



**2013**

# **Management Plan**

**Health &  
Consumers**

**Directorate-General**



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## 1. EXECUTIVE SUMMARY

Our mission of "making Europe's citizen's healthier, safer and more confident" is central to building a safe and secure Europe. SANCO policies address issues that confront citizens and governments across Europe, but also in the rest of the world. Human, animal or plant diseases and dangerous food and consumer products do not respect barriers.

We put consumers at the centre of the Single Market, increasing their confidence by reinforcing consumer safety, enhancing knowledge, stepping up enforcement and securing redress, aligning consumer rights and policies to changes in society and in the economy.

In 2013, SANCO will present the co-legislators a package composed of a modernized General Products and Services Directive, a new Single Market surveillance Regulation and a multi-annual market surveillance plan that will lead to reductions in cost and administrative burden and will improve coordination between national authorities.

We will continue our cooperation on product safety policy with China and US, ensuring product monitoring along the supply chain and improving product traceability.

Consumer information and education will be enhanced by awareness raising campaigns in the context of 2013 European Year of Citizens and by developing a smart phone application for the European Consumers Centres Network. An interactive educational platform for teachers in secondary schools will also be launched in the first half of 2013. We will provide support to national consumer organizations via online and offline tools.

The 9th consumer scoreboard will focus in 2013 on cross-border retail internal market and consumer environment in Member States and the 10th will rank the 51 most important consumer markets. These will be complemented by market studies (on vehicle fuels, second-hand cars, voluntary food labelling schemes, green claims in non-food markets) and behavioural studies (on tobacco, food information, credit card payments, online gambling, consumer vulnerability in key markets), all of which will deliver policy recommendations aimed at improving consumer conditions.

We will pursue efforts to render enforcement more effective, efficient and consistent across the EU. In preparation of the revision of the CPC Regulation in 2014, an impact assessment will be carried out this year. Following adoption by the co-legislators of the Alternative Dispute Resolution and Online Dispute Resolution legislative package, we will monitor transposition and adopt the relevant implementing and delegated acts.

Enhanced action will be taken towards more effective integration of consumer interests in other EU policies such as energy (to enhance transparency in bills, prices and offers, to better manage and control energy consumption at home), financial services (on financial education and third pillar pensions, on bank accounts, bank fee transparency and switching), transport (on accessibility, affordability and health), digital agenda (on multi-territorial licensing in music, copyright, private copying levies, cloud computing strategy, telecom services) and sustainable consumption policies.

EU health policy contributes to a smarter, inclusive and more sustainable Europe as part of the EU2020 strategy. We will continue to foster good health in an ageing Europe and protect citizens from health threats, while promoting dynamic health systems and new technologies.

In order to respond to the big challenge of an ageing population in the EU, the implementation of the European Innovation Partnership on Active and Healthy Ageing will

be continued. The revision of the Tobacco Products Directive will be adopted by the Commission in 2013 and the "Ex-smokers are unstoppable" campaign will run for the 3rd and last year. Cooperation will continue with MS and stakeholders on health determinants and chronic diseases prevention in order to reduce the long-term burden for health systems. Work will also be pursued on cancer and rare diseases, contributing to improved diagnostics and treatment. The 2013 Report on organ donation and transplantation will be accompanied by quality and safety standards ensuring improved traceability and vigilance.

EU citizens' protection from serious cross-border health threats will be enhanced through a Decision to be adopted by the co-legislators in 2013. Commission actions on pandemic preparedness will be carried forward, with the finalization of the joint procurement of pandemic vaccines at EU level. Cooperation on risk management of specific threats and the fight against rising threats from anti-microbial resistance will also be continued, as well as the work on patient safety and hospital acquired infections. Further HIV/AIDS policy options will be developed as well.

The current EU HIV/AIDS policy will be further implemented with a strong focus on the promotion of early diagnosis and care, and prevention of HIV. Actions to fight discrimination and stigmatisation in the context of HIV/AIDS will remain in the focus. During 2013, a conference on HIV and human rights will be organised together with UNAIDS. More broadly, in addition to addressing health inequalities in the EU, anti-discrimination in health is an important priority. Certain groups can be denied or have difficulties in accessing health services or prevention and treatment related to specific diseases and conditions because of nationality, residence status, or sexual orientation. To this end, a conference is envisaged in 2013 on "Discrimination in the Health Sector", open to all stakeholders.

We will support dynamic health systems and new technologies that promote high quality, safe and efficient healthcare. The finalization in 2013 of the transposition of the Directive on patient's rights in cross-border healthcare and the establishment of the European Reference Network will facilitate access to high quality health care for patients. The actions to be carried out under the EU Action Plan for Health Workforce aim at improving planning and forecasting, anticipating better the needed skills, all with the aim of simulating the exchange on recruitment and retention of health workers in cooperation with WHO.

Several proposals will be dealt with by the co-legislators in 2013: medical devices, in vitro medical devices, clinical trials (adopted by the Commission in 2012) and veterinary medicines (to be adopted by the Commission in the 2nd quarter 2013). The Commission will also adopt delegated and implementing acts for falsified medicinal products and pharmacovigilance.

We will continue to support in 2013 the wider use of e-Health solutions and will set up a network of national authorities and bodies for Health Technology Assessment that would bring concrete benefits to citizens. The Expert Panel on investment in health will become operational in 2013, offering independent and highly qualified advice.

A high level of **food and feed safety, animal health and welfare** is essential to achieve the key public health and economic objectives of the EU. We will enhance and manage the regulatory framework and ensure effective and harmonized implementation.

In 2013, the Commission will adopt the package on a Healthier Animals and Plants and a Safer Food Chain. The modernized legal framework for a more competitive EU is composed of:

- A more efficient framework for official controls along the food chain, simplifying and clarifying legislation and establishing a more uniform risk based control framework;
- EU plant health legislation simplifying, streamlining and increasing transparency and cost effectiveness, as well as establishing better import control to reinforce the protection against new pest and diseases from third countries;
- EU plant health reproductive material law to reduce overall administrative burden by modernising and simplify the legislation through the replacement of 12 Directives on seed and plant propagating material with one single act;
- Animal health law, bringing significant simplification (replacing over 40 current rules) and increasing internal coherence between animal health issues and related areas.

In order to boost innovation as a driver for smart growth, proposals on novel foods, cloning and food contact materials will be adopted by the Commission in 2013 and implementing work will start for the legislation on foods for particular nutritional uses (dietetic foods) once it will be adopted by the co-legislators in 2013.

On GMO cultivation, the Commission aims to reach a common position in the Council. Guidelines for GM food/feed will also be adopted. A recommendation on environmental monitoring of the GMO cultivation will also be proposed.

We will review the Hygiene Package legislation, the legislative framework for the harmonized monitoring of anti-microbial resistance (AMR) in food and animals and the medicated feed legislation in order to ensure safe practices in the Single Market. Also foreseen for adoption in 2013 are the Regulations on pig and poultry meat inspections. The re-evaluation of all feed additives will also be launched this year.

Work will be carried out on the preparation of the EU animal welfare law, including a pilot project on the Coordinated European Animal Welfare Network.

The implementation of the electronic identification of bovine animals, the pet movement between Member States and the Honey Directive will start after the adoption of these proposals by the co-legislators.

We will continue to manage the authorization process for food additives, enzymes, flavourings, food contact materials, GM food and novel food. Work on the approval dossiers for active substances, on the setting up of maximum residue levels of pesticides in food and on implementing measures for plant protection products will continue, with special emphasis on endocrine disruptors.

In order to ensure proper enforcement, the Food and Veterinary Office will carry out 250 audits in 2013, covering a wide spectrum of sectors, including organic farming and geographical indicators, such as Protected Denomination of Origin, Protected Geographical Indications and Traditional Specialities Guaranteed.

**Better implementation and enforcement** of legislation in all policy areas is crucial: over 75% of resources are devoted to this in any given year.

In the area of **international relations**, globalization has a dominant influence on the context in which we create and implement our policies; therefore, we pursue our objectives through multilateral rule making and governance cooperation in different fora, but also through bilateral relations and agreements, as well as training and technical cooperation.

## 2. MISSION STATEMENT

*"Making Europe's citizens healthier, safer and more confident"*

The mission of DG Health and Consumers is to improve the health, safety and confidence of European citizens. This goal is central to what many people think of when they talk of European values, or 'well-being', in the sense of the Lisbon Treaty.

In practice, the pursuit of this goal requires that we:

- ✚ empower and where necessary protect citizens in consumer markets,
- ✚ improve and where necessary protect human health,
- ✚ ensure that all food is safe,
- ✚ protect animal and plant health, and
- ✚ promote the humane treatment of animals.

The achievement of these goals in coherence with EU 2020 objectives has an important economic dimension. A high level of confidence in the safety of goods and services is essential to the stability of markets, and of trade within the internal market in particular. This requires a sophisticated regulatory framework and enforcement measures to ensure that markets can operate in an environment of high levels of safety and consumer confidence. We are responsible for several important sectors such as food, pharmaceuticals, medical devices, childcare articles and cosmetics where safety is paramount. We are equally responsible for ensuring that consumers are well informed of their rights and protected from certain unfair or deceptive commercial practices.

We aim to fulfil these goals by developing and maintaining soundly based and proportionate policies, laws and programmes, in respect of Better Regulation, by ensuring compliance with existing legislation and by communicating clearly and effectively with citizens and stakeholders. In pursuing these goals, we aim to contribute to citizens' confidence in Europe, competitiveness, the creation of jobs, a sustainable environment and mutually beneficial relations with the EU's international partners.

The policies and laws for which we are responsible touch the daily lives of citizens. We must ensure they are designed, applied and enforced in a way that delivers results that benefit citizens. In this respect, we will ensure that we are always at the service of the citizen through openness and transparency in our working culture.

We will endeavour to ensure a high level of protection and continue our work in identifying, preventing and managing risks.

When EU action is needed to address a problem, we will make proposals that are practical, sensible and proportionate. Where national or regional authorities are better placed to solve a particular problem, we will support their efforts and provide them with our experience and facilitate exchange of best practices. We are open to using both binding legal instruments and other policy tools that bring effective results.

We strive for close working relations with the Council, the European Parliament and the other institutions and bodies of the EU.

Our actions will be based on the best available data, the best possible objective scientific advice, including the impact of technological advances, and the widest possible consultation. All substantive initiatives will be supported by proportionate impact assessments. We will work in synergy with other EU policies, such as those aimed at protecting the environment and boosting the EU's economic competitiveness, and we will seek the integration of our goals in relevant initiatives developed by other Commission services. Policy coherence (integration) across EU policies and activities remains essential in order to ensure that they are mutually supportive and they deliver results which are beneficial to citizens and stakeholders.

The professional pursuit of the public good is our guiding objective. We will respect the integrity and professionalism of those with whom we work within Member States and elsewhere. We will also be guided by the ambition to operate in a way that is efficient, open and professional.

This means, in particular:

- ✚ A prudent management of our finances. We will ensure efficiency, accountability and best value for taxpayers' money.
- ✚ An ambition to pursue our mission with limited resources against a background of increasing demands on the Commission and the context of the financial crisis. We will develop and best use all talents in a healthy working environment, combat discrimination and ensure equality between men and women. We will manage priorities so as to minimize the stress placed on individual colleagues and ensure all can achieve an appropriate work-life balance.
- ✚ We will pursue proper planning and efficient organization: flexibility without improvisation. We will work on the basis of a programme that balances tasks and resources.
- ✚ We will ensure appropriate communication of our actions to the citizens and operate in full respect of the principles of consultation.

### 3. THE CHALLENGES THIS YEAR AND BEYOND

Our mission of "*Making Europe's citizens healthier, safer and more confident*" is central to building a safe and secure Europe. The impact of our actions boosts EU competitiveness and supports the EU 2020 strategy objectives.

SANCO policies address issues that concern citizens and governments across Europe but also in the rest of the world. Human, animal or plant diseases and dangerous food and consumer goods do not respect barriers. Drawing together knowledge, experience and resources to combat common problems brings huge economies of scale for Member States, and brings benefit to business and consumers from the single market.

Informed, empowered, confident and demanding consumers spur competition, drive innovation and growth and stimulate business efficiency. *EU Consumer policy* improves consumer welfare through greater empowerment and effective protection. It contributes to a thriving internal market where goods and services are safe, and where consumers have an equally high level of confidence in products, traders, technologies and selling methods throughout the EU.

The cost-benefit of our actions is clear: a study has showed that the losses reported by European consumers, from problems for which they had a cause for complaint, are estimated at approximately 0.3 % of EU GDP. Our actions to facilitate the development of a European market for e-commerce help eliminate barriers to cross-border shopping, which could lead to aggregate gross savings of around €5.3 billion per year to European consumers.

Public health is a key driver for competitiveness and growth in an ageing Europe. Investment in health delivers value for money for society and for citizens. A healthy population means more productivity, more time at work, more employed people, older people at work and less demand on healthcare. 10% fewer deaths at working age due to cardiovascular diseases would give a 1% increase in GDP per capita. A healthy Europe is a cornerstone for economic success in a highly competitive, globalised world. The health of the European population plays the vital role in determining a successful delivery of Europe 2020 objectives aiming at smart, sustainable and inclusive growth.

*EU health policy* helps restore growth by supporting and supplementing Member States' action to address key challenges including health inequalities. The value of investing in preparedness, prevention and coordination of measures on health threats and communicable diseases at EU level was clearly demonstrated in the H1N1 outbreak in 2009. Strengthening the capacity to manage serious cross border health threats is an area where significant EU added value can be obtained. We can also deliver significant benefits from EU action on the development of cost-effective health technologies and innovative healthcare, cross-border issues such as cross border healthcare, health inequalities and the promotion of healthy ageing through a European Innovation Partnership. Many chronic diseases are preventable and are linked to risk factors such as smoking, alcohol-related harm, nutrition and physical



activity. The health, social and economic impact of non-communicable diseases was highlighted in the UN High Level Meeting of the General Assembly in September 2011.

In the pharmaceutical and medical device sectors, EU action is aimed at developing and maintaining a favourable environment for medicinal products and medical devices in the European Union. This guarantees a high level of protection of public health, through quality, safety and efficacy of medicinal products and safe and performing medical devices; contributes to the completion of the single market in medicinal products and medical devices, and fosters a stable and predictable environment for innovation in medical technology and competitiveness. The negotiations on the 2012 proposals for new rules on medical devices and in vitro diagnostic medical devices will be progressed as a priority in 2013, at the same time ensuring a stricter application of the existing legislation as laid down in the Action plan following the PIP Breast implants events. In 2013, the focus will be on the revision of the legislation for veterinary medicines. This will be combined with a review of the conditions for production of medicated feed, of which veterinary medicines are a raw material.

A high level of food safety remains a key public health and economic priority. Preventing and reducing the incidence of animal and plant diseases supports farming and the rural economy. The impact of major livestock diseases such as Avian Influenza or Foot-and-Mouth disease can be devastating on farmers and the economy as a whole. Maintaining a high level of animal and plant health is a key contributor to growth and jobs in Europe by ensuring that European farmers remain competitive. Equally, it ensures that the food industry, Europe's largest manufacturing sector and biggest employer, is supported by a regulatory environment which promotes high and uniform levels of safety throughout Europe.

Action at EU level against animal and plant diseases and pests is far more efficient and cost effective than individual efforts at Member State level. Member States cannot successfully control and eradicate animal and plant diseases in isolation, as their efforts would be undermined by the risk of re-contamination from neighbouring Member States. In addition, only common efforts by Member States can be successful to ensure that animal and plant diseases are not introduced into the EU from outside. Work will continue to achieve and sustain a high and harmonised level of EU policies for Food Safety, Animal health, Animal Welfare and Plant Health. This will materialise notably in 2013 with the proposal to review the EU animal health law, the EU plant health and seeds law and the approach to official controls.

Health is a top priority and concern for EU citizens: it is the first element that citizens consider as important in their life. Consumer policy is crucial for enhancing product safety and the economic interests of citizens.

A strong emphasis on implementation and enforcement will help fully unlock the potential of the Single Market. Our work co-ordinating and supporting the enforcement of EU requirements ensures citizens' security and safety and a level playing field in which the competitiveness of our industry can develop. This in turn can help strengthen the competitiveness of European exporters on world markets, supported by the high levels of consumer confidence in the safety of their produce.

2013 will see a particular focus on the review of the product safety rules, which can play a key role in building consumer confidence in the Single Market.

