

Chapter 3 – Identifying impacts in evaluations, fitness checks and impact assessments

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TOOL #18. IDENTIFICATION OF IMPACTS

The identification and assessment of the most significant impacts is a core task of every impact assessment, evaluation, and fitness check. Given the need to consider impacts across the economic, environmental, and social pillars, this screening is important to ensure that the subsequent assessment focuses on the most important impacts for each specific case, in line with the principle of proportionate analysis. Once an initiative has been adopted and implemented, it is also important to monitor and ultimately evaluate to see whether the impacts originally expected in the impact assessment materialise and to what extent. This tool looks at the initial identification of impacts from the impact assessment perspective, but the typology of impacts will also be valid for evaluations and fitness checks.

1. DIRECT AND INDIRECT BEHAVIOURAL CHANGES AND POLICY GOALS

A policy option should aim to deal with the identified problem by inducing direct and indirect changes to the behaviour of those influencing it (i.e. addressing the problem drivers). These changes are also likely to have a bearing on the achievement of other policy goals. **The first step in impact analysis is the identification of this chain of impacts.**

A. Start by considering direct behavioural changes	
Why?	As a direct result of an option, someone somewhere will be incentivised to do something differently (or maintain a certain activity) than would have been the case without the policy intervention.
Who?	Those directly affected by an initiative. In the case of a legislative proposal, these include the addressees of any regulatory obligation, the public authorities responsible for implementation and enforcement and those who are expected to be the final beneficiaries of the proposal. It is suggested to refer to the following categories of potentially affected groups for your analysis: Citizens – whenever changes are widespread and do not affect any particular subgroup. Consumers – whenever users of a particular product/service are affected. Workers – whenever employees in general or in a specific industry are affected. Enterprises – businesses in general or in a specific sector. It is necessary to distinguish enterprises according to their size (micro, small, medium and large) whenever they are to respond to different regulatory requirements (i.e. exemptions and special regimes) or are likely to be affected differently by the same policy measure. Public authorities – distinguish between EU, national and sub-national levels as appropriate. Member States, regions – whenever impacts are different across Member States or where the option addresses regions differently according to their industrial, environmental, geographic or social characteristics (e.g. urban, rural, cross-border, or as regards the EU outermost regions). Third countries – whenever they are directly affected. Relevant subgroups of countries (main trading partners, developing or neighbouring countries, etc.)

	and, within countries, entities (businesses, citizens etc.) should be used.
	The above list is indicative and different groupings should be used whenever relevant given the specific nature of the initiative and its direct implications for specific groups (for instance, <i>innovators, researchers, students, youth, elderly, genders, immigrants, people suffering from discrimination or physical disadvantages</i> , etc.) or people living in urban, rural, island, mountain, cross-border areas or in the EU outermost regions.
What?	To identify direct impacts, ask whether the option under consideration would imply new regulatory obligations? If so, what actions would the targeted parties (businesses, citizens, public authorities etc.) must take to comply with such obligations? How would they need to change their behaviour?
	Would the option exempt certain actors from the regulatory obligations (e.g. micro enterprises) or cover specific regimes (e.g. for SMEs)? What impact would this have?
	What additional actions would need to be taken to implement, monitor, and enforce a new legislative requirement?
	Is any other action expected to be taken as a direct result of the option under consideration?
Examples	Removal of certain (dangerous) products from the market; requiring pollution abatement equipment to be fitted to industrial installations or vehicles; providing consumers with additional information to influence their purchasing behaviour; being able to pay less for EU-level patenting because of reduced translation requirements, lower or no EU taxation on imported products ¹⁹⁹ , etc.
B. Consider indirect behavioural changes	
Why?	Direct changes will often prompt indirect (or second-order) changes and so on. These can be as important as the primary effects and may provide an important link in the chain of actions leading to the solution of the problem.
Who?	Indirect behavioural changes may regard both those directly affected as well as others. The same groups or territories as listed above can be used for the analysis (but a different set of groups may be relevant for second-order impacts).
What?	Consider those second-round effects that are both a direct consequence of the primary changes or further removed (typically the result of changes in the price and/or quality/availability of the goods and services produced in the regulated sector) and territorial spill-overs to neighbouring regions.
Examples	Thanks to a new regulatory measure, EU companies can obtain EU patents at a reduced cost (first round). Thanks to this, the profitability of research and development in the EU is increased. All else equal, this increases incentives for R&D spending (second round).
	Thanks to a new labelling requirement, potential consumers of a given electric good can compare data on energy efficiency more easily (first round). As a result, they increase consumption of more energy efficient products (second round). At the same time, companies' costs increase due to the need to respect

¹⁹⁹ Concerns the outermost regions of the EU.

	the new labelling requirement (first round). Given the existing market structure, these increased compliance costs are transferred on the price of the good. Demand for the good decreases (second round). The net effect needs to be determined.
C. Consider ultimate impacts on relevant public policy goals	
Why?	All the changes identified will eventually affect the state of the world relative to the 'no-policy-change' or baseline scenario.
What?	The analysis should first identify what all these changes imply for the attainment of the specific and general objectives of the initiative in question.
	Secondly, the analysis should look at how other public policy objectives may be (positively or negatively) impacted by the option under consideration.
	The set of potentially relevant public policy objectives is defined by the existing EU/Commission policy commitments, the Commission's political priorities and, ultimately, the EU Treaty. They include goals related to the economic, social, and territorial cohesion and environmental sustainability, as well as respect for the fundamental rights, in line with the UN 2030 Agenda and its sustainable development goals. They can all be considered intermediate goals to the ultimate goal of maximising societal welfare.
	Specifically relevant objectives will vary from initiative to initiative and from option to option.
	An indicative list is provided in the tables below. Specific impact assessment tools or indicative lists of issues are provided for most of them and should be consulted whenever relevant.

At the end of this process, you should have mapped out all potentially relevant impacts according to affected parties and areas of relevance. The next step is to identify which of these impacts are likely to be significant and thus in need of a more focussed analysis.

2. DIRECT AND INDIRECT BEHAVIOURAL CHANGES AND POLICY GOALS

In the impact assessment process, a stepwise approach is followed:

- (1) identifying potential impacts of the selected policy options;
- (2) selecting those impacts which are likely to be significant; and
- (3) assessing the latter quantitatively wherever possible, otherwise qualitatively.

Step 1: Identification of potential impacts

The table below summarises the key impacts, which should be screened objectively to identify all potentially important impacts – considering both positive/negative, direct/indirect, intended/unintended as well as short/long-term effects. Some of the categories are cross-cutting and can be analysed from different angles (for example employment, income distribution, impacts on consumers or environmental impacts). A (well-justified) choice

should then be made on the most significant impacts to be retained for a more thorough analysis. More details about the individual impacts²⁰⁰ follow in section 4.

Overview of key impacts to screen*			
Impact on	Economic	Social	Environmental
Climate			✓
Quality of natural resources (water, soil, air etc.)			✓
Biodiversity, including flora, fauna, ecosystems, and landscapes			✓
Animal welfare			✓
Working conditions, job standards and quality		✓	
Public health & safety and health systems		✓	
Culture		✓	
Governance, participation, and good administration		✓	
Education and training, education, and training systems	✓	✓	
Conduct of business	✓		
Position of SMEs ²⁰¹	✓		
Administrative burdens on business	✓		
Sectoral competitiveness, trade, and investment flows	✓		
Functioning of the internal market and competition	✓		
Public authorities (and budgets)	✓		
Sustainable consumption and production	✓		✓
Efficient use of resources (renewable & non-renewable)	✓		✓
Land use	✓		✓
The likelihood or scale of environmental risks	✓		✓
Employment	✓	✓	
Income distribution, social protection, and social inclusion (of particular groups)	✓	✓	
Technological development / digital economy	✓	✓	
Consumers and households	✓	✓	
Capital movements; financial markets; stability of the euro	✓	✓	

²⁰⁰ The obligation to screen these impacts is the consequence of the Treaty on the Functioning of the European Union (Articles 8-14).

²⁰¹ To systematically screen the potential impact on SMEs, the SME-test needs to be performed in all impact assessment reports. See Tool #23 (the 'SME test').

Property rights; intellectual property rights	✓	✓	
Territorial impacts (specific (types of) regions and sectors)	✓	✓	✓
Innovation (productivity and resource efficiency); research (academic and industrial)	✓	✓	✓
Fraud, crime, terrorism, and security, including hybrid threats	✓	✓	✓
Resilience, technological sovereignty, open strategic autonomy, security of supply	✓	✓	✓
Transport and the use of energy	✓	✓	✓
Food safety, food security and nutrition	✓	✓	✓
Waste production, generation, and recycling	✓	✓	✓
Third countries, developing countries, and international relations	✓	✓	✓
Sustainable development	✓	✓	✓
Fundamental rights	✓	✓	✓

* - The 'tick' denotes an indicative dominant category of impact

Step 2: Selection of the significant impacts

Not all impacts for all possible stakeholders need to be examined. The most relevant ones should be selected based on the principle of proportionate analysis (see Tool #12 (*How to apply proportionality to undertake a proportionate impact assessments*)) considering the following factors:

<i>The relevance of the impact within the intervention logic</i>
All key parameters of an option that will directly contribute to the achievement of the policy objectives should be retained for further analysis to assess the effectiveness and efficiency of this option.
In the case of legislative proposals, this implies <u>always</u> retaining for further analysis the changes required to comply with, and to implement and enforce, the proposed legal provisions.
<i>The absolute magnitude of the expected impacts</i>
The analysis should also focus on those impacts with the greatest magnitude.
<i>The relative size of expected impacts for specific stakeholders</i>
While some impacts may be small in absolute terms, they may be particularly significant for some specific party due to: • The relative size of the latter – for instance, micro and small enterprises. • The concentrated nature of the impacts – on specific regions and types of territories²⁰², industry, and stakeholder groups, etc.

²⁰² On the EU outermost regions and on urban, rural, , sparsely populated, mountainous, insular, cross-border territories

• The cumulative impact that new obligations may have on any actor, which is already subject to significant direct regulatory compliance and/or implementing and enforcement obligations.
<i>The importance of impacts for Commission horizontal objectives and policies</i>
When the analysis of impacts shows that there are potentially significant trade-offs between the objectives of the initiative (and its effects) and other politically important objectives (e.g. climate, territorial, or geopolitical), the relevant impacts should be analysed in depth. When the initiative is part of a larger strategy (or action plan or similar), the impact assessment should also assess the contribution of the initiative to the strategy. When it comes to delivering on the SDGs, one important aspect is to address explicitly the interlinkages between the different SDGs, assessing synergies and trade-offs, as a tangible manner to progress towards sustainable development in an integrated manner, balancing its three dimensions (economic, social, and environmental). This is a central requirement to fulfil the commitment to ensure policy coherence for sustainable development. (see Tool #19 and #35)
<i>Sensitivities and diverging views</i>
The impact assessment should help explain the reasoning behind the Commission's proposal. It should therefore also take account of potential sensitivities or diverging views. For instance, if there are specific aspects that are likely to come up in the legislative negotiation process or that stakeholders may be concerned with, these should be covered in the analysis.

The expected significance of impacts should be assessed in terms of changes relative to the baseline²⁰³. However, it is important not to leave out anything that is of relevance for political decision-making. The choice should take account of stakeholders' views and relevant expertise, including within the interservice coordination group.

At the end of this process, you should have selected those significant impacts that need to be further analysed and have a good idea of their sign (positive or negative), their intensity, and of whom they would benefit or burden. The choice of impacts to be retained for deeper assessment should be clearly justified.

However, regardless whether they are relevant for a given initiative, there is still a need to report on some specific impacts in all impact assessments and justify why you have not assessed them further, should this be the case. This concerns specifically impacts on SMEs, competitiveness, and fundamental rights.

Step 3: Assessment of significant impacts

The key principles to be followed in analysing the significant impacts are explained in the 'better regulation' guidelines covering impact assessment.

There is no single best method which would apply to all possible Commission initiatives. There is, however, an obligation to make the most sensible methodological choice given the specificities of the case at hand, the availability of data, and the requirement to carry out a proportionate analysis.

²⁰³ See Tool #60 (*Baselines*)

Significant impacts should be assessed qualitatively and, whenever possible, quantitatively.

However, the analysis should not be done in function of the available data. All significant impacts must be assessed even if they cannot be quantified. The analysis should indeed be quantified as far as possible (though in a proportionate manner), but when data are lacking for significant impacts, this should be complemented with or replaced by a qualitative analysis (see also Chapter 8 and Tool #4 (*Evidence-informed policymaking*)).

All legislative revisions require identification of the simplification potential and – whenever feasible – quantify the burden reduction (see Tool #2 (*The Regulatory fitness programme (REFIT) and the Fit for Future Platform*)). Quantification of administrative costs is also crucial for implementing the 'one-in, one-out' approach (see Tool #59 (*Cost estimates and the 'one in, one out' approach*)).

3. METHODOLOGICAL GUIDANCE

For methodological guidance, seek the advice of your DG (or the Secretariat-General) 'better regulation' support function as well as that of the specific help desks set up in various DGs for specific types of impacts.

Refer to the various tools on how to assess impacts²⁰⁴, costs and benefits²⁰⁵ and to the other tools of relevance for the initiative in question.

4. LIST OF POTENTIAL IMPACTS

The table below can be consulted for further details on each screened impact type and includes a reference to a relevant tool for further guidance²⁰⁶. The last column indicates the most relevant sustainable development goals (SDGs) identified for each listed impact (see also Tool #19 (*Sustainable development goals*)).

Impact on	Key questions	SDG
Climate (Tool #36)	- Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane, nitrous oxide, etc.) into the atmosphere? - Does the option affect economic incentives set up by market-based mechanisms (MBMs) created by Union law (e.g. first and second round incentives and price signals under the EU's Emission Trading System)? - Does the option affect the emission of ozone depleting substances (CFCs, HCFCs etc.)? - Does the option affect our ability to adapt to climate change?	 
Air quality (Tool #36)	Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc.)?	 

²⁰⁴ See Chapter 3 of the toolbox

²⁰⁵ See Chapter 8 of the toolbox.

²⁰⁶ The order corresponds to the order presented in Section 2 above and does not imply a different degree of importance.

Impact on	Key questions	SDG
		 
Water quality and resources (Tool #36)	- Does the option decrease or increase the quality or quantity of freshwater and groundwater? - Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? - Does it affect drinking water resources?	 
Soil quality or resources (Tool #36)	- Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? - Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?	 
Biodiversity, flora, fauna, and landscapes (Tool #36)	- Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? - Does it affect protected or endangered species or their habitats or ecologically sensitive areas? - Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors, or buffer zones? - Does the option affect the scenic value of protected landscape?	 
Animal welfare (Tool #32)	- Does the option have an impact on health of animals? - Does the option affect animal welfare (i.e. humane treatment of animals)? - Does the option affect the safety of feed?	  
Working conditions, job standards and quality (Tool #30)	- Does the option affect wages, labour costs or wage setting mechanisms? - Does the option affect employment protection (the quality of work contracts, risk of false self-employment)? - Does the option affect undeclared work? - Does the option affect work organisation? - Does the option affect occupational health and safety? - Does the option affect the exercise of labour standards? - Does the option affect social dialogue? - Does the option affect access to vocational training and career development advice? - Does the option affect participation, information, and consultation schemes for employees?	 
Public health and safety and health systems	Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education,	

Impact on	Key questions	SDG
(Tool #31)	occupation, nutrition)? - Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? - Does it affect health due to changes in the amount of noise, air, water, or soil quality? - Will the option affect health due to changes waste disposal? - Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? - Are there specific effects on particular risk groups (determined by age, gender, disability, minority of ethnic or racial background, social group, mobility, region, etc.)? - Does the option affect the quality and/or access to health services and the financing and organisation of health systems in particular in urban, rural, mountainous, insular, sparsely populated areas and in the EU outermost regions? - Does the option affect the cross-border provision of health services, referrals across-borders and cooperation in border regions?	
Culture (Tool #31)	- Does the proposal have an impact on the preservation of cultural heritage? - Does the proposal have an impact on cultural diversity? - Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?	 
Governance, participation, and good administration (Tools #10, #28, #30)	- Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? - Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? - Does it affect the autonomy of the EU and national social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? - Does the implementation of the proposed measures affect public institutions and administrations, for example as regards their responsibilities? - Does the option make the public better informed about a particular issue? Does it affect the public's access to information? - Does the option affect political parties or civic organisations? - Does the option consider eGovernment principles?	  
Education & training, and education & training systems (Tools #30, #31, #34)	- Does the option affect the level of education and training outcomes? If yes, will it affect differently the level of education in urban, rural, cross-border, insular, or sparsely populated and mountainous areas or in the EU outermost regions? - Does the option affect the skills used by individuals? - Does it have an effect on the education and mobility of workers? - Does the option affect the access of individuals to education or and/or vocational and continuous training and quality? If so, how are different social groups (determined for example by age, gender, disability, minority	 

Impact on	Key questions	SDG
	ethnic or racial background etc.) affected? - Does it affect the cross-border provision of services, referrals across-borders and cooperation in border regions? - Does the option affect the financing and organisation of education and training systems? - Does it affect universities and academic freedom/self-governance? - Does the option change the productivity of the human capital?	
Conduct of business (Tools #21-25)	- Will it impose additional costs on businesses? - How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? - Does it affect access to finance? - Does it impact on the investment cycle? - Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? - Will it entail stricter regulation of the conduct of a particular business? - Will it lead to creating new or closing down businesses? - Are some products or businesses treated differently from others in a comparable situation? How are individual Member States affected?	   
SMEs (Tool #23)	What is the impact (positive or negative) of the option on the operation and competitiveness of SMEs and micro-SMEs in particular?	 
Administrative costs on businesses (Tool #58)	Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)?	
Sectoral competitiveness, trade and investment flows (Tool #21, 27)	- What impact does the option have on the cost of doing business which includes the costs of intermediate inputs (e.g. energy) and production related factors such as labour and capital? - What productivity effects does the option have? - What impact does the option have on a business' capacity to innovate i.e. its ability to produce more/higher quality products and services that meet customers' expectations? - What impact does the policy option have on a business' market share and comparative advantages in an international context (e.g. imports, exports, investment flows, trade barriers, regulatory convergence, etc.)? - How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? - How will investment flows be affected and the trade in services? - Will the option give rise to trade, customs, or other non-trade barriers? - Will the option affect regulatory convergence with third countries? - Have international standards and common regulatory approaches been considered?	   

Impact on	Key questions	SDG
Functioning of the internal market and competition (Tools #24, #25)	- What impact (positive or negative) does the option have on the free movement of goods, services, capital, and workers? - Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc.?	 
Public authorities (Tool #58)	- Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? - Does it bring additional administrative costs on public authorities? - Does the option require the creation of new or restructuring of existing public authorities?	
Sustainable consumption and production (Tool #36)	- Does the option lead to more sustainable production and consumption? - Does the option change the relative prices of environmentally friendly and unfriendly products? - Does the option promote or restrict environmentally un/friendly goods and services? - Will it lead to businesses becoming more, or less polluting through changes in the way in which they operate?	 
Efficient use of resources (renewable & non-renewable) (Tool #36)	- Does the option affect the use of renewable resources (fish, wood etc.) and lead to their use being faster than they can regenerate? - Does it reduce or increase use of non-renewable resources (groundwater, minerals etc.)? - Does the option lead to changes in business opportunities linked with more efficient use of resources?	     
Land use (Tool #36)	- Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? - Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture, or land abandonment)? - Does the option affect the type of economic activity linked to the change in land use?	   
The likelihood or scale of environmental and climate risks (Tool #36)	- Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions? - Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms? - Does the option affect the developments in the insurance markets?	 

Impact on	Key questions	SDG
		  
Employment (Tool #30)	- To what extent are new jobs created or lost? - Are direct jobs created or lost in specific sectors, professions, regions or countries? Which specific social and or age groups are affected, including groups determined by gender, disability, migrant, or minority of ethnic or racial background? - Are there significant indirect effects which might change employment levels? - Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses? - To what extent does the option influence opportunities and incentives of workers/specific groups to work (i.e. supply of labour through labour market participation or mobility)? - Does the option have overall consequences for economic growth and employment?	
Income distribution, social protection and social inclusion (of particular groups) (Tools #30, #33)	- Does the option affect peoples'/households' income and at risk of poverty rates? - Does the option affect inequalities and the distribution of incomes and wealth? - Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds? - Does the option affect the financing and organisation of social protection systems? - Does the option affect the access to and quality of basic goods and services particularly for those subject to social exclusion and from disadvantaged backgrounds?	  
Technological development / Digital economy (Tool #28)	- Does the option affect processes that could be simplified or even automated? - Does the option potentially create synergies with existing digital policies? - Does the option affect one or several existing digital eco-systems and actor and/or the exchange of data between different actors and systems (including across sectors and borders)? - Does the option consider the reduction of burden and costs for businesses and citizens through the use of digital technology? - Does the option affect the pace of the digital transformation of economic or social sectors, including public services and the take-up of innovative digital technologies? - Does the option affect the digital accessibility or the digital gap?	 
Consumers and households	Does the option impact consumers' ability to benefit from the internal market or to access goods and services from outside the EU?	

Impact on	Key questions	SDG
(Tool #33)	- Does the option affect the prices, quality, availability or choice of consumer goods and services? - Does the option affect consumer information, knowledge, trust, or protection? - Does the option impact the safety or sustainability of consumer goods and services? - Does the option impact vulnerable consumers?	
Capital movements; financial markets; stability of the euro (Tools #21-25)	- How does the option contribute to improving the conditions for investment and the proper functioning of markets? - Does the option have direct impacts on macro-economic stability?	 
Property rights, intellectual property rights (Tools #22, 29)	- Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? - Does it affect the protection and enforcement of intellectual property rights (patents, trademarks, copyright, other know-how rights)?	 
Territorial impacts (specific (types of) regions and sectors) (Tool #34)	- Does the option affect economic activity, environment, or people living in cities, rural, cross-border, insular, mountainous, or sparsely populated areas and in the EU outermost regions to a significantly different extent than elsewhere in the EU? - Is the problem concentrated in certain areas (e.g. rural), regions, or Member States? - Does the initiative affect certain areas (e.g. rural), regions, or Member States in a disproportionate manner? - Does the initiative address regions differently according to their traits/endowments and thus lead to uneven territorial development? - Does one or the other option distort the principle of territorial cohesion as one of the founding principles of the EU? - Does the initiative have an effect on the EU outermost regions taking into account their constraints (as per art. 349 TFEU) and on other island, cross-border and mountain regions taking into account their characteristics (as per art. 174)? <i>If the answer to any of these question is positive, the Territorial Impact Necessity Check will help assess the need of a more in-depth analysis of territorial impacts</i>	   
Innovation (productivity and resource efficiency), research (academic and industrial), (Tool #22)	- Does the option stimulate or hinder research and development? - Does it facilitate the introduction and dissemination of new production methods, technologies, and products? - Does it promote or limit academic or industrial research? - Does it promote greater productivity/resource efficiency?	  
Fraud, crime, terrorism and security, including	- Does the option improve or hinder security, or affect crime or terrorism risks? - Does the option affect the criminal's chances of detection or his/her	

Impact on	Key questions	SDG
hybrid threats (Tool #26)	potential gain from the crime? - Is the option likely to increase the number of criminal acts? Does it have an impact on a specific type of crime (money laundering, fraud, corruption, illicit production and trafficking, cybercrime, etc.)? Will it divert people away from or prevent crime? - Does it affect law enforcement capacity to address criminal activity? - Will it have an impact on security interests? - Does the option risk creating additional vulnerabilities and exposure to hybrid threats²⁰⁷? - Does the option address directly or indirectly a persistent hybrid threat challenge? - Is the option likely to reduce the exposure to hybrid attacks/incidents? - Does it affect the victims of crime and witnesses or their rights? - Does the option affect the risk of environmental fraud?	
Resilience, technological sovereignty, open strategic autonomy, security of supply	- Does the option affect the EU's resilience in the relevant policy area? - Does the option improve or hinder the technological sovereignty of the EU as regards critical technologies? - Does the option reduce or exacerbate existing dependencies on third countries as regards critical technologies and value chains? - Does the option affect the Union's essential security interests, in particular as regards critical technologies, infrastructure and value chains?	
Transport and the use of energy (Tools #21, 22, 36)	- Does the option affect the energy intensity of the economy? - Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc.) used in energy production? - Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? - Does it increase or decrease vehicle emissions? - Will the option increase/decrease energy and fuel needs/consumption?	   
Food safety, food security and nutrition	- Does the option affect the safety of food and feed? - Does the option affect food and nutrition security (both in EU and third countries): production (including agricultural products), distribution, trade, and consumption of food (including access, affordability and nutritional quality)?	 
Waste production, generation and recycling (Tool #36)	Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of, or recycled?	
Third countries, developing countries,	Does the option alter the recognition of the International Labour Organisation's core labour standards and other ratified ILO Conventions	

²⁰⁷ Hybrid activities by State and non-state actors aim to destabilise countries by undermining public trust in government institutions and by challenging the core values of societies and deepening social divisions. Hybrid threats range from cyber-attacks disrupting the economy and public critical services to targeted disinformation campaigns and hostile military actions.

Impact on	Key questions	SDG
and international relations (Tools #27, 35)	(classified as up to date by the ILO) and the implementation of the ILO Decent Work Agenda in third countries? • Are there employment, social protection, and poverty impacts in non-Member States (including developing countries)? • Are there the impacts on gender equality and on the most vulnerable groups of society, including persons with disabilities? • Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy? • Is the option compliant with legal commitments such as WTO Agreements and Free Trade Agreements, Economic Partnership Agreements, investment protection agreements and other preferential trade arrangements? • Does it affect EU foreign policy and EU/EC development policy? Does it comply with the obligation of Policy Coherence for Development? • What are the impacts on third countries with which the EU has preferential trade arrangements? Does it affect the interest of the ACP group of states party to the Cotonou Partnership Agreement? • Does it affect developing countries at different stages of development (least developed and other low-income and middle-income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries?	    
Fundamental rights (Tool #29, #30)	• Does the option impact on any of the fundamental rights endorsed by the EU Charter of Fundamental Rights: – Dignity (<i>right to life, personal integrity, prohibition of torture, slavery, forced labour, the death penalty</i>) – Freedoms (<i>liberty, privacy, protection of personal data, marriage, thought, conscience, religion, expression, assembly, arts and sciences, education, conduct business, work, property, and asylum</i>) ○ Does the option affect any of the individual's freedoms? ○ Does the option involve the processing of personal data and are the individual's right to access, rectification and objection guaranteed? ○ Does the option affect the freedom to conduct a business or impose additional requirements increasing the transaction costs for the economic operators concerned? ○ Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? – Equality (<i>equality before the law, non-discrimination on basis of sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation, cultural, religious and linguistic diversity, the rights of children and the elderly, integration of persons with disabilities</i>). ○ Does the option safeguard the principle of equality before the law and would it affect directly or indirectly the principle of non-discrimination, equal treatment, gender equality and equal opportunities for all? ○ Does the option have (directly or indirectly) a different impact on	         

Impact on	Key questions	SDG
	women and men? ○ Does the option ensure respect for the rights of people with disabilities in conformity with the UN Convention on the rights of persons with disabilities? ○ Does the option affect the rights of the child (or group) and respect of the UN Convention on the rights of the child? – Solidarity (<i>right to fair working conditions, protection against unjustified dismissal, and access to health care, social and housing assistance</i>) – Citizens' Rights (<i>to vote in European Parliament and local elections, to move freely within the EU, to good administration, to access documents and to petition the European Parliament</i>) – Justice (<i>the right to an effective remedy, a fair trial, to the presumption of innocence, the principle of legality, non-retrospectivity and double jeopardy</i>) ○ Does the option affect the individual's access to justice? • Are the rights in question absolute rights, which may not be subject to limitations? • Do the options have opposing impacts on different fundamental rights?	

TOOL #19. SUSTAINABLE DEVELOPMENT GOALS

1. POLICY CONTEXT AND SDGs FRAMEWORK

The UN established its 2030 Agenda for Sustainable Development in 2015. It sets out a framework to steer sustainable development globally via a set of **17 sustainable development goals** (SDGs) and **169 targets**. The SDGs cover **environmental, economic, and social aspects**, and are relevant for the Commission's system of better regulation that aims to mainstream the sustainable developments goals into the policymaking process, so that every legislative proposal contributes to the 2030 sustainable development agenda of the UN²⁰⁸.



The EU is committed to implement the 2030 Agenda. The 2016 Communication 'Next steps for a sustainable European future' announced detailed monitoring of the SDGs in the EU from 2017 onwards. This commitment by the Commission was taken further in the 2019 Reflection Paper 'Towards a sustainable Europe by 2030'²⁰⁹, and the Commission work programme 2020 put the SDGs at the heart of its policymaking²¹⁰. The Commission has given a central role to SDGs across policies, as highlighted in the Commission staff working document 'Delivering on the UN's SDGs – A comprehensive approach'. The OECD is also active in promoting policy coherence for sustainable development. In December 2019, the OECD published a recommendation to help equip policymakers with the necessary institutional mechanisms and policy tools to support and promote coherent policies for sustainable development and the universal commitments made under the 2030 Agenda and the sustainable development goals²¹¹.

An **EU SDG indicator set** with 100 indicators to monitor the EU's progress towards the SDGs underpins the EU SDG monitoring report published annually by ESTAT. The EU SDG

²⁰⁸ For very technical initiatives, it might not be possible to make a link to SDGs. In this case, the report will indicate this transparently. In some cases, links to SDGs are only indirect, which should also be transparently reported.

²⁰⁹ COM(2019) 22 final

²¹⁰ Commission Work Programme 2020, « A Union that strives for more », COM(2020) 37 final of 29.1.2020.

²¹¹ OECD 2019, [Recommendation](#) of the Council on Policy Coherence for Sustainable Development, OECD/LEGAL/0381.

indicator set is open to regular reviews. It is closely related with and complements the UN's indicator list from July 2017 that includes **231 individual indicators** to monitor the global progress towards the SDGs²¹². The Commission's KnowSDGs (Box 1) presents a full description of all the 17 goals and 169 targets, including the list of UN and EU SDG indicators.

Every impact assessment or evaluation process will involve a pragmatic identification of the significant environmental, social, and economic impacts that will be assessed and reported²¹³. Tool#18 links the various impacts with the relevant SDGs. Each specific tool on impacts (tools #21 to #36) includes a table that helps to identify the relevant SDGs and includes a selection of the most relevant indicators. A number of tools also provide support to quantify the various impacts (and potentially changes in SDG-related indicators (see Chapter 8).

Since SDGs are universal, the EU commitment to support their implementation includes not only ensuring progress internally. For this reason, the assessment on progress towards the SDGs should keep into consideration the external effects, including in developing countries, which may call for applying in a complementary manner the tools relating to external impacts, in particular Tool #35 on impacts on developing countries and where relevant Tool #27 on external trade and investment.

2. SDGs IN IMPACT ASSESSMENTS, EVALUATIONS, AND FINAL PROPOSALS

The indicators and monitoring arrangements underpinning the SDGs can be used to describe the status quo, policy objectives, expected impacts of policy options and the observed changes resulting from new policies. As such, the SDG framework is highly relevant for impact assessments and evaluations. In addition, the expected benefits/impacts related to the SDGs should be reported transparently in the proposals that the Commission makes²¹⁴. Given that the 2030 Agenda is universal and applies to the EU (across institutions) and within Member States, this is useful information for the Legislator, consultative bodies, and national Parliaments in their respective treatment of the Commission's proposal.

Impact assessments

The relevant SDGs should be identified²¹⁵ and the associated indicators should be used (if available) when preparing the following sections of the impact assessment report²¹⁶:

- **Problem definition**²¹⁷: It will often be possible to define the problem as a lack of progress in the area covered by one or more SDGs (and linked targets) as evidenced by the available SDG indicators and monitoring data presented at EU and national levels. Even where the SDGs (or linked targets) are not directly relevant to a given initiative it is still possible that some of the monitoring data collected to report on the SDGs in the EU is still useful to describe the consequences of a given problem.

²¹² Currently, 56% of those indicators are classified as tier 1 by the UNSC, meaning that data is regularly produced by countries for at least 50 per cent of countries and of the population in every region, while for the others, data is not regularly produced. (<https://unstats.un.org/sdgs/iaeg-sdgs/tier-classification/>)

²¹³ See Tool #18 (*Identification of impacts*)

²¹⁴ The principle of proportionate analysis applies; thus impacts will be quantified to the extent possible.

²¹⁵ See Tool#18 (*Identification of impacts*) and their link with SDGs.

²¹⁶ In addition, the same issues are relevant when preparing the 'call for evidence'.

²¹⁷ See Tool #13 (*How to analyse problems*)

- **Objectives²¹⁸**: It may often be possible to describe the aims of a given initiative in terms of contributing to the implementation of one or more SDGs. At the initial stage, one should identify the relevant SDGs for the initiative at stake. In many cases, this can be further specified as delivering a qualitative or quantitative improvement in one or more of the indicators linked to one or more SDGs. The same indicators can be used to report on the performance of the initiative once implemented.
- **Policy options – baseline**: The baseline describes how the current situation is expected to evolve over time (without any policy intervention)²¹⁹. Again, the SDG-related indicators can be used to describe important aspects of the baseline.
- **Impact analysis**: The significant environmental, social, and economic impacts of each policy option are assessed in the impact assessment report. Where the SDG-related indicators have been used in the baseline, it is possible to present impacts of policy options in terms of the changes expected in those indicators from a given policy option, particularly for the preferred option. Ideally, such an assessment should be quantitative in nature.
- **Monitoring arrangements**: Every impact assessment should describe how the performance of the intervention will be monitored as part of a future evaluation. There may be a role for the SDG-related indicators²²⁰ particularly where these have been used to define the objectives to be achieved by the initiative.
- **Annex 3**: Every impact assessment must report in a dedicated table identifying the relevant SDGs for a given initiative. In addition, for the preferred option, the table needs to assess the progress towards the identified SDG targets. For the cases, where the SDG targets are quantifiable and so is the progress to reach them, the table should present these estimates. When the progress cannot be quantified, the table should give an indicative direction in relation to the relevant SDG targets (whether the preferred option is likely to get the EU closer to the target / improve, stay neutral or get away from the target / deteriorate). In view of interlinkages across the SDGs, the table should be accompanied by explanations describing possible synergies and trade-offs between specific SDGs and justifications for the proposed policy choices.

Include in the 'call for evidence' the above considerations on SDGs when preparing the documents to be published with the 'call for evidence' defining problems, objectives, policy options and a preliminary assessment of impacts.

For financial programmes and financial instruments²²¹, reference to the SDGs should also be considered for ex-ante evaluations in an analogous manner as for impact assessments.

Evaluations and fitness checks

The monitoring arrangements present the link between the evaluation, impact assessment and the relevant SDGs with their associated indicators and data collection activities.

When impact assessments pre-date the SDGs (and their associated indicators) or do not refer to the SDGs even though they may be relevant:

²¹⁸ See Tool #15 (*How to set objectives*)

²¹⁹ See Tool #16 (*How to identify policy options*) and Tool #60 (*Baselines*)

²²⁰ SDG indicators may be broader than operational objectives of an initiative. It may be difficult to disentangle the effect of a particular measure from other measures also acting on a specific SDG objective.

²²¹ See Tool #9 (*Spending programmes, financial instruments, and budgetary guarantee*)

- In the latter case, the evaluation could still refer to the contribution to the implementation of relevant SDGs.
- The evaluation can still make use of the SDG data sets and indicators when assessing the performance of the intervention so long as an appropriate baseline is used (complemented with the SDGs but consistent with the original impact assessment).
- The evaluation will then have to collect whatever relevant evidence exists to assess performance, linking it to the relevant SDG.

Commission proposals – explanatory memorandum

While it is important to mainstream the SDGs into policymaking processes, it is also important that the Commission reports transparently and effectively on its activities to make progress in the areas relevant to each SDG.

Therefore, when the Commission presents a new proposal (regulatory or financial) it will explain its objectives in terms of contribution to the implementation of the relevant SDGs at stake and expected impacts in terms of their associated indicators. This information will help inform the deliberations of the co-legislators. The explanatory memorandum²²² should summarise the key findings of the impact assessment (or ex-ante evaluation) relevant to the SDGs, based on the analysis presented in Annex 3 of the impact assessment (or the relevant analysis in ex-ante evaluation).

3. ADDITIONAL INFORMATION SOURCES AND AVAILABLE TOOLS

The Commission's website KnowSDGs (box 1) presents a full description of all the 17 goals and 169 targets, including the list of UN and EU SDG indicators. All the information is organised by goal, and for each EU indicator there is a direct link to the ESTAT data browser, where the user can visualise the full description of the indicator and access the corresponding data by country and year.

The platform offers interactive tools to explore: 1) how EU policies relate to the SDGs, 2) what SDG interlinkages are and how they can be identified, and 3) modelling tools that can be used to look at the SDGs through a quantitative lens

Box 1: Tools for the analysis of SDGs - the KnowSDGs Platform

The KnowSDGs (Knowledge base for the Sustainable Development Goals) platform provides interactive and easy-to-use tools and organises knowledge on policies, indicators, methods, and data to support the evidence-based implementation of the SDGs. The following tools are available on the platform to support policy makers in contextualising their policies within the SDG framework.

The **SDG policy-mapping tool** is designed to help policymakers identify the SDGs that may potentially be impacted or linked to their policy. Utilising automatic text classification, the tool provides a semantic analysis of any policy document to identify the relevant SDGs (at goals and targets level) that are addressed in the text, based on a database of relevant keywords. The tool is applicable at different stages of the policy cycle and is a useful guidance for policymakers in bringing the complete picture of SDGs to their attention, along with their extent and the complexity of their interactions.

²²² See Tool #40 (*Drafting the explanatory memorandum*)

In its interactive version – **the SDG Mapper** – the user can upload any policy-related text to a secure portal, and immediately receive a preliminary analysis of the relevant SDGs and targets. It also facilitates the production of infographics on the relevant SDGs, for instance in a draft proposal, thereby making it particularly useful in the 'better regulation' context. Since data interpretation is crucial to assure correct assessment of the relevant SDGs and targets, the JRC can provide additional support for deeper analysis and interpretation of results.

In addition, the **EnablingSDGs tool** facilitates policymakers in the identification of interlinkages – synergies and trade-offs – and interactions between different SDGs, assessing impacts of different policy choices, highlighting second-order effects and potential unintended consequences of the policy proposal. This specific toolkit facilitates engagement of policymakers (and eventually also stakeholders, scientists etc.) in a dialogue to identify and characterise the relevant SDGs interactions. This can contribute in a more tangible manner to ensure a balanced integration of the three dimensions of sustainable development.

Moreover, the **SDGs modelling tool** aims to facilitate the use of models for sustainability assessment in the SDGs framework, through the identification of appropriate model(s) for the assessment of specific policy options. The tool provides the list of all the models run or developed by the Commission and included in the Modelling Inventory and Knowledge Management System (**MIDAS**) and their contribution to the SDGs (at goal, target, and indicator level). This tool offers a transparent mapping of how model outputs can be directly or indirectly linked to EU/UN SDGs indicators, therefore screening which models could be suitable to quantitatively evaluate the impacts of policy options on SDGs, targets, and indicators.

TOOL #20. STRATEGIC FORESIGHT FOR IMPACT ASSESSMENTS AND EVALUATIONS

1. WHAT IS STRATEGIC FORESIGHT AND WHY IT IS IMPORTANT

Strategic foresight seeks to embed foresight, understood as the discipline of exploring, anticipating, and shaping the future, into EU policymaking. The EU must make sure that it develops policies that are robust and future proof, and that policymakers and institutions are prepared to anticipate changes to proactively shape the future according to the EU’s political priorities. Strategic foresight can help anticipate trends, risks, emerging issues, and their potential implications and opportunities to draw useful insights for strategic planning, policymaking, and preparedness. It can also support policymaking in the initial stages of the policy cycle, from initial problem scoping to option design, but also in reviewing and futureproofing existing policies.

This tool focuses on the practical use of strategic foresight in impact assessments and evaluations. More systematic use of foresight analysis for preparing impact assessments, evaluations, and fitness checks, should help Commission services better deal with uncertainty and ensure that Commission initiatives benefit from:

- clearer understanding of megatrends and drivers of change, which may impact the policy problem and its future evolution;
- policy objectives that consider the key future challenges;
- future-proof policy options that are designed to address the key future challenges.

Public consultations could also include foresight-related questions, to capture the stakeholders’ perspective in the given policy area.

2. STRATEGIC FORESIGHT METHODS

Various methodologies and approaches can support embedding the foresight into the ‘better regulation’ framework²²³:

Firstly, impact assessments should take account of **megatrends**. These are long-term global driving forces that are observable in the present and are likely to continue to have a significant influence for a few decades. They have the potential to lead to large- and broad-scale transformations (see Table 1).

Secondly, the analysis of megatrends can be complemented with **the use of future (long-term) scenarios** as the basis for the development of more resilient and future-proof policies. Scenarios are plausible consistent pictures of the future, describing the context of a policy area. They may consider one or more megatrends. They can be used to assess and stress-test how policies and policy objectives would perform in these future situations, leading to strategic reflections of alternative options for policy decisions today.

Using scenarios could allow:

²²³ The Competence Centre for Foresight (JRC-FORESIGHT@ec.europa.eu) can provide support with these methodologies. Other foresight approaches, beyond megatrends and scenarios, may also be used where relevant.

- considering key uncertainties by understanding viable alternative future developments and the role and interests of different stakeholders therein;
- anticipating changes in overarching EU policy objectives in the medium to long term;
- assessing the performance of existing legislation against alternative future situations/scenarios, to identify which policies and strategic objectives need to be revised to become more robust to future scenarios.

The design of scenarios is resource- and time-consuming and should be planned well ahead. If this is not possible, there is a sizeable number of existing scenarios (e.g. developed for climate policies²²⁴ or pension and inter-generational issues²²⁵) and foresight studies²²⁶ that may inform the futureproofing of other policy areas. Scenarios are also closely linked with other 'better regulation' tools such as baselines (Tool #60).

Table 1: Overview of megatrends in the Commission's Megatrends Hub²²⁷

Continuing urbanisation By 2100, the urban population could reach 9 billion. Cities are increasingly functioning autonomously, setting new social and economic standards.	Growing consumption By 2030, the consumer class is expected to reach 5 billion people. This means 2 billion more people with increased purchasing power than today.	Diversifying inequalities Absolute number of people living in extreme poverty has been declining. The gaps between the wealthiest and poorest of the population are widening.	Increasing demographic imbalances World population may reach 8.5 billion by 2030, with rapid growth in many developing economies, while shrinking in many developed countries.
Diversification of education and learning New generations and hyperconnectivity are rapidly changing both educational needs and modes of delivery.	Shifting health challenges Science and better living standards reduced infectious diseases. Unhealthy lifestyles, pollution, other anthropogenic causes turn into health burdens.	Accelerating technological change and hyperconnectivity Technologies are changing the nature and speed of new scientific discoveries and are transforming systems of production, management, and governance.	Changing nature of work New generations entering the workforce and older generations working longer are changing employment, career models, and organisational structures.
Expanding influence of east and south The shift of economic power from the established Western economies and Japan towards the emerging economies in the East and South is set to continue.	Increasing significance of migration The social and political significance of migration has increased. Migration flows and dynamics have become more mixed in an interconnected world.	Increasing influence of new governing systems Non-state actors, global conscientiousness, social media and internationalisation of decision-making are forming new, multi-layered governing systems.	Changing security paradigm Diversification of threats and actors is generating new challenges to the defence and security communities, as well as to society as a whole.
Aggravating resource scarcity Demand for water, food, energy, land, and minerals are rising substantially, making natural resources increasingly scarce and more expensive.	Climate change and environmental degradation Continued unabated, anthropogenic pollution and greenhouse gas emissions will further increase changing climate patterns.		

²²⁴ The [2020 Foresight study on Raw Materials](#) is based on the [2050 scenarios](#) to underpin the Climate Law.

²²⁵ E.g. [The 2021 Ageing report](#)

²²⁶ E.g. [Farmers of the future](#)

²²⁷ If time and other resources allow, a half-day [megatrends workshop](#) can help to understand how the future conditions may affect the policy objectives and policy problems. Ideally, this happens ahead of drawing terms of references for external studies and scoping possible baseline and modelling work (see Chapter 8). Involvement of a carefully selected group of 4-8 colleagues from related policy fields and possibly external experts with diverse and complementary perspectives can provide a multi-faceted assessment of long-term challenges and options.

Where relevant, based on the megatrends or scenarios, the following questions should be answered: (1) which megatrends apply to the policy problem? What do the scenarios talk about the policy problem? (2) which stakeholders are affected by the megatrends and scenarios?

These **findings should be considered in a proportionate way in the relevant sections of the impact assessment** (problem definition and baseline, policy objectives, policy options and their assessment) following the three steps below:

A. Identify the relevant megatrends/scenario that should be used	
Why?	Assure a systematic, future-oriented analysis of the problem drivers and their future evolution.
How?	Reflect on how relevant megatrends/scenario could affect the policy problem and its future evolution.
B. Analyse the impact of the relevant megatrends/scenario and define policy objectives	
Why?	Understand the effect of the relevant megatrends/scenarios on the policy problem and adapt policy objectives accordingly.
How?	Assess the long-term implications on the policy problem: which aspects of the problem would the relevant megatrends/scenarios affect/change? Which stakeholders would be more/less affected from this change?
	Integrate the findings into key challenges that need to be addressed by the policy options.
C. Design policy options to achieve future-proof policy objectives	
Why?	To future-proof the policy options to be resilient to changing boundary conditions.
How?	Develop policy options that address the key challenges identified in Step B to accommodate the evolution of the problem over time.
	Identify potentially weak aspects of other policy options and consider improvements to better address future needs.
	Consider in how far the policy options could themselves impact a megatrend/scenario, and whether this could have any effect on reaching policy objectives.

3. STRATEGIC FORESIGHT IN EVALUATIONS AND FITNESS CHECKS

Fitness checks and **evaluations** inform political priority setting, and contribute to strategic planning, as well as to the revision of existing legislation. While evaluations and fitness checks are ex-post assessment of existing policies, their goal is to provide input to future revisions of the policy instrument, asking: *is the intervention still relevant today and will it be relevant tomorrow?* Evaluations and fitness checks should look beyond the current relevance

and reflect on how the key evolutions, uncertainties and challenges of the future may affect the future relevance, coherence, and effectiveness of the policy area.

4. ADDITIONAL INFORMATION

- Stoermer, E. et al. (2020): Foresight – Using Science and Evidence to Anticipate and Shape the Future. In: Šucha, V and Sienkiewicz M. (ed.) JRC Handbook on Science and Evidence in the Policy Ecosystem. ISBN 978-0-12-822596-7, [DOI:10.1016/C2018-0-03963-8](https://doi.org/10.1016/C2018-0-03963-8)
- Wilkinson, A. (2017): Strategic Foresight Primer, EPSC. ISBN: 978-92-79-75373-2, DOI: 10.2872/71492
- ESPAS (2019): Global Trends to 2030. Challenges and choices for Europe. [ISBN: 978-92-76-04010-1, DOI :10.2872/074526](https://doi.org/10.2872/074526)
- European Parliamentary Research Service, Global Trends Team: Global Trendometer 2019. Essays on medium and long-term trends. [ISBN 978-92-846-6091-9, DOI:10.2861/051532](https://doi.org/10.2861/051532)
- ORBIS, the global foresight hub – online library of prospective studies
- Megatrends workshop tool to assess long-term implications of megatrends

TOOL #21. COMPETITIVENESS CHECK

1. INTRODUCTION

All impact assessments should assess how the proposed policy intervention is expected to affect competitiveness. The Competitiveness check (Annex 5 of the impact assessment) summarises the key impacts on competitiveness of the preferred policy option and the situation of the most affected sectors, when relevant (see step 2). The main report or dedicated annexes can present more detailed analysis.

