impact assessment work

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The nature of illegal logging means that factual information is scarce and will always be. However it is

possible to obtain reasonable estimates by combining qualitative assessments with harder data on trade flows. Further information is needed on cost implications of the options and on whom these costs will fall as well as the cost of a status quo situation, including unfair competition from illegally harvested timber. Analysis will use forest trade modelling to determine the potential impacts at a global level. To the extent possible the analysis will be done on a quantitative level but qualitative assessments will also be necessary, in particular on the environmental and social impacts

Which stakeholders & experts have been/will be consulted, how and at what stage?

A web-based public consultation on the options was carried out in early 2007. The impact assessment study includes provision for stakeholder consultation meetings within and outside the EU. The main stakeholders to be consulted in these meetings will be forest administrations and forest owners, forest sector businesses, retailers linked to the forest sector, NGOs