We also enable the Member States' market surveillance authorities to raise their game (despite the often limited resources) and cooperate effectively and efficiently in monitoring the safety of products made available to European consumers, to make the strong point that unsafe products have no place on the European market. We also highlight the principle of safety at source, asking manufacturers anywhere in the world to take their responsibilities and make their designs and exports safe, with the help of our outreach communication efforts as appropriate.

We will also act to impact the framework for citizens, in pushing for greater transparency on bank fees and flexibility on transfers.

We will contribute to the innovation and economic growth objectives by instilling confidence in new technologies through better integration in our policymaking of accurate public perceptions of risks, different cultural preferences, possible scientific uncertainties and other legitimate factors.

Programmes funded as part of the EU's health and consumer policies contribute to the well-being of European citizens. The added-value of EU health and consumer programmes lies in their capacity to tackle issues that could not be addressed as effectively by Member States acting alone. For example, activities to promote cross-border shopping or to respond to major challenges, diseases or pandemics affecting several Member States require a coordinated and coherent response. Similarly, animal and plant diseases do not respect national borders. Ensuring a uniform and high level of animal health and food safety throughout the EU enables the free movement of live animals and animal products, which is essential to the functioning of the single market, benefits consumers through greater choice and increased competition, and allows EU food producers to enjoy economies of scale.

We will work hard to demonstrate the EU value from the funding for our programmes set out under the multi-annual financial framework from 2014 onwards. We use the financial resources currently available efficiently and effectively. We will have to pay particular attention to the risk that national budgetary pressures undermine enforcement at national and local level and thus the potential benefits.

We work to enhance the credibility and accountability of our policies, and to develop strategic approaches to produce legislation and policy with real EU added-value. We will continue to develop open and participative policy-making with our stakeholders and to help the consumer voice be heard.

We will maintain and develop our unique capacities to manage and where possible predict crises and to communicate on risk in our policy areas, and to use our treaty powers for the effective enforcement of law.

We aim to improve the regulatory framework, through better regulation to maximize benefits and minimize burdens for society, applying the principle of subsidiarity, and in particular by demonstrating the added value and the necessity of EU action. Our ever-improving understanding of motivations and the main determinants behind consumer and health-related behaviours help produce smarter regulation and to use

tools such as social marketing and self-regulation to achieve positive behaviour change towards healthier and more sustainable lifestyles.

Our food, consumer and health policies are part of globalised systems, and we take this into account in developing our policies. Our partners should see Europe as a true 'World Partner' on the international scene, leading efforts at improved levels of protection and reinforcing the role of internationally accepted standards. This ensures that trade can take place on a safe basis.

These principles provide the crucial underpinning for the development of the long term strategies for health, consumers, animal health and welfare, plant health, seeds and food safety.

We recognise that delivering effective policies requires close cooperation with national governments and law-making through both regulation and self-regulation, with a particular focus on enhanced enforcement, within the EU and at our borders.

## 4. GENERAL OBJECTIVES WITH A MULTI-ANNUAL PERSPECTIVE

Our actions are essential for achieving the Commission Work Programme strands of restoring growth and pursuing a citizen's agenda. In doing this we contribute also to the two remaining work programme strands by operating an ambitious external agenda and applying modernised work methods.

### Consumer Policy

The European Consumer Agenda - adopted in April 2012 - presents the strategic vision for EU consumer policy for the years to come. The Agenda puts consumers at the centre of the Single Market by building on four main objectives. It aims to increase confidence by reinforcing consumer safety; enhancing knowledge; stepping up enforcement and securing redress; aligning consumer rights and policies to changes in society and in the economy. The Agenda supports consumer interests in the following key sectors: Food, Energy, Financial, Transport and Digital.

The Agenda also stresses the importance of pursuing an evidence base approach. Our work on consumer market monitoring (in particular market studies) is a key to embedding the consumer interest in Commission wide policy. The Consumer Market Scoreboard has been developed to systematically monitor the outcomes of the internal market and national markets from a consumer perspective. The scoreboard aims to identify failing markets, in terms of economic or social outcomes, using key indicators such as complaints, prices, satisfaction of consumers, data on switching and safety, as well as sector-specific indicators whenever possible. The markets identified as a result become the subject of in-depth market studies.

### Health

Healthcare systems and population health have a crucial role to play in achieving the targets of the **Europe 2020** strategy.

Extending the health EU citizens enjoy is a goal worth pursuing in its own right and health is a value in itself based on universality, access to good quality care, equity and solidarity.

Health also clearly plays an important role in the overall economy and society. Health of the population and the proper functioning of financially sustainable health systems are preconditions for smart, sustainable and inclusive growth. Positive effects are noted in terms of improving population employability, generating high-quality employment, offering an effective safeguard against poverty and beneficial spill-overs from sustained research and development efforts. A population in good health means a more productive workforce, lower healthcare costs and therefore a more competitive economy.

The EU Health Strategy sets out an over-arching framework for EU action on health through legislation, cooperation processes between Member States and via the financial support provided by the Health Programme. The three objectives of the Strategy are:

- (i) Foster good health in an ageing Europe;
- (ii) Protect citizens from health threats;
- (iii) Support dynamic health systems and new technologies.

The objectives are related to broader objectives set by the Commission across policy areas and contribute to the implementation of the Europe 2020 strategy. This is a key focus of the proposed Health programme for the forthcoming MFF (2014-2020). 2013 will be a transition year in this context from the current programme towards the new one.

- (i) Foster good health in an ageing Europe;

The Commission will continue in 2013 to develop the active and healthy ageing partnership and to develop further actions addressing the prevention and management of chronic diseases and work on health determinants. It will also continue to promote the use of safe, innovative and cost-efficient health products, technologies and systems. The Commission will continue to ensure, through EU wide legislation, the functioning of the internal market and the quality and safety of health products (pharmaceuticals, medical devices, substances of human origin) and the regulation of the products affecting health (tobacco products).

- (ii) Protect citizens from health threats;

Communicable diseases, including pandemics, major physical, biological and environmental incidents and bioterrorism all pose major threats to health. It is a core part of the role of the EU in health to coordinate and respond rapidly to health threats globally and to enhance the EU's and third countries' capacities to do so.

- (iii) Support dynamic health systems and new technologies.

The current economic context has put more emphasis on the need to address in a more coordinated way at EU level the pressure on health systems and to work towards more sustainable health systems.

In 2013 the Commission will continue to work with the Member States within the reflection process on health systems with a view to identify and recommend best practices. Health system reform is becoming an item to be further considered as part of the European Semester.

The Commission will continue to work on improving patient safety by following up to the Council Recommendation on patient safety (2009/C 151/01) for which an implementation report was issued in November 2012 - based on information received from Member States.

## **Food and Feed Safety, Animal Health, Animal Welfare and Plant Health**

A high level of food safety is essential to achieve key public health and economic objectives of the EU. Safe and nutritious food is essential to the health and well-being of the European population. It is also essential to enable the food industry, Europe's largest manufacturing sector and biggest employer, to operate in a marketplace protected from the massive disruption which can result from unsafe food. The EU's food safety policy has three general objectives:

- (i) ensure food and feed are safe and nutritious;
- (ii) ensure a high level of animal health, welfare and plant health protection;
- (iii) ensure adequate and transparent information about origin, content and use of foods.

These general objectives are pursued through a holistic approach to the food chain, encompassing legislation, enforcement, communication, scientific advice and international cooperation, while contributing to competitiveness and a sustainable environment.

The EU has put in place a sound and comprehensive regulatory framework to ensure that both consumers and businesses can be confident in the safety of food and the capacity for trade to take place under safe conditions, both between Member States and with third countries. This is reflected in the increasingly integrated European marketplace and the success in both tackling risks to food safety and controlling and eradicating certain animal diseases and plants pests. However, it remains a major challenge to ensure that this framework is fit for purpose given the size, sophistication and complexity of the food chain and the high costs, both human and economic, which can result from system failures. The Commission meets this challenge through an insistence on strict enforcement by Member States of the legislation on food safety and by continually innovating, adapting and where necessary re-designing the EU regulatory framework to ensure it achieves its aims.

In 2013, a range of measures are planned which support the above objectives. The focus will remain on ensuring that consumers remain confident in the safety of their food and that the EU regulatory framework supports an innovative, competitive and high value added food industry founded on high levels on consumer confidence. Enforcement of legislation will continue to be a priority, to ensure a level playing field where safety is not compromised by poorly implemented controls. Efforts will continue also to ensure that measures get the balance right between being firmly based on science but also taking account of wider societal concerns that food should be produced in a sustainable, resource efficient and environmentally-friendly manner. Reduction of food waste will be a key action towards producers, processors, distributors and consumers.

Major new policy initiatives are under development aimed at ensuring that Europe continues to have a safe and nutritious food supply adapted to new challenges and changed circumstances. A complete review of two main pillars at the very start of the food chain will shape a new landscape for the Plant Health regime and Plant Reproductive Material regime. In the area of animal health, work will progress on a

new EU Animal Health Strategy aimed at more effectively tackling existing and newly emerging disease threats. Greater focus will be placed on preventive measures in order to reduce the incidence of animal diseases and minimize the impact of outbreaks when they occur.

The safety of food and feed is based on clear and predictable authorisation processes, which apply to products and substances to be used in the production of primary products as well as in the processing of these products, such as pesticides, GM, additives and flavourings. These are areas with significant potential for growth and innovation and where Europe is already a world leader. For some of these products the EU has recently put in place sophisticated authorisation processes allowing industry to plan and predict their market activities. This allows the relevant industry to have access to the whole EU as a market, which strengthens their competitiveness in the framework of the 2020 agenda.

Once the safety of products is assessed by EFSA, authorisations can be granted allowing the free movement of food products on the market. As the safety standards in the EU are among the highest in the world, products which are authorised for the EU market will further benefit from these high standards. A level playing field, where high levels of safety are the norm, is the precondition for enterprises to develop jobs and trade in an integrated EU market, and is a driver for economic growth.

### **Cross-cutting objectives**

Four decentralised agencies, one executive agency and three scientific committees also participate in and support the Commission in achieving the objectives of the three policy areas of consumer policy, public health and food and feed safety:

- the Community Plant Variety Office (CPVO) grants intellectual protection for new plant varieties throughout the EU,
- the European Centre for Prevention and Disease Control (ECDC), works to prevent disease outbreaks and to react quickly and effectively to minimise their impact,
- the European Food safety Authority (EFSA), provides independent scientific advice on food safety,
- the European Medicines Agency (EMA), evaluates and supervises medicines for human and veterinary use;
- The Executive Agency for Health and Consumers (EAHC) implements the EU Health Programme, the Consumer Programme and the Better Training for Safer Food (BTSF) initiative.
- The European Commission Scientific Committees, the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER), and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), provide independent scientific advice.

Regulations are based on good scientific knowledge. Risk assessment remains a challenge shared by these decentralised agencies [except CPVO] and the three

Scientific Committees. We have revised our procedures to enhance coordination and coherence on governance regarding the decentralised agencies. We have included in the overall coordination the follow-up of the joint statement issued by the three European institutions.

In pursuing the work we use a number of different tools:

**Early warning and crisis preparedness** are essential to deal effectively with the human, animal or plant health emergencies that may emerge, and to ensure the rapid withdrawal of unsafe products from the market.

In recent years much of the focus has been on communicable diseases and the preparation for a possible pandemic. With the proposal for a decision on serious cross border threats to health the scope for health security has been extended to threats arising from other biological threats, chemical events and environmental hazards with an impact on public health. The generic and specific preparedness structures are constantly strengthened in terms of planning and coordination, monitoring and assessment, prevention and containment, health system response and communication, together with our partners such as EFSA, EMA and ECDC.

We have rapid alert and traceability systems which provide rapid and user-friendly information on consumer, food and feed and public health alerts and flow of relevant products (food, animals, etc). The functioning of EU-wide mechanisms for information exchange, consultation, coordination and operation related to the handling of health-related emergencies need to be ensured. To further support the objective, for example, a new alert system on tissue transplants was developed in 2012 and a new Animal Disease Information System (ADIS), well integrated with similar international systems, is being developed with a view to be operational by 2013.

Where an audit by the Food and Veterinary Office (FVO) identifies an immediate threat to consumer, animal or plant health, the Commission may take emergency ("safeguard") measures.

We ensure sustainable and flexible **business continuity mechanisms** covering both normal working arrangements, dealing with the management of relatively low level product safety and food and feed crises; and specific arrangements that may be needed in emergency situations, such as a serious outbreak of animal or human disease, or a major disruption to our work.

In the animal health area an external evaluation of the EU emergency preparedness and crises management system, done in 2012, confirmed that the system works well, nevertheless suggested some changes on certain areas for further improvement and simplification. This evaluation will be duly followed up in 2013 both in the legislative proposal for an EU Animal Health Law (CWP 2013) both by other, non-legislative means (training, coordination, technical assistance etc.) to ensure their best implementation.

**Better implementation and enforcement** of existing legislation is crucial: over 75% of our resources are devoted to this in any given year. Proper enforcement is key to both ensuring a high level of safety and to avoid problems in trade. We are pursuing two goals: developing rules which are easier to implement and update, and making



enforcement networks across Europe more efficient. Stakeholder's views help us to identify priority areas for action.

The FVO's audits are crucial for ensuring effective implementation in the fields concerned. As the "eyes and ears" of the Commission, the FVO plays an important role in verifying on the spot that controls are properly and effectively implemented by Member States and also by third countries' authorities. The reports of the FVO also provide a solid basis for ensuring that legislation is kept up to date.

Effective controls are an essential factor in maintaining high levels of consumer protection, animal health and plant health. The Better Training for Safer Food (BTSF) initiative assists in achieving harmonized and high standards controls which in return ensure a level playing field, a precondition for enterprises to develop jobs and trade in an integrated EU market. Annually around 6000 official control staff from Member States and third country national authorities are trained, in a programme of 160 conferences per year, to ensure that staff are kept up-to-date with relevant EU law in these areas.

Based on experience, food, animal and plant legislation is under constant review and simplified for better implementation and enforcement (reference to Hygiene package review in CWP 2013 Simplification).

In **health**, implementation of key legislation will continue in 2013: with the entry into force of the Directive on patient's rights in cross-border healthcare and the accompanying implementing legislation; and through further implementation measures strengthening the safety of pharmaceuticals through the entire supply chain, from the active ingredient to the patient. Once adopted, a thorough and appropriate implementation of the decision on serious cross border threats to health - currently in codecision procedure- will be crucial in the area of health security.

The Rapid Alert System for non-food consumer products (RAPEX) network, operating under the General Product Safety Directive and the Rapid Alert System for Food and Feed (RASFF) are able to identify products posing a serious risk and removing them from the market. The newly developed Rapid Alert on Tissues and Cells (RATC) strengthens the safety and quality of tissue transplantations. It is envisaged to roll out adapted systems for the fields of organ transplantation and blood transfusion.

The Consumer Protection Cooperation (CPC) network, which links enforcement authorities in the Member States, will continue to carry out joint actions to target on-line markets generating complaints from consumers and to prepare the review of the CPC Regulation due by end of 2014.

The network of European Consumer Centres (ECC-Net) which helps consumers resolve their cross-border problems also contributes to identifying areas where further efforts may be needed. Over the years, the ECCs have carried out joint projects analysing consumer complaints on key issues such as e-commerce, air passenger rights, alternative dispute resolution mechanisms in Europe. These reports offer a valuable insight about how citizens' experience the Single Market.

In the field of cosmetic products a new European IT portal is operational since early 2012. It will be further developed to include by mid 2013 detailed information on all

cosmetic products on the EU market so that Member States competent authorities and European poison centres can respectively better conduct market surveillance activities and prompt the appropriate medical treatment of citizens in the event of poisoning cases involving cosmetic products. A new module of the portal is also developed for nanomaterials to be operational early 2013 which will enable the cosmetics industry to meet the requirements of notifying the nanomaterials they intend to use in their products. On the basis of the data submitted, and should concerns be raised regarding the safety of nanomaterials, the Commission will be able to seek an opinion from the SCCS.

**Integration** across EU policies and activities remains essential in order to ensure that they are mutually supportive and coherent. The Treaty stresses in particular the need to integrate the health, consumer and animal welfare dimensions when formulating and implementing other EU policies. Integration has been highlighted in particular in the Consumer Agenda and Health Strategy.