EU initiatives are likely to affect competitiveness when they affect one or more of the following dimensions:

- **cost and price competitiveness** - the capacity to produce goods or services at a lower cost and/or offer them at a lower price;
- **capacity to innovate** - the quality or originality of goods or services, and technological development and innovation of products and/or processes;
- **international competitiveness** - the sectors' market shares on international markets, which reflect the comparative advantages of European companies;
- **SME competitiveness** – the ability of SMEs to compete with other market participants.

This tool is based on a more detailed operational guide on how to assess impacts on sectoral competitiveness²²⁸. The 2021 OECD report "*How do laws and regulations affect competitiveness: The role for regulatory impact assessment*" endorses and builds on the methodology presented below.

2. GETTING STARTED: ARE IMPACTS ON SECTORAL COMPETITIVENESS POTENTIALLY SIGNIFICANT?

The principle of proportionate analysis means that not all IAs need to assess sectoral competitiveness in depth. The first question to be answered is whether an initiative is likely to have a significant effect on sectoral competitiveness or not.

Step 1. Is the initiative likely to have significant impacts on competitiveness?

While the impacts on competitiveness need to be assessed for every policy intervention, you may use **the checklist** in Box 1 to get a first indication of the depth and scope of the analysis needed. Box 1 uses an example of a proposal to ban the use of hazardous materials in EU industrial products. This first assessment of the expected impacts on competitiveness does not require an in-depth study or quantitative techniques and you can use your expertise only. The replies may not be straightforward and may even change as you advance in your analysis.

²²⁸ [Operational guidance for assessing impacts on sectoral competitiveness within the Commission Impact Assessment system, SEC \(2012\) 91.](#)

Box 1 - CHECKLIST. Is the ban of use of hazardous material likely to have a significant impact on factors affecting the competitiveness of EU companies?

	Likely significant impact
Cost and price competitiveness	
Cost of inputs	Yes
Cost of capital	No
Cost of labour	Cannot say
Other compliance costs (e.g. reporting obligations)	No
Cost of production, distribution, after-sales services	Yes
Price of outputs (e.g. price controls)	Cannot say
Capacity to innovate	
Capacity to produce and bring R&D to the market	Yes
Capacity for product innovation	Yes
Capacity for process innovation (including distribution, marketing, and after-sales)	Cannot say
Access to risk capital	Cannot say
International competitiveness	
Market shares (EU single market)	Cannot say
Market shares (external markets) ²²⁹	No

If the impacts are expected to be significant or when there is considerable uncertainty (i.e. many unanswered questions in the checklist), a further analysis of the impacts on competitiveness would be warranted.

For proposals that are likely to have only a limited impact on competitiveness and for which a deeper analysis would be disproportionate, the assessment may remain mainly **qualitative**, but this should be justified in the Competitiveness check (Annex 5 to the impact assessment). Where impacts are expected to be **significant**, in addition to the qualitative assessment, you should strive to include **quantitative** elements and carry out a quantitative estimation of impacts. Whereas a simple analysis may be limited to direct effects, a deep analysis of competitiveness should consider direct and indirect impacts, both positive and negative, and account for short- and long-term effects.

Step 2. Which sectors are affected? What is the competitive position of the most affected sectors?

Before assessing the expected impacts of the initiative on competitiveness in depth, you should try to **identify the sector(s) most affected by the initiative and assess their current competitive position**.

²²⁹ The sector's market shares on the international markets.

For most **sectoral initiatives**, the identification of the most affected sectors will be straightforward, but some initiatives are **horizontal** and affect the whole economy (e.g. employment or energy policies). In such cases, you should look at the distribution of impacts across sectors. You may need to consider labour, energy, resource and capital intensities to better gauge the distribution of impacts and identify the most affected sectors if feasible.

When trying to identify the most affected sectors, it is important to consider direct impacts and indirect impacts. **Indirect impacts** are triggered by changes in relative prices and changes in supply and demand for inputs and outputs in the directly affected sector. They can affect downstream or upstream sectors as well as markets for complementary or substitute goods and may occur in parallel to the direct effects or with a delay (second round effects). They are important for two reasons. First, they may be greater than the direct effects if they affect many sectors. Second, they can alter the overall expected benefits/costs.

The interservice coordination group can help identify the sectors that are most affected by the initiative. In case it is impossible to identify a few most affected sectors due to the horizontal nature of an initiative, this should be explained and justified in the Competitiveness check (Annex 5 to the impact assessment).

If the policy proposal is expected to affect certain sectors in particular (either because of its sectoral nature or in case of horizontal proposals because some sectors would be more directly affected), **the impact assessment should assess their current competitive position**. The aim is to see if the sectors most affected by the initiative are currently under particular 'stress' due to the cumulative impacts of regulation or other factors. Such analysis should inform policymaking and provide useful context for the competitiveness analysis to see whether the additional regulatory costs seem bearable or whether this might 'push many EU businesses over the cliff'.

This analysis should also allow for a comparison of the competitive situation of EU companies in a given sector with (i) the situation of non-EU companies in the same sector (international competitiveness); (ii) the situation of companies in other sectors that serve as a benchmark, e.g. all manufacturing sectors, possibly differentiating companies by their size (SME competitiveness).

If data are available, the assessment of the current competitive position of the most affected sectors should be **quantitative, based on several indicators** covering different dimensions of competitiveness, and (where available) include a time series to assess the evolution.

The list of indicators in Box 2 below is indicative. It might be adjusted to consider the key impacts of the initiative. For example, initiatives with significant cost implications might require more in-depth analysis in relation to productivity and profitability of the sector, whereas those related to research might require analysing innovation related indicators. The availability of data for the sector concerned will also influence the type of indicators analysed.

Box 2. List of possible indicators

1) Key facts and trends concerning the sector:

- weight of the affected sector in the EU economy, as measured by its share

in value added, turnover and employment, and the evolution of key indicators over time (change in gross value added, turnover and employment in the last several years);

- number and distribution of firms, including the share of SMEs (possibly differentiating between different size classes)²³⁰;
- the “dynamism” of the sector captured by the number of high-growth enterprises (HGEs) and/or the number of employees working in HGEs²³¹.

2) Productivity and profitability of the sector

- labour productivity or total factor productivity of the sector;
- current costs and/or profitability, as measured by net profit margins, gross operating rates or return on equity²³², if possible differentiating between EU and non-EU companies and by size class of companies.

3) International position of the sector

- EU market share in global production or in global exports, and trade flows (EU exports and imports, EU trade balance);
- flow of Foreign Direct Investment (ratio of inward/outward FDI stock to value added). The ratio of inward FDI stock to value added indicates the contribution of FDI to capital formation and signals the attractiveness of the host country. The ratio of outward FDI stocks to value added is an indicator of corporate strength, where companies venture abroad to seize opportunities from foreign markets and resources;
- export market shares show how much of the total ‘world’ export is covered by the export of a particular country for each industry. They reflect the capacity to respond to external demand or to open up new markets in direct comparison to international competitors;
- revealed comparative advantage (RCA), which compares the share of a given industry’s exports in the EU’s total exports with the share of the same industry’s exports of a group of reference countries or the world as a whole;
- relative trade balance (RTB), which compares the trade balance of a particular commodity to the total volume of trade, exports plus imports;
- terms of trade, measured by, for example relative unit labour costs (RULC), to assess the cost of labour in a given industry relative to its productivity (unit labour costs) and relative to the corresponding index in another country;
- firms’ assessments of their competitive position in foreign markets, as inquired by the Joint Harmonised EU Programme of Business and Consumer Surveys.

4) Innovation in the sector

²³⁰ Concentration measures should be analysed in relevant markets. For example, in the context of a regulation about glyphosate, one would want to understand the level of concentration in the glyphosate market, not the entire chemicals sector.

²³¹ [High-growth enterprises - statistics - Statistics Explained - Eurostat](#)

²³² It could also be interesting to analyse distributions of profit margins or return on investment, across firms and across time, using firm-level databases, yet this requires having licenses to access such databases and the technical capacity to use them.

- numbers of innovation active or innovative firms, as a percentage of total firms in the sector;
- R&D expenditure in the sector.

Most of the above data can be found in the Eurostat database, in particular in the sections on Structural Business Statistics, production of manufactured products (PRODCOM) and international trade in goods (COMEXT) [and services](#) (EU trade in services). Furthermore, the OECD database is a valuable source. Section 5 furthermore lists several additional databases which could be consulted.

You should also take stock of existing sectoral and market studies and evaluations completed by the Commission and pay particular attention to the sectors already identified as being at competitive disadvantage, for example in the Draghi report²³³, as well as any other sector that may be identified as strategically relevant. You may also consult the websites and publications of the respective business associations or concerned social partner organisations.

The analysis of the competitive position of the most affected sectors should be summarised in Annex 5 of the impact assessment (Competitiveness check).

3. QUALITATIVE AND QUANTITATIVE ASSESSMENT OF IMPACTS ON COMPETITIVENESS

Annex 5 should present an overview of the **impacts of the preferred option on competitiveness**, along four dimensions of competitiveness, i.e. (i) cost and price competitiveness, (ii) international competitiveness, (iii) capacity to innovate and (iv) SME competitiveness.

Based on the analysis in the main report, Annex 5 should present an **overall assessment (score)** of each of the four competitiveness dimensions in a standardised table. The table should be accompanied by a **synthetic assessment (short narrative)** summarising the expected impacts of the preferred option on competitiveness and the main factors that affect competitiveness, including key figures on costs and benefits and any information that is particularly relevant for the overall assessment (for instance, if impacts are expected to evolve over time). If no impacts on competitiveness are signalled, this should be duly justified.

The assessment of the impacts on competitiveness should include quantitative analysis to the extent possible. Whereas qualitative assessment is mainly a narrative, quantification of impacts on competitiveness may require descriptive statistics, input-output analysis using national or sectoral accounts, applied general equilibrium modelling, or other econometric exercises. For policy proposals that affect a diverse set of sectors, models such as computable general equilibrium (CGE) and macro-econometric input-output models can be used to quantify overall impacts²³⁴. The impacts on competitiveness may vary over time, which should be reflected in the analysis.

The steps suggested below give an overview of possible outputs of the qualitative and quantitative analysis, rather than specific tools and methods to deliver them, as these would

²³³ The sectors identified by the Draghi report are energy, critical raw materials, digitalisation, broadband networks, computing, semiconductors, energy-intensive industries, clean technologies, automotive, defence, space, pharma and transport.

²³⁴ See Tool #61 (*Simulation models*)

depend on the issue at hand. The assessment of the competitive position of the most affected sectors (step 2) provides a valuable context and a starting point for the competitiveness analysis.

Step 3. What is the impact on cost and price competitiveness?

A policy proposal may have impacts on the cost of business operations and thus on returns on investment and investment flows. It may impose direct compliance costs on affected sectors, or it may affect costs indirectly, due to the change of behaviour of suppliers, consumers, employees and investors resulting from the intervention.

When assessing the impacts of the preferred option on cost and price competitiveness, you may consider the following questions:

- Is the initiative likely to affect the production costs for companies, by affecting the cost and availability of production factors such as labour (workers protection legislation, social security contributions, labour taxes, etc.), capital (access and costs of financing), natural resources, intermediate goods and services, energy, etc?
- Is the initiative likely to affect the compliance costs for companies (i.e. adjustment and administrative costs, other costs), such as time spent to comply with new policy requirements, adjustments to the production process, additional equipment, restructuring of the sector, etc?
- What is the likely impact on competition, market power in relevant markets and access to markets? Is the initiative likely to affect the number of suppliers or producers (licenses, permits, authorisation, barriers to entry and exit...), their ability and incentives to compete (price controls, bans or limits to marketing, standards favouring particular technologies...), the choices and information available to consumers (licenced shops, limits to mobility of customers between suppliers or producers, transparency and comparability of information ...), the free movement of goods, services, capital and people (self-employed and workers)?
- Considering the competitive position of the most affected sectors (step 2), what are the likely implications of changes in costs? Does any additional regulatory costs (the difference relative to the dynamic baseline) seem bearable for the most affected businesses?
 - Would the sector need a major restructuring such as closing of production lines, substitution of technologies, substitution of skills, etc.? Might it lead to closing down of enterprises?
 - Would companies, including SMEs or microbusinesses, be able to meet the cost of restructuring? Might the initiative lead to closing down of enterprises, job redundancies, etc.?
 - Will the impacts on costs and prices be different in the short and the long term?
 - Will the initiative help companies to improve their competitiveness in the long term (e.g. due to a first-mover advantage)?

It should be considered that additional regulatory costs may not affect companies uniformly, and in particular **SMEs' competitiveness** may be affected more profoundly by additional costs due to the more limited scope for economies of scale (see also Step 6).

For a more in-depth analysis, you may need to **quantify** the impacts in terms of changes in compliance and/or operational costs. It may be useful to complete the analysis with an overall cost breakdown (cost of labour, raw materials, energy etc.).

Step 4. What might be the impact on the sector's international competitiveness?

The assessment of impacts on competitiveness should consider the possible differential impact of the preferred option on domestic and foreign firms. For instance, if a policy proposal is likely to increase costs for EU producers (by e.g. introducing stricter product-safety requirements on the EU market), it may not affect EU manufacturers' relative prices and market shares if their non-EU competitors face the same requirements and there are no suitable cheaper substitutes. However, if the policy affects the production process (e.g. through stricter resource use or pollution standards), or raises labour costs (e.g. through new safety-at-work requirements), then EU manufacturers may be at a competitive disadvantage compared to firms located elsewhere.

When assessing the impacts on international competitiveness, the typical questions you may answer are:

- What is the likely impact of the initiative on the competitive position of EU firms with respect to non-EU competitors (i.e. level-playing field)?
- What is the likely impact of the policy option on trade and trade barriers (tariffs and non-tariff barriers)?
- Will the proposal impact an area where international standards, common regulatory approaches or international regulatory dialogues exist?
- Is it likely to affect cross-border investment flows, including the relocation of economic activity towards or away from the EU?
- What is the likely impact on resilience of EU companies?
- What is the likely impact on market shares in international markets?

You should consider the competitive position of the most affected sectors (step 2) in comparison with businesses outside the EU. In this context it is important to look at the current profitability of the EU companies as compared to international competitors to see if and to what extent additional costs of the initiative might put EU companies at a disadvantage compared to their international competitors.

See also the Tool #27 (*External trade and investment*).

Step 5. What is the impact on the enterprises' capacity and incentives to innovate?

When assessing the impacts on the capacity to innovate, the following questions should be considered:

- Does the initiative affect the capacity of companies or institutions to carry out R&D? Is it expected to have an impact on relevant skills, protection of intellectual property rights...?

- Is the initiative expected to impact on the capacity or incentives for product innovation (new products or features)? Is it expected to affect the availability of technical skills, new technologies, the respect of technology neutrality...?
- Is the initiative expected to impact on the capacity or incentives for process innovation (production and distribution, marketing, after-sales services)? Is it expected to impact on management and organisational skills? Does it ensure the 'digital by default' principle?
- Does the initiative affect the access of companies or institutions to risk capital and financing?

Within this step, for a more in-depth analysis, you may need to **quantify** the expected impacts on the capacity of affected enterprises to innovate. This analysis should preferably include several input and output indicators on sector innovations. The data from the EU Industrial R&D Investment Scoreboard²³⁵ and the Eurostat Community Innovation Survey²³⁶ constitute a good starting point. Data may also be obtained from the industrial chamber of the corresponding sector.

See also the Tool #22 (*Research & innovation*).

Step 6. What is the impact on SME competitiveness?

The impact of the initiative on the competitiveness of companies may differ depending on the companies' size. The analysis should be built on the findings of the SME test²³⁷, which is an integral part of the impact assessment process, and the analysis of the three dimensions of competitiveness analysed under steps 3-5. While the SME test assesses the impacts of the initiative on SMEs, this step helps to understand whether the impacts of the initiative on the competitiveness of SMEs differ substantially from those of large companies.

When assessing the impacts on SME competitiveness, the following questions should be considered:

- Does the direct impact of the initiative on the competitiveness of SMEs differ substantially from that of large companies?
- Is SMEs' competitiveness likely to be indirectly affected through their position in the value chain or through subcontracting? Are such indirect impacts particularly relevant for SMEs?
- Is the impact on competitiveness of micro-companies likely to differ from the impact on small- and medium-sized ones?
- To what extent is the initiative designed to minimise negative impacts on the competitiveness of SMEs?
- Does the initiative include mitigating measures such as simplified reporting, phasing -in obligations for SMEs...?

You may need first to look at the relevance of SMEs and micro-companies in the affected sector(s). Particular attention may be necessary for micro businesses (under 10 employees) as they may have fewer resources for taking on any possible adjustment costs or administrative

²³⁵ <https://ec.europa.eu/jrc/en/publications-list>

²³⁶ <https://ec.europa.eu/eurostat/web/microdata/community-innovation-survey>

²³⁷ See Tool #23 (*The 'SME test'*).

burdens. Within this step, for a more in-depth analysis, you may need to **quantify** the expected impacts on SMEs competitiveness.

See also the Tool #23 (*The 'SME Test'*).

4. HOW TO MINIMISE ANY NEGATIVE IMPACTS ON SECTORAL COMPETITIVENESS

If the analysis made under the previous section shows that certain sectors are disproportionately affected or disadvantaged, you should consider using possible mitigating measures. The aim is to achieve the policy objectives without compromising the competitiveness of EU companies. The list below sets out some of the approaches you might consider.

- Full or partial exemption of certain sectors or subsectors. This might include less onerous compliance requirements or deeming a certain subset of rules not applicable to certain sectors (e.g.: the Data Protection Regulation sets different requirements for e-mail vs. traditional mail marketing);
- Extended transition/compliance periods before the rules come into force where, for example, a service or product needs to be redesigned to be compliant (e.g. some ecodesign schemes are introduced by phases where lighter compliance requirements are set for the introductory phase);
- Varying requirements by type and/or size of business or type of product/service. For example, SMEs are only required to register but not to be fully licenced; or exempting smaller businesses from having to register or from paying fees.

When considering mitigating measures, it is always important to consider the relevant trade-offs. For instance, excessively extending transitional periods or varying requirements by type of business may entail a risk of reducing the effectiveness of the initiative and may privilege certain types of enterprises and, therefore, harm fair competition or create threshold effects.

The relevant sections of the tools on the 'SME test', impacts on trade and investment and impacts on innovation, can provide more details on how to minimize any negative impacts in these areas.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. EU databases

EUROSTAT: the main source for EU statistics, with data on industrial sectors' performance, structure, development, trade within the EU and outside the EU, employment, etc. Certain specific sections can be particularly useful:

- EU Structural Business Statistics ([SBS](#)): describe the detailed structure, economic activity, and performance of businesses over time, providing data on number of enterprises, persons employed, turnover, value-added, investment, productivity, SME share of added value and employment. It covers industry, construction, trade and services (data available for the EU-27 and for the Member States). The statistics can be broken down to a very detailed sectoral level (several hundred economic activities based on NACE classification).

- **PRODCOM:** Statistics on the production of manufactured goods in the Member States, measured by value (euros) and by volume (kg, m², number of items, etc.). Prodcum data cover the economic activities of mining and quarrying, manufacturing, and materials recovery, which refer to the sections B, C, and E of the 'Statistical classification of economic activities in the EU' (NACE).
- **EU Science and technology database:** R&D, innovation data, patent statistics, knowledge-intensive sectors, human resources in science and technology. It includes the Community Innovation Survey (CIS) - a survey of innovation activity in enterprises. The harmonised survey is designed to provide information on the innovativeness of sectors by type of enterprises, on the different types of innovation and on various aspects, such as the objectives, the sources of information, the public funding, the innovation expenditures etc. The CIS provides statistics broken down by countries, type of innovators, economic activities and size classes.
- **EU Digital economy and society:** statistics on digitalisation, which can be useful to analyse the uptake and usage of ICT, level of digitalisation of businesses, digital skills, etc.
- **EU trade in goods (COMEXT):** monthly data on imports and exports, providing values and quantities of the trade by product and partner country. In addition, data is available aggregated by product group, end use, mode of transport or tariff (if applicable), as well as some seasonally adjusted data and indices. Annual data on trading companies, including information about activity sector, enterprise size-class, ownership, type of trader, and indicators on trade concentration.
- **EU trade in services:** information on international trade in services, international supply of services by mode of supply, services trade by enterprise characteristics.
- **EU Short-term business statistics (STS):** the earliest statistics released by Eurostat to show emerging trends in the European economy, data for industry, construction, trade, services, excl. financial and public services. Include indices for production, turnover, producer and import prices as well as for some other indicators (construction costs, labour input), and quarterly indicators on business registrations and bankruptcies.

AMECO: annual macro-economic database with data for the EU, the euro area, EU Member States, candidate countries and other OECD countries, for a total of over 40 countries. Data is organised in eighteen chapters, from population and employment via main national accounts aggregates such as gross domestic product to sector accounts and the cyclical adjustment of public finance variables.

EU Industrial R&D Investment Scoreboard: The Scoreboard is a benchmarking tool which allows to, every year since 2004, monitor and analyse industrial R&D investment trends in the context of the EU's 3% of GDP R&D investment policy target, which is a key performance indicator of the EU's long-term competitiveness. Currently, it monitors the world's top 2,000 R&D investors. The data is published as a four-year time series to allow, for instance, to examine links between R&D and business performance.

ORBIS: Firm-level database by Moody's (subscription is required) containing comprehensive information on around 580 million companies across the globe. It can be used to research

individual companies, search for companies with specific profiles, and for general analysis, for issues such as turnover, employment, profits, investments, etc.

BACH - Bank for the Accounts of Companies Harmonised: Aggregated and harmonised information on the financial statements of non-financial companies, available for free, from 12 Member States (AT, BE, DE, ES, FR, HR, HU, IT, LU, PL, PT, SK,); 3 firms' size classes (small, medium-sized and large enterprises); 17 NACE sections and about 80 NACE divisions; time series of over 20 years; over 90 items, including assets, liabilities and the profit and loss account. It is used to analyse the assets, liabilities, financial position and profitability of enterprises, according to their sector and size class.

Joint Harmonised EU Programme of Business and Consumer Surveys: The programme interrogates every month some 120,000 company managers from across the EU about various aspects of their business (trend in production, employment, etc.). Once a quarter, manufacturing managers are explicitly asked whether the competitive position of their firm on foreign markets outside the EU improved, stayed the same or deteriorated.

EU KLEMS Growth and Productivity Accounts: For detailed sectoral productivity and total factor productivity for quantitative studies focusing on technical change in the industry (manufacturing).

data.europa.eu – the official portal for European data. A single point of access to data produced by EU, national, regional, and local public administration, as well as by some international organisations.

5.2. International databases

COMTRADE is a UN database that aggregates detailed global annual and monthly trade statistics by product and trading partner. It covers approximately 200 countries and represents more than 99% of the world's merchandise trade.

IEA Statistics & Balances (International Energy Agency). For energy prices, fossil fuel prices, etc.

IMF balance of payments (International Monetary Fund)

OECD.Stat: Contains statistics covering OECD members and the following areas:

- industry and Service Statistics;
- structural Analysis (STAN) Databases including Input-Output databases;
- structural and Demographic Business Statistics (SDBS) including Structural Business Statistics per economic sector;
- international Trade by Commodity Statistics (ITCS); and
- productivity Levels and GDP per capita.

UNCTAD: For data on foreign direct investment (FDI) to assess import and adoption of technical change through capital investment.

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

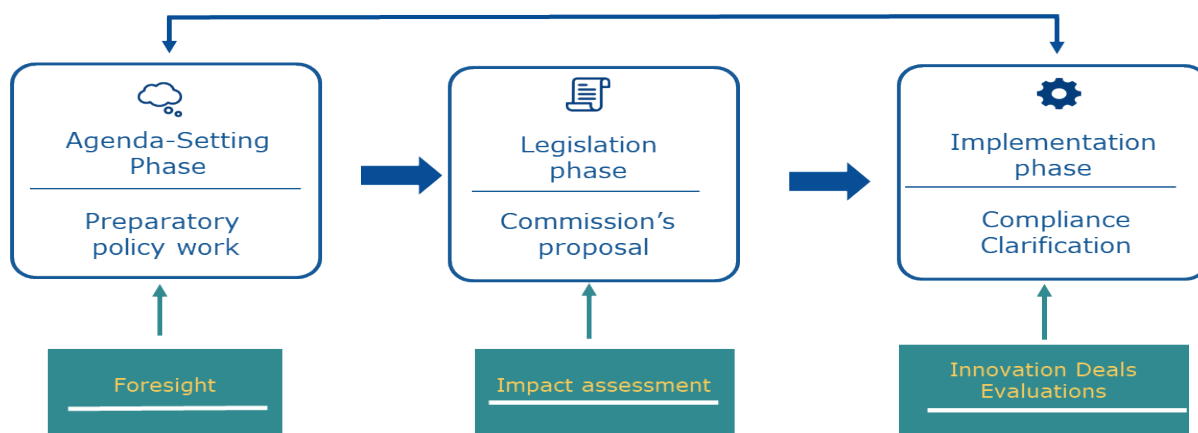
Relevant SDGs indicators	SDGs
<i>EU indicators:</i> • Real GDP per capita • Investment share of GDP • Purchasing power adjusted GDP per capita • Gross domestic expenditure on R&D • R&D personnel <i>UN indicators:</i> • Annual growth rate of real GDP per capita • Annual growth rate of real GDP per employed person • Proportion of small-scale industries in total industry value added • Research and development expenditure as a proportion of GDP • Researchers (in full-time equivalent) per million inhabitants • Worldwide weighted tariff-average	  

TOOL #22. RESEARCH AND INNOVATION

1. INTRODUCTION

This tool provides guidelines for analysing the interaction between EU initiatives and innovation in line with the innovation principle²³⁸. It ensures that the innovation dimension is considered when preparing and implementing EU legislation.

This approach also ensures that EU legislation considers emerging innovations that are in line with EU policy objectives, thus facilitating their development and adoption.



The innovation dimension may be considered at three key stages of the policy cycle:

- **agenda-setting:** foresight and horizon scanning;
- **preparation of EU legislation:** impact assessments;
- **implementation of EU legislation:** innovation deals and evaluations.

2. AGENDA SETTING: FORESIGHT AND HORIZON SCANNING

Foresight uses a range of methodologies, such as scanning the horizon for emerging changes, analysing megatrends, and developing multiple scenarios about the future. It is useful whenever there is a high degree of uncertainty surrounding changes to the relevant future context and to ensure that short-term actions are grounded in long-term objectives²³⁹. Horizon scanning is a methodology for detecting early signs of potentially important developments through examination of potential threats and opportunities, with emphasis on new technology²⁴⁰.

DG Research and Innovation can support an analysis of technological and business process innovation, drawing among others on the results of horizon scanning and foresight, e.g., should it be requested by the ISCG. This kind of analysis is particularly useful when the initiative:

²³⁸ See also Communication “A renewed European agenda for Research and Innovation – Europe’s chance to shape its future”, pp. 9-10: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018DC0306>

²³⁹ See European Commission (2020)493, 2020 Strategic Foresight Report, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0493&from=EN>; and Tool #4.

²⁴⁰ According to the OECD. Foresight: <https://www.oecd.org/strategic-foresight/whatisforesight/>

- (1) involves upstream policy formulation and generation of strategic options for an emerging policy area or a policy area that has not been regulated yet;
- (2) involves an assessment of existing legislation in light of technological changes and business process innovation, especially taking account of the relevance of existing rules;
- (3) touches upon an area or areas characterised by quick technological progress and intense innovation
- (4) affects specific research and innovation rules at EU level.

While having primarily an anticipatory function, horizon scanning can also relate to other stages of the policy-making cycle, including evaluation. For instance, its findings can be used in evaluations preceding legislative reviews, if horizon scanning results point to an important development that could affect the functioning of existing legislation.

DG Research and Innovation is putting in place a **Regulatory Advice Mechanism (RAM)** to provide upstream advice and improve the general understanding of the relation between innovation policy and regulatory policy, thus contributing to the overall resilience of the EU's regulatory framework. The mandate of this expert group is to identify anticipated impacts of beneficial innovations and provide recommendations on regulatory design to maximise their diffusion and use, while ensuring they can be deployed safely and sustainably. The group will:

- scan the horizon for promising discoveries and trends, also building on the work of the Framework Programme for Research and Innovation;
- explore and suggest novel regulatory approaches in the face of challenges cutting across various policy domains;
- deal with technologies, services and business models that have concrete applications and show the potential to bring significant benefits to the EU economy and society, especially to accelerate the green and digital transitions. As an illustration, possible topics could include: customer quality assurance and product guarantee in decentralised customised mass manufacturing (e.g. 3D-printing), recycling of urban biowaste, and innovative personal means of transport.

The **Regulatory Advice Mechanism** can be activated upon request from the concerned Commission services, by contacting DG Research and Innovation.²⁴¹

In cases where scientific advice or scientific evidence are needed to inform policy-making or underpin policy choices (for instance during the agenda-setting phase), the Group of Chief Scientific Advisors, at the heart of the Commission's Scientific Advice Mechanism (SAM)²⁴² can be requested to assist policy- and decision-making with targeted, up-to-date scientific evidence or science-informed recommendations.

This can be done where evidence is necessary to understand and assess the multiple dimensions of policy options and to interpret information and data critical to make informed policy choices. SAM complements and orients the routine assistance of the JRC in better

²⁴¹ Questions can be sent to the functional mailbox : RTD-INNOVATION-PRINCIPLE@ec.europa.eu

²⁴² https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/group-chief-scientific-advisors_en#about-the-advisors. See also Tool #4 (Evidence-informed policymaking).

regulation work. The request should be advanced by the College at the behest of services via the cabinet of the Commissioner(s) responsible for the policy issue at stake.

3. PREPARATION OF EU LEGISLATION: IMPACT ASSESSMENTS

The assessment of the potential impact of a policy initiative on research and innovation starts with the type of initiative and its overall objectives. Consider whether, and to what extent, the initiative may have positive or negative impacts on research and innovation capacity at the firm, sector, or EU level. For example by:

- (1) creating (or reducing) barriers to innovation or weakening (or strengthening) the incentives for investing in innovation²⁴³;
- (2) creating (or reducing) opportunities or incentives for innovation that could better support the achievement of policy objectives;
- (3) affecting specific research and innovation rules at EU level (e.g. patent law, technology transfer legislation) or spending programmes. These will have an effect on the incentives and rewards for innovation, as well as perhaps the location choice of research, development and market entry.

DG Research and Innovation is available to support with targeted analysis, guidance and help in the design of EU initiatives at the request of, and in cooperation with, the lead DG.

The stepwise approach:

Step (1) Include research and innovation angle in consultations

Depending on the extent to which a planned policy initiative is likely to have significant impacts on innovation and research, questions on these aspects should be a central element of the consultation strategy (for which separate guidance exists²⁴⁴). The public consultation should include questions on potential impacts on research and innovation, on emerging techniques and technologies and on impacts on companies scaling up in size²⁴⁵. The public consultation should reach out to relevant stakeholders, in particular start-ups, research institutes, innovation foundations, civil society organisations dealing with sectoral legislation, etc.

There is a risk that this sort of consultation exercise will predominantly identify the views of incumbent firms and therefore may not fully consider the impact on or possible creation of new business models, new firms or new technologies and services. This should be considered in the analysis of responses received²⁴⁶. This risk can also be mitigated by targeted consultation with research and innovation ecosystem actors, for instance through round tables, focus group meetings, hearings etc. DG Research and Innovation may help to identify key stakeholders and facilitate engagement.

Step (2) Assess potential impacts on research and innovation

²⁴³ See also Tool #21(Sectoral competitiveness)

²⁴⁴ See Tools #50 to #54, on consulting stakeholders

²⁴⁵ See COM(2025) 270 final; [The EU Startup and Scaleup Strategy - Choose Europe to start and scale](#) which contains actions to help startups and scaleups that are also linked to SME and internal market impacts.

²⁴⁶ See Ashford/Renda, 2016. <https://www.ceps.eu/publications/aligning-policies-low-carbon-systemic-innovation-europe>

The checklist below provides an indicative set of questions to assess whether the proposed initiative affects research and innovation²⁴⁷.

Impact on research and innovation	Y/N
<i>Does the measure affect the research, testing or demonstration phase?</i>	
Does the intervention impact the generation of new ideas , their adaptation and application (e.g. from the knowledge base to industry)?	
Does it affect the cooperation (e.g. circulation of data, research results or researchers) between public and corporate R&D ?	
Does the proposed intervention potentially affect the establishment of, access to and functioning of R&D infrastructures ?	
Could the measure add or ease an administrative burden to testing, piloting, or demonstrating new goods, services, and products?	
Could compliance costs and time for the development of innovative technologies/solutions be affected?	
Does the intervention provide an equal playing field for public and private actors?	
<i>Does the measure affect application of innovative solutions or to bring them to market?</i>	
Is the intervention in an area with a relatively fast pace of innovation , and where legislation risk being outpaced by technological development?	
Can the initiative affect the introduction of future innovative solutions that may better achieve its policy objectives?	
Can the measure affect the innovation dynamics of specific markets ?	
Can the measure add or remove an administrative burden to bringing new goods, services, and products on the market?	
Will the initiative stimulate multi-disciplinary scientific research?	
<i>Does the measure affect incentives around investment or scaling up in Europe?</i>	
Can the intervention change the innovation incentives and choices for R&D investments?	
Can the intervention lead to a difference in innovation investment incentives in the EU compared to third countries?	
Can the intervention affect the incentives for companies to scale up in Europe?	
Will the proposed initiative lead to societal/organisational innovation?	

If the assessment leads to the conclusion that the proposed initiative has an impact (positive or negative) on research and innovation, further analysis on the specific impacts of policy options should be carried out. DG Research and Innovation will support an evidence base for policy options and the relation with innovation through the screening and feedback to policy of relevant projects funded by the Framework Programme.

Step (3) Address legislative design considerations

²⁴⁷ See Tool #21 (*Sectoral competitiveness*) for guidance on how to quantify the impact of legislation on the capacity of enterprises to innovate.

The interaction between a policy option and innovation depends on a range of factors, including regulation design, implementation, and enforcement. This section will help you to understand (i) the potential impact of the design of your proposal on research and innovation behaviours and outcomes, (ii) how to mitigate negative impacts on research and innovation and (iii) how innovation can be leveraged to better achieve policy objectives. Questions may not be relevant for all types of policies.

The table below describes several ways in which regulation and innovation interact. The description of each issue is followed by a series of questions designed to facilitate further reflection on whether and how it might be relevant to the options being considered in the impact assessment.

If you answer 'yes' to a question, please consider what steps you can take to maximise R&I capacities and the potential of innovation to achieve policy objectives. Where possible, the table points to specific instruments in Step 4 that can be applied to address the identified challenge. These are, however, by no means the only instruments that can be used.

Legislative design considerations	Y/N	Relevant instruments (Step 4)
<i>Flexibility and future-proofing²⁴⁸</i>		
Legislation should remain open to innovative solutions that will help achieve the policy objective of the measure under consideration. It should aim for technology neutrality and seek to avoid lock-in to one specific technology solution or technique. Generally, the less prescriptive and detailed a measure is, the more room it leaves for potential innovation. Excessively prescriptive and detailed regulation can create barriers to entry for innovative solutions, even if the innovation could contribute to achieving the policy goal of regulation. They can also limit the possibility to adapt rules in a timely manner, when circumstances change.		
Does the measure give operators as much flexibility as possible while ensuring that the policy objective will be met? Has the impact on innovation of the proposed measure been examined in the context of the proportionality test?		1,2
Does the proposed measure contain targets? Is it designed to allow for the possibility of emerging technologies or processes that could better meet or exceed these targets?		2, 4, 5
Are definitions used future-proof and unlikely to become outdated with the appearance of new innovations?		3
Are provisions allowing for regular updates of the measure in case of rapid technological developments?		3
Does the measure address a time-specific issue?		3
Is the proposed measure adaptable to scientific progress and new scientific discoveries?		1, 2, 3, 4, 5
Does the proposed legislation respect technology-neutrality?		2, 4, 5

²⁴⁸ According to the OECD, future-proofing means stress-testing existing or proposed strategies and policies. Source: <https://www.oecd.org/strategic-foresight/>

Compliance costs Compliance costs divert resources from other purposes, potentially including research and innovation. Compliance costs may at times discourage innovation if they fall disproportionately on innovators compared to incumbents, for example because of the costs of testing and obtaining authorisation²⁴⁹. Testing and authorisation processes for regulatory compliance may require spending on research – this is sometimes considered 'defensive' R&D as opposed to R&D that itself aims to develop new technologies, processes, or products.		
Have you taken steps to reduce the likelihood that the compliance costs of the policy option will divert resources from R&I activities?		2, 4, 5
Does the policy option seek to achieve a balance between requirements for 'defensive' R&D and incentives for R&D to create novel solutions?		4, 5
Have you taken steps to reduce unjustified variation in compliance costs between incumbents and potential innovators?		1, 2, 4, 5
Have you taken steps to ensure that compliance costs do not create a particular obstacle for innovative SMEs?		1
Regulatory certainty and clarity Regulatory uncertainty can hamper investment, including investment in R&I, because it increases risk and potentially also the cost of finance. Regulatory uncertainty can take different forms. It may be caused by real or perceived instability: is the regulator likely to change the regulatory framework in the foreseeable future? It may also be caused by a gap or lack of clarity in regulation when it is unclear whether an innovation would comply. There are trade-offs between the need to reduce regulatory uncertainty and the need to maintain flexibility.		
Will the proposed measure minimise regulatory uncertainty?		
Is it clear to which products/technologies this policy option applies?		1, 2
Will the proposed measure expire at a certain date or is there a date fixed for its review and possible modification? If so, does it strike the right balance between providing regulatory certainty on the one hand and the possibility for adaption to scientific and technological progress on the other?		3
Timing and stringency There is a balance to be struck about the stringency of regulations. On the one hand, a regulation that is overly stringent or imposes requirements within an unrealistic timeframe may encourage the market to use existing solutions. This can hamper investment and the deployment of solutions. On the other hand, the need to meet ambitious standards can stimulate radical innovation, provided regulation leaves sufficient time and is sufficiently stable to allow the market to develop new solutions.		
Does the initiative introduce new requirements within a timeframe that is in line with the market's investment and innovation cycle?		
The single market and harmonisation and interactions with other policies A lack of harmonisation between Member States, and even between EU Member States and other countries, can discourage investment in the development of innovative solutions and create barriers to market access. The creation of a well-functioning single market can encourage investment in the scaling up of innovations.		

²⁴⁹ Note that this is not always the case, as compliance costs can also have the opposite effect of encouraging innovation; this can only be established on a case-by-case basis when assessing the impacts of a specific policy or initiative.

Will the proposed measure help to ensure a consistent approach across the EU? Will it effectively address any identified problems created by differences in implementation in different Member States?		
Could the implementation of the legislation result in inconsistent requirements or regulatory practices between Member States in relation to innovative solutions?		
Is the proposed initiative aligned with requirements at the international level (e.g. international standards)?		
Does the proposal consider potential interactions with cross-sectoral legislation or requirements governing different sectors?		

Step (4) Apply tools to leverage the potential of innovation and reduce negative impacts

This section provides a non-exhaustive list of approaches to improve the design of your legislation for innovation-friendliness and to leverage innovation for better achieving your policy objectives. These concrete suggestions need to be considered on a case-by-case basis. Using them in legislative design helps formulate legislation with sustainable innovation in mind.

Please also refer to Tool #17 for support in assessing whether the choice of different policy instruments (e.g. directives versus regulations) could allow you to achieve better outcomes for innovation.

Instruments of adaptive regulation:

1. Experimentation clauses²⁵⁰

An experimentation clause enables the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to innovative technologies, products, or approaches, even if they do not conform to all existing legal requirements.

Experimentation clauses can be appropriate when detailed product or technological characteristics must be defined in legislation, but the policy goal could be met in the future by different, innovative solutions. They may also be proposed with the express intention of encouraging innovation and experimentation. A sophisticated experimentation framework is referred to as a regulatory sandbox – testing innovations in a real-world environment subject to regulatory safeguards and support.

The **Regulation on the Approval of Motor Vehicles** (2018/858) defines the process by which Member States certify that a vehicle model meets EU safety, environmental and production requirements. Article 39 (*Exemptions for new technologies or new concepts*) allows Member States, subject to authorisation from the Commission, to approve technologies or concepts even though they do not meet certain requirements. Pending the Commission decision on whether to authorise the exemption, the Member State may grant provisional approval that is valid only on its territory.

²⁵⁰ See also Tool #69 (*Emerging methods and policy instruments*)

2. Outcome-oriented legislation

Outcome-oriented legislation sets a measurable objective without prescribing the exact mechanisms by which the objective is to be achieved. It gives concerned organisations the flexibility to decide how to achieve the objective.

Outcome-oriented legislation should, in principle, be the preferred option unless there is a clear need to define the exact mechanisms by which the objective is to be achieved. It avoids creating a situation of lock-in to a particular technology or approach and creates a more level playing field for innovative technologies or approaches to compete against incumbents.

The **Regulation on personal protective equipment** (2016/425) lays down requirements for the design and manufacture of personal protective equipment to ensure the protection of the health and safety of users. The technical specifications listed in Annex II of the Regulation do not prescribe the specific technology or materials to be used provided they do not adversely affect the health or safety.

3. Sunset clauses

Sunset clauses terminate or repeal some or all provisions of a legal text after a specific date, unless further legislative action is taken to extend them. They can be used to ensure that legislation does not become an obstacle to innovation in rapidly changing market or technological environments. They can also serve as a tool for legislative experimentation, as they allow the lawmaker to test a new legal approach or regulatory framework for new technologies in a clearly delimited way. The risk of regulatory uncertainty must also be considered when considering their use.

The **European Union Agency for Network and Information Security** (ENISA) is an EU decentralised agency created in 2004 for an initial period of five years. Article 25 of Regulation (EC) No 460/2004 specified that its operations must be evaluated to determine whether its mandate should be extended. Under Regulation (EU) 526/2013, ENISA received a new seven-year mandate, with a possibility of extension following an evaluation (Article 32 on 'Evaluation and review' and 36 on 'Duration'). The temporary mandates reflect the rapid evolution of information and communication technologies, the changing threat landscape, and the evolution of Union policy in this field. Since June 2019, ENISA has a permanent mandate (Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 - Cybersecurity Act)

4. Test of alternatives

A test of alternatives requires applicants for regulatory approval to consider potential alternatives, and to justify why their chosen solution is the optimal way to meet the policy goals underlying regulation. Applied rigorously, the requirement to examine alternatives has the potential to encourage innovation and the search for new approaches to existing goals.

A test of alternatives may be relevant when projects, products or technologies have a negative impact on a core regulatory objective like consumer or environmental protection or even fail to meet standards, but a regulator nonetheless has reason to approve due to their wider benefits. In such cases, a test of alternatives can help to ensure that the desired wider benefit is achieved using the best available technology.

The **Environmental Impact Assessment Directive** (2014/52/EU) defines the environmental impact assessment to be applied by Member States when authorising projects likely to have significant effects on the environment. Article 31 specifies that developers must submit an outline of the main alternatives they have studied.

5. Top-runner approach

The top-runner approach refers to legislative provisions that envisage the updating of a requirement to reflect higher performance levels that have become possible because of scientific or technological progress. If an innovation achieves a higher performance level, then that performance level becomes the new requirement. The top-runner approach encourages innovation by rewarding first movers, since other market operators are obliged to adopt that innovation – or seek their own innovation that performs equally well or better.

The **Industrial Emissions Directive (2010/75/EU)** aims to protect human health and the environment by reducing harmful industrial emissions. Member State authorities may grant operating permits for industrial installations only if those installations do not exceed certain emission levels. The emission levels are set according to what can be achieved by Best Available Techniques, as defined in a Commission Implementing Decision. Article 74 provides for the periodic updating of the Best Available Techniques and the acceptable emissions level in accordance with scientific and technological progress.

Combining different approaches and instruments

In practice, legislation may combine different instruments and approaches.

For example, the Industrial Emissions Directive (2010/75/EU) includes provisions that correspond to the top-runner approach (Article 74), outcome-oriented legislation (Article 15, paragraph 2) and an exemption mechanism (Article 15, paragraph 5).

REACH (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) combines the test of alternatives with the top-runner approach (Articles 55, 60 and 61).

4. IMPLEMENTATION OF EU LEGISLATION: INNOVATION DEALS

Innovation deals contribute to future-proof EU legislation by addressing perceived regulatory obstacles to innovative solutions stemming from existing EU rules. They are voluntary agreements with stakeholders: innovators, civil society, national/regional or local authorities and the Commission services. Innovation deals feed in the evaluation and REFIT process of the Commission and may result in a revision of EU rules.

An innovation deal will consist of:

- definition of the perceived regulatory **problem** encountered by innovators and
- identification of a **solution** to this problem in cooperation with the innovation deal team.

Early indications of the innovation deal pilots point towards the need for clarification (instead of revision) of several of the so-called ‘regulatory’ barriers perceived by innovators. Other

barriers may need an intervention at national level or a revision of EU rules to benefit all innovators facing similar obstacles.

So far, two innovation deals were carried out in the area of circular economy: “Sustainable wastewater treatment combining anaerobic membrane technology and water reuse” and “From e-mobility to recycling: the virtuous loop of the electric vehicle”²⁵¹.

New innovation deals can be triggered via an open call, and guidance from DG Research and Innovation is available for all Commission services. Any innovator or group of innovators that encounter an EU regulatory obstacle impeding its close-to-market activities can apply for an innovation deal under conditions specified in an open call, to be prepared by the Commission.

If the existence of an obstacle to innovation arising from EU regulation is confirmed by providing clear evidence from the innovation deal, the Commission will take the results into account when evaluating the legislation in question. The result of an innovation deal can also be used to undertake further real-world testing through a regulatory sandbox, an innovation lab or other similar experimental approaches.

Pilot innovation deal example:

Anaerobic membrane technology for reuse of wastewater in agriculture: The aim of the deal was to investigate the (perceived) regulatory barriers that may prevent a broader application of Anaerobic Membrane Bioreactor (AnMBR) technology to allow reuse of the reclaimed water and nutrients in agriculture. The innovation deal indeed identifies an EU regulatory barrier, as wastewater treatment plants based on the AnMBR technology cannot receive a permit to operate in sensitive areas. Recommendations from the innovation deal include: (1) changing existing rules to enable fertigation in sensitive areas while ensuring that environmental objectives are achieved, (2) developing guidance for Member States to integrate environmental risks relating to nutrients, (3) reflecting on methods for water pricing and recovering costs from polluters when water is reused in agriculture.

5. FURTHER INFORMATION AND SUPPORT INNOVATION PROVIDED BY DG RTD

Catalogue of services on research and innovation:

- Provide Regulatory Advice Mechanism reports with upstream policy advice;
- Support evidence base for impact assessments; identify key R&I stakeholders and stimulate the participation of innovators in stakeholder consultation by enhancing their publicity in the communities of innovators;
- Support the evidence base for impact assessments;
- Develop innovation deals and support the evidence base for evaluations.

Information about the content or application of this tool: RTD-INNOVATION-PRINCIPLE@ec.europa.eu.

²⁵¹ <https://op.europa.eu/en/publication-detail/-/publication/e361ec68-09b4-11ea-8c1f-01aa75ed71a1>

Complementary 'better regulation' tools:

Tool #4 (*Evidence-informed policymaking*) deals with evidence and scientific advice.

Tool #20 (*Strategic foresight for impact assessments and evaluations*)

Tool #69 (*Emerging methods and policy instruments*), deals with regulatory sandboxes.

Tool #21 (*Sectoral competitiveness*) deals with the capacity of enterprises to innovate as part of competitiveness-proofing.

Tool #23 (*The 'SME test'*) considers innovation in the context of small and middle-sized enterprises.

Tool #24 (*Competition*) on the link between market competition and innovation.

Tool #28 (*Digital-ready policymaking*) deals with impacts related to information and communication technologies as well as digital policy aspects.

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> - Gross domestic expenditure on R&D - R&D personnel <i>UN indicators:</i> - Research and development expenditure as a proportion of GDP - Researchers (in full-time equivalent) per million inhabitants All of the above indicators can be mapped against the individual SDGs²⁵² to show the transversal nature of R&D.	

²⁵² An example of such analysis is provided in [Keeping our eyes on the Horizon](#), Monitoring flash series: a Horizon 2020 monitoring report

TOOL #23. THE ‘SME TEST’

1. INTRODUCTION

Small and medium-sized enterprises (SMEs) account in EU-27 for more than 99% of all enterprises in the non-financial business sector and more than 90% of them are microenterprises. The latter are companies with fewer than 10 employees²⁵³. The Commission aims to improve the business environment for SMEs by permanently anchoring the ‘think small first’ principle in policymaking²⁵⁴. This requires considering the specific characteristics of SMEs when designing legislation and simplifying the existing regulatory environment. The principle calls for new legislation, administrative rules, and procedures to be simple, easy to understand, and straightforward to apply.

The ‘SME test’ tool helps to assess the impacts on SMEs in impact assessment reports with the intention to ensure effective and efficient rules and minimise the burden imposed on SMEs²⁵⁵. Since 2022, the Network of SME Envoys identifies in the ‘SME filter’ initiatives that are likely to significantly affect SMEs and that therefore need to be carefully analysed. Since May 2025, impact assessments for initiatives that are considered ‘relevant’ or ‘highly relevant’ for SMEs should include an ‘SME Check’. The check is a mandatory annex to the impact assessment report to provide more transparency and clarity on the results of the ‘SME test’ (see box 1 below).

Minimising burdens on SMEs is particularly important, because the costs of regulation often affect SMEs disproportionately compared to large companies²⁵⁶, while the benefits of regulation tend to be more evenly distributed among companies of different sizes. SMEs benefit less from economies of scale than large companies do and have less capacity to absorb fixed costs of measures. They also find it more difficult to access capital, and their cost of capital is often higher than for larger businesses²⁵⁷. In addition, asymmetries in bargaining power towards larger companies expose SMEs to unfair business practices or conditions.

This is why legislation with simplified procedures benefits SMEs. In addition, regulatory simplification helps SMEs to comply with legislation and fosters the achievement of policy objectives at EU level. When transposing EU law, national, local, and regional authorities can add requirements to legislation that are burdensome to SMEs, it should be standard practice for Member States to make use of their own procedures to assess and measure impacts on SMEs (so called national ‘SME test’).

²⁵³ [SME definition](#)

²⁵⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:et0001>

²⁵⁵ In case an EU policy initiative was considered as “relevant” or “highly relevant” for SMEs at the impact assessment phase, the evaluation of this initiative should also cover the effectiveness and efficiency of the intervention for SMEs.

²⁵⁶ On average, a business with fewer than ten employees faces a regulatory burden (measured per employee) that is roughly twice as high as the burden of a business with more than ten but less than twenty employees and about three times as high as the burden of businesses with more than twenty but less than fifty employees. For bigger companies, the burden per employee is only one fifth or less of that of small enterprises. In other terms: where a big enterprise spends one euro per employee to comply with a regulatory duty, a medium-sized enterprise might have to spend around four euros and a small business up to ten euros. (Report from the Expert Group on “Models to Reduce the Disproportionate Regulatory burden on SMEs”, May 2007).

²⁵⁷ https://ec.europa.eu/growth/access-to-finance/data-surveys_en.

Box 1. Key elements of the 'SME test'

- The 'SME test' must be always performed and all impact assessment reports must give an account on it a proportionate way²⁵⁸.
- This means concretely that the application of the 'SME test' varies with the 'relevance' of the initiative for SMEs. 'The SME' test explains how the level of relevance ('not relevant', 'relevant', 'highly relevant') is established based on the 'SME-filter' and the discussions in the interservice coordination group. It also explains what is to be considered as a proportionate analysis of SME impacts (see section 2 step (1) and box 3).
- All initiatives that are 'relevant' or 'highly relevant' for SMEs should include a compulsory annex on SMEs in the impact assessment report, the 'SME check'²⁵⁹. It provides an overview of the main results of the 'SME test' and can also include other elements that the lead service needs or wishes to provide²⁶⁰.
- The impact assessment report itself (in the section on impacts of the policy options) must also include a reference to the results of the 'SME test' with a cross-reference to the 'SME check' annex for the main findings for 'relevant' and 'highly relevant' initiatives. If the initiative has not been identified as 'relevant', this should also be stated in this section of the report.
- As data about costs for SMEs are often not easily available, it is particularly important to properly plan the consultation process. **The input received from the SME community from consultations should be systematically reported on in the impact assessment.**
- If significant adverse impacts on SMEs are expected or if policy options impose a disproportionate burden on SMEs compared to large enterprises, it is strongly recommended to **consider different ways to minimise burdens** during the design of these policy options. This includes considering mitigating measures and incorporating mechanisms into the legislation to monitor the impact on SMEs (see below section on mitigating measures).
- **Exemptions** should be considered only as mitigating measure of last resort as they may create thresholds. Multiple exemptions across different policy areas taken together may create barriers that can become a disincentive to the further growth of the companies. When an exemption is applied, it is necessary to also consider possible indirect effects that might require additional measures to support SMEs.
- **SME-friendly provisions** are standard legal clauses that can be incorporated in legal proposals where appropriate to tailor rules to the specific needs of SMEs. These include provisions such as longer transition periods and specific guidance for SMEs, the need to pay particular attention to the impact of delegated acts and implementing acts on SMEs, as well as review clauses and sunset clauses. For this purpose, internal guidance is available²⁶¹.

²⁵⁸ See Tool #11 (Format of the impact assessment report).

²⁵⁹ Annex 6 in the template for impact assessment Staff Working Document

²⁶⁰ Annex 6 in the template for impact assessment Staff Working Document and related GoPro guidance.

²⁶¹ [SMEFriendlyProvisions_EN_2024Oct](#)

Small and medium-sized enterprises are defined at the EU level²⁶². There are three main categories – micro, small, and medium – based on the following criteria: staff headcount, financial parameters (annual turnover or balance sheet)²⁶³, and the ownership criterion²⁶⁴. According to the latter, a firm that is controlled or controls other companies (through ownership, control, or other relationships) needs to include part or all the staff headcount, turnover, or balance sheet data from those companies, too²⁶⁵.

To define SMEs for the purposes of (quantitatively) assessing impacts on them, it is recommended to use the headcount criterion. Financial parameters (turnover or balance sheet total) may also be used if relevant, knowing that the related data are scarcer and less readily available. Taking business ownership into account is generally burdensome and the available data are often incomplete and/or not sufficiently reliable.

2. THE APPLICATION OF THE 'SME TEST'

In impact assessments, the analysis of SME impacts should first consider whether SMEs are disproportionately affected compared to large companies. If so, alternative mechanisms or flexibilities in the approach that might help SMEs comply should be considered. The 'SME test' consists of four steps that are applied in a modular way (see box 2).

Box 2. The four steps and key questions to apply the 'SME test'

When applying the test, you are guided through the four different steps by a set of key questions. Answers to those questions will need to be reflected when reporting on the results of the 'SME test' in the 'SME check' annex.

Step (1): identification of affected businesses and assessment of relevance;

Step (2): consultation of SME stakeholders;

Step (3): assessment of the impact on SMEs;

Step (4): minimising negative impacts on SMEs.

²⁶² Defined in [Commission Recommendation 2003/361/EC](#) and its subsequent amendments.

²⁶³ The flexibility to choose either turnover or balance sheet intends to cater for the differences between sectors which have by their nature higher turnover figures (like trade and distribution) and those which tend to have higher asset level (like manufacturing).

²⁶⁴ To qualify as an SME, a company should employ less than 250 staff and have either a net turnover of less than €50 million or a balance sheet total of less than €43 million. Small companies have less than 50 employees and either a net turnover or balance sheet of €10 million, while micros have less than 10 employees and either a net turnover or balance sheet of €2 million. Meeting the staff headcount threshold is obligatory, therefore companies with more than 250 employees can never be considered SMEs, while for balance sheet total and turnover, companies may choose the one that is more favourable to them.

There is some flexibility with regards to the thresholds (staff headcount as well as the financial thresholds): a company can go beyond the thresholds during one year without losing the SME status. If this is also the case in the second consecutive year, the SME status is lost.

²⁶⁵ In 2015, almost all enterprises in the EU had fewer than 250 employees. However, applying the ownership criterion to Orbis data (i.e. including downstream and upstream partner companies and linked companies), would result in excluding approx. 10% of the abovementioned SME population (more than two million enterprises). Analysis of the 2018 SAFE survey micro database suggests that 87% of EU companies with less than 250 employees were autonomous in 2018, compared to 94% for some non-EU countries. Autonomous companies are not evenly distributed by size category: 95% among companies with 0-9 employees, 88% among those with 10-49 employees and 70% among those with 50-249 employees. (Evaluation of the SME Definition, 2021).

Step (1) – identification of affected businesses and assessment of relevance

The 'relevance' of an initiative for SMEs is important because it determines the level of assessment required for performing a proportionate 'SME test'. An initiative can be classified as: 'not relevant', 'relevant' or 'highly relevant' for SMEs. If an initiative is considered 'relevant' or 'highly relevant' for SMEs, its impact assessment must include the 'SME check' (Annex 6). However, the extent to which SMEs are affected, and the relevance of an initiative should already be analysed and flagged when the 'call for evidence' is developed (see Tool #51 (*Consulting stakeholders*)).

The threshold question of step (1) is: **To what extent is the initiative relevant for SMEs ('not relevant', 'relevant', 'highly relevant')?**

Several additional guiding questions help reply to this key question:

- *Are SMEs within the scope of the initiative?*
- *Does the initiative specifically target SMEs?*
- *Will the SMEs be significantly impacted directly or indirectly by the initiative?*
- *Are SMEs impacts likely to be more substantial than on other companies, for example in terms of adverse effects?*

Since January 2022, the SME filter has helped to identify initiatives that are relevant for SMEs. The Network of SME Envoys²⁶⁶ filters EU initiatives to signal to the Commission those that merit close attention from an SME perspective²⁶⁷. The filter is applied to all the initiatives announced with a call for evidence and requiring an impact assessment. The results of the SME filter are public²⁶⁸. To timely feed into the policy preparation process, the Network of EU SME Envoys provides the results of the filtering process to the Commission services no later than 1 month after the publication of the 'call for evidence' on the 'Have Your Say' portal.

The questions listed in italics above and the SME filtering process help to distinguish between 'not relevant' and 'relevant' initiatives. To further identify highly relevant initiatives, the interservice coordination group can be guided by the following questions:

- *The horizontal (cross-sector) nature of the initiative: are SMEs of all sizes (micro, small, medium) across the EU concerned by the initiative?*
- *Is a very high impact of the initiative expected overall on affected SMEs, in particular in terms of compliance efforts?*
- *Has an evaluation identified important problem(s) for SMEs, such as high regulatory costs, supply chain disruptions, a widespread lack of compliance, critical feedback from SMEs and their representative organisations, etc.?*

If the initiative is assessed as 'relevant' or 'highly relevant' for SMEs, the characteristics of the affected businesses/sector(s) should be identified and included in the 'SME check' (Annex 6) of the impact assessment. Examples of elements to consider include:

- proportion of the employment concerned in the different categories of enterprises affected, average number of employees

²⁶⁶ [SME envoys network | Internal Market, Industry, Entrepreneurship and SMEs \(europa.eu\)](https://ec.europa.eu/economy_finance/sme-envoys-network)

²⁶⁷ [Communication-sme-strategy-march-2020_en.pdf \(europa.eu\)](https://ec.europa.eu/economy_finance/communication-sme-strategy-march-2020_en.pdf)

²⁶⁸ <https://ec.europa.eu/docsroom/documents/63274>

- weight of the different kinds of SMEs in the sector(s) (micro, small, and medium ones)
- links with other sectors and possible impacts on subcontracting or along the value chain; for instance, there may be an impact not only on the targeted sector but also on its suppliers or customers; such indirect impacts should also be considered.

Relevant sources of information should be explored²⁶⁹. These could also include information available from organisations representing SMEs' interests.

Even when exempted from the scope of a legislative initiative, SMEs can be affected through the supply chain or subcontracting, or through changes that affect their ability to access finance, the Single Market, non-EU markets, skills, raw materials, data, customers, etc. This indirect effect shall not be underestimated (see step (3) below). Experience has shown that SMEs rarely have enough leverage to counter trickle-down effects; therefore, indirect impacts are, to a certain extent, unavoidable and shall consequently be fully included in the assessment of impacts.

Box 3. Application of the SME-test according to the “relevance” of the initiative for SMEs

The purpose of step (1) of the ‘SME-test’ is to determine whether to move to the next steps based on the reply to the threshold question (see step 1 above). This question needs to be discussed in the **interservice coordination group**.

For initiatives that are likely to have little or no impact on SMEs (‘not relevant’), the impact assessment report can provide an ‘SME test’ which is limited to step 1. In this case, the impact assessment report should reflect this in the section on the impacts of the policy options. Any input received from the SME community, including from the public consultation, should be reported in Annex 2²⁷⁰.

For initiatives that are ‘relevant’ or ‘highly relevant’ for SMEs, the remaining three steps of the ‘SME test’ need to be adequately applied and the results reflected in the ‘SME check’ annex.

For initiatives considered to be ‘highly relevant’ for SMEs, it is necessary to undertake an in-depth analysis of the impacts on SMEs (by size-class)²⁷¹.

Step (2) – consultation of SME stakeholders

Several guiding key questions need to be addressed in step (2):

- *What are the main tools of the consultation strategy to reach out to the SME community?*
- *Is a targeted consultation of SMEs envisaged (e.g., SME panel, workshop, reality checks, etc.)?*

²⁶⁹ A useful starting point to find this information are the Structural Business Statistics produced by Eurostat. To the extent that a differentiation is made of companies by their size, Step 2 “What is the competitive position of the most affected sectors?” of the Competitiveness check tool can provide an analysis on the structure and performance of directly affected sectors (see Tool #21 (*Competitiveness Check*)).

²⁷⁰ Generally, this should be possible without execution of step 2 as public consultation always offers the possibility for SMEs to participate and as the questionnaires of such consultations always allow identifying SMEs (see Summary table in annex 2).

²⁷¹ In case the impact assessment report is supported by a study, this requirement could be included in the terms of reference.

- *What input has been received from different size classes of SMEs (i.e., micro, small, medium) and their representative organisations in the consultations? What are their key concerns and insights?*
- *Are SMEs' views different from those of large businesses?*

When SMEs are affected by the policy initiative, the SME dimension should be a clear part of the consultation strategy (for which separate guidance exists²⁷²). All public consultations of legislative initiatives must allow respondents to identify themselves as individual SMEs (by size, including self-employed) or as organisations representing SMEs. In addition to public consultations, consultation activities may involve targeted actions, consultations such as reality checks, round table discussions, focus group meetings, hearings targeting SME representatives, SME panel consultations carried out with the assistance of the Enterprise Europe Network or other specific consultations – aimed at providing inputs into the ‘SME test’²⁷³. Whenever it is deemed useful and relevant, the start-up community should also be targeted by the consultation activities.

Considering the consultation possibilities outlined here above, for initiatives that are ‘relevant’ for SMEs, consultations of SMEs and/or their representative organisations, such as targeted consultations, can be considered in addition to the public consultation. The public consultation questionnaire will include questions identifying SMEs and specifically targeting them. For initiatives that are considered ‘highly relevant’ for SMEs, the consultation strategy should envisage targeted consultations of SMEs and/or of their representative organisations.

The relevant annexes of the impact assessment report (i.e. Annex 2 on stakeholder consultation and the ‘SME check’ annex) need to reflect the analysis of the input received from the SME community as outlined here under step 2.

- If no SME-specific input has been received, this should be stated.
- For initiatives that are ‘relevant’ for SMEs: the report should describe the differences in stated positions between SMEs and large businesses or other stakeholders. If there are no differences between the position of SMEs and large companies, this should be stated.
- For initiatives that are ‘highly relevant’ for SMEs: in addition, the analysis of replies, position papers, etc. has also to investigate if there are significant differences within different size-classes of SMEs (i.e. micro, small, medium).
- It should be clarified how SME-specific input has been taken into consideration.

The SME dimension in public consultations is also explained in Tool #52 (Consultation strategy).

Step (3) – assessment of the impacts on SMEs

The following guiding questions need to be addressed in step (3):

- *What are the estimated direct costs for SMEs?*
- *What are the estimated direct benefits/cost savings for SMEs?*

²⁷² See Chapter 7 on stakeholder consultations.

²⁷³ DG GROW units A.2 and B.4 coordinate the preparation of these panels.

- *Have indirect effects on SMEs been considered, even if SMEs are exempt from direct obligations?*

Quantification of costs and benefits is often challenging, and evidence sources such as studies, stakeholder consultations, etc. should be used extensively. It is likely that an EU measure would have direct and indirect impacts on SMEs. The direct benefits, such as improved working conditions, increased competition, etc., should (at some stage) be reflected in reduced costs to SMEs. Yet, these benefits may be offset by various regulatory costs some of which may be disproportionately felt by SMEs.

For initiatives that are 'relevant' for SMEs, activities to collect information about the costs must be considered. When initiatives are 'highly relevant' for SMEs, the impact assessment must plan such activities (analysis of existing studies, targeted consultations, studies underpinning the IA, etc.).

Whenever an SME-related threshold is introduced to differentiate the application of a given policy measure on companies, the effects of the threshold on the potential scaling-up of companies should be assessed²⁷⁴. Specifically, policy measures that exempt SMEs have to always carry out an assessment if there can be an indirect impact on SMEs and on their ability and willingness to grow and if it is necessary to accompany that exemption with additional measures that support SMEs and create an environment that does not discourage their growth.

When an indirect impact on SMEs is likely to occur (for instance, through a trickle-down effect in the value chain), considering entire value chains would better highlight the consequences of the proposed legislation on specific companies within that chain. This approach would reveal obligations that could affect SMEs (e.g. through business-to-business contracts), even if they are excluded from the initial scope. In this case, the SME-check annex should include an estimation of how many SMEs could be affected (also expressed in terms of employees) and an estimation of the main indirect impact qualitatively and, where possible, quantitatively or explain why it is not possible.

For initiatives that are 'relevant' for SMEs, costs and benefits²⁷⁵ of the proposals for SMEs (and microenterprises in particular) compared to large companies must be analysed qualitatively for all policy options and – to the extent possible – quantitatively for the preferred option.

For this purpose, the overall costs identified may be compared to the number of persons employed to calculate the average cost per employee²⁷⁶. They may also be compared to the company's profit margin²⁷⁷.

In addition, the following elements should be considered:

²⁷⁴ For example, in the proposal amending Directive 2013/34/EU disclosure of income tax information by certain undertakings and branches, MNE Groups with a total consolidated group revenue exceeding €750 million will be required to prepare the country-by-country reporting. The threshold effect was expressly considered in the IA.

²⁷⁵ See Tool #56 (*Typology of costs and benefits*); and Tool #57 (*Methods to assess costs and benefits*)

²⁷⁶ It is recommended to use the ranges of the SME definition: 0-9, 10-49, 50-249 and 250+ employees.

²⁷⁷ Representative samples of different size of companies can also be used. The use of profit margin considers the cumulative cost of legislation, which is not reflected if turnover is used.

- possible impacts on barriers to entry, competition in the market and market structure, for example in terms of possibilities for SMEs to enter markets²⁷⁸;
- possible impact on innovation²⁷⁹.

For initiatives that are 'highly relevant' for SMEs, the distribution of the costs and benefits of the proposals should be analysed qualitatively and quantitatively²⁸⁰ for each policy option by business size (i.e. differentiating between micro, small, medium and large enterprises) to the extent possible. A one-size fits all approach for all SMEs might not be effective or efficient because the impact on micro-companies is likely to substantially differ from the impact on medium sized ones. Therefore, costs and benefits accruing to each size-class of SMEs should be presented and analysed separately.

When data is unavailable or it is not possible to estimate costs thoroughly, calculating costs could involve providing a concrete example of what one company must do to be fully compliant, or focusing on a limited set of companies to estimate the anticipated costs. Examples could be included in the 'SME test' for different types of companies, such as a micro-enterprise, a small company, and a medium-sized company. Creating focus groups based on company size and estimating or calculating costs in cooperation with the involved companies could be an effective approach.

If despite efforts to quantify costs, the data collection has not been successful to achieve this, the impact assessment report should state it, explain the reasons for it and focus on qualitative analysis.

The key results of the assessment of SME impacts on the preferred option as outlined here under step 3, need to be included in the 'SME check' annex²⁸¹.

Step (4) - minimising negative impacts on SMEs

The following guiding questions need to be addressed in step (4):

- *If SMEs are disproportionately affected by the preferred option compared to large companies, are there any specific subgroups of SMEs more exposed than others?*
- *Is it possible to identify an SME-friendly policy option in the impact assessment to minimise negative impacts and maximise positive impacts of SMEs?*
- *If no SME-friendly option can be identified, what specific mitigating measures can be included in the preferred option? What are their expected benefits?*
- *Have SME-friendly provisions been considered in the final proposal? Which provisions and why?*

A well-designed proposal should aim to be SME-friendly by default, eliminating the need for specific mitigating measures. This requires designing the various policy options with SMEs in mind from the outset. If this is not the case and the options are found to disproportionately

²⁷⁸ See Tool #25 (*Internal market*)

²⁷⁹ See Tool #22 (*Research and innovation*)

²⁸⁰ See Tool #56 (*Typology of costs and benefits*); and Tool #57 (*Methods to assess costs and benefits*)

²⁸¹ The results should also inform the analysis of SME competitiveness (See tool #21 and reported in the competitiveness check annex 5).

affect SMEs or some specific subgroup of SMEs, measures to mitigate such impact are necessary and need to be included in the preferred option.

Mitigating measures

The analysis may show that micro, small and/or medium-sized enterprises are facing a relatively higher burden than large companies and that specific measures, where they already exist, have not proven to address the SME needs sufficiently or adequately. In such case, one might consider the use of specific mitigating measures to ensure a level playing field and the respect of the proportionality principle. For example:

- simplified reporting, exploring possible synergies with already existing reporting obligations, lower frequency for certain obligations or the use of simplified templates;
- simplified obligations
- making available the necessary support measures (such as information and training campaigns, guidelines, IT tools, one-stop-shops/helpdesks/hubs);
- simplification initiatives which can particularly benefit SMEs (example: possibility to use on-line facilities such as digital compliance assistance tools, or lighter treatment for companies that are certified by a third party²⁸², common translated forms);
- reduced fees and additional financial support; proportionality of sanctions/administrative fines;
- self-certification procedures, and longer validity periods for administrative certificates;
- inclusion of SME expertise in expert groups that are relevant for the initiative;
- imposing obligations on SMEs counterparts rather than on SMEs themselves (example: in the case of third-party certification, the certifier could be required to submit the relevant information or certificate directly to the authorities, instead of placing the burden of notifying the relevant authorities on individual companies);
- using exemptions from certain regulatory requirements for SMEs (or specific size categories). However, exemptions can create thresholds and multiple exemptions across different policy areas taken together set up barriers to the further growth of the companies. Therefore, this approach is not always favourable to SMEs and should be used with caution.

If mitigating measures are deemed necessary, it is important that the costs and benefits they may incur are also fully considered and included in the final impact (cost-benefit) assessment. This includes the impacts of any SME specific measures or exemptions (i.e. no fees for micros can turn into higher fees for small companies) and also the effect on the potential scaling-up of companies.

If the SME definition is to be used for clarifying the scope of a mitigating measure, it is good practice to make a dynamic reference to it at least in the recitals²⁸³. In addition, for initiatives that are 'highly relevant' for SMEs, the impact assessment report should consider setting

²⁸² Reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, is one of the criteria to be taken into account in the general [rules on official controls](#).

²⁸³ By using the following reference: "as defined in Commission Recommendation 2003/361 and its subsequent amendments".

specific indicators to monitor the impact of the preferred option on SMEs and differentiate them in their sub-groups, or parts thereof, when relevant²⁸⁴.

Systematic consideration of SME-friendly provisions

SME-friendly provisions are a specific category of mitigating measures and refer to standard legal clauses that can be incorporated in draft proposals. They address aspects of legislation that impact the business environment. They are commonly applicable across multiple legislative acts (e.g. phased implementations) and are designed to ease the practical application of EU legislation by SMEs. The following SME-friendly provisions should be systematically considered where appropriate and justified:

- (1) the possibility of allowing longer transition periods for SMEs, to ensure predictability and facilitate compliance by SMEs;
- (2) requirements for specific guidance for SMEs to be provided by the Commission and/or Member States regarding the implementation of the proposed legislation (e.g. summary of the legislation, online training material) when necessary;
- (3) a requirement for the Commission to pay particular attention to the impact of delegated and implementing acts on SMEs, which often define the level of costs for SMEs;
- (4) a review clause or sunset clause in secondary legislation with the timing consistent with the ex-post evaluation process.

For this purpose, internal guidance is available²⁸⁵.

3. INFORMATION SOURCES AND SUPPORT

Support for the execution of the 'SME test' is provided by DG GROW. You can contact the 'SME Test' Helpdesk via email (see below).

- 'SME test' on Europa
- 'SME test' available support
- 'SME test' Helpdesk: GROW-SME-ENVOY@ec.europa.eu

Data sources

- Structural Business Statistics (Eurostat)
- SME performance review ([European Commission](#))
- ESTAT [business demography](#)
- Survey on access to finance of enterprises ([annual publication since 2013](#))

²⁸⁴ Examples can be found in COM/2020/682 (Art. 10.2 “disaggregated ... by company size”). Impact on SMEs can also be an element to be specifically considered in implementation reports/review (for example, Directive 2019/1152 Art. 23 “the Commission shall, after consulting the Member States and the social partners at Union level and taking into account the impact on micro, small and medium-sized enterprises, review the implementation of this Directive and propose, where appropriate, legislative amendments”).

²⁸⁵ [SMEFriendlyProvisions_EN_2024Oct](#)

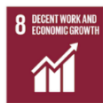
- [Digital intensity by size class of enterprises \(ICT usage in enterprises\)](#) (annual publication since 2002, excludes micro-enterprises)
- [Community Innovation Survey](#) (biannual publication since 2004, excludes micro-enterprises)
- [OECD Data explorer](#) (which includes a section on SMEs and entrepreneurship)
- [Regular Flash Eurobarometers](#) on “SMEs, resource efficiency and green markets” (2012 FL342, 2013 FL381, 2015 FL426, 2018 FL456, 2022 FL498, 2024 FL549) and on “SMEs, start-ups, scale-ups and entrepreneurship” (2020 FL486, 2025 FL559)
- Flash Eurobarometers on “SMEs and skills shortages” (2023 FL537) and on “European Year of Skills: Skills shortages, recruitment and retention strategies in small and medium-sized enterprises” (2023 FL529)

EU definition of SMEs:

- [Small Business Act - COM/2008/394](#)
- [Review of the “Small Business Act” for Europe - COM/2011/0078](#)
- [Definition of SMEs: Commission Recommendation 2003/361/EC](#) 
- [The revised User Guide to the SME definition](#) 
- [SME self-assessment tool](#)

4. RELEVANT SDG INDICATORS

To track progress, the SDG indicators below can also be considered, though the list should not be considered exhaustive.

Relevant SDGs indicators	SDGs
No specific indicators on SME available in SDG-EU framework. However, information can be found at: • Small and medium-sized enterprises: an overview • Structural Business Statistics Database UN indicators: • Average income of small-scale food producers, by sex and indigenous status • Proportion of small-scale industries in total industry value added • Proportion of small-scale industries with a loan or line of credit • Volume of production per labor unit by classes of farming / pastoral / forestry enterprise size	  

Annex 1: Summary table

DIFFERENT STEPS OF THE SME-TEST AND RELATED QUESTIONS		OVERVIEW OF ESSENTIAL ELEMENTS TO BE INCLUDED IN THE IMPACT ASSESSMENT REPORT (by ‘relevance’ of the legislative initiative for SMEs)		
Step (1) Are SMEs among the affected businesses?				
Are SMEs within the scope of the legislative initiative?		If yes, identify the characteristics of the affected businesses/sector(s).		
Will SMEs be likely impacted directly or indirectly by the legislative initiative?		If yes, identify the characteristics of the affected businesses/sector(s).		
Threshold question: To what extent is the legislative initiative relevant for SMEs? Reply to be agreed in the ISCG.				
		‘not relevant’	‘relevant’	‘highly relevant’
Step (2) Are SMEs properly captured in your consultation activities?				
Are SMEs solicited to participate in the public consultations and can they be identified on the basis of the questionnaire?		Identification of SME respondents ²⁸⁶	Identification of SME respondents (enterprises by size and SME organisations)	Identification of SME respondents (enterprises by size and SME organisations)
Has the consultation strategy envisaged adequate tools to reach out to the SME community?			Consider consultations of SMEs and/or of their representative organisations	Plan targeted consultations of SMEs and/or of their representative organisations
Does the impact assessment report analyse the input received from the SME community?		Distinguish SMEs in the analysis of the consultation results ²⁸⁷	Distinguish SMEs in the analysis of the consultation results Report on differences between SMEs and large companies	Distinguish SMEs in the analysis of the consultation results Report on differences between SMEs and large companies Report on differences within SME size classes (where relevant)
Does the impact assessment report describe how the input from the SME community has been taken into consideration?		Description ²⁸⁸	Description	Description

²⁸⁶ This is also required for non-relevant SME initiatives and does not require the execution of step 2.

²⁸⁷ See previous footnote.

²⁸⁸ See previous footnote.

Step (3) Has the impact on SMEs been assessed?			
Have adequate activities been planned to assess the impact on SMEs?		<i>Consider</i> an ad-hoc activity to collect information on costs for SMEs	<i>Plan</i> ad-hoc activity to collect information on costs for SMEs
Does the impact assessment report provide for a proportionate assessment of impacts on SMEs and on their ability to grow?		Assess costs and benefits for SMEs, in particular micros, compared to large enterprises. Qualitative analysis for all policy options and – to the extent possible – quantitative analysis for the preferred option.	Assess costs and benefits differentiating between SMEs and large enterprises and – where relevant – within SMEs of different size-classes. Qualitative and – to the extent possible – quantitative analysis policy option.
Step (4) How has the impact assessment tried to minimise negative impacts on SMEs?			
Is the impact assessment considering options that minimise the negative and maximise the positive impact on SMEs?		Make sure there are options that are favourable for SMEs and their growth.	Make sure there are options that are favourable for SMEs and their growth.
When significant adverse impact on SMEs has been identified under steps 3, does the impact assessment consider measures to mitigate/redress the impact on SMEs?		If the preferred option has a significant adverse impact on SMEs, consider the use of mitigating measures or the design of the option in an alternative way.	If the preferred option has a significant adverse impact on SMEs, consider the use of mitigating measures or the design of the option in an alternative way.

TOOL #24. COMPETITION

1. INTRODUCTION

Competitive markets encourage enterprises to be efficient and innovative, thereby creating more choice for consumers, reducing prices, and improving the quality of goods and services. Increased competition typically improves a country's economic performance, opens business opportunities to its citizens and reduces the cost of goods and services throughout the economy. When governments intervene in markets to regulate the behaviour of businesses, this may in some cases restrict competition further than is necessary to achieve the desired policy objectives.

The first step in competition analysis is to define the relevant market in the internal market and to apply concepts such as market power. This is to be done in accordance with the 1997 Commission Notice on the definition of relevant market, currently in the course of being reviewed²⁸⁹.

The **relevant market** is the market affected by the proposed policy initiative. Broadly speaking, it combines the characteristics and use of as well as the demand for the products or services and their geographic availability,

More specifically, a relevant market comprises all products or services that consumers regard as interchangeable or substitutes by reason of their characteristics, their prices and their intended use (e.g. luxury sports cars are not considered by consumers to be close substitutes with small economy cars, so would not be in the same market).

A relevant geographic market comprises the area in which the firms concerned are involved in the supply of products or services and in which the conditions of competition are sufficiently homogeneous (significant differences arguing in favour of separate geographic markets may include, for example, trade barriers, consumer preferences, language...).

Market power in the internal market is defined as the ability of a firm to raise prices above competitive levels in a profitable way. Market power can arise due to a variety of reasons and last for a shorter or longer period. A firm may be able to temporarily increase prices above competitive levels. However, in the absence of market power, such price increases are unsustainable because customers can then switch to other competitors.

Against this background, in assessing competition effects of policy options under an initiative, the key issue is to determine whether the proposed policy option may lead to an increase in market power, with implications for prices, efficiency and innovation. Any assessment of market power will have to be made in the relevant market.

Once the relevant market has been clearly defined, some characteristics that describe the **structure of the market** should be considered to allow for an assessment of whether there may be a negative impact on competition resulting from the policy option under the initiative. Those variables may include:

- the number of firms;
- the firms' market shares;

²⁸⁹ Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997.

- other competition parameters impacting the relative position of competitors (e.g. strong IPRs, financial resources, brand recognition and first mover advantage);
- existence of entry and exit barriers and
- market power of buyers and suppliers.

All these characteristics will impact the ability of consumers to switch to competitors in case of a price increase and so will be relevant in assessing market power.

An additional key component of a competition assessment is the evaluation of **barriers to entry and exit**, defined as factors that might hinder the entry and exit of firms into and from the relevant market. When important barriers to entry or exit exist in a market, any new regulation imposing additional constraints on competition can cause significant harm.

Different types of barriers to entry include:

- natural barriers, such as strong economies of scale, i.e. cost advantages enterprises obtain due to scale of operation, with cost per unit of output generally decreasing with increasing scale as fixed costs are spread out over more units of output;
- barriers created by the conduct of incumbent firms, for example high switching cost and limited access to networks; and
- regulation that can impose additional entry barriers (e.g. legal restrictions on new entry in certain sectors like licenses, patents, exclusive rights; costly and cumbersome bureaucratic and administrative procedures to start new businesses; local professional body certifications, e.g. medicine, law).

Types of barriers to exit include:

- sunk costs, i.e. costs that cannot be recovered when a firm chooses to exit a market (e.g. set-up costs that cannot be recouped, advertising expenditure);
- labour related exit costs such as staff redundancy costs;
- regulatory exit requirements;
- long-term contracts;
- first mover disadvantage;
- government intervention;
- managerial barriers.

2. CRITERIA FOR POTENTIALLY SIGNIFICANT IMPACTS ON COMPETITION

The checklist below has been developed by the OECD as part of its competitive framework to screen policies for potential detrimental effects on competition. **A more detailed analysis as introduced in sections 3, 4 and 5 should be performed in case of a positive reply to any of the questions in the checklist in Box 1 below, where there is also a first indication that the effect is significant.**

Box 1. The competition checklist

Further assessment and reflection about possibly better policy options should be performed if a proposed policy option may have any of the following effects:

(A) Limiting the number or range of suppliers and producers

This is likely to be the case if the policy option:

- grants exclusive rights for a supplier or producer to provide goods or services (e.g. many municipalities sign a long-term contract with a single supplier of products or services);
- establishes a license, permit or authorisation process as a requirement of operation (e.g. requirements that only companies which fulfil certain minimum requirements for formal education may perform a certain service);
- limits in other ways the ability of certain types of suppliers or producers to provide goods or services (e.g. public procurement requirements for tenderers to have many years of experience may keep out new businesses and start-ups);
- significantly raises the cost of entry or exit by a supplier or producer;
- creates a geographical barrier to the ability of companies to produce or supply goods or services or to invest capital (e.g. strict rules for regional development projects).

(B) Limiting the ability of suppliers and producers to compete

This is likely to be the case if the policy option:

- limits suppliers' or producers' ability to set the prices for their goods or services (e.g. minimum and maximum prices);
- limits freedom of suppliers or producers to advertise or market their goods or services (particularly for potential entrants);
- sets standards for product quality that provide an advantage to some suppliers or producers over others (e.g. by requiring a particular technology or by setting unduly strict standards that are difficult or impossible for the large majority of existing producers to meet) that are above the level that some well-informed customers would choose;
- significantly raises costs of production for some suppliers or producers relative to others (especially by treating incumbents more favourably than new entrants, for instance exempting incumbents from new rules for a certain period or under specific conditions).

(C) Reducing the incentive of suppliers or producers to compete

This may be the case if the policy option:

- creates a self-regulatory or co-regulatory regime which risks collusion or setting high entry barriers by sector associations;
- requires or encourages information on suppliers' or producers' production levels, prices, sales, or cost structures to be published (which could allow cartels to be better policed and the punishment of members if they offer consumers better conditions than those agreed);
- exempts the activity of a particular industrial sector or group of suppliers or producers from the operation of general competition law (e.g. the EU insurance sector and the motor vehicle retail sector benefit from block exemption regulations that other sectors do not benefit from).

(D) Limiting the choices and information available to customers

This may be the case if the policy option:

- limits the ability of customers or producers to decide from which supplier or producer they purchase (e.g. allowing sale of certain products, for instance e-cigarettes, only in certain type of licensed shops or pharmacies);
- reduces mobility of customers between suppliers and producers of goods or services by increasing the cost of changing suppliers (recognising this, some EU legislation prohibit charging consumers for switching cost, for instance of mobile phone services);
- allows suppliers and producers to confuse customers with misleading, unreliable or rapidly changing information that prevents them from shopping effectively (e.g. telecom liberalisation in some countries may temporarily have led to a multitude of ever changing tariffs that confused, rather than helped consumers to make good choices).

3. PRACTICAL ASSESSMENT OF IMPACTS OF OPTIONS ON COMPETITION

The following list of criteria may help in the analysis for impact assessments. The same criteria are also applicable to evaluations. The proportionality of analysis, as with any aspect in the impact assessment process, will depend on the significance of the competition effects. As a rule of thumb, the higher the market power of firms identified in the relevant market, the more careful the assessment should be (e.g. in a very atomised market structure with low entry barriers, market power is very limited). Not all the criteria may be relevant for a particular project or initiative.

Impacts	Key criteria
Impacts on existing firms	<u>Impact on the cost of meeting the regulation:</u> (1) the policy option creates additional costs for existing firms, to be quantified where possible (e.g. new requirements for licences or permits); (2) types of costs: fixed (non-recurring) or variable (recurring) costs; fixed costs may represent an additional entry barrier. (3) Analyse if the size of the costs relative to businesses' annual sales revenues: - vary by the size of the business (for example, where small businesses are more adversely affected); - are higher for new entrants or decrease over time; - depend on other characteristics of the firms or of the market(s) (for instance: vertically/horizontally integrated markets, location such as urban vs. rural, coastal vs. internal etc.) <u>Impact on the exit of firms:</u> (1) where new costs or requirements may lead some businesses to exit the market: - which businesses are more likely to exit (small or large firms; older incumbents etc.?) - in some cases, it could be relevant to make a distinction between a dominant supplier or producer and their competitors.

Impacts	Key criteria
	(2) where the initiative limits growth opportunities of existing competitors; (3) where the initiative favours the incumbent over existing competitors; (4) where the initiative limits the possibility of inefficient firms to exit the market, raising barriers to exit that cause market inefficiency. <u>Impact on the anti-competitive behaviour of firms:</u> (1) impact on the incentive for anti-competitive practices of firms (collusion, etc.); (2) a history of collusion or other anti-competitive practices in the sector should be accounted for in the decision-making process (DG COMP can help to provide such information). <u>Impact of state aid measures:</u> (1) impact on competitors of the firm benefiting from State aid; (2) impact in the form of distortions of competition on the internal market; (3) past evidence of similar measures; (4) appropriateness of the measures and proportionality of the aid granted in relation to the needs.
Impacts on entry of new firms	(1) <u>Restriction of entry:</u> - for all entrants: for example, if a regulation limits the total number of pharmacies per 5,000 people, this applies to all types of pharmacies and will limit the extent of competition in the market in a very explicit manner; - for specific types of firms: new firms rather than incumbents, small and medium entrants rather than large undertakings, foreign firms rather than national firms. (2) <u>Limitation of access to specific resources:</u> for instance input products, know-how, distribution channels.
Impacts on consumer prices	(1) Identify likely causes of price increase: - increase of production costs; - increase in market power; - greater information sharing and cooperation among businesses leading to collusion
Non-price impacts on consumers²⁹⁰	(1) <u>Impacts on the quality and variety of products and consumer choice</u> (for instance where the regulation sets a minimum of quality standard; or creates barriers to entry). (2) <u>Impacts on the incentive to innovate:</u> high barriers to entry or exit through long protection periods for incumbents; prohibition of advertising.

²⁹⁰ See Tool #33 (Consumers)

Impacts	Key criteria
Impact on upstream and downstream markets²⁹¹	Analyse the policy options to determine: (1) different impacts on vertically-integrated firms (e.g. because of the difference in switching costs); (2) incentives to increase vertical integration in the market, thereby potentially increasing entry and exit barriers; (3) how the bargaining power of buyers will be affected; (4) how the bargaining power of suppliers will be affected.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON COMPETITION

Where the initial assessment concludes that a policy option entails significant risks to weaken competition, it is necessary to determine if there are other policy options less likely to distort competition while still achieving the policy objectives.

The question is whether the anti-competitive elements are *strictly necessary* to attain the policy objectives, or if they could be amended to reduce or eliminate their negative impact on competition. There may be cases where no valid alternative options can be found. Nonetheless, before reaching such a conclusion, a thorough analysis of all possible alternative options should be carried out.

Less restrictive measures that can be used in place of more restrictive ones include:

(1) Tailored transition periods or provisions when adopting new legislation

New rules and regulation may place a heavy burden on existing firms who made their investments in production facilities and started operations under the older rules. Since significant changes in the existing structure can be prohibitively costly, in specific cases, existing firms can either be exempt or given a specific timeframe to conform. The extent of the adjustment period may also be conditioned on firm-specific characteristics such as technology, the date at which the capital was required, and firm size.

In such cases, it may be useful to carefully consider the implication of transition clauses. It is important to bear in mind that provisions imposing asymmetric standards on existing firms versus newer ones may deter new entrants (entry barriers), dampen new investment by incumbent businesses, and allow continuation of inefficient production (exit barriers).

(2) Using economic incentives rather than regulation to deal with externalities

Externalities include environmental, economic, health, safety or other costs and benefits generated by a product or service and not reflected in its price or cost²⁹².

²⁹¹ For a given firm, upstream markets are all the markets of its suppliers. Downstream markets are the markets of the firm's clients (that can be both consumers and other firms along the value chain).

²⁹² If a product or activity generates external costs (e.g. negative environmental effects), it will tend to be oversupplied, as the full costs are not reflected in the product's / activity's price or marketplace return. Equally, if a product or activity generates external benefits (e.g. technology spillovers), it will tend to be undersupplied.

Regulation of the quantity supplied, price, or characteristics of externality-generating products or activities is one possible approach of attempting to correct for these externalities. An alternative approach is to use economic incentives, such as subsidies, taxes, or fees, to internalise these products' externalities, so they are reflected in their market price. When feasible, this approach uses competitive market forces to determine efficient prices, quantities, and product characteristics instead of attempting to estimate and regulate outcomes. Another alternative is to create market solutions where none existed before.

Example: The EU Emission Trading System (ETS), by creating emission rights and allowing to trade these rights, reduced the anticompetitive impacts of setting new emission standards.

(3) *Ensuring adequate consumer information rather than mandatory product characteristics*

Protecting consumers is often used as a reason to establish mandatory product characteristics. While health and safety protection should generally be achieved by means of product design and manufacture, in some cases adequate information disclosure may be sufficient, allowing consumers to make informed decisions.

Example: Setting labelling requirements to disclose the content of food products instead of banning those products.

(4) *Voluntary rather than mandatory product specifications*

Setting product specifications and quality norms is often necessary and may serve the public interest. At the same time, stringent rules and regulation on content and minimum quality can, in some cases, clash with consumer preferences and disadvantage those consumers (e.g. low income consumers) who may prefer to pay a lower price for lower quality.

Voluntary standards can permit suppliers to signal that their products meet certain standards, while allowing them to provide other products that do not meet the standards if some consumers prefer such products (provided that they do not entail additional significant risks).

Example: The EU Ecolabel is a voluntary label helping consumers to identify products and services that have a reduced environmental impact throughout their entire life cycle; it promotes environmental excellence without limiting consumers' choice.

(5) *Reliance on enforcement under competition rules in addition to sector-specific regulation to deal with inappropriate competitive behaviour*

As a complement to sector-specific regulation, general competition rules and their enforcement provide a framework for preventing business practices that are likely to harm competition and consumers, while allowing practices that promote competition, innovation, and consumer benefits.

Example: In the pharmaceutical sector, patent settlement agreements between originator and generic companies may result in anticompetitive practices, e.g. delaying generic market entry to the detriment of consumers. The EU approach has been targeted at monitoring the situation and assessing problematic cases individually. As a result, there are fewer and less important settlements that are likely to raise competition concerns, while at the same time the overall number of settlements has steadily increased.

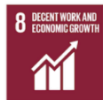
5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- The OECD Competition Assessment Toolkit²⁹³ contains the checklist mentioned above and many useful examples for assessment steps and better option development.
- *Volume 1 ("Principles")* contains a checklist and basic explanations about the interaction between regulation and competition for readers who are not experts in competition policy.
- *Volume 2 ("Guidance")* contains further explanations and examples for readers who want to perform an analysis of competition effects in ex-ante or ex-post assessments of policy instruments.
- *Volume 3 ("Operational Manual")* contains further practical examples and recommendations how to conduct a competition assessment regarding a single policy instrument or regarding the situation in a whole sector.