The Health Strategy has put Health in all policies (HIAP) as one of its four key principles. As an example, increasing concerns on the trends of antimicrobial resistance (AMR) requires continuous attention involving other Commission services and concerned scientific agencies. Risk management strategies and consideration of further prevention and control options are being defined.

The evaluation and assessment of scientific evidence by the Commission Scientific Committees, the European Medicines Agency, the European Food Safety Authority, and the European Centre for Disease Control and Prevention will continue to underpin science based policy making in the EU in order to ensure the highest possible level of health and consumer protection.

The role of scientific evidence in the decision making process for public health is becoming increasingly important on all levels of decision-making. Evidence-based public health means integrating the best available evidence with the knowledge and considered judgements from stakeholders and experts to benefit the needs of a population.

Particularly in the work of the European Centre for Disease Prevention and Control (ECDC), data from observational studies, surveillance and modelling are key elements of evidence base, and more evidence-bases has been written in its work programmes. Furthermore, outbreak investigations need to be better performed and reported as information can only be gathered while an outbreak is on-going.

In the work of ECDC and EFSA uncertainties can arise while producing a risk assessment, as well as during any stage of the decision-making process. That makes transparency and communication to the policymakers extremely important, especially because with time, access to evidence increases and uncertainties can be reduced.

The Consumer Agenda presents a comprehensive vision of the integration of consumer interests into EU policies. It identifies the following priority areas: Digital/telecommunication, financial services, energy, transport, food and sustainable consumption. The results achieved on the integration of consumer interests into EU policies will be presented regularly in a report to the European Parliament.

We will continue raising awareness throughout the Commission on the need to fully incorporate consumers' interests and patient's needs in policy design in order to deliver concrete benefits for businesses and final users - EU citizens as consumers and patients. We will work towards getting political support for these integration priorities, in particular through the Groups of Commissioners on the Internal Market, on the Digital Agenda and on the Innovation Union, and through close bilateral cooperation with all relevant Commission services, including the debate on the future CAP and cohesion policy - post 2013.

**Better regulation** remains high on the agenda, and we will continue to endeavour to be among the pace-setters. Rules that are easier to implement and to keep up to date with evolving needs are a key objective. Our legislation can only work effectively if it is well designed transparent and up to date. Policy needs to be evidence driven: better use of Impact Assessments and the full use of quantification of administrative burden and of associated benefits facilitate this. We will continue to pioneer the use of behavioural approaches and tools within the Commission.

**Communication** today is more than ever important. People all over Europe are unsure about their future due to the economic crisis. One basic principle lies at the heart of the health and consumer portfolio: confidence. Passing on these values to the citizens are an integral part of our policies and necessary to maintain and further strengthen our reputation of honest broker and safeguard for healthier, safer, more confident citizens. We will seek more synergies amongst the different policies and resources of the DG and across DGs; and allow a horizontal approach for a more global, efficient and effective communication.

Our communication objectives will also reflect the Commission's horizontal priorities, in particular with regard to communicating tangible rights and benefits emanating from the EU citizenship, and namely in cross-border situations. To this end, we will use the full range of tools - from the web, over video, events and publications to social media - to reach our stakeholders and in particular citizens throughout the EU, including those at the outermost corners where awareness of the benefits brought by our policies is still a challenge.

We will make a particular effort to tell real life success stories, illustrated by the data we collect and thus contribute to a better dissemination of our important messages. We also identify opportunities to enhance the impact of our communication by pooling our data with similar information from other partners, such as agencies, representations, stakeholders and other organisations.

Through communication we can empower citizens so that they can directly benefit from the rights embodied in our policy and legislation.

On **good governance**, we will continue to develop participative processes. The Advisory Group on the food chain and animal and plant health includes our stakeholders in the food chain. In consumer policy, the annual European Consumer Summit is the main multi-stakeholder event and the Open Health Forum for health policy. We will also pursue our multi-stakeholder approach on specific issues through the multi-stakeholder Working Group on Transparency in EU Retail Energy Markets as a complement to our relations with consumer organisations (through e.g. the ECCG -

European Consumer Consultative Group), the Nutrition Platform, the Alcohol Forum, etc. As a follow up to the workshops at the Consumer Summit 2012, we will coordinate the Multi-stakeholder Dialogues on Environment Claims and Comparison tools to identify the best practices and deliver recommendations.

### **International relations**

Globalization has a dominant influence on the context in which we create and implement our policies. The Union is the world's biggest food importer and one of its biggest food exporters. It is also a key player in the international trade of health products and the largest single market for consumer goods. In this context, it is important to ensure that the EU plays a full role at global level as a leading partner in health, food and feed safety and consumer matters in bilateral and multilateral relations and in international organisations.

Stronger international relationships will be pursued as a cross-cutting objective to ensure that our goals can be reached in this increasingly interlinked world. We will continue to promote the European policy model and safety standards, in order to enhance global governance and to support common interests among regulators, consumers, health professionals and business as well as a high level of health protection. We will aim for fair and adequate participation in the debate and consultation on EU policies for third country institutions and stakeholders, notably NGOs and economic operators. In consequence, in certain policy areas the international aspects represent up to 20% of the total work.

We will pursue these objectives through:

#### ***Multilateral rule making and governance cooperation in different fora:***

As part of its global health policy the Commission collaborates with the World Health Organisation and contributes actively to many international activities relating to health security, medicinal products, products of human origin, public health etc.

In the field of public health information we are stepping up trilateral cooperation with WHO and OECD.

We participate in multilateral fora aiming at the convergence of regulations in the field of medical products and cosmetics, such as the International Cooperation for Cosmetics Regulation (ICCR), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) on the one hand and for veterinary medicinal products (VICH) on the other hand, and the Global Harmonisation Task Force for medical devices (GHTF); the latter undergoing transition towards a more inclusive and more operational International Medical Device Regulators' Forum (IMDRF) for which Europe is likely to take the chair in 2013.

We will keep up our efforts to properly represent EU interests in the World Trade Organisation (Agreement of Sanitary and Phytosanitary measures) and in the international standard-setting bodies (Codex, OIE and IPPC). We will continue our efforts to ensure that all the obligations derived from our membership of the WTO are fulfilled, including defending our interest when trade disputes arise.

Through our membership of the Codex Alimentarius Commission we will maintain a leading role, in close cooperation with the EU Member States, to promote our values and interests on food safety standards. Our aim is to ensure that international standards for food are based as far as is possible on EU norms and values and, where this is not possible, that the effects of a trade dispute are kept to the minimum. We will continue to promote our policy to ensure that trade can continue to take place under safe and fair conditions.

We contribute to improved animal health standards which are better aligned to EU rules and to their implementation at international level through the World Organisation for Animal Health (OIE) to protect the health of animals, to ensure a safe and fair trade in animals and animal products worldwide..

In the consumer policy area, we will continue to engage strongly in multilateral information sharing on policy effectiveness. Within the OECD, we contribute actively to the dedicated working party established to make more concrete the recommendations to enhance internationally consumer product safety information sharing. As concrete actions, as of 2012 together with other members, we have started pooling information about recalls and other similar measures taken against dangerous non-food products. We plan now to use this increased and better organised information in policy work and will encourage Member States to consider if it provides useful input when identifying enforcement priorities. This adds intensity to the otherwise continued regular participation such as the work on a toolkit for policymakers and on consumer-oriented indicators. We will moreover engage in policy development forecasting and information exchanges on policy issues, in particular in networks such as the International Consumer Product Safety Caucus (ICPSC) and the International Consumer Protection and Enforcement Network (ICPEN). We encourage and give advice where asked regarding regional initiatives pooling consumer safety information in different parts of the world.

In the field of plant health, the Commission is a contracting party of the FAO International Plant Convention Organisation (IPPC) and collaborates actively in preparation of the EU position for the Commission on Phytosanitary Measures (the annual IPPC management meeting), and the ongoing development of new international standards for the management of quarantine pests and diseases for plants. At regional level, the Commission participates as an observer to the European and Mediterranean Plant Protection Organisation (EPPO), an inter-governmental organisation with 50 member countries from Europe and the Mediterranean region. In the field of biotechnology, the EU is a party to the Cartagena Protocol under the Biodiversity Convention and participates, together with the Member States, in the development and implementation of its provisions to ensure the safe transfer handling and use of GMOs.

Concerning the field of plant reproductive material, we are actively participating in the development of international rules for certification of seed (Seed Schemes) and forest reproductive material (Forest Scheme) in OECD and for seed potatoes in United Nations Economic Commission for Europe (UN-ECE). As regards the intellectual protection of plant varieties the EU is a contracting party to the International Union for the Protection of new Plant Varieties (UPOV) where we contribute, with the help of CPVO, to the improvement of the standards in a number of technical meetings. In

addition, the EU is a party to the International Treaty on Plant Genetic Resources for Food and Agriculture and participates, with the Member States, in its implementation to ensure the conservation and sustainable utilisation of plant genetic resources. For the all the annual meetings of these four organisations we coordinate the EU positions.

***Bilateral relations:*** Our existing bilateral agreements in the field of food and feed safety, animal health and animal welfare, as well as consumers and health, are implemented in a way to ensure effective co-operation and the smooth trade in safe products. We will continue to work with the USA to build towards a global network on consumer product safety and enforcement cooperation. While no formal agreements with the USA in these areas have yet been finalised, an active bilateral cooperation has become a regular feature and allows both sides to improve the use of existing information and development of policies.

We will also continue to support the Transatlantic Consumer Dialogue (TACD) which is the only forum bringing together consumer organisations from both sides of the Atlantic. It will be important to engage further with the US side in order to ensure that both sides shoulder the responsibility for funding the TACD.

Our existing Memoranda of Understanding (MoU) with the relevant authorities of China ensure continuous effective co-operation and is developed to include the new responsibilities of the Directorate General for Health and Consumers in the fields of medicinal products, medical devices and cosmetics.

***Training and technical co-operation:*** We will continue to step up our work on the provision of technical assistance to developing countries, notably through a range of training seminars on EU food safety standards and rules organized through the initiative Better Training for Safer Food (BTSF). These third countries are very heavily dependent on exports of food and agricultural products to the EU and our sanitary measures are often an important market access barrier. SANCO is increasingly active in assisting capacity building and technical assistance efforts, through its in-depth knowledge and experience, including the reports of the Food and Veterinary Office. Contributions to the preparation of candidate countries for EU accession and regional initiatives (such as the European Neighbourhood Policy) processes will continue. Also training on the RAPEX system is an established part of our capacity enhancing efforts and demand is still growing.

To measure the results of our work we use different ***impact and result indicators***, mentioned in the following tables of objectives for the DG and for each activity area. These represent our best approximation to assess the outcome of our work. Many of the indicators are not dependant solely on our efforts, but are also influenced by other broader factors (e.g. socioeconomic changes, political priorities, media attention, etc.). It is important that the results are interpreted in that context.

GENERAL OBJECTIVES		Impact Indicators																		
	Objective	Indicator	Target (long-term)	Interim milestones	Current situation															
1	Put European consumers at the heart of the Internal Market	Consumer Conditions Index <sup>1</sup>	67 by 2020 (on a scale of 100)	65 in 2016 (on a scale of 100)	62 in 2011 (on a scale of 100)															
2	Protect and improve human health	Number of Healthy life years (HLY) at birth <sup>2</sup>	2 years increase by 2020	increase by 2013 <sup>3</sup>	<table border="1"> <thead> <tr> <th>EU27</th> <th>Female</th> <th>Male</th> </tr> </thead> <tbody> <tr> <td>2010*</td> <td>62.6</td> <td>61.7</td> </tr> <tr> <td>2009:</td> <td>62.0</td> <td>61.3</td> </tr> <tr> <td>2008:</td> <td>62.2</td> <td>61.1</td> </tr> <tr> <td>2007:</td> <td>62.6</td> <td>61.7</td> </tr> </tbody> </table> <p>* for 2010, data is provisional and estimated by Eurostat.</p>	EU27	Female	Male	2010*	62.6	61.7	2009:	62.0	61.3	2008:	62.2	61.1	2007:	62.6	61.7
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3	Ensure food is safe and wholesome	Incidence of Main food-Borne disease (BSE and salmonella) in the EU	<p>BSE: progressive reduction to maximum 10 cases per annum by 2015</p> <p>Salmonella: Sustained negative trend to reach less than 50,000 Salmonella cases by 2018</p>	Each year a 20% decrease in BSE cases and 5% decrease in salmonella cases in humans compared to previous year	30-45% annual % decrease in BSE cases between 2004 and 2011 and 5 % decrease in human salmonella cases compared to previous year															

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<sup>1</sup> The Consumer Scoreboard is the Commission's main tool to monitor the Single Market from a consumer perspective. The Consumer Conditions Index provides an overview of the key indicators describing the consumer environment at national level, as measured through surveys of perceptions, attitudes and experiences of consumers in particular.

<sup>2</sup> This indicator is not entirely under SANCO control; it depends also on actions taken at Member State level

<sup>3</sup> The timeliness of the indicator is around 15 months for most countries, but can be longer in some cases; therefore data for 2013 will not be available for all EU countries until mid-year 2015. The overall accuracy of the HLY indicator is considered to be high; however the indicator is served best by viewing its long-term trend.

## 5. ABB ACTIVITIES

### 5.1. Activity "Consumer Policy"

The European Consumer Agenda - the strategic vision for EU consumer policy adopted in April 2012 - is built on four main pillars:

- Reinforcing consumer safety: for goods, services and food, strengthening the regulatory framework and making market surveillance more efficient.
- Enhancing knowledge: to cope with the increasing complexity of markets, where consumers need the right tools and information to understand everything from the real cost of consumer credit to finding the right place to complain. This is important for both consumers and traders, and the role of consumer organisations is key.
- Improving enforcement and securing redress, without which rights cannot exist in practice. This is all the more relevant given that the detriment suffered by European consumers incurred from problems resulting in complaints is estimated at about 0.4 % of EU GDP.<sup>1</sup> The role of consumer enforcement networks<sup>2</sup> is central.
- Aligning policy to societal change and making it relevant to daily life: to adapt consumer law to the digital age and tackle problems consumers face online; to factor in the needs of vulnerable consumers; to make sustainable choices easy.

It also presents a number of specific initiatives to be implemented by 2014.

Finally, we will continue to pursue our evidence base approach.

#### IMPROVING CONSUMER SAFETY

*More effective enforcement of the product safety system both within the EU and by our main trading partners will be developed further. As one of the twelve key objectives of the Single Market Act II, we propose, in close cooperation with other competent Commission departments, to present to the co-legislators a comprehensive package on product safety and market surveillance including a modernised General Product Safety Directive, a new "Single Market Surveillance Regulation" and a multi-annual market surveillance plan.*

The new Package proposes a streamlining and simplification of the current rules, leading to reductions in costs and administrative burden for economic operators and national authorities. It will also strengthen the coordination between national authorities responsible for market surveillance. This will improve cross-border cooperation, prevent free-riding by rogue operators and improve protection overall.

Product safety policy integration in trade and other international agreements continues. We invest in implementing the extended scope of the Memorandum of Understanding with China. A joint enforcement cooperation project between the EU and China launched in 2012 will aim to ensure in the coming years that products coming to Europe are carefully monitored all along the supply chain.



We continue our regular and fruitful bilateral cooperation with the US. In June 2012, in the framework of a high level Trilateral, we have agreed with our colleagues from the US and China to continue our market surveillance cooperation, especially by better understanding the rules and practices in other jurisdictions, improving product traceability and advising manufacturers about legal requirements. We also seek progress on other identified ideas of enhanced global governance of product safety, in particular in the context of the International Consumer Product Safety Caucus (ICPSC) and in the OECD Committee of Consumer Policy dedicated working party. We also continue to generate more and state of the art European standards for non-harmonised consumer products, so as to guide manufacturers and suppliers and to improve the compliance with the general safety requirements. We are engaging in discussions with some international partners to seek also convergence of standards on selected children's products.

We will launch a debate about the desirability of EU level action on the safety of tourism services in particular accommodation and connected services such as swimming pools and wellness-centres, amusement parks and outdoor leisure activities. In the area of rapid alerts on dangerous (non-food) product we are planning to further reinforce the network of Member State market surveillance authorities and increase the cooperation with customs and other authorities thanks to the efficiency gains from updated IT tools.

In the field of cosmetics, we will monitor the implementation of the full marketing ban of cosmetics tested on animals as of March 2013.

<b>ACTIVITY CONSUMER POLICY</b>		
<b>SPECIFIC OBJECTIVE: IMPROVING CONSUMER SAFETY</b>		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target</i>
% of RAPEX notifications entailing at least one reaction (by other Member States)	43% (843 notifications) in 2010	Increase of 10% in 2020
Ratio number of reactions / number of notifications (serious risks)*	1.07 in 2010	Increase of 15% in 2020
<b>Main outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Comprehensive legislative and non-legislative package including a modernised General Product Safety Directive, a new horizontal Single legislative instrument for Market Surveillance (regulation) and a multi-annual action plan for market surveillance (with DG ENTR)</li> <li>- Broad consultation on the safety of certain consumer services</li> <li>- Launch of the module of Nanomaterials - Cosmetic Products Notification Portal (CPNP)</li> </ul>		
<b>Main expenditure-related outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Development of the IT tools for the Cosmetic Products notification Portal (CPNP) module on Nanomaterials</li> <li>- Joint actions between national authorities of EU Member States and EFTA/EEA countries to improve the effective application of the GPSD regulation</li> <li>- Collaboration with the OECD Consumer Cooperation Policy working party on product safety</li> </ul>		

## **ENHANCING KNOWLEDGE (Consumer information and education, and support to consumer organisations)**

Important information about the outcomes for consumers of the Internal Market and national markets is available through the Consumer Scoreboard. In 2013, the ninth and tenth editions of the Scoreboard will be published in spring and autumn. The spring Consumer Conditions Scoreboard will focus in particular on the cross-border retail internal market and the consumer environment in the Member States. The autumn Consumer Markets Scoreboard will rank the 51 most important consumer markets according to how well they function for consumers. Market studies on the vehicle fuels market, on the market for second hand cars (as a follow-up to the 8th Consumer Markets Scoreboard of November 2012), on voluntary food labelling schemes and on green claims in non-food markets will be completed in 2013. Behavioural studies on tobacco, food information and credit card payments will be finalised, while others are planned on issues including online gambling and vulnerable consumers, and impact of sustainability information on consumer decisions. A study on consumer vulnerability in key markets will be launched in response to the European Parliament's resolution on strengthening the rights of vulnerable consumers. The studies will deliver policy recommendations aimed at improving consumer conditions. The findings of the autumn Scoreboard will be used to identify further market studies. Consumer data will also be used to properly integrate the consumer dimension in the Commission-wide market monitoring exercises.

The Staff Working Document on Knowledge Enhancing Aspect of Consumer Empowerment 2012 - 2014 issued in July 2012 will be revised and updated by the end of 2013 with proposed actions from 2014 onwards. To this end we will consult with Member States and stakeholders, in particular on issues such as vulnerable consumers, adult education, exchange of best practices in awareness raising and options for strengthening the consumer movement in countries of East and South East Europe (as a follow-up to studies in 2011 and 2012).

Awareness raising efforts will focus on the 2013 European Year of Citizens campaign, and on the preparatory work for a campaign on consumer rights in Croatia in cooperation with Executive Agency (EAHC). A smart phone application for the European Consumer Centres network will be developed. Operating grants to EU-level consumer organisations will be evaluated.

The consumer education actions have been redeveloped following an evaluation in 2011. An interactive educational platform targeting teachers of students in secondary school will be launched in the first half of 2013.

As a follow-up of and based on identified training needs of Member States' consumer organisations' staff, on-line and off-line courses for national consumer organisations will be implemented within reformulated capacity building programme, starting in 2013.

We will advance the Multi-stakeholder Dialogue on Comparison Tools, initiated in 2012, which should provide the basis for guidelines to enhance the transparency and reliability of information intermediaries.

ACTIVITY CONSUMER POLICY		
SPECIFIC OBJECTIVE: ENHANCING KNOWLEDGE AND SUPPORT TO CONSUMER ORGANISATIONS		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target</i>
Number of complaint bodies and number of countries submitting complaints to the ECCRS	33 complaint bodies from 7 countries in 2012	70 complaint bodies from 20 countries by 2020
<b>Main outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Report on the outcome of the Multi Stakeholder Dialogue on comparison tools</li> <li>- Follow - up to the Staff Working Document on the knowledge enhancing aspects of consumer empowerment 2012-2014</li> </ul>		
<b>Main expenditure-related outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Launch of education interactive platform for teachers (Consumer Classroom)</li> <li>- Financial support to EU-level consumer organisations</li> <li>- Training courses for consumer organisations (interactive and inclusive new set of capacity actions)</li> <li>- Preparation of the information campaign in Croatia</li> <li>- 2013 Consumer Scoreboards</li> <li>- Public database for Scoreboard data</li> <li>- Market studies on second hand cars, on the vehicle fuel market, on voluntary food labelling schemes, on green claims in non-food markets</li> <li>- Study on consumer vulnerability</li> </ul>		

## IMPROVING IMPLEMENTATION: STEPPING UP ENFORCEMENT AND SECURING REDRESS

The European Commission President's policy guidelines consider the enforcement of EU legislation as a priority. We will pursue efforts with Member States to render enforcement more effective, efficient and consistent throughout the EU. We will launch the debate on how cross-border cooperation could be reinforced during 2013. We will receive input and comments on our initial ideas at a high-level event in spring 2013, adopt a reinforced strategy on enforcement and then consult all stakeholders via public consultation.

In late 2013 we will start assessing the various options to address the current problems in the context of an impact assessment as part of preparing the review of the CPC Regulation due by the end of 2014. As to the short-term actions we are discussing with Member States how to define multi-annual priorities for the annual Enforcement Action Plans of the CPC network. We will also continue to explore the best means of knowledge sharing and developing common understanding of consumer law and its enforcement within the network. We will continue to coordinate online enforcement actions (sweeps).

In order to promote consumers' rights and to make their access to these rights easier; we will continue maximizing the potential of the network of European Consumer Centres (ECC-Net) which provides information on consumer rights and supports consumers having a problem when shopping cross-border. We will strengthen in particular the visibility of the ECC-Net through various communication activities.

After the adoption of the legislative packages on Alternative Dispute Resolution and Online Dispute Resolution, we will monitor the transposition into Member States legislation and will adopt the relevant implementing and delegated acts.

We will also continue the work on a European framework for Consumer Collective Redress with a view to ensuring adequate level of redress for groups of harmed

consumers. This will be based on an initiative on common core principles which any future proposal on collective redress would observe.

<b>ACTIVITY CONSUMER POLICY</b>		
<b>SPECIFIC OBJECTIVE: IMPROVING IMPLEMENTATION, STEPPING UP ENFORCEMENT AND SECURING REDRESS</b>		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target</i>
Number of contacts with consumers handled by the European Consumer Centres (ECC)	71.000 in 2010	Increase of 50% by 2020
% of cases enforcement requests handled within 12 months within the CPC Network	50% (reference period 2007-2010)	60% by 2020
<b>Main outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Finalisation of negotiations/implementation of ADR proposal</li> <li>- Work on a European framework for collective redress</li> <li>- Staff Working Document on a reinforced enforcement strategy</li> <li>- Public consultation on options to develop a more efficient EU level enforcement capacity</li> </ul>		
<b>Main expenditure-related outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Development of ODR platform</li> <li>- Support to ECC network and actions to increase the ECC visibility</li> <li>- Joint enforcement actions in the framework of the CPC Regulation</li> <li>- Consumer Summit on enforcement</li> </ul>		

## **ALIGNING RIGHTS AND POLICIES TO ECONOMIC AND SOCIETAL CHANGE**

Enhanced action will be taken towards more effective integration of consumer interests in other EU policies.

The 2nd Annual Report to the European Parliament on the integration of consumer interests into other EU policies will be published at the end of 2013. Its preparation is coordinated through the Interservice Group on Consumer Policy which is the main platform for liaising with the other Commission services involved in consumer issues.

On *energy*, we will continue our efforts to promote well-functioning electricity and gas markets. Our objective is to enhance transparency in bills, prices and offers and empower consumers with meaningful information to guide their choice. We are also paying particular attention to vulnerable energy consumers. We are working within the framework of the Third Energy Package and the Citizens' Energy Forum. In doing so, the Commission will continue to support the European Consumer Consultative Group (ECCG) sub-group on Energy, which represents energy consumers in a competent manner dealing with often complex and technical questions. On energy efficiency, our focus is on helping consumers better manage and control their energy consumption at home, using smart meters and energy labelling of domestic appliances with a focus on consumer-friendly design and functionalities, data privacy and confidentiality of personal information.

In the *financial services* field, we will work towards promoting consumer capacity building, through the development and spreading of financial education and the

effective representation of consumer interests in financial services. We will also prepare by spring 2013, in cooperation with DG EMPL and DG MARKT, a consultative document on third pillar pensions analysing the possible measures to improve information and protection standards for consumers.

Together with DG MARKT we will work on the adoption of a legislative proposal on bank accounts, bank fees transparency and switching. The aim of the proposal will be giving all EU citizens access to a basic payment account, ensure bank account fees are transparent and make switching bank accounts easier. We will carry out an information campaign on the Consumer Credit Directive in selected Member States, and will publish a report on the implementation of the Directive.

On *transport* we will pursue our efforts to integrate consumer interests - such as accessibility, affordability and health in policies related to the decarbonisation of transport and to the future of transport in the EU. We will support work to strengthen the rights of air passengers in all means of transport and ensure consistency of protection across legislative instruments. We will continue to follow the proposal currently underway to revise the Directive on Package Travel.

We will contribute to the *Digital Agenda* initiatives, including in particular e-commerce, consumer access to digital services and content and consumer online rights. We will contribute to the legislative process on collective rights management, particularly with regard to multi-territorial licencing in music. We will keep pushing for a reform of the EU framework on copyright, which should open the way to innovative business models for the distribution of creative content and enable all European consumers, regardless of their place of residence, to have better access to legal offers that truly meet their expectations, particularly in the digital environment. We will stay closely involved in the mediation process on private copying levies, with the objective of a thorough reform of the system to the benefit of consumers. We will work to guarantee that consumers' fundamental rights are fully respected in the context of enforcement of Intellectual Property Rights online. We will continue to advocate for a stronger protection of the personal data of consumers, personal data portability and more clarity on how consumer privacy is safeguarded in the context of new digital technologies, such as mobile applications and the Internet of Things. We will also be closely involved in the implementation of the Cloud Computing Strategy, particularly in those actions that are of direct relevance to consumers such as contract terms, standardisation and data protection. We will work to ensure that consumers feel as empowered shopping online as offline, by raising awareness on their online rights and developing education tools to enhance their digital literacy.

We will contribute to ensure that consumers will enjoy open, accessible and affordable telecom services. To this aim, we will be committed in the initiatives related to net neutrality, the implementation of the telecom package, the revision of the roaming regulation and of the universal service obligation as well as the deployment of broadband access throughout the EU.

We will continue our work on integrating consumer interests into *sustainable consumption policies*. We will contribute to the implementation of the "sustainable consumption" actions in the context of European Consumer Agenda and in particular to

the discussions on environmental claims and green washing, launched at the European Consumer Summit in 2012<sup>1</sup>. In this respect, we will coordinate the Multi-stakeholder Dialogue on Environmental Claims to identify best practices and deliver recommendations. We will also manage and coordinate the EU study on environmental claims to provide information on the presence of green claims, their level of compliance, consumer understanding and enforcement practices. Our work will include as well engaging with and following actions, initiatives and commitments of stakeholders on sustainable consumption, e.g. in the context of the European Food Sustainable Consumption and Production Round Table - in particular the working group on information tools as co-chair, the Retail Forum for Sustainability or other relevant platforms. Lastly, we will contribute to the development of other consumer related initiatives that aim to foster more sustainable consumption patterns in areas such as food, transport, energy, labelling, corporate social responsibility, behavioural studies and consumer education.

<b>ACTIVITY CONSUMER POLICY</b>		
<b>SPECIFIC OBJECTIVE 4: ALIGNING RIGHTS AND POLICIES TO ECONOMIC AND SOCIETAL CHANGE</b>		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target</i>
Consumer assessment of the functioning of energy services	Consumer Markets Scoreboard 2012 (on a scale of 100) 72.9	75 by 2020
Consumer assessment of the functioning of financial services	73.3	75.5 by 2020
Consumer assessment of the functioning of transport services	75.4	77.5 by 2020
Consumer assessment of the functioning of telecom services	73.6	76 by 2020
<b>Main outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Legislative proposal on bank accounts, bank fees transparency and switching (with DG MARKT)</li> <li>- Report on the implementation of the Consumer Credit Directive</li> <li>- 2<sup>nd</sup> Annual report to the EP on the integration of consumer interests into other EU policies</li> <li>- Report on the outcome of the Multi Stakeholder Dialogue on environmental claims</li> <li>- Report to the Citizens Energy Forum 2013</li> </ul>		
<b>Main expenditure-related outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Behavioural studies in view of legislative development (e.g. online gambling and vulnerable consumers, online information on product energy performance)</li> </ul>		

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<sup>1</sup> See more info a [http://ec.europa.eu/consumers/events/ecs\\_2012/workshops1\\_en.htm](http://ec.europa.eu/consumers/events/ecs_2012/workshops1_en.htm). The report and presentations are available at [http://ec.europa.eu/consumers/events/ecs\\_2012/presentations.htm](http://ec.europa.eu/consumers/events/ecs_2012/presentations.htm)

## HORIZONTAL ISSUES

In 2013, we will finalise with the budgetary authorities the negotiations on the proposal made by the Commission in November 2011 regarding the future financial framework for consumer policy, the Consumer Programme 2014-2020. The proposed Programme focuses on the four following pillars: safety, consumer information and education, rights and redress, and enforcement of consumer rights.

We will pursue jointly with the Directorate-General for Justice the implementation of the Consumer Agenda, and especially the specific initiatives to be implemented in 2013.

Focusing on evidence base, enforcement, cooperation, information and education and redress, the financial work programme 2013 will also contribute to achieving the objectives set out above.

### 5.2. Activity "Health"

EU health policy contributes to a smarter, inclusive and more sustainable Europe as part of the EU 2020 strategy. Health is a value in itself, but also a driver for competitiveness and innovation. Indeed, the challenges set out in Europe 2020 are reflected in the EU Health Strategy challenges.

EU health policy as defined in the EU Health Strategy aims to add value to the policies and actions of Member's States while respecting their responsibilities for the definition of their health policies. It is an overarching framework for EU action on health which focuses on four principles underpinning three objectives for improving health in the EU.

The principles include taking a value driven approach, recognising the links between health and economic prosperity, integrating health in all policies, and strengthening the EU's voice in global health. The strategic objectives are: fostering good health in an ageing Europe, protecting citizens from health threats, and dynamic health systems and new technologies.

The EU strategy aims at an integrated approach implemented through legislation, cooperative processes and supported by a financial instrument, namely the EU Health Programme.

#### FOSTER GOOD HEALTH IN AN AGEING EUROPE.

##### Legislation

In 2013 the Commission will adopt a proposal for the revision of the **Tobacco Products Directive** which will then be negotiated by the European Parliament and the Council.

##### Cooperation

Cooperation developed within the "European Innovation Partnership on Active and Healthy Ageing" will continue in 2013. This project, elaborated under the Innovation

Union flagship initiative, aims at enhancing Europe's innovation potential for tackling the challenges of demographic change associated with ageing. The Partnership was launched in 2011 and aims at increasing Healthy Life Years (HLY) by 2, while unleashing the innovation potential and capacity in the health and ageing areas. The Partnership should contribute to achieving the Health Strategy objectives as well as Europe 2020 objectives of smart and inclusive growth. In 2013 the concrete actions identified in the partnership's Strategic Implementation Plan will be further implemented between the Commission, the Member States and the other participants.

In 2013, the Commission will continue cooperating with Member States and stakeholders on **health determinants and chronic disease prevention**. Work on health determinants is essential in promoting health and thereby both preventing disease and reducing the longer term burden for the health systems. Many of today's debilitating diseases, such as cancer and diabetes, have a direct link with those determinants. The Commission will continue to support activities on a number of key health determinants: social determinants and health inequalities; nutrition and physical activity; and alcohol and tobacco with the anti-tobacco campaign. The Commission will also issue a report for implementation by Member States of the Council Recommendation on smoke-free environments (2009/C 296/02)<sup>1</sup>. Mental health and well-being work will also be taken forward, and the work on these risk factors will be associated with action on major chronic diseases.