More information about EU competition policy is available on DG Competition's website. Its consumer webpage gives an easily understandable overview for non-experts: http://ec.europa.eu/competition/index_en.html

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Real GDP per capita <i>UN indicators:</i> • Annual growth rate of real GDP per employed person	

²⁹³ <http://www.oecd.org/competition/assessment-toolkit.htm>

TOOL #25. INTERNAL MARKET

1. INTRODUCTION

The Treaty on the Functioning of the European Union establishes an objective to create a common market with full respect for the four pillars of free movement covering goods, services, capital, and workers, while paying due attention to legitimate and proportionate public policy interests. In the internal market, all citizens²⁹⁴ and companies are treated equally and in a non-discriminatory manner and the cross-border provision of goods and services should be as easy as within each individual Member State.

The proper functioning of the internal market may constitute the objective of an initiative. It may also constitute an important interest to be borne in mind where the main aim of the initiative is different.

The application of legal bases geared towards the proper functioning of the internal market may raise questions and the Legal Service should be consulted in case of doubt. A few non-exhaustive remarks regarding Article 114 TFEU (by way of prominent example) are described in Box 1.

Box 1. Article 114 TFEU

Article 114 of the Treaty on the Functioning of the European Union provides the legal basis for actions in the area of single market:

"(...) The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market."

- Measures adopted on the basis of Article 114 TFEU should objectively and effectively aim to improve the conditions for the establishment and functioning of the internal market. The risk of impaired functioning of the internal market should be sufficiently concrete: mere disparities between national rules or an abstract risk of infringements of fundamental freedoms or of distortion of competition, are not sufficient. Action may also be justified to prevent the likely emergence of such obstacles.
- Article 114 should not be used as legal basis if the establishment and functioning of the internal market is secondary or incidental to another objective (e.g. health or environment protection).

All Commission policies²⁹⁵ should be assessed for their potential effect on the functioning and effectiveness of the internal market. This tool consists of a series of questions to help you identify different angles in which your proposal may influence the internal market.

In case it is intended to rely on Article 114, having regard to the criteria set out above, the problem definition should include an analysis of the situation of the internal market. The impact analysis section should also discuss the possible impacts of the different options on the functioning and effectiveness of the internal market.

²⁹⁴ The term 'citizen' as used in this tool comprises different relevant (sub-) groups, including consumers, workers, and professionals.

²⁹⁵ https://ec.europa.eu/info/policies_en

When evaluating existing legislation, consider assessing its impact on the internal market. Be aware that some impacts might be unintended or unanticipated at the time your legislation was proposed. Consider these also for legislations that did not have the Single Market as a core objective or were not based on article 114.

2. INTRODUCTION

A number of problems on the internal market have been identified in a [Communication on Identifying and addressing barriers to the Single Market](#) and in the accompanying [staff working document](#), which can be a source of information.

The questions below can be used at various stages of the impact assessment process. They are relevant for both problem definition and analysis of options:

(1) *Questions to describe market structure, identify internal market related problems, market failures, their size and drivers*²⁹⁶:

- What are the trade flows of goods/services inside the EU and/or between Member States? How many companies provide relevant goods/services in the EU? Do they operate cross-border? Do they perform intra-EU sale/purchase of goods/services? Are there specific Member States where they operate and others where they are absent – why? Do companies operate in foreign markets through establishment (e.g. by setting up a branch, subsidiary, joint venture, etc.), or through posting of workers or by cross-border provision of services? What are the revenue and market shares of companies from other EU Member States and from cross-border provision of goods/services?;
- What are the skill and qualification structures of employees/professionals affected by the proposal in the EU and in the Member States? How many do work in other Member States? Do they work as posted workers or are they employed on a temporary or permanent basis? Are there barriers imposed by authorities, professional bodies, labour unions, employers (e.g. in contracts, standards or certificates) or others? Are these barriers especially burdensome for foreigners / targeting foreigners / foreign qualifications or diplomas?;
- If there is no/little cross-border trade, is this because of the type of goods/services that foreign companies provide? Are these goods and services really not tradable? Are there other reasons (e.g. supply or demand specificities at national level like climate, consumer preferences, language, culture)? Can these goods/services become tradable in the future (e.g. due to innovations, IT advances,...)?;
- Are there barriers imposed by market participants (such as territorial constraints on retailers, exclusivity contracts or cooling-off periods preventing competition following the termination of a contract)?;
- Can customers buy cross-border (e.g. can they buy in internet stores of the same company located in another Member State)? Is there a discrimination based on origin/nationality/residence? Are foreign buyers treated differently than locals when buying in another Member State for example by receiving different prices, different

²⁹⁶ See Tool #13 (*How to analyse problems*) for instance for guidance on market and regulatory failure analysis

terms and conditions such as ways of payment, delivery options, possibility to return, guarantee, redress, insurance?²⁹⁷;

- Are there market-imposed obstacles to the free movement of capital? (e.g. Stock Exchange Rules on listings, additional requirements for reporting or requirements to use certain standards such as Accounting Standards, etc.)? Are any of these especially targeting foreign capital providers? Are there differences in treatment of financing provided by financial institutions (e.g. venture capitalists) to companies (especially SMEs) based on their country of establishment? Are there any differences in treatment by type of funding?
- Are there any barriers to cross-border mobility of citizens or businesses that are caused by poor administrative cooperation or information exchange between public authorities?
- For any of the questions above: if digital solutions are involved, is there sufficient consideration of interoperability for cross-border exchange²⁹⁸?

(2) Questions to identify regulatory failures:

- Is the matter under consideration regulated in some Member States? Are there Member States with no rules at all? What are the underlying reasons in both cases, and are they still valid? Is there a risk for regulatory arbitrage if some Member States have rules and others not? How were the rules implemented in practice (e.g. rules on protection of 'whistleblowers')?;
- Is the regulatory framework harmonised – do companies/citizens face different rules/requirements in each Member State?
- In case of different national rules, is there a mutual recognition principle²⁹⁹ in place? How does it work? If not, why not?
- Are there regulatory barriers to foreign companies accessing the market?
- Are they justified by overriding public policy interest? Are they proportionate? Are they cumbersome³⁰⁰? For example, is there a need for obtaining permits, certificates, licences, attestations, passing of exams, provision of certified/translated copies of documents; number of documents to be submitted, need for audit, length of procedures; legal form or shareholder requirements, different accounting, or reporting rules. Are the rules easy to comply with (e.g. electronically via points of single contact; e-procurement platforms) and are translations or rules readily available?
- Are certain rules more cumbersome for foreigners (e.g. need for translation, need to appoint a local representative, need for additional certificates)? Are certain rules easier for foreigners (e.g. mutual recognition means that companies can accept standards/certificates of other Member State)? Is there scope for simplification?

²⁹⁷ Please note that certain EU acts restrict the non-discrimination principle, e.g. the Rome I Regulation (EC 593/2008) grants the consumer protection of his own national law in case the trader directs its activities to the Member States where the consumer is domiciled. The principle is that consumers should not have lower level of protection than in their home Member States.

²⁹⁸ See Tool #28 (*Digital-ready policymaking*)

²⁹⁹ The existing mutual recognition principle covers trade in certain goods as well as recognition of professional qualifications.

³⁰⁰ See Tool #24 (*Competition*)

- Is there 'gold plating' – Member States adding national/local rules to the harmonised EU ones? If so, what are the reasons? Are there rules in other fields that affect the area under consideration? Could all these additional rules discourage cross-border activity?
- Are the procedures to be followed clear, transparent and publicly available? For example, selection mechanism for tender winner in public procurement, non-publication of tenders; lack of meaningful information about regulated professions;
- Can companies/citizens enforce their rights easily?
- Can different levels of law enforcement encourage/discourage cross-border activity (e.g. rules exist but are not used)?;
- What is the cost in terms of time and money to enforce one's rights (e.g. length of court proceedings, etc.)?
- Does the regulated market structure create barriers? For example, very long contracts awarded by authorities that form a barrier to market entry (e.g. highway long term concessions). Is there centralisation of public procurement favouring large scale (national) suppliers (e.g. medicines)?;
- Does the country of origin/establishment influence the ability to access/transfer capital (e.g. obtaining a bank loan, venture capital, listing on stock market, acceptance of payment with a debit/credit card issued in other Member States)? Is the cost of access/move of capital higher for foreigners?

3. ASSESSING IMPACTS RELATED TO THE INTERNAL MARKET

Impact assessments might investigate problems directly related to obstacles/barriers to the freedom of movement of people, goods, services, and capital in the Single Market (a possible corresponding objective being to remove market distortions for companies, workers and consumers). An impact assessment might also look into other policy issues, but the options under analysis could impact the functioning and effectiveness of the Single Market. As a general rule, one should be careful not to concentrate only on long-term or short-term effects as costs are usually born in the short term while benefits generally materialise in the long term.

One should also consider the distribution of impacts. Some benefits and/or costs may concern or concentrate among selected groups only. Therefore, one needs to identify stakeholders, regions or Member States who will be most affected (e.g. in a given sector, benefits can be similar for all companies, but costs to SMEs can be bigger – as percentage of turnover or profit margin – than for large companies)³⁰¹.

Box 2. Key questions for assessing impacts

- What impact (positive or negative) does the option have on the free movement of goods, services, capital, and persons (self-employed and workers)?
- In case of evaluations: were there unintended impacts (positive or negative) of the

³⁰¹ See Tool #23 (*The 'SME test'*)

evaluated legislation on the free movement of goods, services, capital, and workers?

- Will it lead to an increase/reduction in consumer choice³⁰², higher/lower prices due to less/more competition, the creation/elimination of barriers for new suppliers and service providers, the facilitation/prevention of anti-competitive behaviour or emergence of monopolies, market segmentation, more or less convergence of consumer and business conditions across the EU, etc.?

You could further consider using benchmarks to assess the level and effectiveness of market integration, such as goods market and services markets, trade between Canada and USA, trade between US states or trade between EU/EEA Member States³⁰³.

When evaluating existing legislation, consider assessing its impact on the Single Market. Be aware that some impacts might be unintended or unexpected at the time your legislation was proposed. Consider these also for legislations that did not have Single Market as a core objective or were not based on Article 114.

3.1. Identification and measurement of potential direct impacts of options

Based on the evidence gathered in the problem definition phase regarding the additional barriers/burdens borne by citizens and companies involved in cross-border activities, the most probable direct impacts on internal market of the policy options should be identified and measured, including their impact on the identified barriers/burdens.

This should be done by identifying the potential costs and benefits under the various policy options in relation to the baseline scenario of complying with all the national rules for a company that wants to do business in another Member State, or the extra burden a citizen would face when trying to work/shop in another Member State.

To estimate the costs and benefits of EU action, adequate data on the situation in the Member States are needed. These data should ideally describe the current situation in the Member States, as well as projected savings/costs due to EU action. A variety of data sources is available, including constant monitoring of the situation in the Member State, expert groups, representative surveys (e.g. Eurobarometer), dedicated enterprise surveys (Enterprise Europe Network, SME panels), external studies and public consultations³⁰⁴, as well as data produced by European public administrations (see data.europa.eu).

In many cases, the main benefit of internal market harmonisation/rules lies in cost savings following the replacement of 27 different national rules and procedures that companies and citizens face with one harmonised EU regime or by creating a 28th (EU) regime (e.g. costs of patenting fees for an EU unitary patent vs. 27 national patents).

To estimate the potential savings thanks to the internal market or the costs of 'no internal market' one could consider the following conceptual model:

(1) Calculation of individual company/citizen savings/costs following the replacement of national regimes by an EU-wide one

³⁰² See Tool #33 (Consumers)

³⁰³ See Tool #27 (External trade and investment)

³⁰⁴ See Tool #4 (Evidence-informed policymaking)

- 'Baseline scenario' (national rules/regimes): what is the cost per company of following the current regime(s) assuming that it wants to cover/serve all Member States (e.g. obtaining patent protection in each Member State? Under alternative scenarios e.g. only a subset of Member States and related costs can be considered such as following the actual behaviour of companies who choose to protect their patent only in a limited number of Member States).
- 'EU scenario' (harmonised EU rules/regime): what is the cost of following just one EU regime (e.g. obtaining EU unitary patent)?

(2) *Extrapolating the above individual-level costs and benefits/cost savings (for companies or citizens) to the whole sector/market or population*

- When extrapolating, consider the number of citizens/consumers/companies that are likely to be affected by the EU rules. This can be all citizens/consumers/companies or just a subset whose activities are cross-border. You may also consider whether the EU rules might incentivise more citizens/consumers/companies to engage in cross border activities in a longer run.

To make this kind of calculation, detailed data per company and Member State on the costs related to the current regime(s) are necessary (e.g. one-off and recurring costs for each procedure, including required staff and working time, legal representation, translation costs, etc.). In addition, you need to estimate (ranges of) the costs that a future single EU regime would impose and changes in company/citizens behaviour regarding cross-border trade and investment that would follow³⁰⁵.

To extrapolate the above calculated costs and benefits to estimate the cumulative costs and benefits for the whole sector/market or population, and eventually the whole EU, a distinction must be made between static and dynamic scenarios:

- In a static scenario, one takes the number of companies that are active cross-border as given and uses it to multiply the cost estimates per company obtained under point (1) for both 27 regimes and the EU regime for all scenarios analysed under the baseline.
- In a dynamic scenario, estimate expected change in the number of companies' active cross-border in the baseline case and following the EU regime. The cost estimates per company obtained under point (1) then must be multiplied by the number of companies active cross-border in a new dynamic baseline and the estimated number of companies active cross-border under the new harmonised EU regime, respectively.

For quantifying costs you may also consider following the **Single Market Gap** procedure suggested by CEPS in their [2014 study for the European Parliament](#) on "Indicators for Measuring the Performance of the Single Market – Building the Market Pillar of the European Semester"³⁰⁶.

3.2. Identification and measurement of the Single Market benefits

You should strive to assess the benefits of the internal market especially for consumers, companies, and employees. These could be direct (e.g. free movement of citizens) and indirect (e.g. more choice and lower prices due to increased trade and competition).

³⁰⁵ See Tool #57 (*Methods to assess costs and benefits*)

³⁰⁶ For more explanation and detailed examples, see page 70 of the full report.

The benefit analysis is usually qualitative due to inherent measurement difficulties. However, whenever possible, try to quantify. Some examples are presented below on how to measure market integration:

Benefit	Measurement
Trade creation: trade between Member States, improved value chains, outsourcing of goods and services, more trade in internal border regions (especially for services dependent on geographical proximity).	Export/Import to GDP, degree of price dispersion / convergence, wage dispersion / convergence
More competitive markets: leads to bigger choice, higher quality and lower prices for consumers, continuity of supply, lowering switching cost.	Foreign Direct Investments (outward and inward) to GDP, delivery of services through establishing affiliates; Hirschman-Herfindahl index (HHI); dispersion of consumer prices and their evolution over time; choice and switching in consumer markets; consumer and business confidence in cross-border (online) transactions.
Efficiency gains / productivity: economies of scale and scope.	These efficiency gains measured using unit labour costs — defined as the ratio of total labour costs (total hours worked multiplied by the hourly wage) to Gross Value Added, deflated by the Gross Value Added price index. Productivity increases due to backward- and forward-linkages in the value chain/across sectors.
Innovation: sufficient demand to recuperate development cost for product and process innovation.	Expenditure in Research, Development, and Innovation (RD&I), number of personnel employed in RD&I activities, number of patents and innovative activity. Expenditure for digital transformation of business models.
Free movement of people: job opportunities in other Member States, studying abroad, labour mobility, commuting, 'brain gain'	EU citizens working in another Member State as % of total labour force, number of exchange students, cost of qualification recognition procedures; international comparisons – cross-border mobility between EU Member States and in other regions (such as United States, Canada or Australia).
Free movement of capital: More investment opportunities, diversification	Interest rate convergence, foreign listing, share of foreign assets/liabilities in financial sector
Policy influence and synergies, cooperation and coordination	Synergies from having common approach, common institutions, elevating influence of individual MS. Coordination of policies (reduced likelihood of retaliatory actions, addresses coordination failures) Mainly qualitative description.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

3.3. Identification and measurement of the Single Market costs

The same holds for the analysis of costs. A list of potential sources is given below.

Cost	Explanations
Trade diversion	Preference to trade within EU rather than with outside world (share of trade with non-EU countries).
Adaptation cost	Cost for companies to face bigger competition. Possible unemployment in non-competitive sectors. Different market structure (players, supply chains).
Employment and companies	Potential for loss of employment in uncompetitive/unregulated sectors/companies (at least in short term), bankruptcy of underperforming companies; 'brain drain'; other possible social impacts and/or fundamental rights impacts ³⁰⁷ .
Impact on national budgets	Tax arbitrage, tax avoiding schemes; unemployment benefits for redundant workers.
Costs for EU/national budget	The functioning of the Single Market might require dedicated administrative bodies financed from the EU or national budgets.
Administrative costs ³⁰⁸	Costs for companies to comply with new administrative obligations.
Adjustment costs	Cost of applying EU rules.

Sources: Own elaboration based on UK Government: [Optimal Integration in the Single Market: A Synoptic Review](#)

4. HOW TO MINIMISE NEGATIVE IMPACTS ON THE INTERNAL MARKET

According to the fundamental freedoms of the Treaties, certain negative impacts on the internal market are outright prohibited. This applies in particular to discriminations based on nationality or residence. Options that would lead to the illegality of the measure have to be excluded in all cases.

To minimise potential negative impacts on the functioning of the internal market beyond these legal requirements, and depending on the circumstances, you can consider including the following into your options:

In relation to the content of a policy option:

- promoting standardisation (e.g. IFRS accounting rules for listed companies; codes of conduct, European standards, model documents, eGovernment action plan principles, European catalogue of standards, DSI technical specifications and standards, etc.);
- promoting transparency and information (preferably in multiple languages) – e.g. setting information points/one stop shops for (e.g. points of single contact), digital by default and digital once-only principles;

³⁰⁷ See Tool #30 (*Employment, working conditions, income distribution social protection and inclusion*).

³⁰⁸ See Tool #56 (*Typology of costs and benefits*) for definitions

- limiting any unnecessary administrative and private obstacles to cross-border movement/trade;
- mutual recognition, harmonisation and best practice dissemination;
- exploiting synergies and/or implementing relevant mitigating measures in other related policy areas (competitiveness, social/employment, fundamental rights).

In relation to the policy instrument:

- regulations can limit the risk of 'gold-plating' associated with the transposition by Member States of Directives;
- consider an EU regime of common rules that could be applied in cross-border situations without changing national rules (e.g. the European Common Sales Law);
- limiting to a bare minimum the number of implementation options in directives;
- use of IT solutions to foster access to information (e.g. e-procurement; SOLVIT; points of single contact);
- exchange of information between authorities (e.g. internal market information system, RAPEX);

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

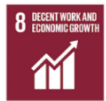
Contact point: GROW-IMPACT-ASSESSMENT@ec.europa.eu

Useful links:

- [Single market scoreboard](#)
- [Barriers to trade](#)
- [Single market for goods](#)
 - [International trade in goods](#) (look for intra EU trade)
- [Single market for services](#)
 - [International trade in services](#) (look for intra EU trade)
- Other [Databases](#)
- [2021 Annual Single Market report](#)

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Real GDP per capita • Gross domestic expenditure on R&D • R&D personnel <i>UN indicators:</i> • Annual growth rate of real GDP per employed person • Research and development expenditure as a proportion of GDP • Researchers (in full-time equivalent) per million inhabitants	 

TOOL #26. PREVENTION OF FRAUD

1. INTRODUCTION

The notion of fraud covers any intentional act or deliberate and wrongful omission, affecting the EU's financial interests and/or reputation. The key element which distinguishes fraud from (non-fraudulent) irregularity, error or non-conformity, is intention. Fraud can happen through various means, e.g. cost mischarging or double funding, false documents, plagiarism, non-disclosure of conflicts of interest, corruption and staff misconduct. Therefore, the definition of fraud cannot be limited down to the narrow understanding of fraud as a criminal offence³⁰⁹.

The risk of fraud, in its wider concept, should be examined in parallel with the risk of corruption. The abuse of a (public) position for private gain takes place when a receiver (passive corruption) accepts a bribe from a giver (active corruption) in exchange for a favour. Corrupt payments facilitate many other types of fraud, such as false invoicing, fictitious expenditure, or failure to meet contractual obligations/specifications.

Fraud can have a significant negative impact on EU policies, both financial and reputational. Financial fraud affects the objectives of EU action by reducing the amount of financial support available for achieving the desired positive impacts. Non-financial fraud may impair product safety, consumer protection and public health, e.g. where the certification of a product is obtained fraudulently. Both financial and non-financial fraud can undermine the trust that citizens and other stakeholders have in the Union's actions and institutions.

Under Article 325 TFEU and Article 36(2)(d) of the [Financial Regulation](#), the Commission is duty-bound to fight fraud. This fight is often illustrated in the anti-fraud cycle:



³⁰⁹ [Directive \(EU\) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law](#)

2. FRAUD-PROOFING OF THE POLICY CYCLE

The [Commission Anti-Fraud Strategy](#) (CAFS) includes the obligation to fraud-proof the legal framework for expenditure and revenue and explicitly refers to the consideration of fraud-related aspects in evaluations and impact assessments³¹⁰.

For most policy proposals, (the reduction of) fraud is not a primary impact to be assessed in the accompanying impact assessment (IA). It should however be screened as a potential indirect impact when assessing different options in the IA.

Box 1. Fraud proofing as part of the impact assessment

In the context of an impact assessment, fraud comes into play at two levels:

1) Fraud potentially obstructing the attainment of policy objectives

Fraud may undermine the effectiveness of a policy option in achieving one or more of the pursued policy objectives, notably because fraudulent activities take away funds from their intended purpose on a large scale or hinder the proper functioning of health and safety rules.

Example:

A regulation limiting the toxicity of exhaust fumes of cars that allows measuring toxicity levels only in a laboratory. The achievement of the regulation's policy objective of protecting public health may be undermined by fraudsters who may develop defeat devices that conceal high toxicity levels during laboratory tests.

2) Fraud as a policy option's potential side-effect

If a certain policy option is susceptible to increase fraud risks that do not directly affect the policy objective, the IA needs to flag such a potential effect as an unintended consequence of that policy option, most frequently in financial and reputational terms.

Example:

To speed up the award and payment of emergency aid, one option is to fully digitalise and automate the application and award procedure. The IA should assess any risk that fraudulent applications might be accepted as an unintended consequence of that option.

Depending on the scale of fraud, this example might as well fall in the first category – large-scale fraud might lead to a suspension of the programme upon detection or might use up the available funds prematurely if it goes undetected. In both cases, the primary objective of the policy will not be reached.

Considering the anti-fraud dimension in an IA will help both the Commission and the co-legislators to understand better the wider implications of the risks associated with various policy options and allow them to identify mitigating measures at an early stage. Assessing the underlying data flows of the policy (see Tool #28 (*Digital-ready policymaking*)) can help detect possibilities for fraud.

Therefore, one should equally consider fraud proofing in other stages of the policy cycle.

³¹⁰ Point 24 of the CAFS Action Plan, SWD(2019) 170.

Box 2. Fraud proofing beyond impact assessment

Apart from some specific cases³¹¹, the IA is usually the first stage in the lifecycle of a policy initiative at which fraud risks, their potential detrimental effects, and ways to mitigate them become relevant.

Fraud proofing continues, however, after the impact assessment with

- **fine-tuning** the chosen policy-option to minimise fraud risks; and
- **finalising** the Commission decision or proposal in the formal procedures of **inter-service consultation** and **adoption** and accompanying it through the **legislative process** where applicable;
- including, in this context, **standard anti-fraud clauses** in legislative acts, especially spending programmes, **for the Multiannual Financial Framework 2021 – 2027**.

Fraud proofing extends further to the implementation of the adopted policy, for example through a fraud-resilient design of:

- delegated and implementing acts where applicable;
- guidance and templates (for calls for tenders/proposals/expressions of interest, model contracts/agreements) with systemic importance;
- internal procedures;
- IT solutions;

and concludes with the **evaluation** of the policy in question, including its anti-fraud stance.

As stated in Points 23 and 24 of the CAFS Action Plan, fraud proofing comprises the whole policy cycle. It is primarily the responsibility of a policy-making DG, but **OLAF should be associated to that exercise from its early stages**. This is particularly relevant for complex and time-bound projects and for negotiations with implementing partners; in both cases the course of action may be steered into certain directions early on.

Apart from fraud and corruption in public procurement processes, other weaknesses in the enforcement of EU law, such as lack of effective enforcement of environmental rules, or breaches of safety in transportation, can cause serious harm to the public interest and create significant risks for the welfare of society. Any new proposal should include effective systems of compliance.

Whistleblowers play a key role in preventing and detecting breaches of EU law. They are often the first to know about threats or harm to the public interest inside their organisation. Their reports and public disclosures feed therefore national and EU enforcement systems with information leading to effective detection, investigation, and prosecution of breaches of Union law. Accordingly, policymakers should assess in the impact assessment whether enforcement of the proposed legislative act would benefit from introducing rules on reporting by and protection of whistleblowers exposing infringements of that legal act (see also section 3 below).

³¹¹ When it comes to policy projects that focus on the fight against fraud (such as the establishment of the European Public Prosecutor's Office), fraud-related considerations will already determine the development of policy options, i.e. before the impact assessment sets in.

3. MANAGING AND COUNTERING FRAUD RISKS

OLAF's experience with preventing and investigating fraud shows that the design of (spending) programmes is the first step in effective fraud prevention. OLAF and other Commission services have encountered many types of fraud that had negative economic and social impacts and put the Union's reputation at risk. When screening policy options for fraud, it is important to keep in mind that preventing or detecting fraud is often not the direct target of a programme design, but still is to be considered as an additional component of the overall structure and process. Identifying fraud risk requires not only factual knowledge of the background situation (nature of the business, the environment in which it operates, the effectiveness of the existing internal controls), but it also involves some sort of creativity, assumptions, and acceptance of approximation.

Because managing fraud risk aims at proactively identifying, assessing, and addressing vulnerabilities, it requires *communication* and *knowledge*.

Communication is the first requirement of fraud risk management. It becomes effective by making the management process visible. Communication actions must be tailored to the peculiarities of the organisation in such a way to facilitate the participation and involvement of all relevant actors.

Knowledge is the second essential requirement of this process. The management of fraud risks should involve different layers of the organisation: management, authorising officers, finance cell teams, legal departments or legal advice units, geographical desks, auditors and, where appropriate, external consultants. The available tools for fraud risk identification and assessment include interviews, surveys, focus groups, and anonymous feedback mechanism.

"The ability to think the unthinkable" or "thinking like a fraudster" is useful in this exercise, while basing oneself on factual references in the real working environment. For example:

- considering previous fraud incidents and what could have been done to prevent them;
- evaluating the existing control systems in four steps: 1) *mapping* the existing controls; 2) *testing* them; 3) *validating* them; and 4) *integrating* (considering the results of the tests run to enhance further the efficiency and effectiveness of the control systems).

The assessment of the impact of the policy proposal on the exposure to fraud may be facilitated by asking the following questions:

- To what extent do the options identified rely on statements or documentation from parties involved in the implementation?
- How can deception adversely affect the objectives of this policy?
- Are there any significant differences in terms of negative impact of potential fraud between the identified options?

The fraud risk management process should also ask how the risks of exposure to fraud could be reduced. Beside measures of a general nature, such as including the anti-fraud dimension in the framework of checks and audits or tailor-made anti-fraud controls specific to the policy in question, the following approaches could be useful:

- **Procedures to detect potential fraud.** When transactions are processed, ex ante checks should increase the level of assurance to identify possible inconsistencies leading to

suspicion of frauds. Ex post controls on the other hand will allow a more in-depth scrutiny for the riskier projects thanks to on-the-spot audits.

- **Diversification of the sources of information.** Where funding relies on contractors' or beneficiaries' statements on their compliance with the financing conditions or certification criteria, the policymakers should think of ways of collecting information from other sources for verification purposes. In particular, one should consider a specific reference to the applicability of the [Directive on the protection of persons who report breaches of Union law](#). It allows whistleblowers to report breaches affecting the financial interests of the Union and ensures their protection in case they suffer retaliation (see section 3 below).
- **Increasing transparency.** Increase the transparency of the envisaged policy options, for example by requiring to make certain statements public or publish findings about the implementation of the policy, with due respect for the protection of personal data³¹².

The consideration of fraud-related aspects in evaluations, fitness checks and impact assessments will be facilitated through (and the quality of these instruments in this respect will benefit from) the implementation of the [Commission Anti-Fraud Strategy, which has two objectives](#):

- [to strengthen the Commission's](#) capabilities in the collection and strategic analysis of fraud-related data;
- to foster coordination and cooperation in the fight against fraud and tighten corporate oversight in this respect.

Box 3. Fraud-risk management

The management of fraud risk should provide information about its level in a given policy area and how the policy proposal is likely to increase or decrease fraud risks in that area. In summary, three components may be distinguished:

- **Identification of fraud risks related to each policy option**

This task may be inspired by the DG's own risk register and anti-fraud strategy, reports by European Court of Auditors and Internal Audit Service, OLAF's case compendia, specific final reports and other documents that **reflect past experience and allow drawing parallels to the policy in question**. More importantly, the task requires creative **thinking 'out of the box' and cooperation** among a variety of actors – at least the policy unit in charge, the OLAF correspondent and other services concerned (including OLAF and executive agencies if they need to implement the policy).

- **Assessing the fraud risks: rating the likelihood and impact of fraud risks materialising**

This exercise involves checking the **fraud vulnerabilities** in the policy area concerned and how these may be influenced by each policy option. Similarly, the fraud risk assessment needs to estimate the damage that various types of fraud could do under the different policy options, including **financial damage, reputational damage, and damage to the attainment of policy objectives** (if any – see Box 1). In general, assessing *likelihood* and *impact* of fraud risks mainly serves to rank fraud risks by significance and by priority of containment. In the framework of an impact assessment, such rating should ideally quantify the potential impact

³¹² See e.g. the Commission's [Financial Transparency System](#)

of fraud risks to facilitate their integration into the overall comparative analysis of the different policy options.

- **Conceiving mitigation measures**

Before drawing a conclusion on the impacts of a policy option, the impact assessment needs to review possible improvements and/or mitigating measures to reduce its negative impacts. As part of the impact assessment, the fraud risk assessment should focus on the **residual risk** after considering existing anti-fraud measures as well as additional ones, especially tailor-made measures that could be introduced to counter fraud risks induced or increased by the policy option in question. The impact assessment should also try to estimate the **cost of complementary measures**. **Red flags** should be developed to swiftly identify symptoms of potential frauds.

Methodological guidance

For guidance on risk management, see Tool #14 and the Commission's [Risk Management Implementation Guide](#). Pragmatic guidance for the estimation of the cost-effectiveness of controls has been issued by DG BUDG³¹³.

The fraud risk assessment should respect the requirement of **proportionate analysis**, depending, for instance, on the magnitude and relevance of the impact analysed. When quantitative analysis is not possible or proportionate, impacts should be assessed qualitatively and the reasons for not having undertaken quantification explained in the IA report.

4. WHISTLEBLOWER PROTECTION

The EU protects persons who report breaches of Union law. With a view to strengthen the enforcement of EU rules, the relevant [Directive on whistleblower protection](#) obliges Member States:

- to **establish internal (within the organisation) and external (to the competent authorities) reporting channels** for potential whistleblowers to report on breaches of EU law under a strict confidentiality regime, and
- to **provide for measures of support and protection** in case the whistleblowers are retaliated against due to their internal or external report or public disclosure, provided they satisfy the conditions established by the Directive.

When drafting an impact assessment for new legal acts or for amending existing ones, policymakers should assess whether providing for reporting channels and for protection for whistleblowers would strengthen enforcement of these acts, by checking the following:

- Does the legal instrument **fall within one of the policy areas** of the material scope of the Directive³¹⁴?
- Could breaches of the rules of the legal instrument **cause harm to the public interest**?³¹⁵

³¹³ [Guidance on the estimation, assessment and reporting on the cost-effectiveness of controls, 2018](#).

³¹⁴ As spelled out in Article 1 of the Directive on whistleblower protection: (i) public procurement; (ii) financial services, products and markets, and prevention of money laundering and terrorist financing; (iii) product safety and compliance; (iv) transport safety; (v) protection of the environment; (vi) radiation protection and nuclear safety; (vii) food and feed safety, animal health and welfare; (viii) public health; (ix) consumer protection; (x) protection of privacy and personal data, and security of network and information systems.

- Is there a need to **strengthen the means of enforcement of the legal instrument** (i.e. would the instrument benefit from additional tools to ensure an effective enforcement beyond, for instance, complaints, audits etc.)?
- Would reports by **whistleblowers strengthen enforcement** of the EU legal instrument (i.e. namely because they can bring to light hidden unlawful practices that only 'insiders' can reveal), so that providing for clear and confidential reporting channels and for protection of whistleblowers would be **likely to increase detection** of breaches of those rules?

If the answer to the above questions is affirmative, it is recommended to include rules on whistleblower protection in the proposed or amended legislative acts by including a reference to Directive 2019/1937 and amending its annex to add the concerned legislative act in its scope.

For more details, please refer to the [Note on "Inclusion of rules on reporting on breaches of EU law and protection of the reporting persons \(i.e. rules on "whistleblower protection"\) in future EU legal acts: criteria and legislative technique"](#)³¹⁶.

5. SUPPORT

On prevention of fraud, OLAF Unit C.1 Anti-Corruption, Anti-Fraud Strategy and Analysis can provide further assistance: OLAF-FM-C1@ec.europa.eu

On the need to introduce whistleblower protection to a new legal act, DG JUST Unit C.2 (fundamental rights policies) can provide further assistance:

EU-WHISTLEBLOWER-DIRECTIVE@ec.europa.eu

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Perceived independence of the justice system • Corruption Perceptions Index • Population with confidence in EU institutions <i>UN indicators:</i> • Financial Soundness Indicators • Proportion of businesses that had at least one contact with a public official and that paid a bribe to a public official, or were asked for a bribe by those public officials during the previous 12 months	 

³¹⁵ Some examples of breaches of EU rules considered as harmful to the public interest: breaches of rules on Union harmonised and non-harmonised products; on safety transport; on environmental protection, on nuclear safety, breaches of the Union food and feed law; breaches affecting the internal market, such as of the rules on financial services, on anti-money laundering, on consumer protection or of procurement rules, etc.

³¹⁶ Ares (2020)1980728.

TOOL #27. EXTERNAL TRADE AND INVESTMENT

1. INTRODUCTION

External trade and investment are powerful engines for growth and job creation. As tariffs have largely been dismantled, disproportionate regulatory requirements or unnecessarily divergent regulations have become the main barrier to trade. It is more difficult to identify them and to quantify their impacts than it is for tariffs or measures applied at borders. This is particularly true for services which, given their intangible nature, are often hard to identify in statistics and other analyses.

Regulations and standards adopted in pursuit of various public policy objectives may constitute technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) or fall under the general WTO disciplines on goods or services and other non-tariff measures (NTM). These can have significant impacts on both exports and imports by requiring firms to spend resources to adapt their products, duplicate testing of safety requirements, undergo burdensome certification procedures, interpret, and comply with several sets of legislation, etc. This can be especially the case for developing countries, as well as for SMEs. Considering the obligation to consider Policy Coherence for Development, potential negative impacts from a measure on the EU's efforts to promote sustainable development in these countries need to be identified.

EU legislation and other types of policy measures must comply with the EU's existing international legal commitments. The EU is legally bound by many international trade agreements: first and foremost, the World Trade Organisation (WTO) Agreements; but also bilateral, multilateral and plurilateral agreements containing – for example – provisions on trade in goods, services, digital trade, intellectual property, or investment matters, many of which go considerably further than WTO Agreements. In terms of easing possible negative impacts on developing countries and leaving them more time to adapt, it should be noted that the principle of Special and Differential Treatment (SDT) for these countries is enshrined in the WTO as well as in the sustainable development goal (SDG) 10.a in the Agenda 2030 for Sustainable Development.

While an impact assessment certainly does not constitute a legal assessment of the compliance of proposed regulatory measures with WTO rules, it is important that services systematically consider the broad legal obligations as well as the broader policy objectives associated with the EU's trading regime when formulating (and assessing) their policy options. Any option that is clearly in breach of the EU's international legal obligations should be discarded at an early stage. Therefore, the assessment should begin as soon as possible after starting to prepare a legislative proposal, so that the scope can be adjusted and adapted while the legislative proposal develops.

While promoting the EU's role and leadership in international standard-setting, it is also important to avoid as far as possible unnecessary divergence, tensions, and sources of conflicts with EU's trading partners. The international dimension of the issue should therefore be carefully considered when the options are assessed, and engagement with the main trading partners should be sought from an early stage, including through outreach activities. In particular, the impact of a measure under the various policy options should be examined also in relation to third country producers or service providers. The impact assessment should also ascertain that the preferred option does not result in *de facto* discrimination of third country goods and companies in a manner that would go counter to

established trade rules. Due consideration should also be given to the impact on developing countries. Indeed, these requirements and regulations may prominently affect developing countries, and in particular least developed countries, as these may lack the awareness or the capacity to be able to identify and handle them. Consideration should also be given to the impact of the envisaged initiatives on EU neighbouring countries and those that are candidates to accession to the EU. The issue of potential external spillovers of EU initiatives, including trade initiatives, on developing countries may lead, where appropriate, to assessing to impacts by also having recourse to Tool #35 (*Developing countries*).

2. SCREENING OF OPTIONS AGAINST THE EU'S INTERNATIONAL LEGAL COMMITMENTS

When designing the options, the following issues should be considered³¹⁷:

2.1. Consistency with the WTO Agreements

The WTO Agreements cover a wide range of issues. A full-fledged analysis of WTO compatibility can and should be undertaken by specialist lawyers in the Legal Service and DG TRADE and should not be performed either by the Commission's services themselves or as part of an external consultant's report in support of an impact assessment.

However, at the stage of identifying options in the context of an impact assessment, it is important to rule out those that would obviously lead to an outcome incompatible with WTO or other international obligations. The impact assessment should focus only on options that are, in principle, legally viable. In this regard, certain basic questions should systematically be considered when designing the options:

- Does the option allow imported goods or foreign services or service suppliers to enter the EU market, when they are WTO-compliant? If not, see Box 1 for further details on whether exceptions to WTO rules are available.
- Does the option ensure *de iure* and *de facto* non-discrimination between imported goods or foreign services or foreign service suppliers, and goods produced in the EU or EU services or EU service suppliers (the 'national treatment' principle)? If not, see Box 1 for further details on whether the exceptions to WTO rules are available.
- Does the option ensure *de iure* and *de facto* non-discrimination between goods or services or service suppliers of different WTO member countries (the 'most-favoured nation' principle)? If not, see Box 1 for further details on whether the exceptions to WTO rules are available.
- If the option involves product requirements that would be covered by the Technical Barriers to Trade (TBT) Agreement³¹⁸ or the Sanitary and Phytosanitary (SPS) Agreement³¹⁹, can you demonstrate that the requirements are proportionate to the objectives pursued (see Box 1 below)?
- If the option regulates the movement of goods on sanitary or phytosanitary grounds, is it based on a risk assessment supported by sound scientific evidence (see Box 1 below)?
- Is the option compliant with WTO rules on subsidies, intellectual property, and procurement?

³¹⁷ Assistance from DG TRADE on these matters should be sought whenever appropriate.

³¹⁸ http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

³¹⁹ https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

Box 1. Trade agreements and the pursuit of legitimate public policy objectives**WTO exceptions**

GATT Article XX of the General Agreement on Tariffs and Trade (GATT) allows governments to adopt trade-restrictive measures that would otherwise be inconsistent with GATT obligations (in respect of non-discrimination or import restrictions) in order to (among other things) protect public morals, human, animal or plant life or health, as well as exhaustible natural resources, provided that the measures adopted are necessary to achieve genuine public policy objectives, their design do not entail arbitrary or unjustifiable discrimination between countries where the same conditions prevail and they do not constitute disguised protectionism. In particular, it should be assessed whether less trade restrictive alternative measures are reasonably available and capable of achieving the objective equally effectively.

GATT art XXI provides exceptions for security reasons. Similar exceptions exist in WTO rules for trade in services, investment, procurement, etc.

The Sanitary and Phytosanitary Measures Agreement (SPS)

- SPS measures are measures that aim to protect human, animal or plant life or health from risks arising from pests or diseases of plants or animals or from food safety risks. The SPS Agreement seeks to balance the protection of health with the liberalisation of trade in primary and processed agricultural products. WTO Members can set their own standards to protect human, animal or plant life or health within their territory based on a risk assessment underpinned by science. Restrictive SPS measures should be applied only to the extent necessary to protect human, animal, or plant life or health. They should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.
- WTO Members must rely on international standards, guidelines, and recommendations where they exist. However, if those international standards do not achieve the required level of protection, WTO Members may use measures that result in higher standards if there is scientific justification. The SPS Agreement also allows for provisional SPS measures where there is some indication that a risk exists, but a risk assessment is not possible due to a lack of sufficient scientific evidence.
- The SPS Agreement includes provisions on control, inspection, and approval procedures. Governments must provide advance notice of new or changed sanitary and phytosanitary regulations, and establish a national enquiry point to provide information. Specific rules may apply to developing countries to facilitate their compliance with SPS standards.

The Technical Barriers to Trade Agreement (TBT)

- The TBT Agreement regulates technical regulations, standards, testing and certification procedures, and seeks to ensure that they do not create unnecessary obstacles to international trade. Domestic measures shall not be more trade-restrictive than is necessary to fulfil a legitimate objective, such as the prevention of deception practices, national security requirements, the protection of human health or safety, animal or plant life or health, or the environment.
- Procedures used to decide whether a product conforms with relevant technical regulations have to be fair. The TBT Agreement discourages methods that would give domestically produced goods an unfair advantage and encourages mutual recognition of standards and

procedures.

- WTO Members are required to establish national enquiry points and to keep each other informed through the WTO. Around 900 new or changed regulations are notified each year.

Finally, note also that under WTO law it is possible under certain circumstances to regulate the way certain products, including imports, are produced or to restrict imports because of concerns about their production methods. However, in light of the potential not only for trade disruptions and for trade tensions, any such action should focus on issues of overriding legitimate public policy interests, in particular those that have a global dimension and have an impact on the EU (such as climate change, cross-border pollution). It should be based wherever possible on internationally agreed standards or principles, and supported by solid evidence, and should not be used to protect EU producers from competition or to level the economic playing field. The measure(s) taken would need to be designed particularly carefully to fulfil the conditions for WTO compatibility. Any such measure should also be manageable from the point of view of monitoring compliance and should not create a disproportionate burden for economic operators or for third country exporters, in particular those in developing countries. Priority should be given to the less trade restrictive measures available and, where possible, solutions should be used that allow sufficient flexibility for third countries to adapt and for the EU to cooperate with third countries.

2.2. Consistency with the EU's Free Trade Agreements (FTAs) or the customs union with Turkey

The EU has free trade agreements (FTAs)³²⁰ or other trade agreements with many countries in the world (Japan, Canada, Singapore, Vietnam, South Korea, Colombia, Peru, Central America, Southern Mediterranean countries, Chile, Mexico, South Africa, etc.), and has recently concluded or is currently conducting negotiations with several others. These are coherent with and incorporate some of the WTO rules mentioned in the previous section (including the relevant exceptions), and on many accounts also go beyond what would follow from the WTO agreements. The more recent agreements build on the WTO rules and contain detailed provisions on regulatory matters³²¹, some dealing with specific sectors (cars, electronics, pharmaceuticals, digital trade, energy, and raw materials, etc.). They also regulate – in more detail than the WTO Agreements – trade in services, investment, or intellectual property; and often have more far-reaching provisions on procurement. They also contain commitments on Trade and Sustainable Development. In recent negotiations, the EU is introducing also new disciplines on sustainable food systems. The customs union with Turkey (concluded in 1995) is a deeper agreement that ensures the free movement of all industrial goods and requires Turkey's alignment to the EU's external customs tariffs as well as to broader commercial policy in areas such as intellectual property rights (IPR) and competition.

³²⁰ For further detail, please refer to <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/>

³²¹ Including provisions regarding the level playing field in the FTA with the United Kingdom. In future FTAs, a chapter on Sustainable Food Systems may also be included.

2.3. Consistency with investment protection provisions/agreements

Investment protection provisions can be found in Member State agreements (there are more than 1000 of them)³²², in the Energy Charter Treaty, and in FTAs or in specific investment EU investment agreements. Generally, they provide for the possibility of requesting compensation when measures discriminate against investors and their investments, unlawfully expropriate³²³, or amount to arbitrary treatment of the investment. These protections are comparable to protections found in the European Convention on Human Rights, the EU Charter on Fundamental Rights and in Member States constitutions. It is important to avoid measures that could be inconsistent with such provisions. Note however that the reform of investment protection provisions promoted by the EU through changes to substantive policy and in the Investment Court System has been confirmed by the Court of Justice as protecting the right to regulate to pursue legitimate policy objectives. Investment provisions should not be interpreted in a way that hinders this prerogative of the EU.

2.4. Other legal effects

Two additional elements should be considered when designing the options. Through Agreements on Conformity Assessment and Acceptance of Industrial Products³²⁴ (ACAAs) with some neighbouring countries, the EU has “expanded its regulatory space” in some sectors. In these sectors, ACAA-countries have aligned their law to the EU *acquis* and would therefore be affected by any legislative changes. When designing an option in a sector covered by an ACAA, attention should be paid to the administrative capacity of partner countries to implement this new EU legislation.

On the other hand, the EU has concluded Mutual Recognition Agreements (MRAs) with some trade partners (US, Japan, Canada, Australia, New Zealand, and Switzerland) which cover some specific sectors. In some situations, involving EU rules (for example on testing of products), the operation of these MRAs provides sufficient assurances that the imported products meet the relevant EU standards.

3. HOW TO ASSESS IMPACTS ON EXTERNAL TRADE AND INVESTMENT

A series of questions should be examined when analysing the potential economic impact of the options considered:

3.1. Which economic operators should be considered?

All economic agents, producers and consumers, firms and households, should be considered. Producing firms are also consumers of intermediate goods and services (such as raw materials, components or business services). EU firms increasingly rely on the global economy for both diversified supplies of goods and services and sustained demand for their output. The impact analysis should therefore not restrict itself to the direct effects of the

³²² For a list of investment agreements between Member States and third countries, see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:131:0002:0098:EN:PDF>

³²³ In order to be lawfully expropriated, property held by foreign investors must be: taken for a public purpose; on a non-discriminatory basis; in accordance with due process of law; and accompanied by compensation. Unlawful expropriation includes both direct and indirect expropriation.

³²⁴ For more on ACAA, see http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/acaa-neighbouring-countries/index_en.htm.

options on the specific sector concerned but should also consider the sectors and firms along the value chain.

The analysis should also consider the impact on third countries. It is also important, for instance when consulting stakeholders in the impact assessment context³²⁵, to provide equal opportunities for third country operators and EU importers to express their views.

Measures may have differentiated impacts on companies of different sizes. The impact on SMEs should specifically be considered, as administrative compliance requirements tend to disproportionately burden these operators.