This will be based on the outcome of the reflection process to identify common goals and possible tools to address the chronic disease burden which the Commission has undertaken in 2011 together with the Member States<sup>2</sup>. At the same time, health systems are increasingly facing the question of how to respond to the challenge of chronic disease patients. The reflection process, which will be finalised in 2013, will identify areas of EU added value to support Member States to better face the challenge, both in relation to prevention, but also to empowerment in chronic diseases management.

Within the work on chronic diseases there will be a particular focus on neurodegenerative diseases, such as Alzheimer, where the prevalence is likely to rise as a result of demographic change.

In 2013, work will continue on cancer and rare diseases. Cancer is the second biggest cause of death of men and women. The aim of the European Partnership on Action against Cancer as set out in the Commission Communication<sup>3</sup> is to reduce cancer incidence by 15% by 2020. EU action on rare diseases pools fragmented resources across the Member States. This contributes to improved diagnostics and treatment. The Commission Communication on rare diseases: Europe's challenges<sup>4</sup> and the Council

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<sup>1</sup> [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009H1205\(01\):EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009H1205(01):EN:NOT)

<sup>2</sup> Council Conclusions "Innovative approaches for chronic diseases in public health and healthcare systems", Brussels 7 December 2010

<sup>3</sup> COM(2009) 291 final of 24 June 2009

<sup>4</sup> COM (2008) 679 final of 11 November 2008



Recommendation on an action in the field of rare diseases<sup>1</sup> set the framework for activities supported by this work plan. Moreover, the implementation report on the Council Recommendation in the field of rare disease will be made available.

In 2013, the 'Ex-smokers are unstoppable' campaign will run for the third and last year. The focus will be on celebrating those who succeeded to quit smoking. The impact of the campaign will be measured through the media reach and number of people who have subscribed to iCoach, an online tool offering help to quit smoking.

For the Action Plan on Organ Donation and Transplantation (2009-2015) a Mid-term review is under preparation. The report will focus on increased organ availability, on increased safety and quality and on strengthening the organisational set-ups of life-saving and cost-saving transplant therapies.

ACTIVITY: HEALTH																	
FIRST OBJECTIVE: TO FOSTER GOOD HEALTH IN AN AGEING EUROPE																	
Results Indicators	Latest known result	Target															
Number of Healthy Life Years at birth	<table border="1"> <caption>Healthy Life Years at birth (2007-2010)</caption> <thead> <tr> <th>Year</th> <th>Males</th> <th>Females</th> </tr> </thead> <tbody> <tr> <td>2007</td> <td>61,7</td> <td>62,6</td> </tr> <tr> <td>2008</td> <td>61,1</td> <td>62,2</td> </tr> <tr> <td>2009</td> <td>61,3</td> <td>62,0</td> </tr> <tr> <td>2010</td> <td>61,7</td> <td>62,6</td> </tr> </tbody> </table> <p>* for 2010, data is provisional and estimated by Eurostat</p>	Year	Males	Females	2007	61,7	62,6	2008	61,1	62,2	2009	61,3	62,0	2010	61,7	62,6	Increase by 2 years by 2020
Year	Males	Females															
2007	61,7	62,6															
2008	61,1	62,2															
2009	61,3	62,0															
2010	61,7	62,6															
Number of Member States with an adopted national cancer plan	<table border="1"> <caption>Number of Member States with an adopted national cancer plan</caption> <thead> <tr> <th>Year</th> <th>Number of MS</th> </tr> </thead> <tbody> <tr> <td>2008</td> <td>12</td> </tr> <tr> <td>2010</td> <td>21</td> </tr> <tr> <td>2011</td> <td>24</td> </tr> </tbody> </table>	Year	Number of MS	2008	12	2010	21	2011	24	All MS + IS and NO by February 2014							
Year	Number of MS																
2008	12																
2010	21																
2011	24																
Number of Member States with an adopted rare diseases plan	2011 7	All MS by the end of 2013															

<sup>1</sup> N° 2009/C 151/02 of 8 June 2009, OJ C 151, 3.7.2009, p. 7.

Attitudes of Europeans towards smoking <sup>1</sup>	<table border="1"> <thead> <tr> <th>Year</th> <th>Never smoke</th> <th>Stopped smoking</th> <th>Smokers</th> </tr> </thead> <tbody> <tr> <td>2005</td> <td>47%</td> <td>21%</td> <td>31%</td> </tr> <tr> <td>2006</td> <td>47%</td> <td>21%</td> <td>32%</td> </tr> <tr> <td>2008</td> <td>46%</td> <td>22%</td> <td>31%</td> </tr> <tr> <td>2009</td> <td>49%</td> <td>22%</td> <td>29%</td> </tr> <tr> <td>2012</td> <td>51%</td> <td>21%</td> <td>28%</td> </tr> </tbody> </table>	Year	Never smoke	Stopped smoking	Smokers	2005	47%	21%	31%	2006	47%	21%	32%	2008	46%	22%	31%	2009	49%	22%	29%	2012	51%	21%	28%	2% drop of tobacco consumption for cigarettes and roll-your own beyond the baseline, 5 years after transposition of the revised Tobacco Products Directive
Year	Never smoke	Stopped smoking	Smokers																							
2005	47%	21%	31%																							
2006	47%	21%	32%																							
2008	46%	22%	31%																							
2009	49%	22%	29%																							
2012	51%	21%	28%																							
<b>Main outputs in 2013</b>																										
<b>Rare diseases:</b> - Implementation Report on Council Recommendation on action in the field of rare diseases <b>Chronic diseases:</b> - Action plan on chronic diseases <b>Tobacco</b> - Implementation Report on Council Recommendation on smoke-free environments																										
<b>Main expenditure-related outputs in 2013</b>																										
- Scoping study on communication action addressing chronic diseases (200.000€) - Promotional material for communicating nutrition and physical activity (500.000€) - Training packages for health professionals to improve access and appropriateness of health services for migrants and ethnic minorities - "Joint Action facilitating collaboration among Member States for effective operation of the Pharmacovigilance system in the EU".																										

## PROTECT CITIZENS FROM HEALTH THREATS:

### Legislation

In November 2011 the Commission proposed adopted a proposal for a Decision on serious cross border threats to health which aims at improving Health security in the European Union and extending the existing framework for communicable diseases also to hazards caused by other biological, chemical and environmental events. Good progress was made in the legislative procedure on the proposal in 2012 and it is expected that the Decision will be adopted in 2013 The generic and specific preparedness structures will be strengthened in terms of planning and coordination, monitoring and assessment, prevention and containment, health system response and communication. Common standards to monitor and control serious cross-border health threats will be established and the coordination of the response will be improved.

A Commission Directive adopted in October 2012 will facilitate cross-border exchange of organs. The Directive will also ensure an improved traceability and vigilance system. Requests for further changes to the legislation on safety and quality of blood and of tissues and cells will be assessed and amendments will be proposed where needed.

### Cooperation

Pandemic preparedness has become ever more important in the wake of recent H1N1 and e-coli crises. In 2013, the Commission's actions will be continued, taking into account the lessons learnt from these crises. In the context of the decision on serious cross border threats to health the joint procurement of pandemic vaccines at EU level, as requested by the Council, will be finalised and ensure improved preparedness for pandemic influenza with all Member States that take voluntary part in this initiative.

The EU Health Security Committee will continue to provide for cooperation for the risk management of specific threats. Once the European Parliament, the Council and the Commission have agreed on the decision on serious cross border threats to health the Committee will be transformed from an informal committee to an even more important advisory committee responsible for the coordination of response to health threats between the Member States. International cooperation in preparing for and reacting to serious cross border health threats will be continued through the Commission membership of the Global Health Security Initiative, in which the the UK, US, Germany, France, Italy, Japan, Canada, Mexico, WHO and EU work together to improve health security at global level.

The 2011 Action Plan on the fight against the rising threats from Antimicrobial Resistance (AMR)<sup>1</sup>, which established cooperation at EU level in this area, will continue to be implemented in 2013. Based on the 2012 Commission report on the implementation in the Member States of the Council Recommendation on patient safety and hospital acquired infections the Commission will consider further policy options in this area in 2013.

The implementation of the 2<sup>nd</sup> HIV/AIDS strategy adopted in 2009 will be continued with a focus on prevention strategies for HIV and co-infections for priority groups and regions. Furthermore, it is planned to develop future HIV/AIDS policy options.

The Commission will propose a mid-term evaluation of the Action Plan for the strengthening of coordination between Member States organ donation and transplantation. An adapted focus and next steps will be presented consequently.

Our efforts to coordinate vigilance (rapid alerts) and traceability (coding) of substances of human origin will be further strengthened in 2013.

ACTIVITY: HEALTH		
SECOND OBJECTIVE: TO PROTECT CITIZENS FROM HEALTH THREATS		
Results Indicators	Latest known result	Target (mid-term)
Rate of influenza vaccination among EU citizens aged 65+ (percentage who reported to have received one shot of influenza vaccine during the last 12 months)	The VENICE data <sup>2</sup> indicate that so far only in one Member State the vaccination target of 75% of the elderly population has been achieved.	Improved implementation by all Member States of Council Recommendation on seasonal vaccination, providing for 75% vaccination of people aged 65+ by 2014-2015 winter seasons.

<sup>1</sup> [http://ec.europa.eu/dgs/health\\_consumer/docs/communication\\_amr\\_2011\\_748\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf)

<sup>2</sup> Seasonal influenza vaccination coverage data of the 2010/2011 influenza season collected through a survey carried out by the VENICE project which is supported by ECDC.

Share of patients developing hospital acquired infections	5% (= 4,1 million/year) <sup>1</sup>	Improved implementation by Member States of the Council Recommendation on patient safety and hospital acquired infections and reduction of such events.
Extended Early Warning Rapid System (EWRS) for notification of communicable diseases events, threats caused by other biological, chemical and environmental threats operated by the European Centre for Disease Control (ECDC)	Unplanned Interruptions in 2011: 1 minute > 99,99% of availability which confirms constant improvement since 2008 (99,85%), 2009 (99,90%), and 2010 (99,99%).	Working with ECDC to ensure that extended EWRS is fully operational and interruption of service is not more than 30 minutes per day. Availability: 99% scheduled uptime excluding planned downtime for maintenance. Downtime minimized to < 4 hours per incident.
Prudent use of antibiotics assessed as:  % of antibiotics sold with prescription  number of countries with an action plan that has as one of its objectives to have in place an infection prevention and control programme at the level of healthcare institutions addressing organisational and structural arrangements, diagnostic and therapeutic procedures (for example antimicrobial stewardship), resource requirements, surveillance objectives, training of healthcare personnel	2008: 100% - 11 countries (FI, FR, DE, HU, IE, LU, SK, SI, SE and NO) 99% - 7 countries (AT, BE, CZ, EE, IT, NL and UK) 95-99% - (BG, CY, LV, LT, PL) Less than 85% - 1 country (GR)  2011: out of 17 countries with an action plan, such objectives were reported by 15 countries for acute care hospitals, by 11 countries for other hospitals and by 5 countries for nursing homes	2013: 100% - 12 countries 99% - 8 countries 99-95 % - 4 countries Less than 85% - 1 country  2016: out of 24 countries with an action plan, such objectives to be reported by 22 countries for acute care hospitals, by 20 countries for other hospitals and by 15 countries for nursing homes
<b>Main outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Veterinary pharmaceutical legislation</li> <li>- Implementing acts based on the decision on serious cross border threats to health: the procedures for the coordination, the exchange of information and the mutual consultation on preparedness and response planning; the adoption of a list of communicable diseases and special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network, the adoption of case definitions for serious cross-border threats to health; the procedures for the operation of the Early Warning and Response System; the procedures for the coordination of the responses of the Member States; the recognition of situations of emergency at Union level or of pre-pandemic situations with respect to human influenza at Union level.</li> <li>- Joint procurement agreement for pandemic preparedness</li> <li>- Framework contracts on joint procurement of pandemic vaccines</li> <li>- Deliverables as set out in the AMR draft roadmap, such as: study on causes of non prudent use of antibiotics, training, guidance on infection prevention and control in healthcare settings, third Eurobarometer survey on AMR</li> <li>- Interim report on the current state of implementation of the Council recommendations on seasonal influenza (spring 2013)</li> <li>- Report of a stakeholder consultation on reference laboratories for human pathogens</li> <li>- Communication from the Commission on the evaluation of the European Centre for Disease Prevention and Control (ECDC)</li> </ul>		
<b>Main expenditure-related outputs in 2013</b>		
<ul style="list-style-type: none"> <li>- Trainings and exercises on preparedness and response planning</li> <li>- Eurobarometer AMR</li> <li>- Study on prudent use of AMR</li> </ul>		

<sup>1</sup> Estimate made in 2008

## **SUPPORT DYNAMIC HEALTH SYSTEMS AND NEW TECHNOLOGIES:**

### Legislation

The Directive on patients' rights in cross-border healthcare, which is due to be transposed by Member States by 25 October 2013, will help facilitate access to high-quality and cost-effective healthcare for patients. This entails ensuring that patients receive high quality, safe and efficient healthcare in other Member States when that is the most appropriate solution for them, and be reimbursed for it. Through the implementation of the Directive, instruments will be put in place to encourage Member States to work closely together on areas such as health technology assessment, eHealth, creation of European Reference Network. By promoting the exchange of best practices in healthcare, the Commission aims at encouraging improvements in the quality and value for money of all European health systems.

The establishment of European Reference Networks will enhance cooperation between healthcare providers across the EU, with the aim of improving patient access to the highest quality care available in a given field. In 2013, the Commission will prepare and possibly adopt implementing measures on the criteria and conditions the European Reference Networks should fulfil in accordance with the provisions of the Cross-border Healthcare Directive.

In April 2012, the Commission has adopted an Action Plan for the EU Health Workforce as part of the Communication on job-rich recovery (COM(2012) 173 final). The Action Plan puts forward 4 areas of action in order to help Member States cope with the challenges faced by the health workforce: improve health workforce planning and forecasting in the EU, better anticipate skills needs in the healthcare sector, stimulate exchange on recruitment and retention of health workers, and cooperate with WHO on the implementation of the Global Code on the international recruitment of health workers.

In the field of medical devices, the legislative procedure on the revision of the three medical devices directives and the Communication on the promotion of innovation in medical devices will continue in 2013.

In 2013, the Commission will continue working towards the implementation of the Directive on falsified medicinal products adopted in June 2011.

A proposal for the revision of the clinical trials Directive has been adopted by the Commission in July 2012 and it will be followed by discussions by the co-legislators.

The adoption of a proposal on the revision of legislation on veterinary medicines by the Commission is planned for the second quarter of 2013.

The new pharmacovigilance legislation was adopted in December 2010 and applies since July 2012. The Commission will continue working towards a proposal establishing fees for the financing of the activities of the European Medicines Agency with respect to pharmacovigilance. The Commission will also explore the necessity of a delegated act on post-authorisation efficacy studies and will launch a public consultation to this effect.

The Commission will continue to work with the European Medicines Agency to ensure that medicinal products placed on the EU market conform to the EU standards, relating to quality, safety and efficacy. In this context, the Commission manages the marketing authorisation procedure for medicinal products, leading on average to 1500 Commission Decisions per year.

### Cooperation

Health systems in Europe are under financial pressure and the challenge to provide quality and universal healthcare has never been greater. The Commission will continue working with the Member States in 2013 as part of the reflection process established on the future sustainability of health systems.

Through the newly established eHealth Network<sup>1</sup> the Commission will continue to support in 2013 the wider use of eHealth solutions that would bring concrete benefits to citizens. The work priorities of the Network follow the key objectives spelled out in the Cross-Border Healthcare Directive.

The Expert Panel on investment in health, established in 2012, will become operational in 2013 and will offer independent and highly qualified advice and opinions to provide support for Member States and the Commission on the efficiency of health systems at national level.

Health technology and innovation in health are drivers of competitiveness and have the potential to address the challenges health systems face. However, it is important to ensure that these new technologies have the patients' interests at heart. Health Technology Assessment can assist national authorities in achieving best value through identification of the most effective and safe health interventions. In 2013, the Commission will set up a network of national authorities and bodies for Health Technology Assessment in order to enable better informed decisions to use new and old technologies, as well as pooling information on methodologies, data and best practice at EU level.

The Commission will work with the Member States as a follow-up to its November 2012 report on the Council Recommendation on patient safety and hospital acquired infections (2009/C 151/01). The report showed that most Member States implemented actions envisaged by the Recommendation, but there is still room for improvement, mainly in the area of patient empowerment and education and training of health workers. Some Member States reported that the implementation was slowed down due to changing public health priorities which resulted from the economic crisis. As a consequence, the Commission proposed to prepare another report in two years' time, and called for collecting evidence on cost-effectiveness of patient safety programmes.

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<sup>1</sup> Council Conclusions, Towards modern, responsive and sustainable health systems, Luxembourg, 6 June 2011

ACTIVITY: HEALTH		
THIRD OBJECTIVE: TO SUPPORT DYNAMIC HEALTH SYSTEMS AND USE OF NEW TECHNOLOGIES		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target (mid-term)</i>
Share of population worried to suffer an adverse event while receiving healthcare	50 % (2009)	30 % (2014)
Use of the adapted "core Health Technology Assessment model" developed at EU level for assessing pharmaceutical products	For the moment, no figures available as we are in the pilot phase.	20% of all new originator products given market authorisation by 2018
Number of Member States having implemented the provisions of the Council Recommendation 2009/C 151/01	9 (2012)	19 (2014)
<b>Main outputs in 2013</b>		
<b>Cross border healthcare:</b> - Commission Decision setting up the Network for Health Technology Assessment. - Preparatory work on guidelines on non-exhaustive list of data of patient's summary data set under the eHealth Network of the Cross-Border Healthcare Directive.		
<b>Main expenditure-related outputs</b>		
- Cost-effectiveness analysis of health systems across MS - Catalogue of strategies, good practices, scenarios of collaboration to empower patients with chronic diseases in disease management - Early dialogue on pharmaceuticals and medical devices - Analysis of strategies to recruit and retain health workers - Review and mapping of the continuous professional development of health workers - Overview of the legal framework for electronic health records - Study on existing pricing and tariff systems in MS - Communication actions on Directive on patients' rights in cross-border health care - Eurobarometer survey on patient safety and AMR - Good practices in the field of blood transfusion (training programme, guide, web portal etc.)		

## FINANCE AND GOVERNANCE

The following actions will continue to be developed in 2013:

- ✚ Implementation of the second Health Programme (2008-2013) according to the annual work programme in cooperation with the Executive Agency for Health and Consumers.
- ✚ Coordinating the implementation of the EU Health Strategy in the Council Working Party on Public Health at Senior Level. This group, composed of senior public health officials from Member States, meets once per Presidency to provide a steer and identify priority actions.
- ✚ Consulting with stakeholders and in particular the European Health Policy Forum, a group of over 50 civil society organizations including patients groups, health professionals and other health related groups.
- ✚ Generating and making available data and scientific opinions, under the new arrangements, needed to make informed decisions; In 2013, the Commission will continue supporting health policy by up-dating and providing relevant indicators and making information available to the broad health community through the ECHI indicators
- ✚ Promoting the international dimension and in particular working with international organisations in the field of health (mainly WHO) and multilateral fora aiming at the convergence of regulations in the field of medical products and cosmetics, such as the International Cooperation for Cosmetics Regulation (ICCR), the International Conference on Harmonisation of Technical

Requirements for Registration of Pharmaceuticals for Human Use (ICH) on the one hand and for veterinary medicinal products (VICH) on the other hand, and the Global Harmonisation Task Force for medical devices (GHTF); the latter undergoing transition towards a more inclusive and more operational International Medical Device Regulators' Forum (IMDRF) for which Europe is likely to take the chair in 2013. The Commission also participates in and contribute to the work of the European Committees on Organ Transplantation (CDPTO) and on Blood Transfusion (CDPTS) within the Council of Europe, and cooperate with OECD on health data collection. It is important that our internal policies in health are reflected in our external policies. In 2013 the Commission will be involved in the work mandated by the fifth Conference of the Parties (in November 2012) to the Framework Convention on Tobacco Control and in the WHO governance reform process.

### **5.3. Activity "Food and Feed Safety, Animal Health, Animal Welfare and Plant Health"**

In 2013, we will strive to empower the food chain framework by:

- + Placing the consumer first, whilst promoting the competitiveness of private business operators of the food chain;
- + Setting the right standards at EU level, in order to protect plants, animals and consumers;
- + Enhancing a competitive market by adopting Smart Regulation;
- + Assuring effective and efficient control systems and compliance with EU standards in the food and feed safety, food quality, animal health, animal welfare, animal nutrition, plant reproductive material and plant health sectors within the EU, and in third countries in relation to their exports to the EU;
- + Providing information and promote transparency to enhance the possibility for consumers to make informed and nutritionally relevant choices in relation to food, supported by comprehensive impact assessments;
- + Promoting sustainability as an opportunity to create jobs and growth for a more green economy;
- + Monitoring, evaluating, managing threats, and where necessary, alerts and identified risks, in a proportionate manner;
- + Exploring how the food chain policy while ensuring safety can be adapted to sustainability imperatives for example by contributing to preventing food waste along the food chain ;
- + Fostering innovation so as to encourage the use of new technologies and investments in research;
- + Promoting EU standards at the international and multilateral levels, both as examples to follow in the interests of health protection and to protect the interests of our exporters;



- ✚ Managing relations with the European Food Safety Authority (EFSA) and ensure science-based risk management;
- ✚ Managing relations with the Community Plant Variety Office (CPVO) and take part actively to its Administrative Council and technical Liaison Officers working meetings;
- ✚ In the food safety area we are continuously striving to simplify and innovate the legislative framework, and to make it work more effectively. The latter depends heavily on the proper implementation and enforcement of the legislation by Member States and verification by the Commission. Making the framework effective also entails working together with stakeholders in order to find appropriate instruments to facilitate maximum compliance with the legislation.

In order to reach these goals, a series of actions will be implemented at different levels:

### **A more efficient framework for official controls along the food chain**

Official controls are key elements to assure consumers and operators that the measures put in place along the food chain for a safer, more competitive and sustainable market are implemented properly. The review of Regulation 882/2004 on official controls aims at simplifying and clarifying the legal framework related to official controls, at consolidating the integrated approach in all areas related to the food chain and at ensuring that Member States appropriately resource control authorities. The work on the review is being finalised and is expected to result in a proposal to be adopted at the beginning of 2013.

The review focuses on the following main areas for improvement:

- ✚ the extension of the scope of the Regulation to official controls and other official activities in the plant health, plant reproductive material and animal by-products areas is being considered, so as to consolidate the horizontal approach to official controls along the food chain and to complement the upgrades being sought through the very broad and ambitious reform which aims to modernise Union legislation applicable in those areas;
- ✚ the specific rules on official controls on residues of veterinary medicines (Directive 96/23/EC) are also being reviewed so as to integrate them within the horizontal framework established by the Regulation; redundant control and reporting requirements will be eliminated together with the unnecessary and burdensome approval procedures;
- ✚ the rules on official controls carried out at the Union borders on certain commodities are being reviewed in order to establish a more uniform, more risk based control framework, facilitate businesses' operations and increase control efficiency by improved risk prioritization. The review will also seek to improve the current legislative framework, by fully integrating the rules on veterinary border controls into the general framework of Regulation 882/2004, which recognizes that certain commodities, for which specific risks are identified, require specific controls prior to the introduction into the territory of the Union.
- ✚ the review will also address weaknesses of the system of official controls which

are of horizontal nature (duplicated or overlapping reporting and planning requirements, unclear or inconsistent language) and establish principles and general rules common to all sectors;

- ✚ as regards the financing of official controls, the rules governing the establishment and application of control fees will be amended with a view of ensuring that competent authorities in the Member States are provided with adequate funding and that control fees are charged in a fairer and more transparent manner;
- ✚ Based on the latest scientific advice provided by EFSA the Commission has prepared draft regulations on pig and poultry meat inspection for discussion and adoption in 2013 and awaits further scientific opinions on meat inspection of ruminants, horses and farmed game due to be published in June 2013. Current discussions with the Member States on pig meat inspection include issues such as intensifying Salmonella controls and reduction of palpation, incision and trichinella testing.

## **Feed, plants and seeds**

Feed, plants and plant reproductive material are essential sectors for the safety and security of the food chain. We intend to promote in particular innovation by ensuring that this is applied by respecting safety rules, by reducing administrative burden and fostering a smart and greener economy. The following actions are planned for 2013:

- ✚ New legislative proposals for Plant Health and Plant Reproductive Material will be adopted in the beginning of 2013, following the evaluation of the existing legislation. The former aims at simplifying, streamlining and increasing transparency and cost effectiveness, as well as establishing better import control to reinforce the protection against new pest and diseases from third countries. The latter revision fosters innovation and seeks to reduce overall administrative burden by modernising and simplify the legislation through the replacement of 12 Directives on seed and plant propagating material with one single act.
- ✚ Work is on-going on the revision of the legislation on the use of Medicated Feed and a proposal for modernised legislation is expected in 2013. The current Directive dates from 1990 and is widely seen as vague and outdated. The legislation will cover the technical aspects of incorporating medicines on prescription into feed to ensure safe practices in the single market.
- ✚ The reception of the requests and subsequent re-evaluation of all feed additives is the major task and will last for at least 3 years.
- ✚ Management of GM feed and seed authorisations will continue.
- ✚ A follow-up of the evaluation of Community Plant Variety Rights legislation will be prepared and presented for discussion with stakeholders.
- ✚ The proposal giving more freedom to Member States to decide on GMO cultivation is still being discussed in Council. The EP Resolution was adopted in July 2011 and discussions in Council will continue in view of a possible common position. Guidelines for GM food/feed will be adopted and guidelines on the environmental risk including monitoring will be discussed and transformed into a legal document. The Commission followed up the socio-economic report on the impact of the

cultivation of GMOs by launching a process to aid Member States collect and share information. A recommendation regarding environmental monitoring of the cultivation of GMOs by Member States will be proposed. Communication efforts will continue.

✚ As regards plant protection products, the work on implementing measures as foreseen under the regulation concerning the placing on the market of plant protection products will continue. Particularly important is in this context the establishment of criteria for endocrine disruptors, which may have far reaching consequences for other policy areas in DG SANCO. A report on the possibility of the establishment of a European fund for minor uses has been submitted to Council and Parliament. Depending on the outcome of the discussions, follow-up actions may be required. In addition, the processing of approval dossiers for active substances will continue as well as the setting of maximum residue levels of pesticides in food.

## **Animal health and welfare**

In the animal health area we will continue the work started in 2007 by implementing the strategy and by continuously re-evaluating the various aspects of the general policies on animal health and welfare.

- ✚ Under the animal health strategy (2007-2013), the preventive approach is stepped up and existing mechanisms are strengthened. As a key element of the Animal Health Action Plan implementing the Strategy, certain new mechanisms and an overarching legal framework need to be established to provide increased support to a competitive and sustainable European livestock sector and to a safe and smooth EU market of live animals and their products (e.g. semen, ova, embryo etc.). This future framework not only represents significant simplification (replacing over 40 current rules with one where responsibilities are clearer) but will also provide legal basis, flexibility and possibilities for further simplification and reduction of administrative burden (e.g. during the movement of low-risk products, to accommodate local needs, by using modern technology etc.) at later stages. It will also increase internal coherence between animal health issues and related areas (such as EU veterinary expenditure, official controls by competent authorities, zoonoses, veterinary medicines, etc.). Preparatory work for this challenging initiative, the so-called "EU Animal Health Law", is close to completion and expected to be finalised in early 2013.
- ✚ The Action Plan also includes actions designed to use opportunities offered by developments in technology (e.g. electronic certification, Animal Disease Information System, further development of TRACES etc.) or to support other Commission Services in their quest for competitive agriculture and animal health or dedicated research for the area. Their implementation will continue in 2013.
- ✚ To ensure best implementation of the new rules on electronic identification for bovine animals and on pet movements between Member States, proper follow up and Commission rules on the details are planned for 2013. These depend on final agreement on these two proposals (currently being debated in the Council and in the European Parliament).
- ✚ As regards animal welfare, the EU Animal Welfare Strategy 2012-2015 contains

the guiding priorities for our actions in this policy field. The general aim is to ensure that animals do not endure avoidable pain or suffering, to make sure that the owner/keeper of animals respect minimum welfare requirements and to ensure the proper information and education of citizens and operators on animal welfare issues. In 2013, the follow up to the EU strategy for the protection and welfare of animals (2012-2015) will be continued. The Commission will set up an internal working group to examine how the current rules on animal transport could be better enforced. As part of the strategy, it should be assessed to which extent conclusions of the internal working group referred to before could serve as a basis for the preparation of the general animal welfare law. For that purpose, the Commission will perform a pilot project on a Coordinated European Animal Welfare network and mandate a study on information to consumers and education, both initiatives to be used for the impact assessment for a new legislative framework for animal welfare.

- ✚ The Commission will first concentrate its efforts in 2013 in ensuring that enforcement of the legislation on animal welfare is strictly and timely applied, in particular with the forthcoming implementation of the grouping of sows as well as of the regulation on the protection of animals at the time of killing. Under the same objective, the Commission plans to prepare EU guidelines for the protection of pigs as well as a series of reports due by the legislation (implementation of the cat and dog fur ban, genetic of broilers and the stunning of poultry).

## Food

In order to boost innovation as a driver for smart growth we will take measures in the following areas:

- ✚ As regards Novel Foods, a new proposal for a Regulation is in preparation taking into account the progress achieved in Conciliation on the previous proposal<sup>1</sup> on the Novel Food Revision.
- ✚ As regards cloning for food production, we have started to work on an impact assessment to follow up the Commission report on cloning of animals for food production in the context of the good functioning of the internal market. The initiative is tabled for adoption in 2013.
- ✚ In the area of food contact materials, the roadmap on how to address the safe use of materials not harmonized at EU level, will be finalized and where appropriate followed by an Impact Assessment.
- ✚ Following the priorities set by the Commission on encouraging innovation, the definition of nanomaterials as set out in the Commission Recommendation of October 2011<sup>2</sup> will be adapted to the food sector to ensure effective implementation from food safety and consumer information point of view and allowing innovation.

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<sup>1</sup> COM (2007) 872, 14/1/2008

<sup>2</sup> OJ L 275/38, 20.10.2011, p38-40

- ✚ A major proposal for the revision and simplification of the legislation covering foods for particular nutritional uses (dietetic foods) was adopted by the Commission in 2011. In 2012, the Commission engaged in intense negotiations and discussions with Council and European Parliament in the context of the ordinary legislative procedure and adoption is expected in 2013. The Commission will then start the implementation work required by the proposed legislation.
- ✚ Follow-up of the evaluation of GM Food, Feed, Seed legislation, in particular by better implementation. The Commission will discuss the results of the GM free labelling study and its follow-up.
- ✚ The proposal for the amendment of the Honey Directive will be discussed in Parliament and Council.

In view of eliminating bottlenecks for the 21st century single market according to the principle of smart regulation we will:

- ✚ Continue the process of the Review of the Hygiene Package legislation, in force since 2006 and in light of the report on the experience gained since then. Discussions will be held with the European Parliament and Council during 2013.
- ✚ Implement the legislation and manage the authorization for food additives, enzymes, flavourings, food contact materials, GM food and novel food. The legislation will be managed to facilitate harmonized implementation, both for routine and emerging issues. This permanent and systematic work provides a useful perspective to the Internal Market.
- ✚ Providing guidance on the prudent use of antibiotics in veterinary medicine and reviewing the legislative framework for the harmonized monitoring of AMR in food and animals in line with the 5-year Action Plan.
- ✚ Moreover, we will continue to promote the Sustainability of the Food Chain, also covering innovative techniques and behaviour change, as started in 2010. In 2012 priority will be given to food waste minimization linked to food packaging optimization in close cooperation with DG Environment and other relevant Commission services in the framework of the Resource Efficiency Roadmap.

In addition, we will enhance the dialogue and the information within the EU by:

- ✚ Continuing with the implementation of the Regulation on nutrition and health claims. In particular, we expect to continue work on individual applications and to advance work on the list of permitted 'function' health claims which was adopted in May 2012 and will start to apply from 14 December 2012. The establishment of this list which authorizes 222 different health claims throughout the EU will ensure consumer protection and fair competition for food business operators by removing misleading and false claims from the market.
- ✚ Taking forward work on the implementation of the Regulation on the provision of the Food Information to consumers, adopted in 2011. In particular, by 13 December 2013 and following an impact assessment, the Commission will adopt the implementing rules concerning the application of the new rules on voluntary origin indications. Likewise, the Commission shall present report on the need to extend mandatory origin labelling to meat used as an ingredient.
- ✚ Continuing the specific programme of training targeted on sanitary and

phytosanitary measures, the Better Training for Safer Food (BTSF initiative). The main objectives of the programme are to strengthen human capacity by "training the trainers", in particular targeting veterinary and laboratory services; and to help improve the national/regional legal framework towards harmonized systems.