3.2. How will the options affect European exports?

Exporters will be directly affected by measures which increase the costs of production in the EU, and thus either reduce their profit margins or render their products more expensive (and thus possibly less competitive) in third markets. Exporters which are part of value chains and dependent on inputs from third countries will also be affected by barriers affecting their imports (see 3.3 below)³²⁶. EU exporters can also be indirectly impacted by potential reactions by third countries if they perceive that the EU measure does not respect international trade rules or would be driven by protectionist objectives.

3.3. How will the options affect European imports, and value chains in general?

The costs of compliance with a new regulation may in some cases make imported products or operators uncompetitive and may therefore have the effect of an indirect trade barrier, even if the legislation as such is not (formally) restrictive or discriminatory. Many EU firms are dependent on inputs from firms based in third countries. Therefore, measures that directly or indirectly risk having an adverse impact on global value chains may jeopardise economies and jobs (importers also contribute to jobs and growth in Europe).

Generally, the analysis should consider effects throughout the whole value chain, in respect of EU firms dependent on imports but also EU firms competing with imports. The relationship between sectors within the EU can be found in EUROSTAT's input-output table, while the relationship between sectors in the EU and sectors in third countries can be found in the UN Broad Economic Categories (BEC) classification (see also <http://www.wiod.org/home>).

3.4. How will the considered options affect investment flows?

Could the considered options affect costs to such a degree that it could have an impact on investors' foreign direct investment (FDI) decisions? For both EU and foreign firms, there is a risk of relocation if a regulation is thought to be too costly. Conversely, if a regulation is seen as comparatively inexpensive to comply with, it can provide incentives for further FDI in the EU³²⁷. Policy options may also affect decisions on investment location through other means than costs.

³²⁵ See Chapter VII on stakeholder consultations

³²⁶ See Tool # 21 (*Sectoral competitiveness*)

³²⁷ See Tool # 21 (*Sectoral competitiveness*)

3.5. Does the option affect the potential for trade in services?

Trade in services differs in character from trade in goods in that it may be 'invisible' and non-tangible. Virtually all commercial services are tradable, if not by traditional cross-border trade, then by accessing the foreign market as an investor and selling services through a local affiliate. Assessment of policy options affecting service providers from third countries should be undertaken. Special regard should be given also to digital trade and the disciplines on data localisation requirements as agreed for instance in the EU-UK Trade and Cooperation Agreement.

3.6. Could developing countries be affected?

Article 208(1) of the Treaty on the Functioning of the European Union (TFEU) sets a legal obligation to ensure policy coherence for development (PCD) by providing that the EU "*shall take account of the objectives of development cooperation in the policies that it implements which are likely to affect developing countries*".

Developing countries are very heterogeneous. The 2012 Communication on 'Trade, Growth and Development' sets new policy orientations for the EU's policy on trade and development for the next decade. In particular, it prioritises Least-Developed Countries (LDCs) and other countries most in need³²⁸. The following questions should be examined in particular:

(1) *Are the products covered by the proposal to a large extent produced in developing countries, particularly LDCs and other countries most in need?*

Particular attention should be given to cases where a country is markedly dependent on a specific export.

The Partnership Agreement between the European Union and members of the Organisation of African, Caribbean and Pacific States³²⁹ obliges the EU to inform the OACP States in good time of any intention to take a measure which might affect their interests. The CARIFORUM-EU Economic Partnership Agreement contains a similar obligation regarding bananas, rice, rum and sugar. More generally, the EU should seek to engage with developing countries from the early stage and reflect on possible ways to address or mitigate the impact of measures on them.

(1) *Will the proposal have an impact on the competitiveness of exports from developing countries, particularly LDCs and other countries most in need?*

Developing countries should not face obstacles that make their preferential access to the EU market (through low or zero tariffs) impossible to enjoy in practice, i.e. situations where their cost competitiveness resulting from the tariff preferences is eroded by costs imposed on them by new regulations. Adjustment costs are normally much higher and may be prohibitive for firms in developing countries. This needs to be considered when enacting regulations for products that are significant exports for a developing country.

Such an analysis is particularly important for LDCs and other developing countries which are very dependent on a few export commodities and therefore liable to be affected

³²⁸ See Tool #35 (*Developing countries*)

³²⁹ Article 12 of the Cotonou Agreement, signed in Cotonou on 23 June 2000, revised in Luxembourg on 25 June 2005 and revised in Ouagadougou on 22 June 2010.

disproportionately by the proposal. Particular attention should be paid in cases where vulnerable groups in developing countries are affected negatively. Accompanying measures (technical assistance, capacity building) should also be considered.

Consideration should also be given to the cumulative impact of the measure at stake with other measures taken in parallel and having similar effects on the same developing countries.

(2) *What are the sustainability impacts of the measure relevant for developing countries?*

In addition to the issue of potential barriers to trade, another aspect to be considered in relation to trade and developing countries is the impacts on sustainable development more broadly, which implies looking beyond trade balances and trade flows quantitatively. For example, a particularly employment-intensive sector might be disproportionately affected by a measure. An EU measure can also have unintended negative environmental side effects in developing countries. Inspiration can be drawn from Sustainability Impact Assessments (SIAs), which precede trade agreements signed by the EU and which explore such channels. Sustainable development chapters in trade agreements can be leveraged to mitigate potential negative effects.

This may often imply considering an external dimension for a range of environmental and social impacts that are the subject of dedicated tools (e.g. on climate, biodiversity and other environmental concerns, and social aspects such as labour conditions). These measures aiming at promoting holistically sustainable development will also relate to the broader Tool #19 (*Sustainable development goals*), as these need to be pursued both within the EU and externally, including in our relations with partner countries in the context of the sustainable development chapters of trade agreements.

3.7. *Will the proposal increase or decrease regulatory convergence with the main trading partners?*

Unnecessary regulatory differences between the EU and its trading partners can reduce or even prevent trade and investment. Beyond the internationally applied regulations and international norms or agreements with which the EU is legally bound to comply (e.g. the WTO GATT, GATS, TBT, SPS Agreements), it is important to verify whether the proposal will be in line with any other non-binding international arrangements between the EU and third parties, or with initiatives which the Commission or Member States are pursuing at a global level (e.g. harmonisation of technical regulations or standards at the International Maritime Organisation, the World Forum for Harmonization of Vehicle Regulations at the UN Economic Commission for Europe, the International Civil Aviation Organisation, or the International Telecommunications Union).

It is also important to assess whether the options considered will contribute to greater regulatory convergence with the EU's main trade partners (such as US, Japan, China) and whether it allows possibilities for regulatory cooperation (see also section 4 below).

When developing a new regulation or standard, the analysis should include an assessment of the main regulations affecting the products/services covered by the proposal in major third countries' markets, and a comparison between these regulations and the options considered by the Commission.

The assessment of regulatory approaches (e.g. delegated and implementing acts) should also consider how to enable the EU to engage in and adapt to any further development of rules in an international context.

In areas where there is a proliferation of overlapping unilateral measures from different trading partners, this should also be considered as it is liable to create a trade barrier especially for SMEs and smaller trading partners.

4. HOW TO MINIMISE NEGATIVE IMPACTS ON EXTERNAL TRADE AND INVESTMENT

Unnecessary trade distortions from the specific perspectives of TBT and SPS can be avoided or minimised by considering the following elements:

- The measure could be accompanied with an external outreach and communication plan especially towards countries identified most likely to be affected. This can be done in the WTO (see below), under dialogues of relevant FTAs, but also through EU delegations in the respective countries.
- When the European Commission gives a mandate to standardisation bodies to develop a new standard, those bodies should be instructed to consider, as a basis for European standards, international standards that are in use in the global marketplace. This is in line with the WTO TBT Agreement.
- The TBT and SPS agreements in the WTO require all WTO members to notify draft technical regulations and conformity assessment procedures or SPS measures that might have a significant impact on international trade to the WTO TBT and SPS committees for scrutiny. This forum provides a good opportunity to avoid unnecessary trade frictions with third countries before technical regulations or SPS measures are adopted and develop into trade barriers.
- The Commission has several regulatory dialogues or high-level platforms with third countries in areas such as product safety, information society, raw materials and energy, as well as financial services, in particular with major economies such as the US, China, Japan, Russia as well as FTA partners. Without prejudice of the EU right to regulate in the general interest, these dialogues provide useful tools to avoid unnecessary frictions and barriers.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- For information about [WTO rules](http://www.wto.org/english/docs_e/docs_e.htm), see http://www.wto.org/english/docs_e/docs_e.htm
- For a list of EU trade agreements see <http://ec.europa.eu/trade/policy/countries-and-regions/agreements/> and for a list of investment agreements between Member States and third countries see <http://ec.europa.eu/trade/policy/accessing-markets/investment/>
- Information is available from the following freely available databases about:
 - which countries produce and export to the EU the goods or services covered by an initiative and what is the value of this trade (EU imports)
 - to whom the EU exports the goods or services covered and the value of the trade

- which countries invest in the sector/s in the EU affected by the legislation and what is the value of these flows and stocks of investments
- [EUROSTAT – COMEXT that include the EU28 imports and exports](#) of goods with all partners and all products disaggregation (see <http://ec.europa.eu/eurostat/data/database>).
- [WITS and UN COMTRADE that cover trade in goods](#) of all countries in the world with all the partner countries.
- [EUROSTAT – Balance of Payments statistics](#) that covers trade in services and FDI by partner country and product (see <http://ec.europa.eu/eurostat/data/database>).
- To [distinguish between final goods and input goods](#), please refer to the United Nations Broad Economic Categories (BEC).
- Operational Guidance for assessing impacts on sectoral competitiveness with the Commission Impact Assessment System SEC(2012) 91
<https://ec.europa.eu/transparency/regdoc/rep/2/2012/EN/2-2012-91-EN-F1-1.PDF>

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Real GDP per capita • Investment share of GDP • Employment rate • Purchasing power adjusted GDP per capita • Adjusted gross disposable income of households per capita • EU imports from developing countries <i>UN indicators:</i> • Annual growth rate of real GDP per capita • Proportion of informal employment in non-agriculture employment, by sex • Proportion of tariff lines applied to imports from least developed countries and developing countries with zero-tariff • Worldwide weighted tariff-average • Developing countries' and least developed countries' share of global exports • Average tariffs faced by developing countries, least developed countries and small island developing States	   

TOOL #28. DIGITAL-READY POLICYMAKING

1. INTRODUCTION

In line with the 2030 Digital Compass Communication³³⁰, ‘better regulation’ will promote the ‘digital by default’ principle in forthcoming EU legislation as an important instrument to support digital transformation.

This tool aims to help policymakers make the best use of digital technology and data in their policies thus meet the call of Member States to propose digital-ready and interoperable policies by default³³¹. Best use of digital technology and data helps deliver on the needs of businesses and citizens with and without digital skills, benefiting from the opportunities and mitigating the risks of the digital age.

Policies (and legislative acts) are digital-ready if they enable smooth and digital by default policy implementation and foster digital transformation through best use of digital technologies and data.³³²

This implies that policymakers work in a multidisciplinary team and consider the following digital-ready components:

1. user-centric processes ready for automation,
2. alignment with digital policies (for example on accessibility, eID...),
3. the once-only principle and the reuse of data,
4. the evolving ICT landscape,
5. innovation and digital technologies, and
6. digital-ready drafting.

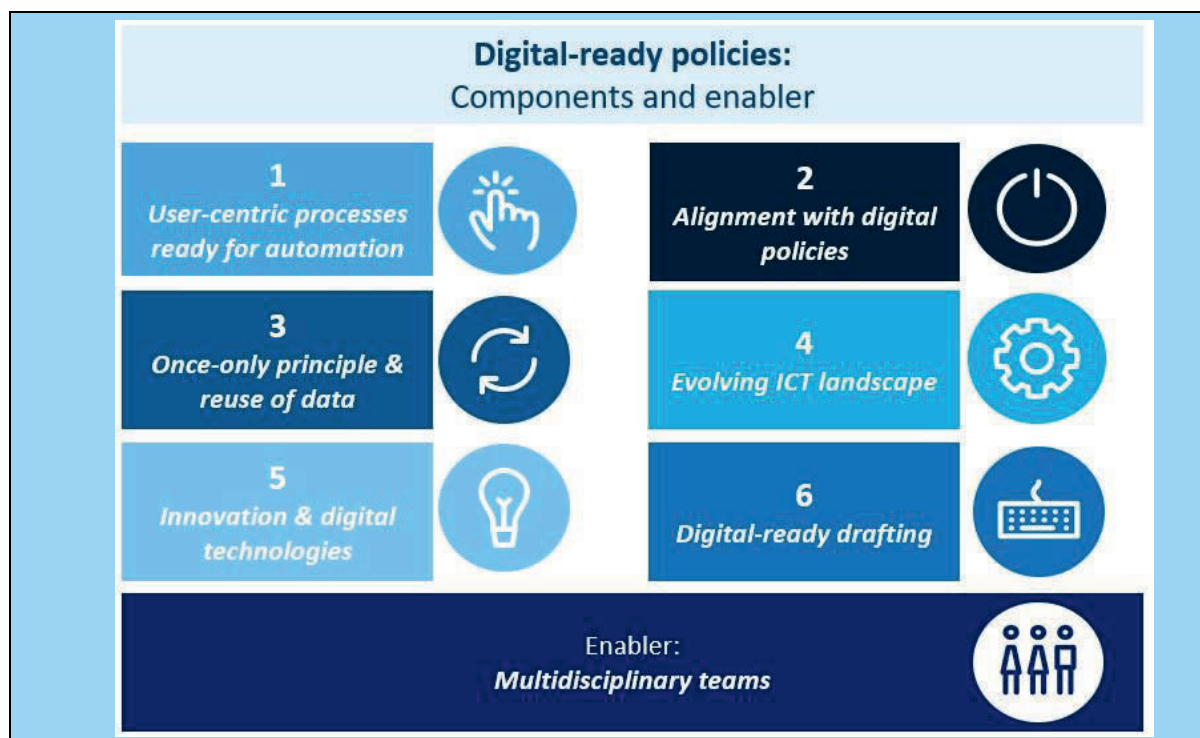
Digital-ready policies consider the fast-evolving world of digitalisation and technology; thus, they are digital, interoperable, future-proof and agile by default. By addressing the gap between policy formulation and its digital implementation, they deliver cost-efficient, user-centric, and interoperable digital services. The lack of interoperability³³³ between systems, organisations or countries can be especially costly. Achieving interoperability can mean cost reductions, enhanced user satisfaction and may hold significant potential in achieving policy objectives more effectively in the long term.

³³⁰ Commission Communication, [2030 Digital Compass: the European way for the Digital Decade](#), COM(2021) 118., COM(2021) 118.

³³¹ [Berlin declaration on digital society and value-based digital government](#), signed at the ministerial meeting of 8 December 2020: Call on the Commission to ensure through the ‘better regulation’ framework that policies and legislative acts proposed by the European Commission are digital-ready and interoperable by default.

³³² The [Commission’s ‘better regulation’ Communication](#) commits to promote the ‘digital by default’ principle in forthcoming EU legislation as an important tool to support digital transformation. According to the [Commission’s Digital Strategy](#), digital by default means that the default choice of Directorates-General (DGs) will be to deliver services digitally via multiple channels.

³³³ Interoperability is defined in the [European Interoperability Framework](#) (EIF) as the “*ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems*”



To reap these benefits, it is important that policymakers in all phases of the policy cycle:

- work in multidisciplinary teams (section 2);
- consider the components of digital-ready policies (section 3);
- assess digital-ready impacts (section 4);
- seek support on digital and data management matters (section 5).

2. MULTIDISCIPLINARY TEAM

Good practice example:

- ☺ When revising the Union legislation on blood, tissues and cells, DG SANTE identified opportunities to create a system of data platforms in this policy domain, by linking existing databases and prototyping an umbrella platform. For this reason, DG SANTE reached out to *data and ICT experts* in DG DIGIT already in the policy design phase, to run a feasibility study on various technical options and their impact on the policy options.

The EU Policymaking Hub calls for [collaboration across policy areas](#) to reconcile different views, priorities and perspectives during policymaking. The emphasis is on policy collaboration, ensured through the interservice work, including the interservice coordination group meetings and the interservice consultation. The multidisciplinary team complements and reinforces the effectiveness of this traditional policy collaboration, by inviting colleagues with diverse professional profiles in the core team of the lead service. Those colleagues can be part of the lead DG or come from other services. When designing digital-ready policies, the **multidisciplinary team** should ideally include:

- **Business analysts** to help analyse, simplify, and document the processes and data flows, and to ensure the smooth implementation of the policy (see sub-section 3.1).

- People with an overview of **the EU digital legislative landscape** able to identify cross-links, dependencies, possible conditionalities or synergies with other digital initiatives (see sub-section 3.2).
- **External experts** to provide their expertise in the policy area (see sub-section 3.2).
- **Data experts** to provide information on existing and reusable data, on their use and visualisation (see sub-section 3.3).
- Your **Data Protection Coordinator** to help detect questions of data protection early in the process (see sub-section 3.3),
- People with **digital / ICT knowledge – including knowledge about**
 - **security**,
 - **accessibility** for persons with disabilities and alternatives for people with fewer digital skills,
 - **the current ICT landscape** and future necessities and possibilities for the digital implementation of the policy (see sub-section 3.4).
- People with **policy implementation experience** to make the policy fit for purpose. Policymakers may contact colleagues in decentralised agencies or in Member States³³⁴ who could involve experts with first-hand experience of implementing the policy (see sub-section 3.4).
- People with **knowledge about innovative digital technologies** to give advice on their potential use (see sub-section 3.5).
- **Experts in legal drafting** to help with clear and simple wording, which is a must for smooth digital implementation (see section 3.6).

As first step in a multidisciplinary policy-design, the team needs to agree **on clear policy goals** that ensure a shared understanding.

Have I considered...

- ☐ early in the process to set up a multidisciplinary team to make sure that the needed resources are available.

3. COMPONENTS OF DIGITAL-READY POLICYMAKING

This section explains the main components of digital-ready policies. Each component is introduced by good practice examples and closed with a checklist for the policymaker. The components may depend on each other; for this reason, an iterative implementation approach is suggested.

3.1. User-centric processes ready for automation

Good practice example:

- ☺ Setting inland waterway transport rules for vessels must consider the cross-border

³³⁴ Policymakers can reach out to various policy implementation actors through the [Better Legislation for Smoother Implementation community](#).

nature of the policy as the inland waterways network do not stop at borders. Some ports are both in inland and maritime, which requires also cross-sector considerations. In the [Digital Synergy Study](#) the potential for streamlining the use of existing digital solutions has been thoroughly analysed from the users' point of view, allowing for both cross-border and cross-sector interactions.

- ☺ When the [e-invoicing policy](#) was introduced, e-invoicing was not widespread among SMEs. Instead of introducing an obligation for companies to only use e-invoicing with public administrations, the legislation imposed on public administrations to accept (also) e-invoices according to the relevant EU standards and provided a reusable technical solution ([CEF building block](#)).

Policies aim to solve real-life problems by selecting the most appropriate course of actions to move away from the existing (as-is) situation towards the desired (to-be) situation **defined by the policy goals**. By doing so, policies affect various **business processes** (for example, how a public administration provides a service, how a business applies for funding or which entity has the mandate to act)³³⁵. By assessing the affected business processes with the help of the main stakeholders involved³³⁶, policymakers can identify opportunities for simplification and automation³³⁷, which should result in **user-centric processes** supported by digital technology – thus respecting the principle of 'digital by default'. This can reduce administrative burden for businesses, citizens, and administrations, while increase users' satisfaction at the same time.

Policies can sometimes unintentionally set barriers for Member States, businesses or even for the Commission itself in performing their business processes with the support of digital technologies. To avoid creating barriers and to facilitate automation, policymakers should **analyse the business processes of the different stakeholders** affected by the policy. This will help them make informed decisions on where streamlined processes are necessary³³⁸ and where variations should be allowed or even enabled. Policymakers can seek advice from a *business analyst* or from DG DIGIT's UX Office at this stage³³⁹, who can ensure that the analysis of the business processes is **centred on users' needs**³⁴⁰ and **pays attention on cross-sector or cross-border links between business processes**, as they can create interoperability barriers if not considered early on.

If the policy is affecting the treatment of personal data, a clear description of processes can also help perform the [data protection impact assessment](#)³⁴¹ (if necessary) – possibly as part of the general impact assessment³⁴².

³³⁵ The operation of organisations (public or private) is bound by legal acts and they need to ensure that their business process comply with the legislation in force and get adapted when the legislation changes.

³³⁶ A right approach to perform business process improvement is to involve stakeholders early on. Tool #1 provides the necessary guidance on the principles to follow when performing a stakeholder consultation. In addition, [Chapter 7](#) provides guidance on the operations to follow for conducting a stakeholder consultation. When digital technologies are used those stakeholders may become users.

³³⁷ Automation means that the business process can be partially or entirely executed through digital technology.

³³⁸ For example, the business process around regulatory reporting that will be steered by the European Commission or its Agencies.

³³⁹ For support, contact the Commission's business process management community – [BPM@EC](#) or [User Experience Framework - EC Extranet Wiki \(europa.eu\)](#)

³⁴⁰ User-focus is one of the leading principles of the [European Commission Digital Strategy](#).

³⁴¹ The data protection impact assessment (DPIA) is regulated in Art. 39 Regulation (EU) 2018/1725 for data to be processed by Union institutions, bodies, offices and agencies and in Art. 35 GDPR for data to be processed by the Member States or others. For DPIAs to be carried out by the Commission as controller, the [Commission's data protection officer](#) provides templates.

Have I considered...

- ☐ which business processes are being affected by my policy?
- ☐ getting advice on how to analyse business processes with the users' needs in mind?
- ☐ giving special attention to cross-border and cross-sector aspects of the problems being tackled – for example a need for transnational data flows or ICT systems?

3.2. Alignment with digital policies**Good practice example:**

- ☺ DG HOME has realised that its policy proposal on *strengthening the automated data exchange under the Prüm framework* would benefit from interoperability considerations³⁴³. It has invited DG DIGIT in the interservice coordination group timely, so this policy can be designed with interoperability in mind.
- ☺ During the COVID-19 pandemic, DG SANTE worked with Member States, to develop digital contact tracing technologies. Involving DG CNECT and DG DIGIT enabled a secure, interoperable technical solution for digital contact tracing technologies in the EU to be developed, and to set up the necessary IT infrastructure, the European Federated Gateway Service for citizens to be able to use their national apps in other EU countries.

When designing the policy, it is imperative to assess the consistency and interaction with existing legislation and with on-going policy developments, to avoid incoherent regulatory requirements or conflicts with overarching policy objectives. This is highly relevant for digital policies because of their cross-cutting nature. Important digital policies regulate for example open data, personal data, e-Identity, security and privacy, data and internet governance, web and ICT accessibility, digital connectivity infrastructure and its take-up. As this is a fast-evolving regulatory environment, important legislation and policy initiatives are presented in [this repository](#) outside of the toolbox.

To ensure consistency and promote digital transformation, policymakers should also assess the links between their future policy and existing international or European standards in the field. For further guidance on standards please check Tool #17 (*The choice of policy instruments*).

Policymakers are invited to consider the spill-over effects that digital policies, infrastructure, services and technologies might have not only for the EU digital sector's competitiveness (supply of ICT equipment, cloud technologies and solutions, data analytics, AI, high performance computing, connectivity infrastructure, etc.), but also as drivers for digital transformation across different policy domains (poverty, inequality, inclusion³⁴⁴, health,

³⁴² See Article 39 (10) of Regulation (EU) 2018/1725 (for data processed by EU bodies) or Article 35 (10) of Regulation (EU) 2016/679

³⁴³ Learn more about public sector interoperability policy, which enables digital transformation, on the [EU policymaking hub](#).

³⁴⁴ See also Tool #30 (*Employment, working conditions, income distribution, social protection & inclusion*).

transport, education, working conditions, agriculture, smart mobility, social security coordination) and public administration³⁴⁵.

A good way to get input on EU digital policies is to invite DG CNECT and DG DIGIT to the inter service group preparing the policy proposal.

Have I considered...

- ☐ the digital legislation and policies in place and how my initiative relates to them?
- ☐ the possibility to promote the objectives of digital policies³⁴⁶ through my initiative (for example increasing the speed and efficiency of digital network deployment)?
- ☐ inviting DG CNECT and DG DIGIT to the interservice coordination group to explore room for cooperation?

3.3. Once-only principle and reuse of data

Good practice example:

- ☺ Regulation (EU) 2018/1999 on the governance of the Energy Union and Climate Action sets out an approach around five dimensions (energy security; the internal energy market; energy efficiency; decarbonisation; and research, innovation, and competitiveness) on how the Commission and Member States should work together and how individual countries should cooperate to reach the 2030 targets of the Energy Union. In order to alleviate the administrative burden of reporting, it systematically reuses information, for example collected through [EU ETS](#) (greenhouse gas emissions), [Copernicus](#) (geo-spatial data) and [Eurostat](#) (statistical data).
- ☺ The [proposal for a Directive on pay transparency](#) allows Member States to entrust an existing body to compile the required reporting information based on (existing) administrative data, such as data provided by employers to the tax or social security authorities.

Today, citizens and businesses often must provide the same information multiple times when interacting with public administrations. The [Once-Only Principle](#)³⁴⁷ should allow public administrations in Europe to reuse or share data and documents that people have already supplied, in a transparent and secure way. The [Single Digital Gateway](#) is one important instrument to implement the once-only principle but every EU policy can contribute to it.

³⁴⁵ For example, smart villages and communities are promoted through the Common Agricultural Policy Rural Development, EU Cohesion Policy, EU Framework Programme for Research and Innovation, Connecting Europe Facility, Recovery and Resilience Facility, etc.

³⁴⁶ For example, on Gigabit connectivity the [Europe's Digital Compass](#) expects that by 2030, all European households will be covered by a Gigabit network, with all populated areas covered by 5G. Read more on connectivity targets [here](#).

³⁴⁷ "The once-only principle means that citizens and businesses provide data only once to public administrations, while public administration bodies take actions to share and reuse these data at regional and national level, or across borders – always in respect of data protection regulations and other constraints." ([ECDS Handbook](#))

Data is a relevant resource that EU policies should increasingly tap into. Policymakers should know what data assets³⁴⁸ are linked to their policies and aim to remove obstacles to acquiring, sharing, combining, and reusing these data assets, while ensuring coherent data governance and continuous data management. The [EC data advisory service](#) provides consultancy and support on data governance and data management matters to Commission staff, while the [EC Data Catalogue](#) allows Commission staff to look for data that the Commission already holds.

To enhance the potential of data reuse – also outside the Commission – and understanding of the context and how the data was used to inform EU policies, data should be used in the impact assessment and evaluation reports in the way that allows the traceability of the data and the analytical steps to draw conclusions in the medium to long term³⁴⁹. Using data standards is a key enabler for data re-use. Data used in impact assessment and evaluation reports should be made available for internal reuse on the [EC Data Catalogue](#), as long as their licensing conditions allow for it.

Before starting a data collection, speak to your local data correspondent and IT contacts. Look for **reusable data assets**, for example

- [existing data managed by the Commission](#) (for example in the [EC Data Catalogue](#)³⁵⁰),
- public sector data made open by public sector bodies and research institutions in Member States (in line with the '[Open data Directive](#)') available on the [European Data Portal](#),
- the forthcoming [European Single Access Point \(ESAP\)](#), a repository of reporting from financial and non-financial businesses, that will contain a wide range of information disclosed from businesses,
- other reliable sources (for example UN, OECD).

When **personal data** is processed, speak to your Data Protection Coordinator (DPC). There may be domain-specific rules relating to personal data (e.g. for health). Your local data correspondent will know more about this and can advise you on such subjects. Keep in mind the requirements of GDPR/Regulation (EU) 2018/1725. This means that when preparing legislative texts, for example setting up interoperability gateways or mandating re-use of data, you should ensure that the text will provide a lawful basis for the processing of the data³⁵¹.

When personal data is aggregated for statistical purposes, such data may be further used for different purposes, including regulatory reporting or strategic foresight³⁵². If you own such reusable data sources, make them easily findable for your colleagues for example by including them in the EC Data Catalogue.

³⁴⁸ A data asset is any collection of data, any data set or any information that is somehow linked, e.g. by common codes or metadata, which has been created by the Commission, collected from Member States or other stakeholders, or acquired from third parties in the context of projects, policy or administrative processes. Data assets may be structured or unstructured, static or dynamic, raw or curated. Data assets are in digital formats. ([Data governance and data policies at the European Commission](#))

³⁴⁹ See Tool #4 for guidance on transparent use and communication of evidence within the policy cycle.

³⁵⁰ Currently as interim version (until 2023). The interim EC data catalogue solution is to allow Local Data Correspondents and statistical correspondents to manage metadata of their data assets more autonomously.

³⁵¹ The conditions for reusing personal data for other purposes are further set out in Art. 6 (4) of Regulation (EU) 2016/679 or for data processed by Union institutions in Art. 6 of Regulation (EU) 2018/1725.

³⁵² An alternative for aggregating data is to transform it to synthetic data. The JRC.B.6 is piloting this approach.

Beyond data, it is also important to **reuse concepts**³⁵³, which should be well-defined to avoid overlaps. This applies particularly to regulatory reporting³⁵⁴, where the burden generated by regulatory reporting clauses should be minimized, making the most of reusing concepts and related datasets³⁵⁵.

Have I considered...

- ☐ assessing which data is needed to design, implement, and monitor my policy?
- ☐ exploring what data is already available for reuse across policy domains, within the Commission and beyond (from Member States or third parties) and contacting the EC data advisory service and my Local Data Correspondent?
- ☐ fostering the reusability of the data sets managed under my policy?

3.4. Evolving ICT landscape

Good practice example:

- ☺ [eDelivery](#) is a digital [building block](#) that supports the exchange of electronic data and documents in an interoperable and secure way. It was mandated in the Inland Waterway Transport policy to serve the exchange of navigation information between Member State systems and the central European system. Such approach reduces the implementation costs in Member States as it reuses existing infrastructures³⁵⁶. This was achieved thanks to a close collaboration between the ICT experts of DG DIGIT and the policymaker.

When designing the policy options, policymakers should involve *ICT experts* to analyse the capabilities provided by the existing ICT landscape, which may offer opportunities, but may create limitations at the same time, together with the potential future landscape that should anticipate the evolution of the context.

Reusing existing ICT solutions could reduce costs and accelerate implementation. Reuse can be understood as the case of one Commission DG benefitting from a solution developed by another DG³⁵⁷, but also existing solutions developed in Member States³⁵⁸. The reuse of the most prominent reusable [EC building blocks](#)³⁵⁹ should be assessed for any European initiative together with the IT components available in the [Reusable Solutions Platform portal](#). IT experts may consider the reuse of opensource interoperable solutions available on [Joinup](#), a

³⁵³ A concept is an abstract notion representing a class of things. Data are instantiations of concepts. E.g. Country is a concept. Belgium, Netherland are two instances of the concept Country.

³⁵⁴ Visit the [regulatory reporting community of practice](#) for more guidance on reporting and see Tool #43.

³⁵⁵ Examples for concepts and core vocabularies can be found on the EU Vocabularies tab on the Portal [of the Publication Office](#).

³⁵⁶ See Annex 1 of the Commission [Delegated Regulation \(EU\) 2020/473](#).

³⁵⁷ For example, the [IMI system](#) owned by DG GROW to provide Member States with the tools that they need to cooperate with each other in order to improve the implementation of Internal Market legislation reused by DG EMPL in the context of professional qualifications. Other examples are the [EU Single Window](#) and [Traces](#) solutions that can now be re-used by other DGs.

³⁵⁸ Some of the also available on [Joinup](#)

³⁵⁹ Available building blocks are: Big Data Test Infrastructure, European Blockchain Services Infrastructure, Context Broker, eArchiving, eDelivery, eID, eInvoicing, eSignature and eTranslation.

collaborative platform created by the European Commission. Using building blocks also helps ensure interoperability between different solutions e.g. e-Delivery.

To start with, policymakers should contact *their DG's IT unit* for advice. It could also be useful to get in touch with *the decentralised agencies managing ICT systems* for the policy and with *contacts in the Member States* using these ICT systems. In case a policy option may entail a solution to be supported by the EC, the [corporate IT Governance](#) should be involved promptly, in order to timely learn about the opportunities and limitations within the Commission's ICT ecosystem and to ensure good planning and efficient use of resources.

Have I considered...

- ☐ the opportunities for costs or administrative burden reduction by reusing an available ICT building block?
- ☐ contacting my DG's IT unit and/or the corporate IT Governance for advice?

3.5. Innovation and digital technologies³⁶⁰

Good practice examples:

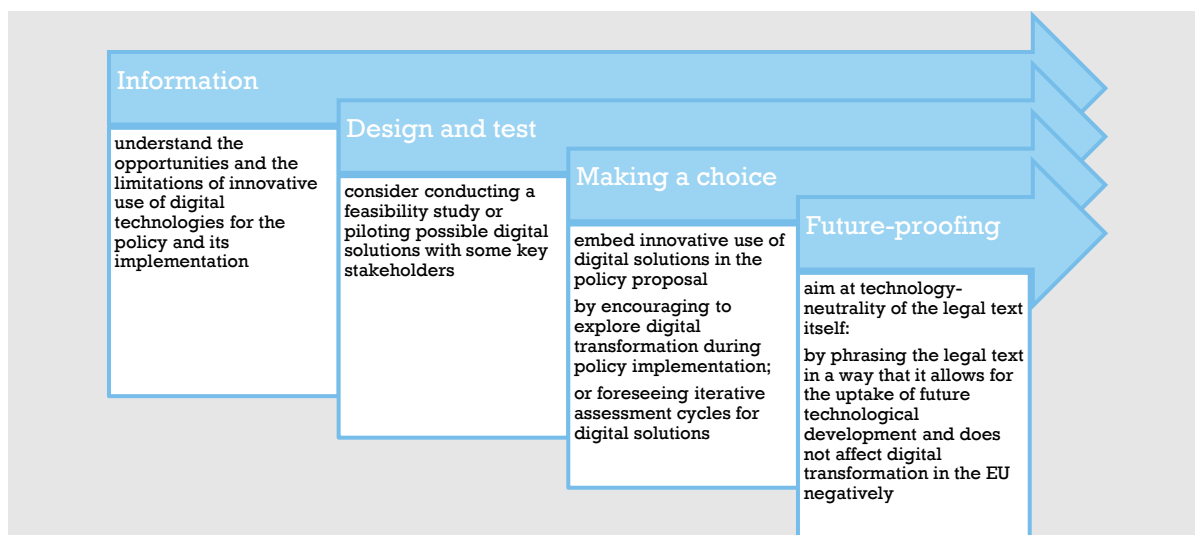
- ☺ Since 2018, DG AGRI has modified the Common Agricultural Policy legislation to allow an alternative operational control method, checks-by-monitoring, which uses free-of-charge Copernicus sentinel satellite imagery, automatically interpreted by deep learning algorithms to replace traditional on-the-spot checks of CAP beneficiaries. During the COVID-19 crisis this and other technologies (e.g. geotagged pictures) proved very useful to carry out checks without the need to visit the farms³⁶¹.
- ☺ DG JUST ordered a [study on the use of innovative technology in the justice field](#) that can help future digital-ready policymaking in the whole sector.
- ☺ DG EMPL, to address the identification and authentication of mobile citizens and the verification of their social security entitlements, has launched a pilot project, called European Social Security Pass (ESSPass) together with DG CNECT, DIGIT and the Italian social security institution, INPS, to assess the technical feasibility, the cost and the legal requirements for potential future large-scale deployments.

Digital technologies help respond to old problems in new ways thus fostering digital transformation. Given the increasingly complex or rapidly changing nature of the problems, innovative digital technologies may offer the only way to ensure the outcomes citizens and businesses are expecting. The [EU Policymaking Hub](#) gives an overview of the ongoing work on emerging digital technologies in the Commission and links to learning resources.

To embrace innovation through digital technologies in the policy, policymakers need to:

³⁶⁰ Please consult Tool #22 for guidance on innovation in general.

³⁶¹ Learn more about AGRI's use of innovative technologies to replace on-the-spot checks [here](#) and for the specific technological solution developed to better cope with Covid conditions [here](#).



Piloting the preferred digital solution to better assess the present regulatory constraints and the need for new regulation, or the revision of existing ones, is an important and useful step to consider. The implementation can be fostered through the roll-out of supplementary technical assistance programmes to enable the development of the technologies and build the capacities needed for their effective implementation at EU and national levels.

Strategic foresight³⁶² may bring valuable information on future digital trends, which may help policymakers to boost creativity/innovation and trigger further (indirect) socio-economic benefits while creating new opportunities for start-ups and SME.

When considering the take-up of digital solutions, policymakers should assess and address potential limitations, like the high costs of the phase-out of ICT legacy systems³⁶³ or the lack of agility, digital skills and ICT expertise, accessibility problems for people with disabilities or other barriers for vulnerable groups and people with fewer digital skills, and also the ethical legal barriers aiming at protecting fundamental rights³⁶⁴.

The [Innovative Public Service](#) – action of the European Commission and the [OECD Observatory of Public Sector Innovation](#) offer further resources on the topic.

Have I considered...

- ☐ whether innovative digital technologies could add value or reduce burden in the implementation of my policy?
- ☐ whether the proposed rules are technology-neutral?
- ☐ consulting with DG CNECT on innovative digital technologies?

3.6. Digital-ready drafting

Good practice example:

- ☺ DG FISMA Knowledge Online on European Legislation (KOEL) provides a catalogue of concepts and terms for reuse – initially for the finance domain and more recently for other policy domains too. This helps policymakers to reuse existing

³⁶² Explained in Tool #20 (*Strategic foresight for impact assessments and evaluations*)

³⁶³ Legacy systems are ICT systems that have been since many years implemented in an organisation.

³⁶⁴ More about digital policies around AI are available [here](#).

terms and ensure clear and consistent drafting.

- ☺ DG EMPL ‘easy-to-read’ version of the [Strategy for the rights of persons with disabilities 2021-2030](#).

To draft the policy proposal in a digital-ready manner, the policymaker is advised to:

- set out clear rules in the legislative act while keeping those rules future-proof to technical development by including, where necessary, empowerments or delegations for the Commission to act and consider which technical aspects need to be set out in the legal act and which should be placed in the annexes³⁶⁵;
- where a policy requires the establishment of a system that is co-owned by European Commission and Member State³⁶⁶, define clear roles and mandates for the governance of the system in the legal act;
- use simple, precise, and concise wording – especially for the parts the implementation of which is likely to be automated (see also section 3.1)³⁶⁷;
- reuse existing concepts from the policy domain and ensure alignment with those in related policy sectors thus ensuring interoperability (see also section 3.3). This approach is particularly important when describing business-agnostic processes, like monitoring and reporting (see Tool #43);
- prepare an implementation strategy or other necessary compliance promotion tools (see Tool #38), highlighting opportunities for reuse as well as contact points for support;
- avoid setting the entry into force date right after bank holidays (e.g. 1 January) or setting ambitious deadlines not aligned with the complexity of the supporting information system. If not, there may be a lack of sufficient ICT support when the solution goes live;
- consider introducing experimentation clauses. These legal provisions enable the authorities tasked with implementing and enforcing the legislation to exercise – on a case-by-case basis – a degree of flexibility in relation to testing innovative technologies, products, services, or approaches. For example, they may serve as a legal basis for [regulatory sandboxes](#)³⁶⁸;
- explain in the explanatory memorandum of the legislative proposal how the initiative contributes to achieving the European way for a digital society and economy.

Have I considered...

- ☐ showing the draft proposal to my IT colleagues to see whether it facilitates digital implementation?
- ☐ facilitating the digital implementation of my proposal by accompanying it with an

³⁶⁵ Technical specifications for IT systems will normally not be fully replicated in legal text.

³⁶⁶ Examples for such systems are the [Coronavirus EU interoperability gateway](#) or the [European Union spatial data infrastructure](#) under the INSPIRE directive.

³⁶⁷ For general drafting advice, see the [Drafters’ Assistance Package \(DAP\)](#).

³⁶⁸ A sophisticated experimentation framework is referred to as a regulatory sandbox – testing innovations in a real-world environment subject to regulatory safeguards and support. See Tool #69 (*Emerging methods and policy instruments*) for more details.

- implementation plan addressing possible ICT challenges and by leaving the technical details for future implementing acts?
- ❑ contacting the [quality of legislation team](#) of the Legal Service for general advice on drafting?

4. DIGITAL-READY IMPACTS

The digital-ready impact questions listed in Tool #18 (*Identification of impacts*) can give guidance on important digital-ready impacts.

To detect all digital impacts, make sure that the stakeholder consultations explicitly cover digital aspects, where this is relevant. Consider as well any information gathered during the evaluation phase about whether more could be done for a successful digital transformation.

When performing the analysis of the policy options, consider modelling the digital impacts with the support of the JRC modelling competence centre³⁶⁹.

The assessment of the preferred option in impact assessments needs to cover the analysis of the 'digital by default' principle. This means that the preferred option should allow for delivering services digitally, thus be digital-ready.

When assessing different technical solutions, ask support from ICT experts³⁷⁰, who may benefit from the [ICT Impact Assessment Guidelines](#) developed by DIGIT and from [further guidance materials](#) on digital-ready impact assessments³⁷¹.

When a digital solution is a key element of the policy proposal, policymakers should consider running a **feasibility study on the selected technical scenarios** to inform the impact assessment. They may also pilot the preferred technical solution with interested Member States.

5. FURTHER RESOURCES

For more guidance on any of the digital components presented in this tool, policymakers are invited to visit the [digital-ready policymaking wiki](#).

Moreover, consider reaching out to the below-listed services:

Suggested service	Expected support	Topic
BPM@EC	Business process modelling	User-centric processes
UX office of DG DIGIT	Advice on delivering user-friendly digital solutions with the end-user in mind right from the start.	Digital policies
DG CNECT	Advice on the current digital policy environment and on potential links between the planned initiative and existing ones. Support designing and assessing policy options that fit for both the digital and the physical world.	
DG DIGIT	Advice on the Corporate IT Strategies and on the	

³⁶⁹ Models are currently used to quantify environmental, economic, and social impacts of policy options but could be extended to questions of digital transformation. See also Tool #61 and the [Commission's modelling inventory MIDAS](#).

³⁷⁰ When procuring external contractual support for the impact assessment, the terms of reference should specify the need for IT expertise and indicate this tool of the 'better regulation' toolbox as reference document.

³⁷¹ Like list of potential digital risks to consider or a decision supporting tool on interoperability.

	ICT and interoperability aspects of future public services and related digital solutions	
EC Data Catalogue	The Commission's internal data catalogue.	Reuse of data
data.europa.eu	The official portal for European data. A single point of access to a range of data produced by EU, national, regional, and local public administration, as well as by some international organisations.	
Data advisory service	Advice on data management and analytics	
Local Data Correspondents	The single point of contact for data management in your DG/service	
Data Protection Coordinators	Advice on personal data aspects	
Corporate IT Governance	Information on the opportunities and constraints of the current EC ICT ecosystem	Existing ICT landscape
Your DGs IRMs	DG's information resource manager (IRM), DG's IT systems.	
DG CNECT	Information on innovative digital technologies and their possible use. Help to increase the effectiveness of data collection and analysis of stakeholders' consultation processes (e.g. through 'big data' approaches or by pooling some open public data sources).	Innovative digital technologies
Legal Service - Quality of legislation	Advice on technology-neutral and clear legal drafting	Drafting clear rules for digital implementation
Further support		
One-stop shop for collaboration	Help to work in multidisciplinary teams	Multidisciplinary team
EU Policymaking Hub	Overview of the available support and training along the policymaking cycle	Policymaking process
JRC – competence centres for policymaking	Analytical tools, methods, and integrated solutions, covering among others the digital aspects of policymaking.	
Regulatory reporting community of practice	You can find help in this multidisciplinary community on how to set digital-ready reporting requirements.	
The EU Policy Lab	Creative space dedicated to bringing innovation in the European policy-making process.	Innovation
Digital innovation lab	Creative space dedicated to digital innovation.	

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDGs indicators	SDGs
<i>EU indicators:</i> • Gross domestic expenditure on R&D <i>UN indicators:</i> • Research and development expenditure as a proportion of GDP • Number of science and/or technology cooperation agreements and programmes between countries, by type of cooperation • 17.6.2 Fixed Internet broadband subscriptions per 100 inhabitants, by speed	 

TOOL #29. FUNDAMENTAL RIGHTS, INCLUDING THE PROMOTION OF EQUALITY

1. INTRODUCTION

Fundamental rights³⁷² afford basic legal protection for political, social, and procedural rights to individuals and legal entities. The [Charter of Fundamental Rights of the European Union](#) (the Charter) is an instrument of primary EU law that enshrines the fundamental rights people enjoy in the EU. It covers a wide range of rights and principles, such as human dignity, fundamental freedoms, equality, solidarity, EU citizens' rights and justice. All Commission acts and initiatives must comply with the Charter³⁷³. EU legal acts can be challenged before the Court of Justice of the European Union if they do not comply with the Charter.

To help implement this obligation, this tool gives an overview of salient points to consider when identifying and assessing impacts related to fundamental rights within impact assessments. This tool can also be used to assess impacts on fundamental rights in the context of the evaluation of an existing policy or legal instrument (especially in case the preceding impact assessment had to address fundamental rights issues).

Box 1. Fundamental rights

The Charter contains provisions on rights, freedoms and principles divided into six titles: Dignity, Freedoms, Equality, Solidarity, Citizens Rights, and Justice. The seventh title, General provisions, governs the interpretation and application of the Charter.

The Charter rights are relevant to all EU policies and to all EU institutions, bodies, and Agencies.

Some Charter rights are absolute and cannot be 'limited' or 'restricted', no matter how important the policy objective (see second point in box 2).

Other rights can be subject to limitations but only if such limitations respect the strict requirements set out in Article 52 of the Charter (see last two points in box 2 below).

2. STEP-BY-STEP ASSESSMENT

Aspects of fundamental rights may be of relevance in the problem definition³⁷⁴. This may be the case specifically where the Union intends to act to protect individuals against interferences with fundamental rights in the policy area concerned³⁷⁵.

³⁷² For pragmatic reasons, the impact assessment of initiatives with only an internal EU dimension should focus on the analysis of fundamental rights (guaranteed by the Charter of Fundamental Rights), while for initiatives with an external dimension the analysis should focus on human rights, which may be different to the fundamental rights guaranteed by a partner country, and which arise from international treaties and customs.

³⁷³ As expressed in the Charter of Fundamental Rights and other legal documents.

³⁷⁴ It should be recalled that the Charter of Fundamental Rights cannot form the legal basis for a legislative act. All Union legislative acts should respect fundamental rights and observe the principles recognised by the Charter, seek to ensure full respect for those rights and principles, and be implemented accordingly.

³⁷⁵ See Tool #13 (*How to analyse problems*)

Depending on the nature of the problem and the policy context, respect for fundamental rights may be presented as one of the general or specific/operational objectives. This will ensure that at every step of the impact assessment, the relevant aspects be consistently addressed from the perspective of these objectives (link between objectives and problem analysis, identification of policy options, assessment and comparison of options, future monitoring and evaluation activities).

To ensure an evidence-based assessment, questions on fundamental rights should be addressed during the early preparatory stage of any envisaged initiative, i.e. from the planning stage or at the latest when drafting the 'call for evidence'. Stakeholder consultations and studies should include – wherever possible – collection of data on any potential impacts on fundamental rights. If an early screening suggests that fundamental rights might be or have been affected and further guidance is needed, one should consult the Legal Service, SG and DG JUST, which should also be invited to participate in the interservice coordination group.

The sub-section below highlights the importance of performing an in-depth analysis of the fundamental rights impacts of each option, to document carefully the reasons for discarding, retaining and/or modifying them, and their subsequent comparison.

For further details on this and other impact assessment steps or on ex post evaluation needs, please refer to the [operational guidance](#) mentioned below³⁷⁶.

3. ANALYSING IMPACTS OF POLICY OPTIONS ON FUNDAMENTAL RIGHTS

Policy options can have both positive and negative impacts on fundamental rights. In case of negative impacts, since limitations to fundamental rights can only be justified if they meet with the requirement of necessity and proportionality, a simple cost/benefit analysis is not sufficient when assessing impacts on fundamental rights of a policy option.

To ensure the use of correct methodology, all identified policy options should be screened against the fundamental rights checklist (see Box 2). In addition, the promotion of equality is addressed in a specific checklist, against which the identified policy options should also be screened.

Box 2. Fundamental rights checklist

- **What fundamental rights are affected?** Screening the envisaged policy options against the fundamental rights 'key impact questions' section in Tool #18 (*Identification of impacts*) provides a first indication of which fundamental rights may be concerned.
- **Are the rights in question absolute rights?** While the Charter does not explicitly list which rights are absolute, the case-law of the Court of Justice of the EU indicates that the prohibition of torture and inhuman or degrading treatment or punishment (Article 4), prohibition of child labour (Article 32) and prohibition of slavery or servitude (Article 5) are protected in absolute terms. If the conclusion is that the examined policy option limits an absolute right, **it should be discarded already at this stage** and a further analysis under the following points is not needed.
- **What is the impact of the various policy options under consideration on**

³⁷⁶ The operational guidance will be updated in 2021/2022

fundamental rights? This step aims at identifying any positive impacts (promotion of fundamental rights) or negative impacts (limitation of fundamental rights). The options might have both a beneficial and a negative impact, depending on the fundamental rights concerned (for example, a negative impact on freedom of expression and a beneficial one on intellectual property). Should the analysis reveal that the policy option would have no negative impact on fundamental rights or only positive impacts, there is no need for further analysis under the points below. If the opposite is the case, the following points should be considered for each individual limitation:

- Would the limitation of / negative impact on fundamental rights be **provided for by law** in a clear and predictable manner?
- Would any such limitation / negative impact:
 - genuinely meet an objective of **general interest** of the Union or **protect the rights and freedoms of others** (this step should identify the relevant objective of general interest or the rights and freedoms of others)?
 - be **necessary** to achieve the desired aim? (This step should examine whether the policy option is appropriate and effective for attaining the policy objective pursued without going beyond what is necessary to achieve it. Why is no equally effective but less intrusive measure available?)³⁷⁷
 - be **proportionate** to the desired aim?
 - **preserve the essence** of the fundamental rights concerned?

If the general interest objective indeed justifies maintaining a policy option impinging on one or several fundamental rights, the impact assessment needs to consider and develop appropriate **safeguards** to ensure that the negative impact would not amount to a violation of the fundamental right(s) concerned.

Box 3. Ensuring non-discrimination and promoting equality checklist

In addition to ensuring that EU legislation complies with fundamental rights as provided by the Charter (including its Article 21 on the prohibition of any form of discrimination), Articles 8 and 10 TFEU and the [UN Convention on the Rights of Persons with Disabilities](#) require the EU to aim to promote equality between women and men, to combat discrimination on grounds of sex, ethnic origin, religion or belief, disability, age, and sexual orientation and to ensure respect for the rights of people with disabilities. The following steps and questions should be considered when checking the impact of various policy options on equality:

- **Is the policy to be prepared people-related? Will it affect people's lives?** For many EU policies, the answer to these first questions is 'yes.' If so, the next step is to identify equality relevance in more detail.
- **Identifying equality relevance in more detail.** At this stage, it is important to check whether in the policy area in question, some parts of the overall population experience inequalities based on sex, ethnic origin, religion or belief, disability, age, or sexual

³⁷⁷ The European Data Protection Supervisor has produced [additional guidance materials](#) for application in the fields of access to documents and data protection.

orientation – or a combination of these characteristics – which could be addressed by the policy option in question. The following steps are useful:

- identify existing inequalities based on sex, ethnic origin, religion or belief, disability, age or sexual orientation in the respective policy area;
- analyse the causes and consequences of these inequalities;
- identify ways in which a policy initiative could address these inequalities.

For further information on how to do this, please refer to the Commission's equality mainstreaming toolbox, in particular its [chapter 2 on equality mainstreaming across the policy-cycle](#) and [chapter 3 on equality data](#). Equality data are key tools to detect inequalities and monitor progress achieved through a specific policy option.

- **Assessing impacts.** Policy decisions that appear neutral may have a differential impact on specific groups, even when such impact was neither intended nor envisaged. Negative impacts leading to discrimination based on sex, race, colour, ethnic origin, religion, sexual orientation, age and disability are prohibited under Article 21 of the Charter and should be assessed accordingly. Furthermore, equality impacts of the policy options should also be assessed to see if an option is likely to affect the existing inequalities. The following questions should be considered:
 - Does the option have (directly or indirectly) a different impact on women or men? Is this a desired outcome or was it unintended? If the analysis reveals that the policy measure has a negative impact and leads to discrimination based on sex, the specific policy option shall be analysed in accordance with the checklist under Box 2, concerning potential limitations of fundamental rights.
 - Does the option promote equality between women and men? How?
 - Does the option have (directly or indirectly) a different impact on specific groups, such as people with a minority ethnic background, including Roma, religious communities, LGBTIQ people, children, older people, or persons with a disability? Is this a desired outcome or was it unintended? If the analysis reveals that the policy measure has a negative impact and leads to discrimination based on race, colour, ethnic origin, religion or belief, disability, age or sexual orientation, the specific policy option shall be analysed in accordance with the checklist under Box 2, concerning potential limitations of fundamental rights.
 - Does the option contribute to combating discrimination on grounds of sex, ethnic origin, religion or belief, disability, age, or sexual orientation? How?
 - Does the option ensure respect for the rights of people with disabilities in conformity with the UN Convention on the Rights of Persons with Disabilities? How? Depending on the initiative, this means checking whether the option ensures disability inclusive reforms of education, labour market and health sectors, accessibility of buildings and infrastructure, services and websites, as well as transition from institutional to community-based services.

4. FURTHER INFORMATION

While the [Charter](#) and its [Explanations](#) are the main reference documents, a number of other resources can be used to identify the rights that could be affected by a particular initiative:

- The Commission developed [operational guidance](#) on taking account of Fundamental Rights in Commission impact assessments. Specific guidance also exists for [trade related initiatives](#) and for [implementing the European Structural and Investment Funds](#) ('ESI Funds'). It is to be noted also that the [Regulation laying down common provisions for specific EU funds](#)³⁷⁸ provides for arrangements to ensure the compliance of EU funded programmes with the relevant provisions of the Charter.
- The [Commission's 2010 Charter strategy](#) sets out the Commission's approach to implementing the EU Charter of Fundamental Rights and can be a source of inspiration.
- The [Commission's 2020 Charter strategy](#) proposes specific actions to strengthen the application of the Charter.
- The [Commission's 2021 EU strategy on the rights of the child](#) sets out the Commission's approach to strengthening the protection and promotion of children's rights across EU policies (notably its [Annex 1](#)).
- The [Commission's EU Action Plan against racism 2020-2025](#) sets out measures with which the Commission will ensure that Member States fully implement relevant EU law and further strengthen the legal framework, if needed (link with Chapter 2.1 of the Charter).
- The [Commission's 2020 EU Roma Strategic Framework for equality, inclusion and participation](#) puts forward new targets and recommendations for Member States on how to achieve the key areas covered by the strategy.
- The [Commission's Gender Equality Strategy 2020-2025](#) presents policy objectives and actions to make significant progress towards a gender-equal Europe (notably its Chapter 5).
- The [Commission's LGBTIQ³⁷⁹ Equality Strategy 2020-2025](#) sets out a series of measures to step up action and to integrate LGBTIQ equality in all policy areas (notably, its Chapters 3 & 5).
- The [Commission's Strategy for the Rights of Persons with Disabilities 2021-2030](#) sets out measures to ensure the full participation of people with disabilities in society, on an equal basis with others in the EU and beyond.
- The [European e-Justice Portal](#) also contains relevant information on the application of the Charter.
- The [EU Agency for Fundamental Rights](#) (FRA) collects and analyses information on fundamental rights issues. Please liaise with DG JUST - Fundamental Rights Policy Unit to know whether the Agency could be of help with providing specific data.
- The [European Institute for Gender Equality \(EIGE\)](#) has developed a [step-by-step guide to gender impact assessments](#).
- The [European Data Protection Supervisor \(EDPS\)](#) can advise about ensuring compliance with rights to privacy and the protection of personal data.
- To develop a deeper understanding of any fundamental right guaranteed by the Charter, **the case law** of the Court of Justice of the European Union, of the European Court of Human Rights and when appropriate, the opinions and general comments of the UN

³⁷⁸ See in particular the horizontal enabling condition 'Effective application and implementation of the EU Charter of Fundamental rights' provided in Annex III of the Common Provisions Regulation.

³⁷⁹ LGBTIQ stands for lesbian, gay, bisexual, trans, intersex and queer people.

human rights monitoring committees should be consulted. The Fundamental Rights Agency's '[Charterpedia](#)' is a useful tool to obtain an overview of the Charter rights and of the relevant case law.

- **Other international instruments**, such as the [European Convention on Human Rights](#) or the UN [Convention on the Rights of the Child](#) are also relevant for interpreting the Charter on Fundamental Rights.
- The [UN Convention on Rights of Persons with Disabilities \(UNCPRD\)](#)³⁸⁰, is part of the EU legal order.

In accordance with Article 53 (Level of protection) of the Charter on Fundamental Rights nothing in the Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognised, inter alia in international agreements to which the Union or all the Member States are party, as it is the case of the UNCPRD.

5. SUPPORT

On Fundamental Rights, DG JUST Unit C.2 (Fundamental rights policy) can provide further assistance:

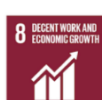
JUST-FUNDAMENTAL-RIGHTS@ec.europa.eu On methodological issues related to impact assessments and evaluations, the 'better regulation' team in DG JUST Unit 03 (Economic analysis and evaluation) can help;

JUST-03-IMPACT-ASSESSMENT-EVALUATION@ec.europa.eu

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

³⁸⁰ Council Decision of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities ([2010/48/EC](#)).

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • People at risk of poverty or social exclusion • Self-reported unmet need for medical care • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Population unable to keep home adequately warm • Gender employment gap • Population reporting occurrence of crime, violence or vandalism in their area • Perceived independence of the justice system <i>UN indicators:</i> • Proportion of population covered by social protection floors/systems, by sex, distinguishing children, unemployed persons, older persons, persons with disabilities, pregnant women, new-borns, work-injury victims and the poor and the vulnerable • Proportion of population living in households with access to basic services • Proportion of total adult population with secure tenure rights to land, (a) with legally recognized documentation, and (b) who perceive their rights to land as secure, by sex and type of tenure • Proportion of countries where the legal framework (including customary law) guarantees women's equal rights to land ownership and/or control • Proportion and number of children aged 5–17 years engaged in child labour, by sex and age • Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law • Proportion of children aged 1–17 years who experienced any physical punishment and/or psychological aggression by caregivers in the past month • Number of victims of human trafficking per 100,000 population, by sex, age and form of exploitation • Proportion of young women and men aged 18–29 years who experienced sexual violence by age 18 • Proportion of victims of violence in the previous 12 months who reported their victimization to competent authorities or other officially recognized conflict resolution mechanisms • Unsentenced detainees as a proportion of overall prison population • Number of verified cases of killing, kidnapping, enforced disappearance, arbitrary detention and torture of journalists, associated media personnel, trade unionists and human rights advocates in the previous 12 months • Number of countries that adopt and implement constitutional, statutory and/or policy guarantees for public access to information	         

TOOL #30. EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION

1. INTRODUCTION

This tool covers three categories within the broad category of social impacts: impacts on 1) employment, 2) working conditions, and 3) income distribution, social protection, and inclusion, including impacts on perspectives and life-situations of people in, or at risk of poverty³⁸¹.

Box 1. Things to keep in mind when assessing social impacts³⁸²

- Impacts are diverse, complex (affecting different population subsets, territories and economic sectors) and strongly connected with economic and environmental impacts.
- There may be trade-offs where social impacts point in different directions. Carefully compare these diverging impacts. A policy change could encourage the creation of new jobs in a sector/region while at the same time lowering job quality or wages for some workers in this (or another) sector.
- Always keep potential distributional effects in mind. Global (aggregate) figures could be misleading as they might hide controversial trade-offs.
- Always use a combination of qualitative and quantitative tools for your assessment as many social impacts might not be quantifiable and models available might rely on controversial assumptions.
- The most practical solution to a lack of EU-wide data and strong differences in labour markets and institutional contexts is in-depth research on 'typical' target groups or 'clusters' of Member States with similar characteristics.
- Positive social impacts often materialise only in the long run. When assessing impacts do differentiate between one-off and recurrent costs/benefits, as well as, between short-term and long-term impacts.
- When significant negative effects are identified, ask yourself whether there aren't ways to mitigate them. Possible solutions could include an exception for the most disproportionately affected stakeholders (e.g. vulnerable groups) or other mitigating measures, such as longer implementation periods, training and job search measures to support people losing jobs. Think about the ways to use the EU funds (e.g. European Social Fund Plus - ESF+ and European Globalisation Adjustment Fund for Displaced Workers - EGF).

³⁸¹ According to the Horizontal Social Clause of the TFEU (Art 9), the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health in defining and implementing its policies and activities.

³⁸² Contact DG EMPL 'better regulation' unit for further reference, information sources, background material and methodological issues.

2. WHO ARE THE RELEVANT STAKEHOLDERS?

In order to effectively **map stakeholders**, keep in mind those who might not be your usual interlocutors, especially those from **disadvantaged backgrounds** (like children from poor households or people with migration or minority ethnic or racial background), or those facing **multiple disadvantages** (like women living in rural areas with poor access to services and infrastructure).

In practice, it is useful to start by examining whether there are any systematic impacts on well-defined stakeholders (for instance by gender, age, income, disability, level of education and training, migration, or minority ethnic or racial background, or sexual orientation and gender identity, or by the place of residence like remote/rural areas with poor infrastructure). A gender perspective should always be considered. The assessment of potential impacts on gender should take into account the existing differences between women and men in the given policy field (e.g. gender pay gap). Various [European umbrella NGO networks](#) promote social inclusion, gender equality, and represent and defend the rights of people exposed to discrimination.

European social partners – employers' organisations and trade unions – should be specifically consulted in case of initiatives in **the field of social policy**³⁸³ and for **initiatives with social implications for the economy as a whole or for a specific sector**³⁸⁴. Contact [EMPL Social Dialogue Unit](#) in case you need more information about Sectoral Social Dialogue Committees, cross-industry social dialogue and social dialogue texts database.

Member States can be consulted via Employment Committee (EMCO) and Social Protection Committee (SPC). Contact EMPL Coordination Unit in case you need more information.

The identification of those stakeholders for whom there may be significant negative impacts may help foresee resistance and may point to mitigating measures to reduce negative impacts.

3. ARE IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION POTENTIALLY SIGNIFICANT?

To help identify potential impacts, sections 3.1 to 3.3 below include a few relevant **questions** accompanied by illustrative examples. Social impacts, positive as well as negative ones, often materialise in the long run, therefore it is important to differentiate between short- and long-term impacts. See section 5.1 for employment and social indicators and sources.

³⁸³ There are specific Treaty provisions for consulting social partners (management and labour), regarding initiatives in the field of social policy e.g. health and safety in the workplace, working conditions, social security and social protection of workers, and information and consultation (see Treaty Articles 153-155 TFEU, and particularly Article 153 TFEU on the policy fields concerned). This consultation process includes two stages: first, social partners are consulted on the general direction of an initiative; then, in a second stage, on the envisaged content (see Tool #10 (*Treaty-based social partner consultations and initiatives*))

³⁸⁴ If an initiative will create social implications for a sector for which a sectoral social dialogue committee exists, it shall be consulted (Article 2 of Commission Decision 98/500). If an initiative has social implications for the whole economy or for several sectors, social partner consultations can take the form of a dedicated hearing organised at services' level or of a political meeting at the level of Executive Vice-Presidents or Commissioners.

3.1. Impacts on the level of employment

Impacts on the level of employment can be expected whenever demand or supply for labour changes. For example, labour demand increases if companies want to employ more people due to increase in demand for their products. Labour supply increases when more people are available and willing to work.

The main question is **whether there will be more or fewer jobs (more or fewer hours worked) overall or for specific stakeholder categories, in a specific geographical area**. It will give you an indication whether a larger/smaller workforce will be needed and/or whether redistribution of labour is to be expected (e.g. between sectors or occupations).

The following questions and illustrating examples explore various dimensions of employment impacts.

(1) *To what extent are new jobs created or lost?*

Options improving access to funding for SMEs can create new industrial activity that can employ directly or stimulate indirect job creation through the purchases of goods and services from suppliers. Free trade agreements can create new jobs by increasing exports and demand for certain domestically produced goods but also destroy jobs by replacing other domestically produced goods or even services³⁸⁵ with imported ones. The impact on employment should refer to direct and indirect creation or loss of jobs, including short and long-term impact when possible.

(2) *Are direct jobs created or lost in specific sectors, professions, qualifications, regions or countries or a combination thereof? Which specific social groups are affected?*

Initiatives fostering greener energies might increase the need for certain skills (e.g. installation of photovoltaic panels) to the detriment of others (e.g. skills needed in extracting coal). Creation of jobs in new renewable sectors can be at the cost of employment in traditional extractive industries (skill-mismatch) and regionally unbalanced (e.g. jobs created at the off-shore wind farms and lost in coal mining regions). Jobs can be created or lost in male-dominated or female-dominated professions.

Reforming the common agricultural policy for wine growing is expected to have no employment impact in those Member States with (almost) no wine growing, very little impact in those Member States where the sector had already undergone significant reforms and significant impact in those Member States where such reforms had not yet taken place. However, depending on the respective structure (age of farmers, size of farms), these impacts can differ even in those countries.

(3) *Are there indirect effects which might change employment levels?*

New industrial activity can stimulate indirect job creation through increased purchasing power of newly employed workers (e.g. retail or leisure).

Initiatives fostering green energies might increase the need for certain skills but raise wages at the same time with a complex effect on employment levels. This might also increase the need for training and trainers leading to indirect employment impacts.

³⁸⁵ E.g. due to digital transition.

(4) *Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses?*

Delays in acknowledgement and certification of new qualifications or a lack of arrangements to provide for a transition can create significant employment problems.

Initiatives improving energy efficiency of buildings might increase demand for workers in construction sector with relevant skills. If the necessary skills are not available (e.g. lack of relevant educational/training programmes, non-recognition of skills acquired abroad) the effectiveness of the policy risks to be limited.

Transition between winning and losing sectors/occupations/skills/regions is not automatic. A worker losing a job in the car manufacturing or agriculture sector may not become a health or domestic service sector worker within a couple of months and without support/training. While analysis often implies easy adaptation processes, an important aspect of employment-related impacts requires explicit consideration for timing and sequencing of the intervention.

(5) *To what extent does the option influence the availability and willingness of workers/specific groups to work (i.e. supply of labour through labour market participation or labour market mobility)?*

Several factors can influence the supply of labour: tax and benefit systems, relative earnings, barriers to entry into profession/occupation, accessibility for persons with disabilities, work-life balance policies, work intensity and working conditions, length of working life, the occupational/geographical mobility of labour, migration policies.

An initiative aiming at regulating professions (e.g. by requiring a specific degree or special exam) can act as a barrier to entry, hold back the labour supply and limit occupational mobility, but it can at the same time support the safety and quality of the goods or services provided.

Work-life balance policies that help parents to balance professional and family responsibilities by increasing their availability/willingness to work and can have a positive impact on labour market participation of women.

Initiatives shortening the length of compulsory education, increasing the age of retirement, or supporting active ageing (like better ergonomics of working places, reskilling, ICT tools etc.) can increase the supply of labour of specific age groups and therefore total labour supply.

An initiative improving transport infrastructure and transport services can enhance the geographical mobility of workers by reducing the time and/or costs of travelling. More workers would be able to daily/weekly commute to cities/regions where jobs are available without the need to relocate and thus prevent depopulation of remote and rural areas. The geographical mobility of workers can be improved also through initiatives on property markets (e.g. affecting rents, conditions for mortgages etc.).

3.2. Impacts on working conditions

Impacts on working conditions are more difficult to capture. They often require a mix of qualitative and quantitative assessment and cover a broader range of outcomes, which may become tangible only in a medium to long term. Initiatives that e.g. enhance the creation of a business-friendly environment and liberalisation and/or deregulation of activities are likely to

have an impact on working conditions. In cases where value chains involve third countries, conditions of workers along the full value chain should be considered. This is particularly important for workers in industries in developing countries, as working conditions are often below European standards.

The following questions and illustrating examples explore various dimensions of impacts on working conditions:

(1) Does the option affect wages, labour costs and/or wage setting mechanisms?

Initiatives changing income taxation or social security systems can impact **wages and labour costs**³⁸⁶. Elements to be considered are: i) a relative dimension of wage: wage dispersion, changes in income-distance to another group of workers considered as reference group, or ii) its absolute dimension: wages, which are insufficient to allow for a decent standard of living.

Impacts on labour costs should be assessed in conjunction with changes in (labour) productivity. For example, initiatives introducing obligatory employers' training or health and safety requirements can increase labour costs. However, this may not be negatively correlated with the competitiveness of goods produced as those measures can increase the productivity of workers due to better skills and reduced absenteeism. While the costs might be relatively easy to estimate (e.g. prices of protective equipment, number of hours away from workplace dedicated to training), the benefits may be visible only in the longer term and are more difficult to quantify.

The **wage setting mechanism** affects the level or conditions of minimum wages, the coverage of workers by collective agreements and negotiating power of social partners.

(2) Does the option affect directly or indirectly employment protection, especially the quality of work contract or bogus self-employment³⁸⁷?

Employment contracts that don't provide for a minimum number of working hours and/or reduce job security make employees' income less predictable and lead to instable living conditions and uncertain career prospects. Initiatives aimed at facilitating technology-driven activities leading to new forms of work can open up employment opportunities to people further away from labour market but also reduce job security and predictability and also challenge the effective exercise of collective labour rights. Initiatives fostering entrepreneurship and self-employment can have a positive impact on job creation, but they can also undermine employees' rights and protection if the initiative leads to 'bogus self-employment' or to dependent self-employed persons in systems in which the recognition of their specificities, e.g. as to their social protection needs, is low.

³⁸⁶ Wages (or earnings) are the compensation that workers (employees) receive for their work. They safeguard labour income and are positively correlated with consumption. Net wages are calculated as a difference between gross wages, social contributions payable by the employee and any amounts which are due to government, such as income taxes. Labour costs are broader concept and reflect employers' expenditure on personnel. They include wages and salaries paid to employees, social contributions payable by the employer and other costs, such as taxes on labour, training costs, costs related to working cloths etc.

³⁸⁷ Bogus 'self-employed' or 'false self-employed' are formally self-employed but in practice employees. In some of these cases, workers are obliged to adopt a self-employed status while having a contract with a single firm that avoids paying social security payments.

Typically problematic contractual arrangements are: frequent use of short-term contracts, excessive use of traineeships, employment relations which do not give access to social security schemes, very short lay-off periods, excessively long probation periods, no fixed volume of working hours, involuntary and bogus self-employment, intensive use of temporary work agencies or subcontracting/outsourcing.

On the other hand, excessively protective employment protection legislation can adversely affect segmentation of the labour market with large differences in costs and rights between permanent and non-standard forms of work.

(3) Does the option affect the risk of undeclared work?

Undeclared work can take various forms, from completely undeclared work (e.g. a care assistant taking care for elderly people without signing any contract, or seasonal and temporary workers in agriculture without having a proper employment contract) to situations where only part of the work and income is undeclared (e.g. IT specialist working in a big company officially earning the minimum salary while receiving an additional amount by his employer 'cash-in-hand'). It has negative effects on workers (e.g. lack of security, reduced benefits, poor working conditions), employers (e.g. unfair competition) and on public finances (e.g. unpaid taxes and social security contributions).

Initiatives changing income taxation or social security systems, work or responsibilities of public administration (e.g. enhancing the frequency of checks by labour inspectorates), recognition of qualifications or initiatives in the area of migration are some of the examples that can affect the risk of undeclared work.

(4) Does the option affect the work organisation?

Work autonomy, level of teamwork and job rotation, pace of work and work intensity are important elements of work organisation. Work organisation can influence various aspects of working conditions (physical risk factors, work-related health and safety risks, work-life balance, or in general the satisfaction with working conditions) and therefore have an impact on labour productivity.

Liberalisation of activities (e.g. ground-handling in aviation sector) can stimulate growth and job creation but aggravate the working conditions of the workers (e.g. work in shifts or split work). Work organisation can change because of industrial restructuring but also with the introduction of new technologies. For example, the development of IT and the deployment of algorithmic management practices for recruiting, directing, and monitoring workers (or other ways of using artificial intelligence at work), and GPS tracking systems can reduce the work autonomy and increase the work intensity. Also, they need to be used cautiously to avoid negative impacts especially on vulnerable people such as people with disabilities. On the other hand, the IT development can support flexible working arrangements and, in some cases, contribute to better work-life balance.

(5) Does the option affect health and safety at work?

Health and safety at work³⁸⁸ encompasses several elements such as: safety and health aspects; organisation and adaptation of the workplace and working environment so as to ensure the

³⁸⁸ See also Tool#32 (*Health impacts*), as health and safety at work is closely linked with general health impacts.

health and safety of workers; ensuring adequate personal protective equipment limiting exposure to potentially harmful agents or situations (including exposure to risks leading to musculoskeletal disorders; to physical agents such as noise or vibration; to radiation; to chemical agents, carcinogens and mutagens; to biological agents etc.), proper protective and preventive framework for work in a particularly challenging work environment/sector; or a combination thereof. Health problems do not only originate from physical strain at the workplace, but also from the overall psychological stress to which an employee is exposed. Therefore, aspects such as stress levels, tight/unsocial working hours and reconciling work and private life should also be considered, especially in view of an ever-growing digitalisation of the workplace and work-tools. The benefits of technology-enabled work (e.g. telework) should nonetheless be evaluated against the drawbacks of an increasingly blurry boundary between private and professional life, as well as a reduced ability for workers to 'digitally disconnect'.

Satisfying work and good working conditions constitute a value in itself, but their absence leads to discontent and can also produce significant negative effects on workers (e.g. death, disability, poor health, injuries, loss of present and future income, direct and indirect medical costs and rehabilitation costs); employers (e.g. absenteeism, lower productivity, production disturbances, damage to equipment and to a company's image, administrative and legal costs, negative impacts on insurance premiums); governments (e.g. sickness payments, increased health expenditure, increased social security expenditure (for disability or early retirement), tax revenue losses, direct and indirect medical and rehabilitation costs, administrative and legal costs).

Initiatives reducing regulatory burden by introducing, for example, less stringent requirements to monitor the working place, to guarantee preventive work clothes or to ensure preventive medical check-ups can increase health risks.

(6) Does the option affect the social dialogue?

Social partners (trade unions and employer's organisations) **determine** working conditions and carry out wage negotiations. Social dialogue between employers' and employees' representatives is an important mechanism for conflict resolution and can be a means to internalise external effects which take place at sectoral level.

Social dialogue within a company can be impacted by initiatives that, for example, exempt SMEs from ensuring the representation of workers in the management. Attention needs also to be paid to the extent to which the option affects the autonomy of social partners in the areas for which they are competent. Does it, for example, affect the right of collective bargaining at any level or the right to take collective action?

Another issue that might need to be considered is the impact on the transparency of workplace-level employment relationships. For instance, some initiatives aimed at facilitating technology-enabled work may lead to a de facto 'digitalisation of the workplace', which in turn causes a physical dispersion of the workforce, thus making it difficult for workers to collectively organise and for social partners to proactively reach out to them.

(7) Does the option affect access to vocational education and training and to career development/advice? How are different social groups affected³⁸⁹?

Training / lifelong learning opportunities (including their availability and affordability) and returns to it (recognition of skill acquired in other companies or in other Member States) can influence career perspectives and employability of workers in the long run. Employers offering training opportunities can be more attractive among job seekers and thereby increase the pool of potential work candidates. Career advice can improve the match between job and worker, increase job satisfaction and productivity and reduce staff turnover. Tax reforms or financial incentives can have an impact on companies' willingness to invest in vocational education and training (VET) and career development.

Initiatives exploiting IT development and supporting distance learning can improve the availability of training opportunities for a large part of the population, but might be still unavailable to some, such as people with low incomes, persons with a minority racial or ethnic background, living in poverty or people living in remote and rural areas with inadequate access to digital infrastructure/broadband who can't afford to buy a computer or have an internet connection. Persons with disabilities may be disadvantaged in case accessibility of digital services is not ensured.

(8) Does the option help/endanger the effective exercise of labour standards in the EU?

Labour standards largely rely on national legislation or social partner agreements. European level intervention can have an impact on these arrangements even without explicitly intending to do so, by e.g. setting new rules in an adjacent area; by changing the structure of a market; by introducing standards for consumers which could have – positive or negative – impacts on workers or by concluding external agreements (e.g. free trade agreements, international conventions).

The normative interpretation of these impacts, i.e. whether a change should be considered as improvement or not, depends on the context. In this sense, discussing and presenting these issues in an impact assessment report enhances the transparency of policy debates.

3.3. Impacts on income distribution, social protection, and inclusion

These impacts relate to social fairness considerations, including social inclusion and protection of people against various risk and needs throughout their lives. Such impacts may be particularly significant in interventions which affect the tax system or introduce changes to the transfer system. Most EU financial instruments (such as the Structural Funds, the Common Agricultural Policy), but also liberalisation or deregulation efforts, have income distributional impacts. Similarly, changes in legislation, for instance concerning equal opportunities/reconciliation or access to services for disabled people or people from disadvantaged backgrounds can affect their attitudes and their chances on the labour market. Changes in EU legislation can also indirectly impact the income distribution and social protection of workers in third countries, e.g. by creating a race-to-the-bottom situation. In a similar way, the analysis should cover the possible impacts on income of people working/living in the EU because of changes in labour costs outside the EU. Perpetuation of income and wealth inequality patterns should be avoided.

³⁸⁹ See also Tool #31 (*Education and training, culture and youth*)

The following questions and illustrating examples explore various dimensions of impacts on income distribution, social protection, and inclusion:

(1) Does the option affect people/households' income and risk of poverty?

Disposable income is an important indicator of social status and of someone's living standard. If it falls below a certain threshold, people will risk becoming poor and/or having to rely on social assistance. The **three dimensions of "poverty or social exclusion (AROPE)"**³⁹⁰ comprise: very low work intensity and/or severe material and social deprivation and/or at-risk of poverty (relative poverty)³⁹¹.

As examples, initiatives leading to job losses (part 2.1 above) are very likely to have an impact on income and risk of poverty by increasing the number of unemployed or inactive people with low income and households with low work intensity. This is even more pertinent when there are few re-employment opportunities or the people losing jobs are from vulnerable groups (e.g. older workers, low qualified). Initiatives deteriorating working conditions (part 2.2 above) are also likely to have an impact on income and risk of poverty by increasing the number of people with low income when wages are reduced. If policies fostering green energies increase the price of energy this can increase household spending on energy and aggravate energy poverty.

(2) Does the option affect inequalities and the distribution of incomes and wealth?

Increasing income inequalities³⁹² threaten social cohesion and can be linked to several factors, such as wage dispersion, tax wedge or social protection systems.

Initiatives such as moving from direct taxation (e.g. taxing the income) to indirect taxation (e.g. increased VAT) raise the disposable income of certain stakeholders (the workers) but reduce that of the others towards poverty and negatively affect their chances to participate fully in society (inclusion). This may be counter-balanced by increased job opportunities created by the reduced labour cost. The overall impact on risk of poverty would have to consider the extent of such opportunities and the chances that the unemployed would be able to take advantage of them. A policy change may also have a distributional impact if existing inequalities are aggravated. If for example, only high skilled jobs are created this could increase the inequality with lower skilled people who already have more difficulties to find a job.

When assessing the impact on income inequality, consider also which segments of the income distribution would be affected (e.g. 'relative impoverishment' of the middle class).

³⁹⁰ AROPE – at-risk-of-poverty or social exclusion.

³⁹¹ **Work intensity** is the ratio between the number of months that household members of working age (with some exclusions) worked and the total number of months that could theoretically have been worked. Very low work intensity refers to situation where persons of working age (with some exclusions) living in the household worked less than 20.0% of their total potential in the previous 12 months. **Severe material and social deprivation** is the inability for a person to afford seven items out of a selection of 13 items of reference that are considered to be necessary or desirable to lead an adequate life. **At-risk-of poverty (AROP)** rate is the share of people in the total population with an equivalised disposable income (after social transfers) below 60% of the national median equivalised income after social transfers. This indicator measures low income in comparison to other residents in that country, which does not necessarily imply a low standard of living.

³⁹² Income inequalities arise from distributional impacts on income. Income refers to equivalised disposable income.

(3) Does the option affect the access to and quality of social protection benefits, including social services of general interest, particularly for those subject to social exclusion and from disadvantaged backgrounds?

Social services play a crucial role in improving quality of life and providing social protection against the risks and needs associated with unemployment, parental responsibilities, sickness and healthcare, invalidity, loss of a spouse or parent, old age, housing, and social exclusion. Social services are an important enabler of social inclusion in remote and rural areas contributing towards the reduction of inequalities in those areas.

Access to and adequacy of **social protection benefits** depends on the eligibility, duration and level of benefits, type of risks covered and rights to receive benefits when moving to another Member States beyond the obligatory rights. They will be likely affected by the initiatives that affect the organisation and financing of social protection systems (e.g. insurance vs solidarity; range of membership, private vs public provision; tax financed vs contribution based) as well as the cross-border provision of services, referrals across-borders and cooperation in border regions (e.g. provision of services by public employment services).

The changes would have to be assessed in view of their direct impact on the beneficiaries and on their behavioural impact on people who might leave or enter the scheme or other schemes. For instance, raising pension ages may encourage more people to join disability schemes. The increased prevalence of new forms of work (e.g. platform work) may impact the access and adequacy of social protection.

(4) Does the option affect the access to and quality of basic goods and essential services, particularly for those subject to social exclusion and from disadvantaged backgrounds?

Basic goods and essential services include, for instance, energy, water and sanitation, transport, financial services, and digital communications³⁹³, healthcare, education and training and housing. It might be important to assess the access to and quality of these goods and services especially for people not covered by social protection schemes and people living in remote and rural areas with inadequate access to those services.

Interventions increasing the price of basic good/services, e.g. energy prices, can aggravate material and social deprivation and energy poverty of certain categories of the population and exacerbate social exclusion and inequalities. On the other hand, initiatives aiming at increasing access to essential services, such as a bank account or internet can increase social inclusion. Social services of general interest can play a crucial role in improving life quality³⁹⁴.

3.4. Which impacts are potentially significant?

Among the five criteria to identify potentially significant³⁹⁵ impacts for more detailed assessment, the following three are especially relevant for social impacts:

³⁹³ A non-exhaustive list of essential services is provided in [principle 20 of the European Pillar of Social Rights](#).

³⁹⁴ https://employment-social-affairs.ec.europa.eu/policies-and-activities/social-protection-social-inclusion_en

³⁹⁵ i) The relevance on the impact within the intervention logic, ii) the absolute magnitude of the expected impacts, iii) the relative size of expected impacts for specific stakeholders, iv) the importance of impacts for

- **Relative size of expected impacts for specific stakeholders** (i.e. Are certain categories of stakeholders or regions/countries/sectors particularly affected?) For example, new rules (e.g. labelling, selling restrictions) regarding a particular product might have more serious consequences in terms of employment in those EU regions specialised in its production. Big job losses in a small region without viable alternatives for re-employment can be an example of a significant impact. The size of the EU population with no access to basic bank services is pretty modest. Still, regulations that would render those services more expensive/less accessible can have important negative consequences for that population (e.g. financial exclusion).
- **The importance of impacts for EU objectives and policies** – (i.e. Could the initiative undermine EU objectives in the social area?) E.g. initiatives that would lead to significant job losses, negatively impact health and safety at work or with significant impacts on households’ income could undermine efforts in building a fairer Europe and strengthening its social dimension in line with the principles of the [European Pillar of Social Rights](#)³⁹⁶. Such initiatives would also have a negative impact on the EU’s progress in achieving the SDGs.
- **Sensitivities and diverging views** - (i.e. How divergent are stakeholder views?) detailed assessment could be envisaged for potentially **politically sensitive issues**, such as impacts that could be considered as unfair (e.g. initiatives reducing tax burdens for companies and increasing those for workers).

4. HOW TO ASSESS IMPACTS ON EMPLOYMENT, WORKING CONDITIONS, INCOME DISTRIBUTION, SOCIAL PROTECTION, AND INCLUSION?

Given the diversity of impacts and affected stakeholders, start with a **systematic qualitative scoping**: i.e. go first through types of impacts and then stakeholders to be affected and in which way. Any assessment should focus on a **limited number** of impacts. A good and operational approximation is to identify three to six issues (combination of impact and stakeholders affected) that are the most important from a social perspective.

4.1. What to pay attention to in assessing social impacts?

Level of analysis and distributional impacts: The transition of employment between winning and losing sectors (or regions, qualifications, occupations) is not automatic. For employment and social impacts, it is important to understand where the adjustment occurs and therefore **net effects are not very informative**³⁹⁷. In the presence of important distributional effects, **global (aggregate) figures could be misleading as they might hide controversial trade-offs**. Disaggregated analysis can help you to look for alternative options or mitigating measures to minimise potentially negative impacts.

As an example, a trade agreement can be beneficial for the overall EU economy but have important opposite effects in different regions or sectors as well as the economy or specific sectors of the partner country. Likewise, liberalisation measures in the transport sector should

Commission horizontal objectives and policies and v) Sensitivities and diverging views. See step 2 in Tool #18 (*Identification of impacts*) for more details.

³⁹⁶ The European Pillar of Social Rights is accompanied by a ‘[social scoreboard](#)’ that monitors the implementation of the Pillar by tracking trends and performances across EU countries in three areas and feeds into the European Semester.

³⁹⁷ Net job changes are the difference between gross jobs created and destroyed (lost).

generally lead to lower prices for transport users but also to prohibitive prices for people living in remote areas. Moving from direct to indirect taxation raises the disposable income of certain population groups but reduces other groups to poverty and negatively affects their chances to participate fully in society. In such cases, calculating the average general impact on the total population could be misleading, and would be insufficient. Distributional impacts may for example vary by sex or age.

Different labour markets and institutional context: European countries have organised their labour markets and welfare states in different ways, relying to various degrees on market, family, and the State. The functioning of the labour market (e.g. social dialogue or labour market legislation) and different institutional settings can influence the direction and the magnitude of the social impacts. Those differences require an analysis at a national level or alternatively grouping of countries in clusters based on the similarity of their institutions. E.g. the transition of employment between winning and losing sectors is expected to be faster and more successful in countries with well-developed and efficient active labour market policies and public employment services. When a particular policy initiative is expected to have negative effects on job quality, Member States with strong union presence could face stronger opposition to it, but they could also be able to reduce the negative effects or secure mitigating measures via social dialogue. See (in particular) Eurofound for more information.

Sectoral and regional dimension: If the impacts are not economy-wide but concern a specific sector only, it is always better to refer to a [NACE](#) classification sector. When moving away from the NACE classification, consistent and reliable data is more difficult to get. However, if the impacts refer only to part of the sector, or parts of different sectors, it is reasonable to either adjust the NACE data source, or if possible, refer directly to those parts affected. For regional impacts it is essential to align with the [NUTS classification](#).

4.2. Can impacts be quantified and what is the availability of data?

A **quantitative analysis** can be easier to undertake when assessing impacts on **employment and income levels** as those impacts are quantitative in nature (e.g. number of jobs can be easily counted, wages, labour costs, disposable income are expressed in monetary units).

For assessing the impacts on income inequalities consider indicators such as income quintile share ratio (e.g. S80/S20) or the income share of the bottom 40% (S40). For overview of indicators see table “Relevant sustainable development goals (SDG) indicators” at the end of the tool.

In other areas, such as **working conditions**, **impacts are qualitative by nature and converting them into quantitative units will require the use of an indicator that acts as a proxy**³⁹⁸. E.g. the ‘number of occupational accidents’ can be used as a proxy to assess safety at work. Days of workers’ sickness in a certain sector, short-term contracts or part-time work indicate potentially problematic situations – however, this might also happen for other reasons (it is therefore crucial to understand the underlying causes or drivers). These indicators will be rather context specific – as for example in the situation of work contracts – and will normally be a compromise between accuracy and precision and the costs and time required to collect and process the necessary information.

³⁹⁸ See Tool #43 (*Monitoring arrangements and indicators*)

In some areas, you will most probably **analyse impacts qualitatively**. E.g. the impact on the access to social security services might be quantified (e.g. number of social services users), but the impact on its quality will be analysed qualitatively. Similarly, it will be difficult to quantify impacts related to social inclusion.

Complete, credible and EU wide comparable data is particularly important in the case of a quantitative analysis, but also your qualitative assessment will need to be underpinned with facts or examples. The availability of sound and up-to-date data will also condition the level of analysis. If impacts are concentrated on small groups, it will be difficult or impossible to find suitable data or a reasonable model. An inventory of the sources of data more relevant to the impacts covered in this tool is provided in section 4.2.

4.3. Using models in assessing social impacts?

If considerable social impacts are expected, a model should be used where possible.

Quantitative approaches to assessment range from relatively simple measurement, mainly based on past observations, to counterfactual analysis and up to highly complex formalised (and data-hungry) models, like Computable General Equilibrium (CGE) models or econometric models of the (world) economy.

The use of the model will be case-specific³⁹⁹. Some very well-known models, e.g. the input-output model, deliver results at a macro level and you will have to complement them with qualitative assessment to assess the distributional impacts. You may capture distributional impacts using augmented CGE models. If the expected impacts are restricted to certain sectors, a partial equilibrium model seems suitable to quantify those impacts. Otherwise, general equilibrium models might be more appropriate.

When using the models, pay attention to the **underlying assumptions about the labour market**. For example, Computable General Equilibrium (CGE) models generally assume full employment of all factors and perfectly competitive markets (which is far from the reality in many Member States' labour markets). In addition, there are strong differences among the Member States' institutional contexts related to the employment and social areas.

In complement to macro-economic models (useful to determine the impact on employment and wages), the use of micro-simulations (e.g. in the [Euromod](#) tool managed by Joint Research Centre) would be relevant to assess the impact of the option on income inequalities and the risk of poverty.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. Key EU-level data sources

- The [European Union Labour Force Survey](#) (EU LFS) is the most important survey for labour market data, providing monthly/quarterly/annual data on employment,

³⁹⁹ For further information on methods and models see Tools in Chapter 8. For an overview of models to be used for assessing social impacts see Annex 1 in *Review of Methodologies applied for the assessment of employment and social impacts* (2010) and table 4.3 in [Assessing the Employment and Social Impacts of Selected Strategic Commission Policies](#) (2009)

unemployment by sectors, age, qualification, sex, migrant background, per countries/regions. Micro-data are available upon request.

- **Other [labour market statistics at EUROSTAT](#)** are available on job vacancies, earnings, labour costs, labour market policy, labour disputes based on various surveys. Micro-data are available upon request.
- The **[European Working Conditions Survey](#)** enables monitoring of long-term trends in working conditions in Europe. Themes covered include employment status, working time arrangements, work organisation, learning and training, physical and psychosocial risk factors, health and safety, worker participation, work-life balance, earnings and financial security, as well as work and health. Micro-data are available upon request.
- The **[European Quality of Life Survey \(EQLS\)](#)** examines both the objective circumstances of European citizens' lives and how they feel about those circumstances and their lives in general. It looks at a range of issues, such as employment, income, education, housing, family, health, and work-life balance. It also looks at subjective topics, such as people's levels of happiness, how satisfied they are with their lives, and how they perceive the quality of their societies. European Foundation for the Improvement of Living and Working Conditions (Eurofound). Micro-data are available upon request.
- The **[European Company Survey \(ECS\)](#)** gives an overview of workplace practices and how they are negotiated in European establishments. It is based on the views of both managers and employee representatives. Micro-data are available upon request.
- For health and safety, Eurostat's statistical data on accidents at work, and work-related problems are available: **[European Statistics on Accidents at Work \(ESAW\)](#)**, and the **[LFS ad hoc modules on accidents at work](#)** and **[European Occupational Diseases Statistics \(EODS\)](#)** and **Statistics on work-related health problems**.

Important information about occupational safety and health (OSH) management arrangements in enterprises can be drawn from the **[European Survey of Enterprises on New and Emerging Risks \(ESENER\)](#)**, by EU-OSHA.

- The **[European Union Statistics on Income and Living Conditions \(EU-SILC\)](#)** collects comparable multidimensional micro-data on an annual basis on income, poverty, social exclusion and living conditions. Micro-data are available upon request.
- The **[European system of integrated social protection statistics \(ESSPROS\)](#)** provides a coherent comparison between European countries on social benefits to households and their financing.
- The **[Continuous Vocational Training Survey \(CVTS\)](#)** provides comparable statistical data on enterprises' investment in the continuing vocational training of their staff. Continuing vocational training (CVT) refers to education or training measures or activities which are financed in total or at least partly by the enterprise (directly or indirectly). Information is grouped around the following topics: provision of courses and other forms of CVT, CVT strategies, participants, costs, time spent in CVT courses, characteristics of CVT courses, and assessment of CVT activities. The sixth Continuous Vocational Training in Enterprises Survey conducted in 2020 is the most recent available wave of data collection. Micro-data are available upon request.
- The **[Adult Education Survey \(AES\)](#)** covers participation in education and lifelong learning activities (formal, non-formal and informal learning). The following information is available: participation, volume of instruction hours, characteristics of the learning

activities, reasons for participating, obstacles to participation, access to information on learning possibilities, employer financing and costs of learning and self-reported language skills. The fourth Adult Education Survey, conducted in 2022/2023, is the most recent available wave of data collection.