## **Global dimension**

The promotion of international relations will ensure the respect of multilateral obligations and the representation of the EU in international fora, particularly concerning the WTO, the Codex Alimentarius, the World Organisation for Animal Health (OIE), the International Plant Protection Convention, and the International Union for the Protection of New Varieties of Plants (UPOV), the Cartagena Protocol on Biosafety, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the OECD. Furthermore, the management of the EU's bilateral agreements in the field will be pursued.

## **Enforcement**

The audits of DG SANCO's audit service, the *Food and Veterinary Office* located in Grange - Ireland (FVO), are crucial for ensuring proper implementation in the fields of food and feed safety, animal health and welfare and plant health and for providing feedback on the operation of national controls and any problems arising within these sectors. During 2013, the FVO in accordance with its audit programme will carry out approximately 250 audits in Member States, candidate countries and third countries exporting to the EU. Since 2012, the FVO's programme also includes audits on organic farming and geographical indicators<sup>1</sup>. From 2013, the FVO will extend its audit activities to the health sector with joint audits with Member States of Notified Bodies in the field of medical devices and, in the event of applications by third countries, on imports of active pharmaceutical ingredients for medicinal products for human use.

In its reports the FVO makes recommendations to the competent authority of the country concerned to deal with any shortcomings revealed during the audits. The competent authority is requested to present an action plan to the FVO on how it intends to address shortcomings. Verification of the completion and effectiveness of corrective actions through a number of systematic follow up activities is an integral part of FVO activity. The FVO revisits Member States regularly to monitor progress in relation to the outstanding issues with a view to getting action. Persistent problems may be the subject of high-level meetings between the Commission and the authorities concerned. As a last resort, legal action under EU law may be taken by the Commission to ensure that Member States meet their obligations under EU law.

Where an audit identifies an immediate threat to consumer, animal or plant health, the Commission may take emergency ("safeguard") measures. These may include legal action to prevent trade in, or imports of, animals, plants or their products. In other cases, where serious, but less urgent, problems are found, or where a competent

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<sup>1</sup> Protected Denominations of Origin, Protected Geographical Indications, Traditional Specialities Guaranteed

authority fails to take satisfactory corrective action, the Commission may use the audit report as one element in deciding to start infringement proceedings against a Member State or, in the case of a third country, to refuse, withdraw or modify authorisations for exports to the EU.

The FVO also produces overview reports to ensure that the results of audit series are presented in a manner which facilitates understanding of the state of implementation of EU legislation and the problems and good practices identified across the Member States.

Since the entry into force of Regulation (EC) No 882/2004<sup>1</sup>, the FVO assesses Member States' Annual Reports on the implementation of their Multi-Annual National Control Plans and provides feedback to Member States, aimed at improving the quality of these reports. The FVO is carrying out a number of activities in 2013 - in dialogue with the Member States - to further promote sound regulatory practices in the implementation of controls including identification and exchange of information and good practices. A new series of systems audits is being introduced with the purpose of focussing on selected horizontal elements of Regulation (EC) No 882/2004, e.g. verification procedures and enforcement, to identify good practice as well as difficulties encountered with implementation. The Commission reports annually on the operation of official controls along the food chain in the Member States<sup>2</sup>.

In addition to audit and follow-up, the FVO carries out a range of other activities, including the evaluation of residue control plans from Member States and from third countries exporting food of animal origin to the EU, the management of lists of approved third country establishments for the production of food of animal origin, the evaluation of Border Inspection Post plans and the operation of the Europhyt plant health interception notification system. The FVO also contributes to the Commission's technical assistance for third countries to help them meet EU food safety, animal and plant health standards, as well as to the Better Training for Safer Food Programmes.

Finally, the results of FVO activities assist in ensuring that our legislation is kept up to date, relevant and fit for purpose.

The Rapid Alert System for Food and Feed (RASFF) is a critical information system about enforcement actions taken in Member States for products in which a health risk is identified. For further strengthening and improving the RASFF, a legal proposal on implementing measures for the Rapid Alert System for Food and Feed (RASFF) was adopted in January 2011. The Standard Operating Procedures for the operation of the RASFF, complementing the new Regulation, have been developed and are on schedule to be published in early 2013. A new interactive and high performance IT platform for RASFF is being introduced in Member States with full implementation expected in early 2013. As a result, RASFF will be better prepared for the continuous increase in information exchange as well as for particular crisis situations placing very high demands on the system.

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<sup>1</sup> Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

<sup>2</sup> Report from the Commission to the European Parliament and to the Council on the overall operation of official controls in the Member States on food safety, animal health and welfare, and plant health <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0122:FIN:EN:PDF>

## Crisis preparedness and management

In addition, the infrastructure for crisis preparedness has been developed as a cross-cutting action.

A full time presence (365/365) of the RASFF is ensured to act, inform and disseminate information to the appropriate management chain in case of a food and feed alert. The RASFF team also acts as the DG's Duty Officers, responding to the multi DG alerts (crisis management or business continuity) managed by the Commission Secretariat General.

ACTIVITY: FOOD SAFETY, ANIMAL HEALTH, ANIMAL WELFARE AND PLANT HEALTH		
SPECIFIC OBJECTIVE: TO ENHANCE AND MANAGE THE REGULATORY FRAMEWORK AND TO ENSURE EFFECTIVE AND HARMONISED IMPLEMENTATION		
<i>Results Indicators</i>	<i>Latest known result</i>	<i>Target (mid-term)</i>
Satisfaction rate from the participants to the Better Training for safer Food Programme	85% (Oct 2012) 6100 participants trained	85% or higher(2015) Achieve steady state of around 6000 participants per annum
Effective management of review of existing maximum residue levels (MRLs) for pesticides taking into account that only MRLs safe to European consumers should be confirmed	The reviews of MRLs for around 30 (2012) substances was finalised by EFSA and presented to the Commission	40 more substances (2013)
Animal health improvement indicated by percentage of programmes for eradication of bovine tuberculosis and brucellosis that achieve a reduction in prevalence from the previous year	78% (2010)	80% (2013)
Animal health improvement for a disease under a compulsory or voluntary eradication regime, indicated by the number of regions being officially free from bovine brucellosis, bovine tuberculosis and Aujeszky's disease	It is being established on the basis of the recent 2011 64/432 report: state of play as end of 2011	Continuing annual increase in number of such regions
Number of BSE cases for bovines	Preliminary results for 2012 indicate a decrease of more than 28% compared to 2011.	20% decrease in BSE cases in 2013 compared to 2012
Number of Salmonella cases	In 2010, a total of 100,921 confirmed cases of human salmonellosis were reported in the EU. This represents a 7% decrease from 2009 in the MSs. In 2011, a total of 85,000 confirmed cases of human salmonellosis were reported in the EU. This represents a 15% decrease from 2010 in the MSs.	5% decrease in Salmonella cases in humans in 2012 compared to 2010
Ensure a high level of stake-holder's involvement (consumers, distribution, industry, animal welfare NGOs) in EU food legislation (including animal health, animal welfare and plant health) and its implementation by ensuring compliance with the standards of transparency, deadlines and representativity measured through number of meetings of the Advisory Group of the Food Chain (plenary and WGs)	2 Plenary, 3 Animal Health Advisory Committees, and 7 ad-hoc WGs respecting the standards (by end November 2012)	2 Plenary and 10 WGs respecting the standards yearly (2013)
<b>Main outputs in 2013 (including policy)</b>		
<ul style="list-style-type: none"> <li>- Use of cloning technique for food production (CWP 2013)</li> <li>- Regulation on novel food</li> <li>- Proposal for an EU Animal Health Law (CWP 2013 - Annex II on simplification)</li> <li>- Adoption of additional Union list of permitted health claims made on foods, provided for in Article 13(3) of Regulation (EC)</li> </ul>		



- No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food
- Adoption of delegated/implementing acts foreseen in the revised framework Regulation. (infant formula and follow-on formula, cereal based foods and other baby foods, foods for special medical purposes, probably gluten free foods, Union list of substances)
  - Medicated feed legislation (CWP 2013)
  - Implementation of the grouping of sows for all pig holdings concerned (Article 3 (9) of Directive 2008/120/EC)
  - EU guidelines for the protection of pigs
  - Report to the European Parliament and the Council on the various methods of stunning poultry (Regulation 1099/2009)
  - Report to the European Parliament and the Council on the impact of genetic selection on the welfare of chickens bred and kept for meat production (Directive 2007/43/EC)
  - Report to the European Parliament and the Council on the application of Regulation (EC) No 1523/2007 banning the placing on the market of cat and dog fur
  - Alignment and possible review of Regulation (EC) N° 999/2001
  - Commission Regulation on meat inspection in pigs
  - Commission Regulation on meat inspection in poultry
  - Review of the Hygiene package (Simplification initiative in CWP2013)
  - Updating of Common Catalogues of plant varieties

**Main expenditure-related outputs in 2013**

- Approval and implementation of 140 programmes aimed at the eradication and monitoring of animal diseases and zoonoses in all Member States
- Financing of 45 EU Reference Laboratories in the fields of Food Safety, Residue Control and Animal Health to ensure harmonisation of analytical methods and the availability of the necessary high quality activities, facilities and skills.
- Operation of the Better Training for Safer Food Programme to improve food safety standards.
- Assisting Member States in actions to counter serious animal disease (emergency fund) to ensure rapid and effective actions, thus limiting spread and economic impact.
- Financing of plant health solidarity dossiers for the eradication or containment of regulated harmful organisms after outbreaks in Member States

**ACTIVITY: FOOD SAFETY, ANIMAL HEALTH, ANIMAL WELFARE AND PLANT HEALTH**

**SPECIFIC OBJECTIVE: EFFECTIVE CONTROL OF APPLICATION**

<i>Results Indicators</i>	<i>Latest known result (results end September 2012)</i>	<i>Target for end 2013</i>
Current percentage of FVO recommendations for which commitments have been obtained from the Member States to take corrective actions (for specified three year rolling cycle).	91% <sup>a</sup>	90% <sup>a</sup>
	91% <sup>b</sup>	92% <sup>b</sup>
Of those, percentage of recommendations with confirmation obtained by the Commission that the necessary corrective actions have actually been taken	39% <sup>a</sup>	60% <sup>a</sup>
	52% <sup>b</sup>	71% <sup>b</sup>
	<sup>a</sup> = For recommendations resulting from audits in the reporting cycle 2010-2012	
	<sup>b</sup> = For recommendations resulting from audits in reporting cycle 2009-2011	

**Main outputs in 2013(including policy if relevant)**

- Report from the Commission to the European Parliament and to the Council on the overall operation of official controls in the Member States on food safety, animal health and welfare, and plant health

## 6. HORIZONTAL ACTIVITIES

### 6.1. Activity "Policy Strategy and Coordination for DG Health and Consumers"

This Activity includes all actions that support, guide or co-ordinate the policies for which DG Health and Consumers is responsible. The actions under this activity contribute directly to the success of our main policies.

This Activity supports and drives the policy definition, preparation and implementation in order to achieve the overall mission of the DG within the timescales laid down. It promotes a strategic planning culture within the DG in accordance with the Commission's strategic planning and programming cycle. It actively promotes the main policies of the DG through information, internal and external communication, awareness-raising and dialogue with stakeholders. It supports the coherence of the different activities within the DG, ensuring liaison with the horizontal services, the Cabinet and other institutions. It provides legal advice so that SANCO policies are legally sound and comply to correct procedures. It aims to develop an administrative culture of independence, objectivity and fairness founded on principles of proportionality and better regulation.

*This Activity includes the following functions:*

- ✚ Policy strategy definition and coordination, better regulation including impact assessment;
- ✚ Strategic planning and programming;
- ✚ Internal and external communication;
- ✚ Coordination of institutional affairs;
- ✚ Management of legal issues and coordination of legal processes.

#### **Policy strategy definition and coordination, better regulation including impact assessment**

The better regulation best practices of the DG will continue to be improved through the provision to policy sectors of suitable instruments for quality Impact Assessment (IA), and assistance in the preparation of internal information documents ensuring effective management and delivery of new initiatives (Road Maps) and the establishment of priorities and guidelines on a general strategic vision for policy making. In this regard, the quantitative strategic analysis for policy making and advice on cost benefit analysis will be improved.

DG SANCO will achieve further coordination and coherence in the supervision of the four Regulatory Agencies for which it is the Commission's interlocutor<sup>1</sup>. This will involve exploring new governance tools with the Agencies, e.g. codes of conduct, improved performance indicators, harmonised conflict of interest policy as well as developing

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<sup>1</sup> (1)The European Centre for Disease Control, "ECDC", the Community Plant Variety Office "CVPO" the European Food Safety Authority "EFSA", and the European Medicines Agency", "EMA".

SANCO positions in Secretariat General led dialogue between the Commission and EU Agencies generally.

Access to accurate and reliable data will continue to be improved as an important part of good policymaking.

Under this activity the development of new strategies is fostered, such as in the food safety and plant health areas, GMOs, and support of the implementation of others like the EU Animal Health Strategy.

In accordance with the political guidelines of the President, DG Health and Consumers' is currently finalising the "fitness check" of most of its policies, such as Animal Health, Animal Welfare, Plant Health, Consumer and Public Health policies.

<b>OBJECTIVE: Support the decision-making process by thorough evaluations and impact assessments, by systematic consultations with stakeholders and by suitable measures and methods so that the mission of DG Health and Consumers is fulfilled. Contribution to the reduction of Administrative Burden for businesses.</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Stakeholder consultations - Respect of the 12 weeks minimum consultation standard (as from 2012 onwards)	100% (2012)	100%
Opinion of Impact Assessment Board (IAB). Resubmission rate.	As of September 2012, 10 IAB opinions. Resubmission: 6	36 % resubmission (Commission average 2011 - 36%)

## Strategic Planning and Programming

This action ensures the implementation of the Commission planning and programming process and at facilitating the use of the planning tools to support daily management and to ensure a holistic approach, providing for a better overview and coherence from Commission Work Programme to unit planning implementation level.

<b>OBJECTIVE: Implement the Commission planning and programming process so that the Directorate General delivers its policy objectives contributing to the overall Commission strategy in an effective, timed, efficient, coherent and accountable manner</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Implement the Planning Cycle: <ul style="list-style-type: none"> <li>• 2013 Work Programme input</li> <li>• 2011 Annual Activity Report (Part I)</li> <li>• 2013 Management Plan</li> </ul>	CWP 2012/2013 input, MP 2012/2013 and AAR 2010/2011 submitted, all within deadlines (100% timely submission). (2011 and 2012)	High quality documents delivered on time (100% timely delivery). Positive assessment from central services.
<b>OBJECTIVE: Simplify and modernise the DG Health and Consumers planning to facilitate the use of the planning tools to support daily management and to ensure a holistic approach, providing for a better overview and coherence from Commission Work Programme to Unit planning implementation level.</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Provide guidance and tools for the development and improvement of Unit Management Plans across the DG	Guidance provided 20 September 2011 after approval of the new UMP template by Management (2011) Guidance provided 17 September 2012 after approval of procedure by Management (2012)	Good quality instructions and guidance (from 15 September until finalization) that could contribute to improved quality of plans.
Planning reports for management and the Commissioner every other month Keep Agenda Planning up to date.	Completed on time for each output (100% timely delivery)(2011 and 2012)	Documents of good quality for management decision and reporting to the Commissioner prepared in time (100% timely delivery) for the overall planning meetings with the Commissioner
Organisation of DG Planning Group (SPG)	Meetings organised monthly except	Organisation of effective and

meetings, biannual MP meetings (June and November).	August (2011) Meetings organized every other month (2012)	informative meetings every quarter or as needed.
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## Internal communication

This action encompasses the contribution to an effective Internal Communication within the Directorate General across the three sites by promoting the exchange of information and coordinating updates on the Intranet; and managing the Commissioner's Europa site.