- [Skills forecast by CEDEFOP](#) provide comprehensive information on the future labour market trends in Europe looking at employment growth, developments in sectors, the types of job opportunities that may emerge, changes in qualification levels and demographic trends. Micro-data are available upon request.
- [The Programme for the International Assessment of Adult Competencies \(PIAAC\)](#). The Survey measures the key cognitive and workplace skills. It includes 3 elements: direct-assessment of skills (literacy, reading, numeracy, problem solving in technology-rich environment), collection of information about the skills use (the survey asks adults how intensively and how frequently they use cognitive, interaction and social, physical and learning skills at work), and background information (e.g. education, social background, engagement with literacy and numeracy and ICTs, languages, current activity of respondents, employment status and income, health status, volunteering, political efficacy, and social trust). Micro-data are available upon request.
- [World Input-Output Database](#) (WIOD) allows analysing impacts of the global value chain on skilled and non-skilled labour demand across EU countries and 15 other major countries in the world for the period from 2000 to 2014.
- [EUKLEMS](#) database which allows the analysis of productivity and growth. The EU KLEMS Release 2019 provides a database on measures of economic growth, productivity, employment, capital formation, and technological change at the industry level for all European Union member states, Japan, and the US. In addition, it provides supplementary indicators on intangible assets.
- Cross-country intangible investment data website, [INTAN-INVEST](#) is an open access database on intangible assets that allows the linking of employment data at macro level.

5.2. Other useful sources

This is a non-exhaustive list of potentially useful sources in the area of employment, working conditions and income distribution and inequality

- [Employment, Social Affairs & Inclusion Directorate General](#) (DG EMPL) – It coordinates and monitors national policies; promotes the sharing of best practices in fields like employment, poverty and social exclusion and pensions; makes laws and monitors their implementation in areas like rights at work and coordination of social security. It provides information and analysis. It provides analysis of various employment and social topics as well as descriptions of EU-funded projects.
- [Eurofound](#) – European Foundation for the improvement of Living and Working Conditions (EU decentralised agency). It provides information, advice and expertise on living and working conditions, industrial relations and managing change in Europe.
- [Cedefop](#) – European Centre for the Development of Vocational Training (EU decentralised agency). It provides information, advice and expertise on vocational education and training, identification of skills needs, understanding of qualifications and development of lifelong learning.

- **OSHA** – European Agency for Safety and Health at Work (EU decentralised agency). It develops, gathers, and provides reliable and relevant information, analysis, and tools to advance knowledge, raise awareness and exchange occupational safety and health (OSH) information and good practice which will serve the needs of those involved in OSH.
- **EIGE** (EU decentralised agency) – European Institute for Gender Equality. It contributes to the promotion of gender equality, including gender mainstreaming, in all European Union policies and the resulting national policies, and the fight against discrimination based on sex, and raise Union citizens' awareness of gender equality by providing technical assistance to the European Union institutions, in particular the Commission, and the authorities of the Member States.
- **European Social Policy Network** (ESPN) provides the Commission with independent information, analysis, and expertise on social policies
- **Social Scoreboard** – This monitoring tool of the European Pillar of Social Rights screens employment and social performances of EU Member States.
- **Europe Sustainable Development Report** (ESDR) is an independent quantitative report on the progress of the European Union and its member states towards Sustainable Development Goals (SDGs) which also measures spillover effects on third countries.
- **EDE – European Disability Expertise** – Experts' reports on legislation, policy and the situation of persons with disabilities including in the area of employment and transition from education to employment of persons with disabilities.
- **Skills Intelligence** (EC/CEDEFOP) is a central access point for data, information and intelligence on skill needs in occupations and sectors that provides a European perspective on trends in skill supply and demand and possible skill mismatches, while also giving access to national data and sources.
- **ILO** – International Labour Organisation brings together governments, employers, and workers representatives of 187 member States, to set labour standards, develop policies and devise programmes promoting decent work for all women and men. ILO provides good quality data and analysis of various employment and social topics.
- **OECD** – Organisation for Economic Co-operation and Development brings together 34 Member States and provides a forum in which governments can work together to share experiences and seek solutions to common problems. OECD provides good quality data and analysis of various employment and social topics available in their [library](#).

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant Sustainable Development Goal (SDG) indicators	SDGs
<i>EU indicators</i> • People at risk of poverty or social exclusion • People at risk of income poverty after social transfers • Severely materially deprived people • People living in households with very low work intensity • In work at-risk-of-poverty rate • Self-reported unmet need for medical care • Adult participation in learning • Gender pay gap in unadjusted form • Gender employment gap • Inactive population due to caring responsibilities by sex • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Final energy consumption in households per capita • Population unable to keep home adequately warm • Young people neither in employment nor in education and training • Long-term unemployment rate • People killed in accidents at work • Purchasing power adjusted GDP per capita • Disparities in adjusted gross disposable income of households per capita • Relative median at-risk-of-poverty gap • Income distribution <i>UN indicators:</i> • Proportion of population living below the national poverty line, by sex and age • Proportion of men, women and children of all ages living in poverty in all its dimensions according to national definitions • Proportion of population covered by social protection floors/systems, by sex, distinguishing children, unemployed persons, older persons, persons with disabilities, pregnant women, newborns, work-injury victims and the poor and the vulnerable • Proportion of population living in households with access to basic services • Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population) • Proportion of youth and adults with information and communications technology (ICT) skills, by type of skill • Parity indices (female/male, rural/urban, bottom/top wealth quintile and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated • Whether or not legal frameworks are in place to promote, enforce and monitor equality and non-discrimination on the basis of sex • Proportion of population using safely managed drinking water services • Proportion of population with access to electricity • Proportion of population with primary reliance on clean fuels and technology • Proportion of informal employment in non-agriculture employment, by sex • Average hourly earnings of female and male employees, by occupation, age and persons with disabilities • Unemployment rate, by sex, age and persons with disabilities • Frequency rates of fatal and non-fatal occupational injuries, by sex and migrant status • Level of national compliance with labour rights (freedom of association and collective bargaining) based on International Labour Organization (ILO) textual sources and national legislation, by sex and migrant status • Proportion of people living below 50 per cent of median income, by sex, age and persons with disabilities	        

Relevant Sustainable Development Goal (SDG) indicators	SDGs
• Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law • Labour share of GDP, comprising wages and social protection transfers • Proportion of population that has convenient access to public transport, by sex, age, and persons with disabilities • Proportion of cities with a direct participation structure of civil society in urban planning and management that operate regularly and democratically	

TOOL #31. EDUCATION AND TRAINING, CULTURE AND YOUTH (ETCY)

1. INTRODUCTION

Investing in a high level of education and training, culture, and youth has positive impact on individuals (e.g. higher chance to be employed) and the economy/society as a whole (higher productivity, innovation capacity, competitiveness, social cohesion, and sustainable growth). Education and training fuels employability, productivity and adaptability, and improves the ability of an economy to generate and absorb innovation. It can also foster important values such as democratic engagement, sense of citizenship, tolerance, solidarity, and European belonging. Any measure that helps improving the efficiency and performance as well as the inclusiveness of education and training systems (expressed, for example, as higher skills, better qualifications or a lower share of school drop-outs including for disadvantaged groups of learners) helps Europe to sustain economic growth and social benefits. EU policies concerning e.g. trade, foreign investment, and migration, might also impact educational outcome in third countries.

Box 1. Relevant provisions of the Treaties

- Article 6 TFEU states that the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, among others in (c) culture; (e) education, vocational training, youth, and sport.
- Article 9 TFEU obliges the EU to consider the requirements linked to a **high level of education and training** in defining and implementing its policies and activities.
- Article 3.3 TEU invites EU to “respect its rich **cultural diversity** and ensure that Europe’s cultural heritage is safeguarded and enhanced” and Art 167.4 TFEU invites EU to “take **cultural aspects** into account in its action under other provisions of the Treaties”
- Article 165 TFEU stipulates that the Union shall contribute to the development of quality education by encouraging cooperation between Member States and, if necessary, by supporting and supplementing their action, while fully respecting the responsibility of the Member States for the content of teaching and the organisation of education systems and their cultural and linguistic diversity.
- Article 166 TFEU concerns the EU implementing a vocational training policy that shall support and supplement the action of Member States while fully respecting the responsibility of the Member States for the content and organisation of vocational training.

2. ARE IMPACTS ON ETCY POTENTIALLY SIGNIFICANT?

To identify potential impacts on ETCY a few key questions should be asked regarding each area. These can be interlinked and can be of different magnitude, one-off or recurrent in relation to the transitory or permanent effects that take place. In addition, a distinction between direct and indirect impacts should be made.

2.1. Education and training

- *Is the initiative/policy designed to contribute to the achievement of a high level of education and training? Is there any impact on education and training systems, their financing, performance, or efficiency? Is there an impact on institutional autonomy, academic freedom, or integrity?*
- *Does the initiative contribute to mobility of students, learners and teachers, and/or promote deeper cooperation among educational institutions?*
- *Does the option contribute to implementing lifelong learning?*
- *Does the initiative have an impact on access to education and training and equitable outcomes (from early childhood to adult learning) especially for learners from disadvantaged backgrounds or learners from remote and rural areas with inadequate access to digital infrastructure and insufficient access to quality service (including quality education institutions)?*
- *Is the inclusiveness and accessibility for learners with disabilities considered?*
- *Does the option contribute to preventing or remediating early school leaving?*
- *Does the option have an impact on educational outcomes especially for learners from disadvantaged backgrounds?*
- *Does the initiative contribute to social inclusion or non-discrimination in education and training?*
- *Does the initiative promote gender equality in education and training?*
- *Does the option promote educational institutions' service to society? Does it encourage cooperation with business, local governments, and civil society?*
- *Does the initiative contribute to enhancing civic and intercultural competences?*
- *Does the option have an impact on the need for individuals (or groups of individuals) to upgrade their level of knowledge, skills and competences, as well as their ability to sustain employment, growth and innovation, and if so, does the option envisage measures to address those needs?*
- *Does the option affect the access to skills formation? Does it impact on the skills used by individuals (e.g. by increasing the relevance for labour market needs, by improving the visibility and comparability of skills and qualifications, etc.)?*
- *Is the quality of teaching both in formal and informal learning settings affected by a policy option?*

The initiatives that enhance the accessibility of people to acquire key competences can improve access to good jobs and fuller participation in society. Initiatives that affect the quality and relevance of skills formation (e.g. vocational training) facilitate the transition to employment and maintain and update the skills of the workforce. Initiatives that can impact on validation and recognition of skills and qualifications, increase the use of acquired skills and foster labour market mobility both internally and abroad. Initiatives that promote learning mobility, cooperation of European education institutions and their role in their local communities, may contribute to high quality learning, innovation capacity of education, and development of democratic societies.

Impacts on different education and training sectors need to be considered. These include pre-school, primary/secondary school, vocational education and training (VET), higher education, adult learning, non-formal learning, e.g. through youth work. These impacts need to be considered in the light of different societal groups/age cohorts, regions, and sectors.

Screening should not be restricted to a particular societal group or age cohort but should comprise (a) societal groups with different background and living conditions, such as minority racial or ethnic background, or migrant background, (b) learners with different abilities, (c) different regions/countries and (d) different economic sectors.

2.2. Culture

– *Is there an impact on cultural diversity?*

The 2005 UNESCO convention on the protection and promotion of cultural diversity, to which the EU is a party, defines cultural diversity as the manifold ways in which the cultures of groups and societies find expression. These expressions are passed on within and among groups and societies.

– *Is there an impact on cultural heritage?*

The Treaties require the EU to safeguard and enhance Europe's cultural heritage and to "contribute to the flowering of the cultures of Member States, while respecting their national and regional diversity and at the same time bringing common cultural heritage to the fore". The Treaty also recognises the specificity of heritage for preserving cultural diversity and the need to ensure its protection in the Single Market. Cultural heritage is both tangible (buildings, sites, etc.) and intangible (traditions, music etc.), and it includes landscapes. It may for example be affected by EU initiatives on environmental protection, transport, or energy efficiency (impact on historic buildings, natural landscapes). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

– *Are individuals' access to and participation in cultural and creative activities affected? Is accessibility for persons with disabilities considered?*

Participation in culture is a fundamental right⁴⁰⁰. It usually covers both attendance (passive) and participation (active) in cultural activities, and is measured through quantitative and qualitative surveys, including household expenditure surveys, to gauge the economic consumption of culture.

– *Is there an impact on cultural and creative sectors?*

Possible impacts on the cultural and creative sectors could, among others, include legal aspects (e.g. copyright, intellectual property rights), financial (e.g. state aid, VAT), economic and social aspects (e.g. employment).

2.3. Youth

– *How to reach out to young people in consultations and decision-making?*

⁴⁰⁰ See Art. 27 of [Universal Declaration of Human Rights](#)

As per the TFEU, young people should be encouraged to participate in democratic life⁴⁰¹.

Young people often stand apart when it comes to their civic and democratic engagement; they tend to be under-represented in traditional forms of representation and decision-making, but they are active and have opinions frequently expressed in various ways, including loose movements and social media actions.

The Commission supports a [platform of youth organisations](#) and upholds an [EU Youth Dialogue](#) to facilitate the mobilisation and targeting of young people.

- *Is there an impact on social inclusion and integration of youth? Are the needs of young people from disadvantaged backgrounds and of young persons with disabilities duly considered?*

Provided that youth can be particularly prone to certain measures during their transitional phase to adulthood and can often face risk of exclusion (for example youth in rural and remote areas with inadequate digital infrastructure is prone to higher risk of social exclusion than their cohorts living in urban/cities areas), insufficient socio-economic integration and negative impact on well-being, analysis of how these can affect young people is necessary to avoid possible negative outcomes.

- *Is there an impact on learning opportunities in respect to youth?*

Young people can potentially benefit from learning opportunities that exist outside school or higher education, for instance through leisure time activities, youth clubs or volunteering.

- *Is there an impact on labour market, continuity of transition between education and professional performance in respect to youth?*

Aspects such as effects on activation of young people in terms of employment and self-employment, period between leaving education and finding a first job, transition from internships to work contract, as well as potential impacts on population of young people not in employment, education and training (NEET), and vulnerable young people should be considered in this part.

Box 2. Policies known to have impacts on ECTY
Education and training
– Changes in expenditure scheme – e.g. reallocation of spending from higher to lower levels of education, expanding coverage in specific regions, low-income areas. – Changing financing scheme – e.g. introduction of school fees, switching to/from community to state financing providing incentives for individuals or enterprises to get involved in education and training. – Systemic changes – e.g. changing governance structures in education and training to involve social partners in organisation, delivery and financing of learning; introducing reforms in schooling material, altering school systems, targeting specific studying programmes (increasing numbers of students on vocational education and training)

⁴⁰¹ Under Article 165 TFEU, the EU shall encourage youth participation in democratic life in Europe. It could be for example, participation in social and civic activities and organisations, volunteering, opportunities to express opinions in decision-making processes

(VET), reducing numbers of students of particular specialisation at universities). – Policies influencing fiscal stability, as they can limit public resources and investments in education. – Policies related to the digital and green transitions, innovation, employment, social inclusion, industrial policy, cohesion, and sustainable development. – Policies reforming digital markets, economy, and society – the potential of ICT to enhance the way people and institutions teach and learn⁴⁰². – Social policies and inclusion can help disadvantaged families (both younger and older age groups) participate or not in education, policies on maternity/parental leave can influence decisions to put children in crèche as well as gender policies. – Migration and border control policies might prevent student exchanges and/or influence knowledge, skills, and competence shortages.
Culture – Policies related to digital transformation, innovation, employment, education, social inclusion, cohesion, and sustainable development. – Policies impacting cultural and creative sectors, such as EU laws on intellectual property rights, VAT or state aid. – Policies impacting cultural heritage – for example the Directive on the return of cultural objects unlawfully removed from the territory of a Member State (recast), legislation on energy efficiency (impact on historic buildings), legislation on green deal (impact on cultural and natural heritage).
Youth – Policies impacting youth participation in democratic life and civic engagement in solidarity. – Policies impacting education and learning. – Policies impacting labour market. – Policies impacting health and well-being. – Policies impact youth inclusion and fight against poverty.

3. HOW TO ASSESS IMPACTS ON ECTY?

The following section aims at describing how to measure impacts that are significant in the areas listed above. The suggestions provided outline the most widely used methods of assessment including illustrative examples of possible impacts in some areas. Some of the indicators may overlap.

3.1. Education and training

European education and training systems are monitored through qualitative and quantitative indicators and targets, as adopted in the Resolution on a strategic framework for European

⁴⁰² See Tool #28 for guidelines on digital-ready policymaking.

cooperation in education and training towards the European Education Area and beyond (2021-2030)⁴⁰³.

Assessing impacts on education and training must consider different components:

– *The specificity of national education and training systems*

Evidence suggests that significant differences persist in the effectiveness of national education and training systems (young adults with nominally equivalent levels of educational attainment from different Member States scoring with considerable differences in competence tests).

– *The effects of expenditure in education – investing in skills, qualification, and new technologies*

Investing in people through providing better education and skills will raise productivity, employability and will generate economic growth, social benefits, and prosperity in general.

Statistics on these can be found at different levels of aggregation (national, regional, level of education, private/public), providing insight on expenditure levels both per student and overall. It is important to measure in monetary terms how the various stages of learning processes are supported and how they interact with investment in skills. In addition, it is useful to gather statistics on investing in new technologies serving learning processes paving the way for smart innovation.

– *Levels of literacy, numeracy, and digital numeracy*

Levels of literacy, numeracy and digital numeracy significantly affect a population's potential to contribute to a developed society, providing a basis for economic well-being and equity. The basic skills target is used to monitor this.

– *Level of knowledge, skills, and competences*

Increasing the level of knowledge, skills and competences of individuals has a great potential to create social value, to drive innovation and entrepreneurship and to reinforce Europe's strong social foundations. Demand and supply for skills and competences are ultimately guided by demographics, labour force quality and participation in education and training. Educational outcomes tend to converge towards high levels of skills and competences in general, and on science, technology, engineering, and mathematics (STEM) fields in particular. The digital transformation of the economy, the changes in work organisation and the dynamics in sectoral specialisation create new demands for skills leading to skills gaps and mismatches with the needs of the labour market.

Information on levels of knowledge, skills and competencies can serve as essential guidance for analysis of potential impacts⁴⁰⁴. Equally important is to assess if an initiative has an impact on the visibility and comparability of skills and qualifications (e.g. validation/recognition) and therefore on the opportunities for individuals to use the acquired skills in the labour market (either in the home country or abroad).

– *Level of progress on early childhood education and care*

⁴⁰³ <https://ec.europa.eu/eurostat/web/education-and-training/policy-context>: on Basic skills, Digital skills, early childhood education and care, early leavers from education and training, tertiary educational attainment, vocational education, and adult learning.

⁴⁰⁴ See also https://ec.europa.eu/education/policies/school/key-competences-and-basic-skills_en

Early childhood education and care refers to teaching and focusing on young children as regards the care aspect and development of social skills in the period before starting compulsory primary education. EU guidance is available to monitor quality in the quality framework on ECEC⁴⁰⁵.

– *Tertiary education attainment*

A high level of tertiary education attainment is viewed as one of key ways to promote a well-developed society, fostering growth and innovation, despite the fact that there is some evidence of skills mismatches in terms of those with a tertiary education being employed on positions requiring lower qualifications.

– *Adult participation in lifelong learning*

To foster coherence of learning processes it is necessary to support lifelong learning as a continuum of human development. Furthermore, higher levels of participation in lifelong learning impacts positively on work performance.

– *Teachers and educators*

Quality of teaching is essentially influenced by preparedness of teachers and the attractiveness of the teaching profession. Here, important areas are improving entry routes to, and the quality and relevance of, initial teacher training; ensuring attractiveness of the teaching profession and diverse career pathways; improving teachers' access to high-quality continuing professional development and empowering teachers to practice innovative and inclusive teaching.

– *Early school leavers statistics*

High levels of early school leavers adversely affect the transition from school to work, with unemployment levels among early leavers being considerably higher than average.

– *Inclusiveness of education*

To foster equality among students and to facilitate access and accessibility to education and training for every individual, it is necessary that the different policy measures, relevant for education, all foster social inclusion. It is important to consider how individualised support, scholarships and contributions are provided for particular groups of students and how services are provided for students with disadvantaged background and students living in the areas that face disadvantages in terms of accessing quality education, flexible educational pathways, recognition of prior learning and short learning options. Different aspects like gender equality, migrant, or minority ethnic or racial background, disability, should be considered. The provision of scholarships and access for citizens from developing countries to education and training in the EU, in particular European universities can create positive impact on sustainable growth in third countries.

Data on students' social situation is provided by the Erasmus+ funded Eurostudent survey. Eurostat collects data on gender aspects.

– *Statistics on recent graduates' participation in the labour market*

Better transition of young adults into labour market may be facilitated in several different ways, including by provision of high-quality traineeships, apprenticeships and dual

⁴⁰⁵ https://ec.europa.eu/education/policies/early-childhood-education-and-care_en

vocational education and training systems. Activating learning environment, work-based learning, and cooperation of education institutions with the local community and with employers may all foster labour market transition.

Data may be found in graduate tracking surveys⁴⁰⁶, and in European data collections like the Labour Force Survey.

3.2. Culture

When carrying out an assessment of impacts on culture, and in accordance with the list above, the following aspects should be considered:

– *Cultural diversity*

EU initiatives which may result in reducing consumer choice in cultural goods can, for example, have an impact on cultural diversity, e.g. merger between large music and internet companies or of large audio-visual companies could reduce consumer choice in music or film.

– *Cultural heritage*

Cultural heritage is both tangible (buildings, sites etc.) and intangible (traditions, music etc.), and it includes landscapes. It may, for example, be affected by EU initiatives on environmental protection or energy efficiency (impact on historical buildings). Similarly, state aid rules for agriculture and forestry may affect funding for rural heritage.

– *Participation in culture*

Economic policies can affect cultural activities. As an example, new EU initiative on VAT or on crowdfunding can have an impact on the way cultural sector is funded by public or private means; broadband availability affects access to culture (e.g. online collections/event tickets); or reduced funds for cultural events/sites raises prices, or causes closure⁴⁰⁷. Including cultural actors from third countries and facilitating global cultural exchange can have positive impact on the diversity of artistic expressions.

– *Cultural dimension of sustainable development*

The implementation of the [2030 Agenda on sustainable development](#) and the achievement of the SDGs directly concern the culture sector (impact on cultural activities and cultural offers) and cultural policies and actions contribute in many ways to achieving the SDGs (most of the 17 SDGs).

3.3. Youth

Young people⁴⁰⁸ are particularly prone to certain measures, which might affect their transition from dependent childhood to adulthood in terms of social and economic integration, social inclusion, well-being, and labour market. Impacts on employment, social conditions and education of this group can often be of higher magnitude compared to other

⁴⁰⁶ <https://op.europa.eu/en/publication-detail/-/publication/c5669b4b-6adb-11eb-aeb5-01aa75ed71a1>

⁴⁰⁷ [Eurobarometer on Cultural access and participation](#)

⁴⁰⁸ Definitions of young people vary; the EU Youth Strategy does not operate with an official definition for the specific period in life when a person is considered to be 'young'. This definition varies from one Member State to another and the age to consider differs with time and socio-economic development. Age range 15-29 is often selected for statistical purposes at EU level.

cohorts thus this aspect should be considered when measuring such impacts. For a specific example on assessment of impacts, see Box 3.

Young people's attitudes and actions regarding democratic engagement and expressing their views tend to differ from other generations. Measures can have an impact on young people's ability and interest to participate in social/civic activities, such as volunteering, or to get involved in decision-making that directly affects them. In case young people's views are sought, a targeted and focused consultation through established youth channels could be undertaken.

As a part of the everyday life of the majority of European youth, formal education and training, non-formal learning (courses outside school, etc.) or informal learning by engaging in meaningful activities (e.g. solidarity activities, voluntary work) play an important role in development of young adults. Thus, for those policy options which affect aspects of educational activities, it will be necessary to estimate the impacts of these effects on youth development. For detailed list of corresponding impacts on education and training, please see above.

Box 3. Example of cost-benefit assessment in the Youth Guarantee approach

- The [Youth Guarantee](#) approach is tackling youth unemployment with assuring that all young people under 30 get a good quality and concrete offer (e.g. job, apprenticeship, traineeship) within 4 months from either leaving formal education or becoming unemployed⁴⁰⁹.
- See [The European Pillar of Social Rights Action Plan \(europa.eu\)](#)
- In the [study](#), a cost-benefit analysis is included with estimates on what are current costs of leaving young people not in employment, education or training and what would the costs of implementation of the Youth Guarantee.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

The basic data and information sources that can help in assessing the policy impacts in areas of education, culture, and youth (ECY) are outlined below. Background materials and guidance can be found on internal [DG EAC web pages](#) or via the EU Youth Coordinator (EU-YOUTH-COORDINATOR@ec.europa.eu).

4.1. Education and training

The core quantitative information and data required are described and further annually assessed in the [European Education and Training Monitor](#). This annual report illustrates, in a succinct document, the evolution of education and training systems across Europe. It considers the European Education area targets and indicators, as well as recent studies and policy developments.

⁴⁰⁹ As part of the new headline target on employment, the social pillar action plan sets the following target: 'decrease the rate of young people neither in employment, nor in education or training (NEETs) aged 15-29 from 12.6% (2019) to 9%, namely by improving their employment prospects.' See [The European Pillar of Social Rights Action Plan \(europa.eu\)](#)

Additional useful sources of information include:

- **Eurostat** – data on participation rates, staff, financing, investment, training, ICT related to education, educational attainment, exposure to work-based learning, participation in adult learning, continuing vocational training, etc. ([UNESCO OECD Eurostat \(UOE\) joint data collection](#), [Labour Force Survey](#), [Adult Education Survey](#), [Continuing Vocational Training Survey](#)); the indicators to monitor the **Sustainable Development Goals**, more specifically (but not exclusively) the indicators to measure SDG 4 (Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all)⁴¹⁰.
- **DG EAC - Erasmus+** – data on mobile vocational education and training learners;
- **OECD** – information on teachers and their professional development (TALIS), annual study on students' performance (PISA), assessment of adults' skills (PIAAC);
- **EURYDICE** – data and analyses of the European education landscape, national descriptions, comparative thematic analyses, evidence-based reviews on specific issues, quantitative indicators and secondary analyses, trends and reforms;
- **CEDEFOP** European Centre for the Development of Vocational Training (EU decentralised agency) – indicators and annual studies on vocational education and training, thematic secondary comparative analyses and skills forecasts;
- **CRELL** (JRC) - [Centre for Research on Education and Lifelong Learning](#) – secondary comparative analyses on education and lifelong learning using the results from large scale surveys, conceptual work on the definition of indicators and prospective analyses;
- [JRC Human capital and employment](#) – develop scientific evidence to support policy making in the areas of learning and education; quantitative and qualitative methods, socio-economic impact assessment, behavioural insights and data analytics;
- **EENEE** – analysis and reports by network of experts in the field of economy of education and training;
- **NESET** – analysis and reports by network of experts in the field of equity in education and training.
- Other interesting sources of information are the UNESCO Global Education Monitor (GEM) Report, EASNIE (European Agency for Special Needs and Inclusive Education) as regards learners with disabilities, ETF (European Training Foundation).

4.2. Culture

- Cultural diversity: [2005 UNESCO convention on the protection and promotion of the diversity of cultural expressions](#);
- Participation in culture: [2013 Eurobarometer on cultural access and participation](#); Household expenditure surveys;
- Public policy in the area of culture, including funding: [2013 EENC report on trends in public funding for culture](#);

⁴¹⁰ [SDG 4 - Quality education - Statistics Explained \(europa.eu\)](#)

4.3. Youth

- The EU Youth Strategy provides common objectives and a detailed work plan for Commission and Member states in the field of youth. It also includes the eleven European youth goals that have been designed by young people in one of the latest cycles of the EU Youth Dialogue. These goals identify cross-sectoral areas that affect young people's lives and point out challenges, and the Council has agreed that the EU Youth Strategy should contribute to realising this vision of young people.
- The EU Dashboard of Youth Indicators provides some 41 indicators across different sectors that provide a comprehensive picture to illustrate the situation of young people. It is being updated in 2020 with the help of an expert group, which is also developing policy indicators. The core data on young people can be accessed via Eurostat youth dataset. The Youth Guarantee contains an indicator framework on youth employment⁴¹¹.
- The Youth Wiki is an online encyclopaedia in the area of national youth policies in Europe. The platform is a comprehensive database of national structures, policies and actions supporting young people.
- EU Youth Reports every three years describe relevant policy measures taken in support of young people and an analytical overview of the situation of young people, at EU level and in Member States⁴¹².
- Additional sources of information include reports from Expert groups set up by the Council of Youth Ministers on the contribution of non-formal learning and youth work to youth development:
 - [Expert group on the contribution of youth work in the context of migration and refugee matters](#)
 - [Expert group on the contribution of youth work to preventing marginalisation and violent radicalisation](#)
 - [Expert group on developing digital youth work](#)
 - [Expert group on the 'contribution of youth work and non-formal and informal learning to address the challenges young people are facing, in particular the transition from education to employment'](#)
- The study on the value of youth work depicts the contribution of youth work in different fields of action relevant to young people.
- Flash Eurobarometer surveys regularly address the opinions and engagement of young people:
 - 478 “How we build a stronger more united Europe: the views of young people” (2019);
 - 455 “European Youth” (2017);
 - 395 “Youth in Europe” (2014);

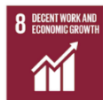
⁴¹¹ <https://ec.europa.eu/social/main.jsp?catId=1143&langId=en#YGIF>

⁴¹² https://europa.eu/youth/strategy/library_en

- 375 “European Youth: Participation in Democratic Life” (2013);
- 319 “Youth on the Move” (2011).

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Early leavers from education and training • Tertiary educational attainment • Participation in early childhood education • Underachievement in reading, maths and science • Employment rate of recent graduates • Adult participation in learning • Young people neither in employment nor in education and training • People at risk of income poverty after social transfers <i>UN indicators:</i> • Proportion of children and young people (a) in grades 2/3; (b) at the end of primary; and (c) at the end of lower secondary achieving at least a minimum proficiency level in (i) reading and (ii) mathematics, by sex • Proportion of children under 5 years of age who are developmentally on track in health, learning and psychosocial well-being, by sex • Participation rate in organized learning (one year before the official primary entry age), by sex • Participation rate of youth and adults in formal and non-formal education and training in the previous 12 months, by sex • Proportion of youth and adults with information and communications technology (ICT) skills, by type of skill • Parity indices (female/male, rural/urban, bottom/top wealth quintile and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated • Proportion of population in a given age group achieving at least a fixed level of proficiency in functional (a) literacy and (b) numeracy skills, by sex • Extent to which (i) global citizenship education and (ii) education for sustainable development, including gender equality and human rights, are mainstreamed at all levels in (a) national education policies; (b) curricula; (c) teacher education; and (d) student assessment • Proportion of schools with access to (a) electricity; (b) the Internet for pedagogical purposes; (c) computers for pedagogical purposes; (d) adapted infrastructure and materials for students with disabilities; (e) basic drinking water; (f) single-sex basic sanitation facilities; and (g) basic handwashing facilities (as per the WASH indicator definitions) • Volume of official development assistance flows for scholarships by sector and type of study • Proportion of teachers in: (a) pre-primary; (b) primary; (c) lower secondary; and (d) upper secondary education who have received at least the minimum organized teacher training (e.g. pedagogical training) pre-service or in-service required for teaching at the relevant level in a given country • Proportion of youth (aged 15–24 years) not in education, employment or training NEET • Proportion of people living below 50 per cent of median income, by sex, age and persons with disabilities • Total expenditure (public and private) per capita spent on the preservation, protection and	     

Relevant SDG indicators	SDGs
conservation of all cultural and natural heritage, by type of heritage (cultural, natural, mixed and World Heritage Centre designation), level of government (national, regional and local/municipal), type of expenditure (operating expenditure/investment) and type of private funding (donations in kind, private non-profit sector and sponsorship) • Proportions of positions in national and local institutions, including (a) the legislatures; (b) the public service; and (c) the judiciary, compared to national distributions, by sex, age, persons with disabilities and population groups • Proportion of population who believe decision-making is inclusive and responsive, by sex, age, disability and population group	

TOOL #32. HEALTH IMPACTS

1. INTRODUCTION

Human health is a fundamental value and an investment in economic growth and social cohesion. Improving people's health is improving their quality of life. Healthy people are less likely to be socially excluded and much more easily employable. A healthy workforce costs less and is more productive, and reduces the burden on healthcare services and health systems. Resilient and efficient health systems contribute to the optimisation of health spending, public and private. Healthcare services and health industries (pharmaceuticals, medical devices, and health research) are a key knowledge-intensive economic sector that enables to maintain and improve public health and creates jobs. The Treaty (Article 168 TFEU) states that a *"high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"*, which also relates to the approximation of laws in the single market (Article 114 (3) TFEU). Furthermore, the Charter of Fundamental Rights (art. 35) establishes that *"everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices."*

This tool is focussing on human health. When you need to consider impacts on animal welfare you can contact SANTE-CONSULT-G5@ec.europa.eu for advice.

2. TYPES OF HEALTH IMPACTS AND THEIR SIGNIFICANCE

Many EU policies have the potential to result in health impacts. Such impacts must be assessed during the policymaking process.

Health impacts are gains or losses that need to be identified⁴¹³ early in the policy making process. Health gains are always intended for policies with health as an objective (i.e. health and food safety, occupational health and safety) while losses are often unintended and might be the result of initiatives where health is not an objective or where the intervention needs to strike a balance between conflicting or different interests (e.g. transport, trade etc.). Unintended health impacts may not always be anticipated in an impact assessment but should be analysed in an evaluation.

Health gains consist mostly in the improvement of the health status of individuals or populations⁴¹⁴, or in the improvement of national health systems' performance and sustainability (including their resilience during health crises).

Health losses may be generated by a policy initiative for some groups of people (e.g. limited access to healthcare for elderly people in case of digitalisation of services, difficulty in access to cross-border care by telemedicine in case of limited reimbursement policies). Health losses are generally unintended or the result of a trade-off in the policy design.

Health gains and losses can be direct or indirect. A policy initiative can generate direct health gains such as increased life expectancy or reduction of prevalence/incidence of a disease in specific or wider population groups. For example, the [Asbestos at Work Directive](#) or the [Tobacco Products Directive](#). The first protects workers from the risks related to asbestos exposure at work that may cause serious diseases while the second governs the

⁴¹³ Tool #18 (*Identification of impacts*)

⁴¹⁴ Other examples: health/quality of life, reduction of prevalence/incidence of disease, improved life expectancy, decrease of mortality and morbidity, etc.

manufacture, display, and sale of tobacco and related products protecting consumers across the EU from tobacco use which is a leading health risk factor. An indirect health gain is, for example, a decrease in morbidity and mortality generated by the modification of the socio-economic⁴¹⁵ and environmental determinants of health. Typically, reducing energy poverty in underheated dwellings could reduce mortality amongst people from vulnerable groups during winter, improvements in road safety reduce the number of accidents and the number of people injured in road accidents. Improving air quality can affect our health with both long- and short-term effects, given that reducing urban outdoor air pollution decreases the risk of acute (e.g. pneumonia) and chronic (e.g. lung cancer) respiratory disease as well as cardiovascular disease.

Direct health losses to people such as loss of work capacity/increase in disability may be generated by policies not ensuring a sufficient level of health protection, while indirect health losses may be generated by policies such as subsidising the cultivation of tobacco or governing the use of nanomaterials in products (due to existing risks and emerging hazards). Losses to health systems may be determined directly or indirectly by several policies not primarily addressed at the healthcare systems, which nonetheless influence the rules that relate to the provision and quality of healthcare services by impacting on their staff, equipment, communication, and infrastructure. For example, policy on the protection of personal data which may prohibit under certain conditions the processing of specific categories of data in some instances.

For all identified potential health impacts it should be examined if **specific population groups** (for instance risk groups such as children, persons with disabilities, pregnant women, older people, LGBTIQ people, people with a minority ethnic or racial background, low-income groups) or specific geographical areas are affected differently and disproportionately by the intervention, resulting in increased (or reduced) inequalities in health status⁴¹⁶.

The significance of health impacts depends on the policy initiative, and it is a case-by-case assessment made at an early stage of the design of an intervention taking into account all relevant factors⁴¹⁷. In any case, the outcomes of the stakeholder consultation should contribute to the identification of significant impacts. The specific expertise of health stakeholders may prove valuable in identifying and properly assessing those impacts.

3. HOW TO APPROACH THE ASSESSMENT OF HEALTH IMPACTS?

When designing EU initiatives, potential health impacts should be identified together with other potential socio-economic impacts. Before establishing whether those impacts are significant or not, the *health relevance* of the initiative as well as its interplay with health policies should be assessed. The *appraisal* of those impacts should allow for preparatory work in view of the selection of significant impacts and contribute to such selection, especially where the health relevance is uncertain, thus complementing the model in Tool #18 (*Identification of impacts*).

The depth of the analysis should be proportionate and consistent with the importance/type of initiative and the nature and magnitude of the expected impacts (e.g. legislative/non-legislative, REFIT initiative, implementing measures, etc.). This relates not only to the

⁴¹⁵ [2010 World Health Organization: A conceptual framework for action on the social determinants of health Discussion Paper Series on Social Determinants of Health, no.2 ISBN: 978 92 4 150085 2](#)

⁴¹⁶ Linked to this analysis is also the dimension of discrimination (e.g. in the access to healthcare) on grounds of e.g. racial, ethnic or social, religion, or belief, disability, age or sexual orientation.

⁴¹⁷ See the Tool #18 (Identification of impacts)

impact assessment process⁴¹⁸ but is also relevant during ex-post evaluations, irrespective of whether health impacts had been identified when the initiatives was adopted.

3.1. Establish the health relevance of a policy initiative

To decide if it is relevant or not to assess health impacts, it is to be considered:

- (a) how the initiative will impact (or has impacted) **health factors**⁴¹⁹ **and/or factors influencing the health systems capacity to deliver** and remain sustainable;
- (b) **how** these health factors or influencing factors, in turn, will **affect or have affected people's health and/or the performance of health systems**.

To accomplish this step evidence and knowledge on health determinants, their distribution in the population and relationship with health impacts, as well as health systems factors is required. The following checklist may facilitate the screening.

Box 1. Questions to help establish the health relevance of an initiative

1. **Does the policy affect the Union's health objectives, as codified in the Treaty (Article 168 TFEU) and in relevant secondary legislation** (e.g. on [cross-border health threats](#), [cross-border health care](#), [tobacco control](#), [pharmaceuticals](#) and [medical devices](#), or [substances of human origin](#))?

Major policies and initiatives with cross-sectoral impact (e.g.: agricultural, social, education, marketing/TV/digital/social media, taxation, or regional development) should, by default, be checked for their health impact.

2. **Does the policy otherwise affect factors influencing people's health or the performance of health systems?**

The analysis should be directed at identifying the possible effects of the initiative on [health determinants](#) such as alcohol, tobacco, physical activity, nutrition (e.g. alcohol consumption is influenced by taxation or advertising/information placed on the label), on important health factors (e.g. air pollution or chemicals), or on the performance of health systems (e.g. new waste disposal rules in hospitals, university curricula for healthcare workers). [Social determinants of health](#)⁴²⁰, namely poverty, and [commercial determinants of health](#)⁴²¹ need also to be taken into consideration.

3. **Does the policy affect the population as a whole or some population groups?**

The whole population; women; men; children; adults; older people; chronically ill; people with special needs people (e.g. physical or mental impairment, allergy; people with an addiction); unemployed; immigrants; refugees; single-parents; people with low income; homeless people; LGBTIQ; people with a minority ethnic or racial background; other groups.

⁴¹⁸ See Tool #12 (How to apply proportionality to impact assessments)

⁴¹⁹ European Health Indicators https://ec.europa.eu/health/social_determinants/indicators_en

⁴²⁰ Income and social protection; education; unemployment and job insecurity; working life conditions; food insecurity; housing, basic amenities, and the environment; early childhood development; social inclusion and non-discrimination; structural conflict; access to affordable health services of decent quality. https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1

⁴²¹ <https://www.who.int/bulletin/volumes/97/4/18-220087/en/> or [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(16\)30217-0/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(16)30217-0/fulltext)

3.2. Selection of significant impacts

Once the potential health relevance of the initiative is established, **significant impacts should be selected**. A series of questions (Box 2) might facilitate this work, which should **establish the relevance of the health impacts within the intervention logic, the absolute expected magnitude of those impacts, their relative size for specific stakeholders, their importance for the Union's objectives and policies**.

Box 2. Questions to help identify significant health-related gains and losses

Direct health impacts

- a) Does the option/initiative directly affect the health and safety of individuals/populations, including life expectancy, mortality, and morbidity?
- b) Does the option/initiative increase or decrease the likelihood of health risks due to substances or living organisms harmful to the natural environment?
- c) Does the option/initiative affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs?
- d) Are there specific effects on particular risk groups of people (determined by age, gender, disability, social group, mobility, region, etc.)?
- e) Does the option/initiative affect the quality and/or access to health services and/or the financing and organisation of health systems?
- f) Does the option/initiative affect the cross-border provision of services, referrals across-borders and cooperation in border regions?
- g) Does the option/initiative reduce health risks to people/patients (or create new ones) or does it affect their safety? For instance, by addressing the exposure to chemical substances (e.g. chemicals, pesticides in food, contaminants, etc.) or other factors (e.g. radiation, noise etc.) bearing an influence on the natural environment and the human body (e.g. air, soil and water quality, noise, unsafe consumer products).
- h) Does the option/initiative affect the effectiveness and sustainability of healthcare and long-term care services?
- i) Does the option/initiative affect the access of certain populations (including vulnerable ones) to medicinal products and information, health, or long-term care services, in particular by altering their availability, quality, affordability and cost?

Indirect health impacts

- a) Does the option affect the socio-economic and environmental health determinants (working environment, income, education and training, occupation, housing, nutrition, energy consumption, transport, etc.)?
- b) Does the option affect or the policy initiative has affected the factors influencing health systems capacity to deliver efficiently and effectively and remain sustainable?
- c) Does it affect health due to changes in the amount of noise, air pollution, reduced water or soil quality?
- d) Will it affect health due to changes in energy use and/or waste disposal?
- e) Does the option indirectly target population's lifestyle-related determinants of health such as diet, physical activity, use of tobacco, alcohol, or drugs?

If the answer is YES for any of the above, for those answer also the sub-questions:

- a) To what extent?
- b) Which groups of individuals are affected? Single population groups with same characteristics/living in a specific area etc.?

- c) What is the group's size?
- d) Are all social groups affected or only some of them?

The questions above should be asked in relation to the various steps of the intervention logic: consider all key steps in the intervention that need to take place to achieve the objectives of the policy and consider how each of the steps may affect health objectives. Consider absolute and relative size of impacts (some impacts may be small in absolute terms, but they may be particularly significant for some specific group).

3.3. Assessment of impacts on people's health

If health impacts qualify as significant, they need to be assessed⁴²². The assessment of health impacts should always *start from the qualitative dimension*, the core of which should be the discussion about the causal links involved in the impacts identified (direct and indirect). Draw information from relevant studies (in particular, peer-reviewed literature and previous Commission studies, impact assessments and evaluations) on which the analysis is based. Other relevant elements are the identification of the populations most affected, the rough size of those populations and the extent to which they are affected, the interplay among potential impacts as well as possible mitigation measures.

If sufficient relevant and robust data is available, these arguments should be supplemented by a quantitative dimension. The quantification of impacts should proceed from the most objective and robust measures to those that are more speculative and involve more assumptions. Such quantified impacts may be of many sorts, may be measured in different units, and may not be directly comparable among themselves. Special care should be taken to spell out uncertainties and caveats, whether these concern the reliability of sources, the assumptions made to bridge gaps in the existing data and/or analysis, or the passage from hard data to statistics and probabilities. Where quantifications are uncertain, they should be accompanied by a sensitivity analysis to make clear the range of possible values and to which parameters the analysis is most sensitive.

If proportionate, quantification in terms of concrete outputs (for example, not only direct indicators such as interventions performed or deaths avoided, but also indirect indicators such as absences from work, air pollution levels, etc.) *can be complemented by the monetisation of the health outcomes associated with them.* Several methodologies that can be used for this are reviewed below in section 3.

Monetisation needs to build on the causal analysis provided in the qualitative assessment and the primary data provided in the first step of quantification, but cannot be a substitute for them. Where appropriate, monetisation can be used to evaluate and compare different health outcomes (though even this may raise ethical issues, for example, if comparing outcomes which do not affect all population segments uniformly). Any monetisation of health outcomes should be *presented with all appropriate caveats* and should be seen above all as a way of illustrating the scale of a problem, or for differentiating between policy options, and not as in itself the principal basis for a final policy decision.

The **identification of the most appropriate methodology or mix of methodologies** to use will depend on the characteristics or nature of the options under assessment⁴²³. The

⁴²² See Tool #18 (Identification of impacts) and Tool #12 (How to apply proportionality to impact assessments)

⁴²³ For an example of choice of indicators, please see: "[Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task](#)"

availability of data and information, their granularity and the costs and time needed for gathering such data and information will influence the approach taken. Quantification of health impacts should only be used where proportionate. To assess impacts on health, it is in any case necessary to have at least a general knowledge of health policies and health systems and to identify the populations and the timeframe concerned. Health systems are defined as those systems that aim to deliver healthcare services to patients – be they preventive, diagnostic, curative, and palliative – whose primary purpose to improve health⁴²⁴.

DG SANTE can assist in identifying appropriate health policy stakeholders at EU level, who would be able to help determining or evaluating a possible impact on health. For health impacts related to environmental impacts, DG Environment can assist in identifying appropriate stakeholders at EU level.

3.4. Assessing the impacts of health risk management measures

In some instances, in line with the Treaty, the legislator has empowered the Commission to act as a risk manager and adopt measures or actions with the aim to eliminate, reduce or avoid a risk to health, **based on a sound assessment of the risk in question**⁴²⁵. The powers thus granted are subject to specific processes and conditions, which define the discretionary margin of the Commission acting as risk manager, including where it is recognised that risk assessment alone cannot provide all the information on which a risk management decision should be based and other factors relevant to the matter under consideration should be considered.

In such cases the most important limitation of the Commission decision-making powers is represented by the objective of the risk management measures or actions (i.e. ensuring a high level of health protection), which frames and therefore may limit the discretionary power of the Commission.

In the light of the nature of those objectives, health considerations are necessarily considered first and shape the design of the content of those measures or actions. The margin of discretion of the Commission in such cases is utilised to consider 'how' (not 'whether') to act in pursuit of the health objective mandated by the legislator.

In specific cases, the risk management measures on health-related matters may be subject to an impact assessment (in line with 'better regulation' requirements, see Tool #14 (*Risk assessment and management*)) to support the decision to be made on how to pursue the health objective. This should happen when 1) the context allows sufficient room for manoeuvre for the Commission and different viable options are available to manage the identified risk, 2) those options are expected to have significant impacts that impact stakeholders to different extent and 3) there is no urgency.

Should an impact assessment be required on the basis of the above considerations, it should always be proportionate to the need of comparing different ways of achieving the mandated health objective and consider the timely adoption of the risk management decision to minimise health risks.

⁴²⁴ Commission Communication, [On effective, accessible and resilient health systems](#), COM(2014) 215 final

⁴²⁵ See Tool #14 (Risk assessment and management)

3.5. Approaches and methods to assess health impacts

Choosing the right methodology for assessing health impacts depends on the policy context and on the nature of the policy initiative at hand. First, it is recommended to check how the same or similar potential health impacts have already been dealt with [in existing Commission impact assessments](#)⁴²⁶, at Member State level or by third parties more generally⁴²⁷. The evaluation of health impacts in a retrospective evaluation should take the assessment in the impact assessment as a starting point.