<b>OBJECTIVE:</b> Develop implement, monitor and adapt internal communication in the DG and establish direct communication, consultation and feed-back channels between management and staff, so to ensure that staff understands and shares the vision and objectives of their department and works effectively together, by sharing and having access to the information they need.		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
News and information flow on Intranet, video messages as well as knowledge hours, statistics on consultation.	12 Knowledge hours organised at DG, directorate level and with other DG's (DG ECFIN, DG CLIMA, DG AGRI) (Compared to 7 in 2011).	4 Knowledge hours in 2013 (aiming for fewer but on more substantial issues of wide interest)  Staff satisfaction of at least 60% on 1) satisfactory news and information flow on Intranet and 2) the Intranet helps me perform my work. (to be measured with staff survey)
Staff satisfaction on management communication	60% of staff are satisfied (2011 staff survey)  No Staff Survey executed in 2012	In Staff Survey 2013, at least 65% of staff having good and above judgment on the fact that DG SANCO's mission and policies are clearly communicated to the them.

## External communication

The main objective is to plan of communication actions in line with policy-related communication priorities, to be determined with the Commissioner, focused on well-chosen specific themes and issues reflecting the horizontal priorities of the European Commission as well as the Commissioner's portfolio agenda.

External communication includes communication campaigns, Web and print publications, events and media relations. This is delivered through horizontal co-ordination across the DG supported by media and communication steering from a new centralised Communication unit.

In 2013, policy websites for Food and Consumers will be totally revamped in time for the communication actions. The pages dedicated to priority topics such as: tobacco, cross-border healthcare, plant and animal health, consumer credits, food labelling and health claims will also be redesigned.

Horizontal co-ordination and support involves internal coordination, handling relations with DG COMM, managing Framework Contracts and drawing up the DG's

communication strategy, providing expertise and advice as well as assistance, as appropriate, for the development of external communication actions by policy directorates.

By the end of 2013 SANCO website will migrate to the CWCMS Documentum, or at least a roadmap specifying the outstanding steps for the project to be completed will be produced not later than mid 2014.

Media relations involve communication with written press, TV, radio, and social media. This is implemented in close liaison with the Commissioner's Spokesperson.

<b>OBJECTIVE: Develop, implement, monitor and adapt an external communication strategy to actively promote the main policies and initiatives of the DG, and make them more visible and understandable to different audiences and highlighting their concrete benefits to the citizens of the EU</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Completion of campaigns/communication plans within the set time limits	New indicator	90% completed on time
Percentage of communication actions following a communication plan developed jointly by the policy unit and the communication unit	New indicator	50%
Efficiency of SANCO websites: hits	Hits: Public Health: 2.348.185 (2011) 3.047.402 (2012) Food Safety: 1.778.565 (2011) 2.227.292 (2012) Consumer affairs: 2.004.093 (2011) 2.175.551 (2012) Health EU Portal: 854.063 SANCO frontpage: 322.041	Hits: same levels as in 2012

### **Institutional affairs**

This action encompasses the co-ordination of the relations of the DG with the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, including notably preparation of European Parliament and Council sessions/meetings, ensuring report/follow-up, handling of questions of the Parliament, petitions, Ombudsman's complaints, preparing and overseeing the preparation of other speeches by and briefings for the managerial and political hierarchy on institutional matters.

We will work to maintain and develop the good relationships established with the Parliament and the Council formations relevant to the portfolio.

<b>OBJECTIVE: Establish and maintain dialogue and cooperation channels with the other institutions, and the Presidencies so that progress of legislative proposals and non-legislative initiatives put forward by the DG is smooth and efficient through the institutions.</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Parliamentary Questions replied to within the deadline	78,7 % (2012) <sup>1</sup>	100%
Holding meetings with forthcoming and pending Council Presidencies	Preparatory meetings organised at service level, per sector - at least 3 meetings for each policy pillar	Preparatory meetings organised as needed at service level, per sector

## Legal affairs

This action encompasses the coordination of legal affairs of the DG through providing coherent legal advice in close collaboration with technical units and the Legal Service, and to support the Management Team and the Cabinet in the management of legal risks. It also encompasses contributing to the administrative culture of independence, objectivity and fairness in the processing of inquiries and complaints as well as improving legislation on the basis of the principles of proportionality and better regulation. The legal affairs unit also acts as a watchdog in ensuring that each action is based on a sustainable legal basis and that each decision avoids discrimination or abuse of power and enhances trust from the European citizen.

<b>OBJECTIVE: To act as the DG's internal legal adviser to:</b>		
<ul style="list-style-type: none"> <li>- advise on interpretation of current legislation and manage legal risks in close collaboration with the Commission's Legal Service, the Management Team and the Cabinet;</li> <li>- contribute to the development of new legislation that is legally sound, clear, simple and effectively achieves its policy goal;</li> <li>- effectively process complaints and infringements on the basis of good administrative practice and prioritisation;</li> <li>- provide appropriate legal advice on implementation of the Lisbon Treaty and coordinate the progressive alignment of SANCO basic acts to the new regime of delegated/implementing acts in order to support the Management Team through the Policy Legislation Committee.</li> </ul>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Timely and appropriate review of requests for legal assistance	Meet deadlines 80% of the time (2011)	Meet deadlines 80% of the time.
Review of significant legislative and non-legislative proposals.	Timely review of all CWP items 100% of the time within set deadlines for intra-SANCO consultation i.e. 10 working days (2011)	Timely review of all CWP items 100% of the time within set deadlines for intra-SANCO consultation i.e. 10 working days.
Review of other proposals.	Timely response 80% of the time within set deadlines for intra-SANCO consultation i.e. 10 working days (2011)	Timely response 80% of the time within set deadlines for intra-SANCO consultation i.e. 10 working days.
Efficient processing of complaints and infringements.	Meeting Commission benchmarks for processing complaints/infringements 80% of the time when there are no grounds for justified slower processing (2011)	Difficult to predict inflow of complaints and infringements. Target to meet Commission benchmarks 80% of the time unit resources permitting.

<sup>1</sup> It should be noted that SANCO continues to receive an increasing number of Parliamentary Questions (SANCO ranking No1 in quantity within the Commission) and in consequence, when this % is applied to the new total number of questions received, it means that in reality we are treating more questions than in the previous year. Thus, the indicator is not so indicative of real improvement.

## 6.2. Activity "Administrative support for DG Health and Consumers"

The Activity "Administrative support" includes actions that are necessary for the functioning of the organisation as such and are indirectly linked to the policies for which the DG is responsible.

This Activity promotes and maintains sound and efficient management of human, financial and IT resources within the DG, and ensures that resources are allocated to achieve the policy objectives of the DG. It ensures the soundness of internal control established in the DG's operational management and its financial accounting and reporting systems, and provides internal audit advice within the DG.

The Activity includes the following functions:

- ✚ Human resource management;
- ✚ Financial management;
- ✚ Management of information and communication technologies (ICT);
- ✚ Document management;
- ✚ Internal audit;
- ✚ Internal control and risk management.

### Human resource management

DG Health and Consumers seeks to attract, deploy, develop and retain sufficiently qualified and experienced staff. The Commission Human Resources (HR) policies are tailored to the needs of the DG as an organisation and to its staff. HR processes are carried out in Units, with the Human Resources Unit operating as a centre of competence in all the DG. In 2013 the Commission will face important challenges due to the forthcoming decisions affecting directly the working conditions of staff, and the progressive reductions in staff numbers. It will be important to adapt working methods and organisation and to review HR policies to ensure staff motivation and engagement remains at a high level.

The objectives are to

- ✚ Ensure that the DG has qualified and experienced staff, the right person in the right place at the right time;
- ✚ Develop a coherent approach to talent management to ensure that all staff can make use of their full potential, develop the competencies and fulfill their careers development;
- ✚ Develop working conditions that are conducive to high productivity in a supportive work environment and allow reconciliation of private and professional life;

<b>OBJECTIVE: Ensure that the DG has qualified and experienced staff and make use of their full potential, and develop working conditions that are conclusive to high productivity and allow reconciliation of private and professional life.</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Vacancy rate of posts	4% (August 2012)	Less than 5%
Female AD officials non-management	42,2% (August 2012)	43%
Female middle managers	34,9% (August 2012)	30%
Share of staff having a job	97,4% (September 2012)	95%

description		
Positive training evaluations	82, 9% (June 2012) 78,9 % (31.12.2011)	> 80%
Timely completion and delivery of CDR elements	100% (8.2.2012)	>95%
Local support and coordination staff ratio	11,3% (August 2012)	10,9%

## Financial management

The main objectives of this function are to ensure that DG Health and Consumers obtains the financial resources it needs to meet its policy objectives, and to ensure that operational and financial activities are legal and regular, that financial regulation requirements are met and that financial and management reporting is reliable.

This is achieved by co-ordinating the implementation of the budget, performing risk-based ex-ante verifications and on-the-spot financial controls on funding provided by the DG, and by co-ordinating and reporting on the implementation of the internal control and management standards in the DG.

<b>OBJECTIVE: Plan, perform, monitor and report on the spending of financial resources so that sound financial management is ensured throughout the DG's activities</b>		
Indicators	Latest known result	Target 2013
Ensure execution of allocated commitment and payment credits managed by DG SANCO (without credits transferred to EAHC)	95% (AAR 2011) Commitment Appropriations (CA) 94% (AAR 2011) Payment Appropriations (PA)	99% CA 98% PA
Payment times/payments made on time both in number and amount	96% (AAR 2011)	95%
Share of total budget subject to on-the-spot controls (audit scope)	60% (AAR 2011)	60%
Actual on-the-spot control coverage	54% (AAR 2011)	50%
Thorough ex-ante controls on both financial transactions (2 <sup>nd</sup> level verification) and procurement procedures (Comité de marchés publics) (CMP)	<ul style="list-style-type: none"> <li>2<sup>nd</sup> level verification: 77% of CA and PA verified (AAR 2011)</li> <li>CMP: contracts &gt; €125 000 100% reviewed (AAR 2011)</li> </ul>	<ul style="list-style-type: none"> <li>2<sup>nd</sup> level verification: 75% of CA and PA verified</li> <li>CMP: contracts &gt; €130 000 100% reviewed</li> </ul>
<b>OBJECTIVE: ensure preventive action as well as detective action in order to prevent and identify cases of suspected fraud and reporting them</b>		
Indicators	Latest known result	Target 2013
Percentage of contracts/grant agreements subject to close monitoring or additional controls due to a assessed high risk of fraud	New indicator since 2012 (first results will be available for the 2012 AAR)	10% (9 contracts/grants)
Percentage of contract amounts subject to close monitoring or additional controls due to a assessed high risk of fraud	New indicator since 2012 (first results will be available for the 2012 AAR)	1% (about EUR 5 million of payments)
Action listed in the anti-fraud action plan (SEC(2011)787) and relevant to DG SANCO implemented on time	One action applicable to DG SANCO taken on time (100%)	100%
OLAF investigations covered by appropriate follow-up and reporting	No investigation closed or started (October 2012)	100%

## Management of Information and Communication Technologies (ICT)



The main objective of this function is to promote and use Information Technologies capabilities to better serve the policy objectives of the DG.

In 2013, the focus will be on an important input by SANCO to the rationalisation of information systems in the Commission, given the DG's active role in an important portfolio of systems, while ensuring maintenance of the necessary day-to-day services to SANCO staff. The main focus will be on three major new systems: Online Dispute Resolution, Clinical Trials and Medical Devices. These systems, together with the more limited maintenance and evolution of existing systems, will mobilise most of human, financial and IT resources. An active participation in the Open Data Portal initiative will allow the DG to share data more efficiently with SANCO's numerous stakeholders.

<b>OBJECTIVE: Define, plan, set up, maintain and develop high quality Information and Communication Technology (ICT) infrastructures, tools and services, so that the staff is adequately supported in their operation</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Number of systems implemented on time	90% (2012)	90%
Streamlining business processes between SANCO and agencies	799 Visio conferences (2007 to 2011) and 88 Audio-Web conferences 6 business processes in place (2012)	Two more business process in place concerning EFSA (data collection and video-audio-web conferencing)
Helpdesk calls and % of timely resolution	99% (11700) within 3 days (2012)	95% within 3 days
IS support	99% (8000) within 3 days (2012)	95% within 3 days

## Document Management

The main objective of this function is to improve efficiency of the DG functions by optimising and rationalising the internal document flows and process.

The focus in 2013 will be on consolidating the use of the ARES system, not only as a central register, but also as a major tool to streamline the management of electronic and paper documents and mail (simplification of circuits, electronic visas, very low probability of loss, and acceleration of the document flow). The central register should help to improve the efficiency and quality of the DG's responses in the area of transparency and access to documents. On document knowledge management we intend to deploy tools in order to make better use of the knowledge contained in the document portfolio of the DG.

<b>OBJECTIVE: Put in place and maintain effective document management system so that any document connected with the DG's official functions can be electronically filed, stored and retrieved in any moment irrespective of its original form and the document management system in place</b>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
% of Interservice consultation answered on time	97% (2012)	98%

## Protection of Personal Data

The main objective of this function is to ensure that all of our processes and information systems are in line with the regulations in this domain, through advice and support to services. Permanent contact is maintained with the Data Protection Officer of the Commission, as well as a constructive dialogue with the European Data Protection Supervisor's services.

OBJECTIVE: Ensure that all the measures are in place in order to comply with the relevant regulation		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Review on Data Protection processes and measures on new IT systems and procedures	100% of new systems (including systems inherited from other Commission services) reviewed (2012)	100 % of new systems reviewed

## Internal audit including evaluation

The main objective of this function is to perform audit and evaluation activities in order to provide support and advice to the DG and management with independent, objective opinions for developing and maintaining high standard of management practices and management controls. Evaluations are performed to provide a necessary and useful input to ensure sufficient and improving quality of the policy development and implementation in the DG.

<p><b>OBJECTIVE:</b> Internal audits</p> <ol style="list-style-type: none"> <li>1. Ensure that the Internal Audit Capability is operated as an independent, objective assurance and consultancy activity and improve the effectiveness of risk management, control and governance processes.</li> <li>2. Ensure that audit recommendations from audits performed by the Internal Audit Service and the Internal Audit Capability are duly taken into account and that relevant action plans are designed and implemented.</li> </ol> <p>Evaluation</p> <ol style="list-style-type: none"> <li>1. Ensure integration of evaluation into the decision making process of DG Health and Consumers as useful, accepted and broadly applied information tool</li> <li>2. Based on the Commission evaluation standards ensure consistent quality of <ul style="list-style-type: none"> <li>* the evaluation plan;</li> <li>* individual evaluations;</li> <li>* the implementation of the evaluation recommendations in the DG</li> </ul> </li> </ol>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
1. Degree of implementation of the IAC annual work plan	71% 5 audits were carried out (on 5 audits + 2 audit follow-up initially planned) (2011) 71% 5 audits were carried out (on 5 audits + 2 audit follow-up initially planned) (2012)	100%
2. Level of acceptance by the auditees of audit recommendations issued by the IAC	89% (2011) 100% (2012)	100%
3. Multi annual evaluation planning horizon covering at least n+5 years	100% (2011) 100% (2012)	100%
4. Assistance in drafting ToRs for studies requested by operational units and participation in evaluation committees for studies	100% (2012)	100%

## Internal control and risk management

This activity encompasses the coordination and update of risks and action plans and communication on the progress of the implementation of action plans and the emergence and management of new risks with a special focus on critical risks. It also contains development, update and review of guidelines and documentation related to Internal Control Standards, Baseline Requirements and how to measure and demonstrate control effectiveness.

<p><b>OBJECTIVE:</b> Implement, maintain and report on an effective and reliable internal control system so that:</p> <ul style="list-style-type: none"> <li>✚ Reasonable assurance can be given that resources assigned are used according to the principles of sound financial management;</li> <li>✚ Risk of errors in operations is minimised and</li> <li>✚ The control procedures put in place give the necessary guarantees concerning the legality and the regularity of the underlying transactions</li> </ul>		
<i>Indicators</i>	<i>Latest known result</i>	<i>Target 2013</i>
Degree of timely implementation of mitigating measures for critical risks	97% (December 2011)	100%
Degree of timely implementation of audit recommendations (IAS, IAC and ECA) rated "critical" or "very important"	<ul style="list-style-type: none"> <li>• "Critical": n/a</li> <li>• "Very important": 70% (December 2011)</li> </ul>	100%
Correction rate of 2 <sup>nd</sup> level ex-ante verification	0,1% in value (AAR 2011)	< 2% in value
Residual error rate of on-the spot controls (ex-post) per ABB activity	4,3% (AAR 2011) for ABB activity "Food and Feed policy area"	< 2% in value for all policy areas