Qualitative methods provide an insight into how an intervention or a policy option leads to a health impact and which factors influence this impact. Quantitative methods provide information on the extent of a health impact, for example, based on dose response functions. This means quantifying the health benefits such as healthy life years gained, the monetary estimates of social wellbeing and costs to the health system.

Qualitative approach

Qualitative analysis allows for demonstrating causality. In both an impact assessment and an evaluation, *the starting point for the assessment is the intervention logic* which describes how and why a desired change is expected to happen, i.e. a theory of change. This *theory needs to be tested and evaluated* to see if it fits the data available and that assumed causal links are correct. This will involve both looking for evidence which could prove or disprove the causes that have been hypothesised and exploring evidence which might point to other possible causes that lie outside the theory of change from which the assessment departs. Several methods have been developed which can help make such qualitative analysis⁴²⁸ highly rigorous, even if alternative hypotheses can rarely be tested at scale in the real world.

Only once we have good reason to believe that the assumed outcome is (or will be) a result of the intervention, and did not arise independently of, or even despite, the actions taken, should we continue to put a figure (or a price) on an outcome. The more removed the expected impact is from the actions taken in steps necessary to reach it, the more important it is to establish a high level of confidence in the causal relationships being asserted. This is especially true in the case of health impacts at population level, where both causes are often multi-factorial, and subject to non-linear, systemic effects.

Just as real-world *causality is complex, so the process of testing and refining the intervention logic will most often be an iterative one*. This may include an initial survey of already-available quantitative data to see if it seems, *prima facie*, compatible with the linkages proposed, or would rather suggest the presence (or even dominance) of other factors that have not yet been considered.

Quantitative approach

A quantitative approach can establish the scale of an impact and enable comparisons between different options in an impact assessment. It also allows assessing the extent to which health objectives have been achieved in a retrospective evaluation.

⁴²⁶ For example: [Protection of workers from the risks related to exposure to carcinogens or mutagens at work](#); [Stepping up Europe's 2030 climate ambition Investing in a climate-neutral future for the benefit of our people](#); [Trans-fat, other than trans-fat naturally occurring in fat of animal origin](#); [Clean Air](#);

⁴²⁷ See for instance the "Public health England" website that provides a gateway to Health Impact Assessments (www.apho.org.uk/default.aspx?RID=44539)

⁴²⁸ The Magenta Book: <https://www.gov.uk/government/publications/the-magenta-book>

Monetary and non-monetary quantitative methods can be used to assess direct and indirect health impacts⁴²⁹. The non-monetary methodologies quantify the health benefits of a given intervention without monetising it; to compare different interventions for the same specific health problem using cost and health outcomes (cost-effectiveness analysis) or in cases in which it is needed to compare different interventions for different health problems (cost-utility analysis)⁴³⁰. The monetary methodologies can present a comparison of costs and benefits, although such analysis may not always prove to be possible or the most appropriate when evaluating options affecting human health.

There are areas in which quantification is particularly complex or where it is inherently difficult to predict with accuracy the potential costs/benefits of a policy option (e.g.: regarding introduction of new products, services, or technologies). In this case, quantitative assessments may be presented as ranges to consider the possible margin of error or uncertainty associated with forecast costs and benefits.

Non-monetary quantitative methods

Health gains for people are measured for example with the following methods: *Quality Adjusted Life Years* (QALY)⁴³¹ and *Healthy Life Years* (HLY)⁴³².

Health losses are measured amongst other by: *Disability Adjusted Life Years* (DALY)⁴³³ and *Years of potential life lost* (YPLL)⁴³⁴.

The benefits of health technologies are relevant in terms of health impacts for both individuals and health systems. The European Network for Health Technology Assessment (EUnetHTA) elaborates methodological guidelines for health economic evaluations (including a reflection on discounting)⁴³⁵. Discount rates used for QALYs / YPLL tend to differ (also per jurisdiction). Therefore, cost-effectiveness findings are sensitive to changes in the discount rates⁴³⁶. The latter observation also has implications in terms of generational equity impacts (higher discount rates will for instance imply a lower value attributed to preventative care).

Monetary quantitative methods

Among others, two types of methods could be used, the preference-based, and accounting-style ones, however their use can raise ethical concerns and criticism. It should be clear that they cannot – and do not seek to – place a monetary value on life.

⁴²⁹ 2016 Milan Ščasný and Vojtěch Máca Monetary and Non-Monetary Measures of Health Benefits from Exposure Reduction https://link.springer.com/chapter/10.1007%2F978-3-319-43142-0_7 /

⁴³⁰ <https://yhec.co.uk/glossary/cost-utility-analysis/>

⁴³¹ *Quality Adjusted Life Years* (QALY) using available information on objective improvements in health/quality of life (QoL) and combines it with the duration of that improvement. QALY is commonly used in economic evaluations of specific health interventions (e.g. medicines development). For an example of the use of QALY, see [sec\(2008\) 2163](#) and [sec\(2008\) 2956](#).

⁴³² *Healthy Life Years* (HLY) indicates (gain?) the number of years a person of a certain age can expect to live without disability. In 2012, HLY at birth in the EU was at 61.3 years for males and 61.9 years for females.

⁴³³ Disability Adjusted Life Years (DALY) measures. Originally a measure of the burden of disease, DALY is the number of quality adjusted years lost because of illness/disability in comparison to the benchmark scenario (in general good health status without disability). It is also used to estimate the cost-effectiveness of interventions in terms of cost per DALY.

⁴³⁴ https://ec.europa.eu/eurostat/statistics-explained/index.php/Preventable_and_treatable_mortality_statistics

⁴³⁵ https://eunetha.eu/wp-content/uploads/2020/03/EUnetHTA-JA3WP6B2-5-Guidance-Critical-Assessment-EE_v1-0.pdf

⁴³⁶ E.g. UK discount rate (<https://yhec.co.uk/glossary/discount-rate/>)

The aim of the preference-based methods is to compare the benefits of different policy options by placing an implicit monetary value on health benefits as is, for example, often done in the transport sector to inform decision on safety measures. These methods analyse individuals' stated or revealed preferences with respect to small changes in low-probability risks. While no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to saving time.

The *preference-based methods* measure the individuals (or populations) willingness-to-pay (WTP) and/or willingness-to-accept (WTA) compensation for a preferred policy choice of the intervention logic or for a worsening of certain conditions, respectively⁴³⁷. The preference for health gains is measured for example with methods such as: the *Value of Statistical Life* (VOSL)⁴³⁸ and the *Value of Statistical Life Year* (VOLY). The European Chemicals Agency (ECHA) has developed reference WTP values for the monetisation of health endpoints by Member States (when preparing 'restrictions' on the use of chemicals)⁴³⁹.

- The Value of Statistical Life (VOSL) is derived by investigating individuals' WTP for a lower risk of mortality, divided by that risk reduction. The OECD has undertaken both a literature review and primary analysis to better understand the right values to use in policymaking. It proposed a range for the average adult VOSL for the EU of USD 1.8 million – 5.4 million (2005-USD), with a base value of USD 3.6 million. These base values and ranges are currently being updated as new VOSL primary studies are conducted (contact DG Environment for details)
- The Value of Statistical Life Year (VOLY) measures more generally the WTP for an increase of one additional year of life expectancy⁴⁴⁰.

The *accounting style methods* measure only certain aspects of health impacts on individuals and health systems and should be therefore treated with extreme caution. Such methods are Cost of Illness (COI)⁴⁴¹. The Cost of Illness method comprises only the medical expenses related to the incidence of an illness. If an option lowers the rate of occurrence of an illness the saved medical expenses constitute a benefit. Conversely, if an option leads to an aggravation of a health situation, one can state the associated relevant costs. However, the

⁴³⁷ See Tool #57 on (Methods to estimate costs and benefits)

⁴³⁸ The VOSL measures a *gain* and is derived by investigating individuals' WTP for a lower risk of mortality, divided by that risk reduction. As such, the VOSL method does not measure the value of a life *per se*, instead it puts a monetary value on the willingness to accept slightly higher or lower levels of risk. For more in-depth analysis of the Value of a Statistical Life, including a discussion of VOLY, see: http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01. For an example of use of VOLY and VSL in a recent cost-benefit analysis on air quality effects on health, see: http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP_CBA_corresponding_to_IIASA11_v2.pdf

⁴³⁹ https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

⁴⁴⁰ The VOLY measures more generally the WTP for an increase of one additional year of life expectancy. However, as the VOLY is deemed constant across lifetime, assessments using VOLY and VOSL can produce conflicting results according to the demographics of the population considered. http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmentthehealthandtransportpolicies.htm#Executive_Summary

⁴⁴¹ Cost of illness (COI) is defined as the value of the resources that are expended or forgone as a result of a health problem. It includes health sector costs (direct costs), the value of decreased or lost productivity by the patient (indirect costs), and the cost of pain and suffering (intangible costs).

usefulness of this method is limited as it often does not include other indirect costs to society such as loss of hours worked, or how people value their own health.

In all circumstances, it is advisable to mention both the quantitative and monetary estimates. For example, the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

In any case, the monetary results (costs and benefits) should be discounted, and sensitivity analysis should be performed to see how changes in the parameters affect the results.

4. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Healthy life years at birth • Share of people with good or very good perceived health • Smoking prevalence • Death rate due to chronic diseases • Standardised preventable and treatable mortality (sdg_03_42) • Self-reported unmet need for medical care • Obesity rate • People killed in accidents at work • Population living in households considering that they suffer from noise • Road traffic deaths • Exposure to air pollution by particulate matter <i>UN indicators:</i> • Mortality rate attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease • Suicide mortality rate • Coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for substance use disorders • Harmful use of alcohol, defined according to the national context as alcohol per capita consumption (aged 15 years and older) within a calendar year in litres of pure alcohol • Coverage of essential health services (defined as the average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population) • Proportion of population with large household expenditures on health as a share of total household expenditure or income • Mortality rate attributed to household and ambient air pollution • Mortality rate attributed to unsafe water, unsafe sanitation and lack of hygiene (exposure to unsafe Water, Sanitation and Hygiene for All (WASH) services) • Mortality rate attributed to unintentional poisoning • International Health Regulations (IHR) capacity and health emergency preparedness • Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law	  

TOOL #33. CONSUMERS

1. INTRODUCTION

Many EU policies directly affect EU citizens in their everyday life as consumers. It is obviously the case each time a policy concerns retail markets of goods and services. Other policies affecting supply chains or mobility also have an impact on consumers, and therefore a holistic view of the consequences for consumers is essential in deciding on the best societal choices while ensuring a high level of consumer protection, as required by Article 38 of the Charter of Fundamental Rights.

Box 1. Legal basis

The Treaty establishes that “consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities” (TFEU, Article 12), and that “... the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.” (TFEU, Article 169)

In addition to the Treaty-based legal provisions (see Box 1), in line with the Commission’s political priorities⁴⁴², relevant initiatives should aim at empowering consumers in the green and digital transitions. A New European Consumer Agenda⁴⁴³ adopted in November 2020 elaborates how these priorities will unfold across the different policy areas and on how to increase consumer protection and resilience during and after the Covid-19 pandemic.

Accounting for more than half of EU’s Gross Domestic Product, consumer spending is a powerful economic lever that will have to play its role in Europe’s recovery from the downturn caused by the pandemic. Positive impacts on consumers can be an important argument in support of new policy initiatives, especially to offset possible increases in costs for businesses.

While the section below mostly refers to ex-ante impact assessments, this tool can also be used to assess the impacts on consumers in the context of evaluating existing policy or legal instruments.

2. THE KEY QUESTIONS FOR ASSESSING CONSUMER IMPACTS

The EU common legal definition of ‘consumer’ means any ‘natural person who is acting for purposes which are outside his trade, business, craft or profession’.

In some situations, impacts on businesses might serve as a proxy for consumer impacts that are ultimately passed on to consumers. While in some circumstances **consumers** might best be thought of as individuals, in other cases **households** may be a more relevant unit to consider, including the potential role of children as particularly vulnerable consumers or as in influencing purchasing decisions.

⁴⁴² https://ec.europa.eu/info/priorities_en

⁴⁴³ Commission Communication, [New Consumer Agenda - Strengthening consumer resilience for sustainable recovery](#), COM(2020) 696 final

A common understanding of **consumption** is a prerequisite for an adequate assessment of impacts on consumers. This term can relate to durable or non-durable products and services. The three phases of consumption are: **procurement** (purchase, inheritance, borrowing, exchange, etc.), **use** and **disposal**. The key aspect to consider is the relationship between a consumer and a professional supplier of a good or a service. This relation does not necessarily involve a payment in money. For example, online services provided 'for free' (but in exchange for personal data) also have an important consumer aspect.

When screening for potentially significant impacts on consumers, the following questions should be asked:

(1) *Would the policy option affect consumers' ability to benefit from the four fundamental freedoms of the internal market?*

Attention should be paid to ensuring equal access to retail goods and services, the ability to move freely, access to various services at distance and the possibility to purchase cross-border financial products. Particular attention should be paid to any possible discrimination or other barriers based on nationality or place of residence (the non-discrimination principle⁴⁴⁴).

(2) *Would the policy option affect the prices, quality, availability, or choice of consumer goods and services?*

Increasing competition and decreasing costs for businesses will likely lead to lower consumer prices, more choice of goods and services and possibly also better quality (such as longer product lifetime).

(3) *Would the policy option affect consumer information, knowledge, trust, or protection?*

Policies reducing asymmetric access to information⁴⁴⁵ or excessive costs of accessing information may remedy a market failure, allow consumers to make better-informed decisions, reduce the scope for unfair practices by traders and generally increase consumer trust and protection. Similarly, knowledge of consumer rights, awareness of and trust in redress mechanisms are key to ensuring that consumers fully benefit from the legal protections available.

(4) *Would the policy option affect the safety of consumer goods and services?*

Consumer products sold in the EU are subject to high safety standards and consumers are entitled to expect that all the products they buy are safe. Market surveillance data from competent national authorities shows, however, that in certain cases (mostly imported) products reach the market before they are notified as unsafe and withdrawn, thus creating a safety risk to consumers.

(5) *Would the policy option contribute to more sustainable consumption patterns?*

More sustainable consumption is a key lever to achieving the EU's sustainability goals. Policies affecting different segments of the consumption process – from the supply chain to

⁴⁴⁴ Directive of the European Parliament and of the Council on services in the internal market 2006/123/EC OJ L 376, 27.12.2006, p. 60, art. 20.

⁴⁴⁵ Extreme examples of asymmetric access to information are unfair commercial practices, such as providing misleading information via labelling, advertising or other means. They are prohibited by the Unfair Commercial Practices Directive 2005/29/EC.

distribution, to marketing and post-marketing, maintenance, repair, and recycling – can help promote more sustainable consumption patterns. For instance, logos, labels, and product claims on a product or in its advertising can all influence consumer choices in the marketplace; they can help consumers assess and compare products and guide them towards healthier, more sustainable, and responsible ways of consuming.

(6) *Would the policy option impact consumers in the digital environment?*

With digitalisation being a powerful trend, the Internet continues to show a lot of potential for giving consumers a stronger voice. At the same time, it creates challenges for the effective protection of consumer rights. As a rule, policies that improve the transparency of digital markets, ensure a fair treatment of consumers, reduce misleading marketing practices, online fraud and scams, and tend to have a positive impact on consumers.

(7) *Would the policy option impact vulnerable consumers?*

Consumer vulnerability means belonging to a socio-economic group likely to be less empowered or lacking full capacity to operate successfully in the marketplace as consumers⁴⁴⁶. Consumer vulnerability is a dynamic concept, and every consumer may become vulnerable in certain situations, e.g. due to changes in life situations or because of the complexity of goods, services or marketing practices that make it difficult to verify the validity of their choice⁴⁴⁷. Commercial practices that are likely to materially distort the economic behaviour only of a clearly identifiable group of consumers who are particularly vulnerable because of their mental or physical infirmity, age or credulity, in a way which the trader could reasonably be expected to envisage shall be assessed from the perspective of the average member of that group⁴⁴⁸.

3. HOW TO ASSESS IMPACTS ON CONSUMERS

A broad array of analytical methods, concepts and tools can be used in combination to answer the seven questions listed above. The key concepts for measuring consumer impact are: (i) consumer welfare, (ii) consumer detriment, (iii) consumer conditions, and (iv) consumer vulnerability.

3.1. Consumer welfare

Consumer welfare refers to the individual benefits derived from the consumption of goods and services. It is typically measured by calculating the consumer surplus, i.e. the difference between what a consumer is willing to pay for a good or service and what he/she actually has to pay. When summed across all consumers, consumer surplus is a measure of aggregate consumer welfare⁴⁴⁹. Distributional impact among different categories of consumers should also be considered.

⁴⁴⁶ This can be due to e.g. low income, low education, disabilities, diseases or specific behaviours such as credulity or addictive behaviour, developmental stages that may affect comprehension, reasoning and judgement (children, adolescents and the elderly).

⁴⁴⁷ E.g. because of a lack of technological expertise, time pressure, cognitive overload, lack of transparency of offers, lack of easily available, understandable and balanced information, or ignorance concerning the long term effects of product use.

⁴⁴⁸ Unfair Commercial Practices Directive 2005/29/EC OJ L 149, 11.6.2005, p. 27, art. 5(3).

⁴⁴⁹ In theory, individual welfare is defined by an individual's own assessment of their own satisfaction, given prices and income. Exact measurement of consumer welfare therefore requires information about individual preferences <http://stats.oecd.org/glossary/detail.asp?ID=3177>.

The EU Single Market, globalisation and digitalisation of markets allow consumers to benefit from a much wider choice of products. Market studies of the Consumers Directorate of DG JUST estimate these consumer welfare gains⁴⁵⁰.

Recent advances in behavioural economics have stressed the importance of factors such as the limits of consumer rationality and self-interest, incoherent preferences, limited ability to access, absorb and analyse information, etc. All of these affect how consumers make choices in the marketplace, which in turn impacts consumer welfare.

Behavioural studies⁴⁵¹ show how people make actual choices, based on rigorous observation of behaviour rather than assumptions. Policy design should consider well documented consumer biases, such as the 'status quo bias' (letting the default rule determine our decision), 'myopia' (choosing a small reward today over a larger one later) or 'loss aversion' (preference towards avoiding loss over acquiring gains). For more information on behavioural impacts, see Tool #69 (*Emerging methods and policy instruments*).

3.2. Consumer detriment

Consumer detriment is a measure of harm (whether financial, time loss, health, or quality of life, etc.) that consumers may experience when market outcomes fall short of their potential. Consumer detriment can be structural or personal (see Box 2). An operational method for measuring personal consumer detriment was developed and tested by the Consumers Directorate of DG JUST⁴⁵².

Box 2. Types of consumer detriment

- **Structural detriment** — the loss of consumer welfare (measured by consumer surplus as described above) due to market failure or regulatory failure, as compared to well-functioning markets. The reduction of structural consumer detriment is very relevant to look at in e.g. competition policies (such as antitrust policy) or internal market policies aimed at reducing barriers to cross-border trade.
- **Personal detriment** — the personal experience of those consumers for whom something goes wrong (rather than to all consumers on aggregate), benchmarked against reasonable expectations. This will generally be assessed through surveys inquiring on financial and non-financial detriment (e.g. time loss, psychological detriment). When consumers obtain redress from the retailer (e.g. a replacement product, refund or compensation) this may partly or wholly offset the detriment suffered.

⁴⁵⁰ E.g. the potential from increased e-commerce and a fully functioning internal market in [Consumer market study on the functioning of e-commerce and internet marketing and selling techniques in the retail of goods](#).

⁴⁵¹ The behavioural studies with a consumer focus carried out in recent years are available at: https://ec.europa.eu/info/policies/consumers/consumer-protection/evidence-based-consumer-policy/behavioural-research_en

⁴⁵² See the 2017 [study on measuring consumer detriment in the EU](#) and the [operational guidance for measuring personal consumer detriment](#).

3.3. Consumer conditions

Better consumer conditions contribute to maximising consumer welfare. The conceptual framework⁴⁵³ for measuring consumer conditions has been based on three main dimensions: (i) knowledge of rights and trust among market players⁴⁵⁴; (ii) traders' compliance with consumer legislation and its enforcement; and (iii) consumer complaints and resolution of disputes between consumers and retailers. These dimensions follow the logic of the three main stages of a transaction (before, during, and after) between a consumer and a retailer.

3.4. Consumer vulnerability

The Consumers Directorate of DG JUST developed an evidence-based definition of consumer vulnerability according to which a vulnerable consumer is one who, as a result of socio-demographic characteristics, behavioural characteristics, personal situation or market environment: (i) is at higher risk of experiencing negative outcomes in the market; or (ii) has limited ability to maximise their own well-being; or (iii) has difficulty in obtaining or assimilating information; or (iv) is less able to buy, choose or access suitable products; or (v) is more susceptible to certain marketing practices. This definition was operationalised in measuring consumer vulnerability across key markets in the EU⁴⁵⁵.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

To build a knowledge base, the Consumers Directorate of DG JUST gathers relevant information by monitoring markets and national consumer conditions and by studying consumer behaviour. How the Single Market works for consumers is monitored in two stages: (i) identifying malfunctioning markets and horizontal issues of concern through the Consumer Scoreboards; and (ii) in-depth analysis of these markets and issues through market studies to identify the main problems and suggest policy solutions. Behavioural tests allow comparing alternative policy options and tailoring interventions based on consumer response. This work is underpinned by the development of methodological tools, e.g. for measuring consumer detriment.

The information, data sources, and methodological tools presented below should be seen as a starting point for analysis rather than an exhaustive list of resources:

- The [Consumer Scoreboards](#) track the performance of key consumer markets and benchmark overall consumer conditions in EU Member States. The main data sources for the Scoreboards are the EU-wide [Market Monitoring Survey](#) and the [consumer and retailer surveys](#).
- Findings of [in-depth studies](#) of underperforming sectors and of cross-cutting issues have influenced policy with tangible benefits for EU consumers. Market studies⁴⁵⁶ can be carried out through the [Framework contract for Consumer Market Studies](#).

⁴⁵³ A detailed presentation of the conceptual framework for consumer conditions is available at https://publications.jrc.ec.europa.eu/repository/bitstream/JRC93404/2015-10-12_consumer_conditions_final_report.pdf

⁴⁵⁴ Knowledge of consumer rights, trust in retailers and in relevant institutions, in redress mechanisms, in product safety, in environmental claims, and confidence shopping online.

⁴⁵⁵ See the 2016 [study on understanding consumer vulnerability in the EU's key markets](#)

⁴⁵⁶ These studies allow data gathering through consumer opinion surveys, stakeholder surveys, the collection of prices for goods/services, surveys based on mystery shopping methodology and behavioural experiments.

- The [2017 study on measuring consumer detriment in the EU](#) developed a detailed step-by-step [operational guidance](#) for scientifically sound and resource efficient assessments of personal consumer detriment in markets across the EU, and tested it in six selected markets⁴⁵⁷.
- [Applying Behavioural Sciences to EU Policymaking](#) covers issues to consider when incorporating behavioural insights into the design, implementation, and monitoring of policies. Ex-ante behavioural testing of the effectiveness of policy interventions can be carried out through the [Framework Contract for the Provision of Behavioural Studies](#). The issues that policy officers need to be aware of when carrying out such behavioural testing are outlined in [Seven Points to Remember when Conducting Behavioural Studies in Support of EU Policymaking](#). All the recent [behavioural studies](#) on consumers are available online.

Helpdesk for assessing consumer impacts:

JUST-03-IMPACT-ASSESSMENT-EVALUATION@ec.europa.eu

If impacts on consumers are likely to be significant, DG JUST should be invited to participate in the interservice coordination group preparing the impact assessment and policy initiative.

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Consumption of hazardous and non-hazardous chemicals <i>UN indicators:</i> • Indicator of food price anomalies • (a) Number of commercial bank branches per 100,000 adults and (b) number of automated teller machines (ATMs) per 100,000 adults • Proportion of adults (15 years and older) with an account at a bank or other financial institution or with a mobile-money-service provider • Number of parties to international multilateral environmental agreements on hazardous waste, and other chemicals that meet their commitments and obligations in transmitting information as required by each relevant agreement • Hazardous waste generated per capita and proportion of hazardous waste treated, by type of treatment • Number of companies publishing sustainability reports • Extent to which (i) global citizenship education and (ii) education for sustainable development (including climate change education) are mainstreamed in (a) national education policies; (b) curricula; (c) teacher education; and (d) student assessment	  

⁴⁵⁷ The methodology for measuring personal consumer detriment was tested in the following markets: mobile telephone services; clothing, footwear, and bags; train services; large household appliances; electricity services; and loans, credit, and credit cards.

TOOL #34. TERRITORIAL IMPACTS

1. INTRODUCTION

The European Commission recognizes that the impacts of Union legislation may be different across local and regional levels and for public authorities⁴⁵⁸.

Impact assessments and evaluations should systematically consider territorial impacts when they are relevant and there are indications that they will be significant for different territories of the EU. Thanks to territorial impact assessments (TIA) and rural proofing⁴⁵⁹, the needs and specificities of different EU territories can be better considered (for instance of urban⁴⁶⁰/rural areas, cross-border areas⁴⁶¹ and the EU outermost regions⁴⁶²) to facilitate cohesion across the Union.

Living conditions as well as industrial structures, infrastructure endowment, patterns of land use, and geographical conditions vary substantially across the EU. EU's cohesion and regional policies are designed to mitigate these differences and ensure that poorer regions and territories have means to address regional challenges. Despite good progress in convergence across Europe on many parameters, there is still significant dispersion within the EU. Still many sectoral policy measures address specific territorial areas or have specific consequences concentrated in certain territories of the EU (i.e. insular areas). For example, efforts to ensure more sustainable fishing is likely to have spatially differing impacts which vary according to the distribution of fisheries and their conservation status. In addition, the reduction of poverty and social exclusion is a common objective, but the extent of the problem varies a lot across countries and regions.

The territorial dimension may be relevant for impact assessments for many sectoral legislative proposals and initiatives for two reasons:

- First, the impacts associated with the problem are often heterogeneously distributed across the EU. This means that the design of effective policy options will also bring about an uneven geographical distribution of impacts (costs and benefits);
- Second, a policy option may act unevenly to produce heterogeneous territorial impacts even where a problem is not necessarily unevenly distributed across the territory of the EU.

In policy cases where there is no specific territorial dimension, obviously there is no need for a detailed assessment of the territorial impacts.

Territorial impact assessments are looking into all thematic aspects of impact assessments (economic, social, and environmental) by translating them into the territorial setting (regions).

⁴⁵⁸ Commission Communication: [The principles of subsidiarity and proportionality: Strengthening their role in the EU's policymaking](#), COM(2018) 703

⁴⁵⁹ Commission Communication, The Future of Food and Farming, [COM\(2017\) 713](#) and Commission Communication: A Long Term Vision for Rural Areas, [COM\(2021\) 345](#)

⁴⁶⁰ Pact of Amsterdam: Urban Agenda for the EU (2016) and Council Conclusions on an Urban Agenda for the EU (24.6.2016)

⁴⁶¹ Commission Communication: Boosting growth and cohesion in EU border regions, [COM\(2017\) 534](#)

⁴⁶² defined in Article 349 TFEU, which provides for the adoption of specific legislative measures for the EU nine outermost regions across EU policies, taking into account their permanent constraints.

2. HOW TO ASSESS IMPACTS OF POLICY OPTIONS ON TERRITORIES

One first step is to allow for more active engagement of local and regional authorities in consultation processes. This is an essential element of improving the quality of assessments of territorial impacts. Local and regional authorities should help identify such potential impacts in their consultation responses and feedback on the 'call for evidence'.

The Committee of the Regions and its network of regional hubs (RegHub)⁴⁶³ can help disseminate information about consultations by reaching out to its members.

The impact on territories can be assessed using qualitative and quantitative methods, as well as specific tools developed to support impact assessments or the consultation process.

The approach relies on a description of the spatial distribution of four items:

- 1) The degree to which the problem or driver to be addressed is concentrated in some types of areas (i.e. rural/urban), Member States or regions;
- 2) The capacity of EU policies to respond to the problem/implement the policy;
- 3) The degree to which stakeholders indicate a need for a policy response in the relevant areas and regions;
- 4) The effectiveness of the policy response and its potential impact.

In some cases, the risk of asymmetric territorial impact is obvious. In other cases, only experts familiar with the issue can assess the risk of such asymmetric impacts. Deciding whether that is the case for a given policy or legislative proposal however is not always easy as no policy will affect all regions throughout the European Union exactly to the same extent.

For that reason, when a preliminary screening of impacts⁴⁶⁴ shows that territorial impacts are relevant, the [TIA necessity check](#)⁴⁶⁵ will help assess the need of a more in-depth analysis of such impacts.

Through a series of five steps this online tool will help you decide whether a TIA is useful for a legislative proposal/initiative. It is recommended to use the tool in:

- the 'call for evidence' phase, to determine if a TIA should be part of the impact assessment based on the initial idea for the proposal, and/or
- the impact assessment phase, to determine if based on the more concrete idea for the proposal, a TIA might have become advisable even if it was not considered necessary at the 'call for evidence' phase.

Box 1 presents examples of cases where territorial impacts were relevant.

⁴⁶³ The European Committee of the Region's (CoR) Network of Regional Hubs ([RegHub](#)) is a network of European regions and cities that evaluates the implementation of EU policies.

⁴⁶⁴ In line with Tool #18 (*Identification of impacts*)

⁴⁶⁵ Developed by DG REGIO and the [ESPON](#) Cooperation Programme, which aims to support the effectiveness of EU policies through the production, dissemination, and promotion of territorial evidence. It is co-financed by the European Regional Development Fund.

Box 1. Examples of territorial impacts

1. Commission initiative responds to an uneven problem but acts evenly on the territories of the EU

Example: The [Clean Vehicle Directive](#) – stipulating minimum standards with respect to emissions and technical specifications of the public procurement of vehicles for public use (e.g. public transport, waste collection, etc.). In that case, the application is territorially evenly distributed, but the problem is different in agglomerations (big cities) due to the higher population and vehicle density and in rural areas where public transport is more scattered and people are more dependent on individual vehicles.

2. The initiative responds to an even problem but acts unevenly on the territories of the EU

Example: [EU Climate and Energy framework](#) – this policy package combines measures to successfully achieve the binding overall EU targets for reduction in greenhouse gas emissions, increased share of renewable energy and increased energy efficiency by 2030. The underlying problem is the need to fulfil the commitments made under the Paris Agreement, which are equal for all Member States. In implementing the framework, individual targets for Member States are set, thus representing an uneven policy action.

3. The initiative responds to an uneven problem and acts unevenly on the territories

Example: [EU Cohesion Policy](#) – funding made available through the European Structural and Investment Funds in order to reduce disparities between regions and to promote the overall balanced development of the territories. The problem addressed are the regional disparities, which are inherently unevenly distributed. The funding framework allows for different EU co-financing rates based on regional characteristics and shifts a larger share of overall funding towards specific regions or areas facing specific constraints.

4. The initiative responds to an even problem and acts evenly on the territories

Example: **Emission Trading System** – carbon dioxide (CO₂) emissions are a universal problem all over the EU (with certain peaks and dumps in areas with high/low human activities – e.g. urban agglomerations vs. unpopulated territories). The [Emission Trading System](#), which is a cornerstone of the EU's policy to combat climate change and its key tool for reducing greenhouse gas emissions cost effectively, applies throughout the EU – with a current exemption for flights between airports in the EU outermost regions and other EU/EEA airports – and certificates can be traded freely with no specific national or regional provisions.

A correct assessment of the territorial dimension of the problem will help shaping properly targeted policy options. It can also avoid conducting policies in those areas and regions where no policy response is needed. This could create direct or indirect costs.

The relevant territorial unit or grouping may vary from case to case and should be proportional to the question at hand. It could be specified at the Member State level or in terms of geographical characteristics such as for instance urban or rural areas, coastal areas, island and the EU outermost regions, mountainous regions, cross border regions or densely versus very low populated areas. In other cases, there may be a need for singling out those administrative regions, which are disproportionately affected by a certain policy measure.

3. CHARACTERISING THE PROBLEM

Spatially relevant statistics and information are routinely collected, aggregated, and made available by local and regional authorities, Member States, the Commission and other EU agencies and bodies (see section 8 for some examples). This can be used to characterise a particular problem and to understand whether the problem is characterised by territorial impacts which are unevenly distributed across the Union.

Box 2. Examples where the problem is spatially uneven

- The sensitivity of terrestrial and aquatic ecosystems to acid rain varies across the Union as a function of the underlying geological rock and soil types which means that some air pollution emissions sources contribute more to the environmental damage than others once transport in the atmosphere is considered. The ecosystem sensitivity can be mapped.
- Measurement by the Member States show that the quality of bathing waters and rivers varies across the Union this can be overlaid with spatial information about the various economic activities, which occurs in river basins across the Union.
- The relative wealth of regions in the Union varies significantly, which is considered of in the Union's cohesion and State aid policies. Similarly, unemployment varies significantly across the Union.
- Educational attainment strongly varies across the EU, some regions having more than 70% of their population with tertiary education while in others this share is less than 15%.
- Susceptibility to a changing climate will vary across the Union. Some regions will be susceptible to flooding, encroachment of the sea, hurricanes, and other extreme weather events whilst others are sensitive to reduced rainfall and drought.

If the nature of the problem is spatially varying, then it is important to characterise this early in order that policy options can be designed properly but also to be able to assess the territorial impacts associated with each of the policy options.

A '**territorial baseline**' can be constructed to show how the problem is likely to evolve in the absence of policy intervention. The magnitude of the issue can be further elaborated thanks to the Annual Regional Database of the European Commission⁴⁶⁶ (**ARDECO**). It is a comprehensive territorial database of layers and statistics at various levels, with long time-series demographic and macro-economic indicators for EU regions, geo-referenced population⁴⁶⁷ and detailed maps of land use/cover and services⁴⁶⁸.

If data allows, a projection should be made to show to what extent the problem is likely to grow in the future. Projections with a sub-national component including demographic, economic and land use projections can help to show the likely evolution of the issue at stake.

If the spatial distribution of an issue cannot be measured directly, it can sometimes be derived from case studies or the scientific literature. In some cases, another measure with a similar

⁴⁶⁶ https://knowledge4policy.ec.europa.eu/territorial/ardeco-online_en

⁴⁶⁷ <https://ec.europa.eu/eurostat/web/gisco/geodata/reference-data/population-distribution-demography/geostat>

⁴⁶⁸ <https://ec.europa.eu/jrc/en/publication/luisa-base-map-2018>

spatial distribution can be used as a proxy indicator. For example, opening up trade in textile sector may mean that regions with an uncompetitive textile industry will see high redundancies in that sector. If no data is available on the regional competitiveness of the textile industry, regional employment growth in that sector may help to assess which regions could be more vulnerable.

4. MODELLING INTERACTIONS

A model can support an impact assessment, especially if the policy addresses a problem driver that is strongly linked to other issues. For example, trade policy can have an impact on the agricultural sector or new transport infrastructure can influence economic growth and land use changes. The Joint Research Centre has developed six models⁴⁶⁹ with a sub-national component, including RHOMOLO, LUISA, and TRANSTOOLS.

5. TOOLS TO SUPPORT THE QUANTITATIVE ANALYSIS

[ESPON](#) has developed [ESPON TIA Tool](#) (a web application) to get a quick indication of the possible territorial impacts of policy options. With the ESPON TIA Tool one can assess policy impacts using a vulnerability approach. This approach uses three elements: exposure, sensitivity, and impact. The tool combines local/regional expert knowledge on the *exposure*⁴⁷⁰ of specific regions to the impacts gathered in a workshop with a set of statistical data describing the *sensitivity*⁴⁷¹ of the EU regions to possible policy impacts.

In the process of the assessment of territorial impacts, the ESPON TIA tool produces maps that visualise the impacts on the various territories and serve as input for discussion among the experts. These maps are useful for policy considerations and for enriching an impact assessment report. The tool allows to do a TIA for Europe as a whole, but one can also focus on EU Member States only or on cross-border regions, urban, rural, outermost areas or make a composition of regions of their choice (i.e. coastal etc.). Its main advantage is the possibility to conduct a TIA with a reasonable time (workshops with experts takes half a day) and resource frame and apply it in a horizontal way combining all thematic aspects of impact assessments (economic, social, environmental) as well as governance aspects by translating them into the territorial setting (regions). It may be used in the 'call for evidence' phase as well as in the impact assessment phase. ESPON TIA Tool can also be used for evaluations.

For territorial impact analysis at the regional (NUTS2) level, the model [RHOMOLO](#) developed by the Joint Research Centre and DG REGIO can be used to analyse the impact on economics outcomes such as GDP, employment, investments, prices, exports and wage. There is a simplified web version of the model that can be used as a first approximation of the impact of policies affecting total factor productivity, labour productivity or transport costs. For more complex impact assessment exercises, DG REGIO and JRC can be contacted to run tailored simulations.

For policies with an expected impact mainly at the sub-regional level or when regional boundaries are crossed by the same policy without affecting whole regions, the JRC can provide support to the impact assessment through the [LUISA Territorial Modelling Platform](#) that allows producing projection at high spatial granularity and also to define and implement what-if scenarios.

⁴⁶⁹ See the [Modelling Inventory and Knowledge Management System \(MIDAS\)](#)

⁴⁷⁰ i.e. the potential strength and normative direction of the policy effect on the regions

⁴⁷¹ i.e. the existing territorial condition of the region

6. CONSULTATIONS CAN HELP REVEAL ASYMMETRIC TERRITORIAL IMPACTS

The stakeholder consultation process envisaged in the impact assessment can be used to collect evidence and information about the issue to be addressed and the impact of the policy option on different EU territories. Therefore, services must make an effort to reach out to stakeholders from different territories (urban, rural, cross border, coastal, insular, mountainous, sparsely populated etc.) and from the EU outermost regions. Stakeholders from different territories may have access to more information and thus be in a good position to judge the risk of an asymmetric territorial impact. Therefore, the consultation (public or targeted) could include question/s to check whether the public or the stakeholders expect the legislative proposal/initiative to have an asymmetric impact.

Box 3. Sample questions to include in public/targeted consultations

- According to your knowledge and information, is this problem concentrated in certain areas, regions, or Member States?
- Do you expect that this policy will have a disproportionately large impact on certain areas, regions, or Member States? If yes, please indicate which ones and why.

Under the 'Protocol on Cooperation between the Commission and the Committee of the Regions' (2012) the 'Commission services may ask for support from the Committee in preparing its assessment'. This may be particularly useful if the consultation investigates asymmetric impacts on regions or local authorities.

7. HOW TO MINIMIZE ANY NEGATIVE IMPACTS ON TERRITORIES

Considering potential asymmetric territorial impacts can increase the effectiveness and the efficiency of the policy. It can increase political support for a policy, boost the benefits while addressing excessive spatial concentrations of the costs.

If costs are distributed in a highly asymmetric manner, the policy could be adjusted to reduce the costs of the policy on the most affected regions. If the policy itself cannot be adjusted, mitigation measures including the creation of another instrument to reduce the burden on these regions or areas should be investigated. The territorial assessment can also help the relevant regions and areas by making them aware of the EU policies under development so that they will be able to prepare and take most advantage of the policy once implemented.

Three short examples can illustrate how negative territorial impacts can be reduced:

1. Reducing the concentrations of an airborne pollutant in cities to uniform level within a single deadline may be more difficult to achieve in some cities than others. Concerns about such difficulties may lead to pressure to allow higher concentrations. Assessing territorial impacts could identify such risks and ensure that the EU policy would be able to allow cities with very high concentrations a longer time frame – based on clear criteria – to reach the necessary quality threshold, should they so wish.
2. State aid policy also differentiates its approach according to the level of development of a region and to the size of the market. For example, different possibilities to award State aid apply to areas with an abnormally low standard of living, to insular, mountain and to the EU outermost regions and regions with low population density.

3. Growing global trade integrations tends to benefit the EU, but some regions specialised in a sector vulnerable to further trade integration/globalisation may face a high number of redundancies.

Policies can be adjusted in five ways to address highly asymmetric territorial impacts:

1. Adjust the policy for the entire Union or some of its parts (as for example State Aid policy does);
2. Grant more time to implement a policy in some parts of the Union (as was done for the urban wastewater directive during the accession negotiations);
3. Exempt those parts of the Union which are unaffected by the problem from the policy;
4. Use existing policies to address asymmetric territorial impacts (for example by using Cohesion Policy, etc);
5. Create a new instrument to address asymmetric territorial impacts if/when they arise (for example the European Globalisation Adjustment Fund).

8. INFORMATION SOURCES AND BACKGROUND MATERIAL

- Assessing territorial impacts: operational guidance on how to assess regional and local impacts within the Commission Impact Assessment system, [SWD \(2013\) 3 final](#)
- [TIA Necessity Check](#) can be used by Commission services to self-assess if a legislative proposal may require TIA
- Units B1 and 03 in DG REGIO provide assistance and training to other DGs on TIA
- Training on TIA methodologies and tools via [EU Learn - REGIO - Territorial Impact Assessment - ESPON TIA Quick check tool \(europa.eu\)](#)
- Examples of Territorial Impact Assessments contracted in the framework of IA with the support of DG REGIO: [Regulation on minimum requirements for water reuse TIA report](#)
- **Local typologies:** [Cities and their commuting zones](#); The [degree of urbanisation](#) can be visualised interactively using the [statistical atlas](#) (General and regional statistics, chapter 14). **Sub-national data sources:** Eurostat has been expanding its sub national data offer in the recent years in two dimensions, more domains covered and more detailed geographical levels see [Eurostat web page dedicated to sub-national statistics](#).
- In addition, Eurostat publishes [geographical information](#)⁴⁷² such as reference topographic layers and specific thematic layers.
- The LUISA-RHOMOLO combination for the evaluation of territorial impact of European policies⁴⁷³.
- The **JRC** develops geo-referenced datasets at European and global scale, many of which are relevant for regional or territorial analysis. These datasets cover themes as natural hazards and risk prevention, distribution of species, climate change, agriculture, land cover, soil data, etc. Contact the [JRC Knowledge Centre for Territorial Policies](#).

⁴⁷² GISCO - the Geographic Information System of the Commission <https://ec.europa.eu/eurostat/web/gisco>

⁴⁷³ [JRC Publications Repository - The LUISA-RHOMOLO combination for the evaluation of territorial impact of European policies \(europa.eu\)](#)

- The [Urban Data Platform Plus](#), the *de facto* standard repository for quantitative knowledge and indicators at all territorial levels in Europe.

9. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Settlement area per capita <i>UN indicators:</i> • Ratio of land consumption rate to population growth rate • Proportion of cities with a direct participation structure of civil society in urban planning and management that operate regularly and democratically • Average share of the built-up area of cities that is open space for public use for all, by sex, age, and persons with disabilities. • Proportion of population living in cities that implement urban and regional development plans integrating population projections and resource needs, by size of city • Proportion of local governments that adopt and implement local disaster risk reduction strategies in line with the Sendai Framework for Disaster Risk Reduction 2015-2030. • Number of countries with national and local disaster risk reduction strategies. • Number of countries that have national urban policies or regional development plans that (a) respond to population dynamics; (b) ensure balanced territorial development; and (c) increase local fiscal space • Proportion of the rural population who live within 2 km of an all-season road • Proportion of the population living below the international poverty line by sex, age, employment status and geographic location (urban/rural) • Parity indices (female/male, rural/urban, bottom/top wealth quintile, and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated	  

TOOL #35. DEVELOPING COUNTRIES

1. INTRODUCTION

Assessing the likely effects of different policy initiatives on developing countries is a requirement from Article 208(1) TFEU, which stipulates that the EU “*shall take account of the objectives of development co-operation in the policies that it implements which are likely to affect developing countries*”. This constitutes the legal basis of the concept more generally known as Policy Coherence for Development (PCD). Through PCD, the EU seeks to take account of development objectives in all its policies that are likely to affect developing countries, by minimising contradictions and building synergies. PCD is a fundamental element to progress towards EU’s development cooperation objectives, i.e. reduction and – in the long term – eradication of poverty, and key to implement the 2030 Agenda and its sustainable development goals.

As part of the EU’s commitment to ensure SDG implementation internally and externally, the assessment of potential impacts of internal EU policies and initiatives on third countries is crucial. Tool #35 must be applied in a manner that integrates the SDGs, given that they are a shared universal framework that provides a useful blueprint to assess in a comprehensive manner a range of impacts on developing countries.

When screening process indicates that impacts on developing countries will be significant, relevant targeted consultation should be planned in time and integrate in the overall stakeholder consultation strategy⁴⁷⁴. The targeted consultation, addressing relevant stakeholders in developing countries, should collect their views on expected likely impacts of the EU initiative.

If impacts are significant, a thorough assessment – as explained in this tool – is essential to ensure that the external dimension of the EU initiative is considered from the very start.

Developing countries are very heterogeneous in their social, political, and economic structure. While impacts on the most relevant countries will have to be established on a case-by-case basis, as a rule, the focus would be primarily on the impacts on Least Developed Countries and those countries most in need⁴⁷⁵.

While it can sometimes be cumbersome to identify potentially significant impacts and to distinguish between direct or indirect impacts, many of the EU measures that are likely to have an impact on developing countries are already well-known. See Box 1 below for a non-exhaustive list of these, compiled by OECD⁴⁷⁶.

Box 1. Measures known to have impacts on developing countries

Trade and finance:

- Regulatory measures in the management of EU production (e.g. fisheries) can affect exports and prices of products in developing countries, thereby distorting trade and

⁴⁷⁴ See Tool #51 (*Consulting stakeholders*)

⁴⁷⁵ An updated list of Developing Countries and Least Developed Countries can be found, respectively, at the World Bank’s and IMF’s official websites.

⁴⁷⁶ This list is based to a large extent on an OECD publication (2012). See OECD, Policy framework for policy coherence for development, WP n°1, 2012.

undermining the local production, food security and livelihoods in these countries;

- Tariff barriers or export subsidies for EU products (e.g. in agriculture) can affect the exports, commodity prices, and prices of processed products imported from developing countries to the EU and thereby undermine local production (for domestic or export markets), food security and livelihoods in developing countries;
- Measures regulating the behaviour of private actors such as multinational enterprises also active in developing countries; or measures impacting on the (re)distribution of value added along international integrated production chains (e.g. fair trade initiatives);
- Measures affecting movement of capital such as investment or remittances and the conditions of investment in developing countries, both in positive and negative ways (e.g. measures fighting tax evasion and dealing with tax havens);

Ensuring global food security:

- Regulatory measures regarding food safety and quality, animal welfare and environmental protection in the EU, which may present unintended non-tariff trade barriers to direct/indirect food exports into the EU from developing countries;

Making migration work for development:

- Initiatives affecting movement of people (e.g. migration policy) and conditions for travel of developing countries' citizens to and from the EU;

Strengthening the links between security and development:

- Measures affecting the attribution of development aid, investment or domestic resource mobilisation in developing countries;
- Measures and initiatives affecting fragile states or the EU intervention in international security issues;

Addressing climate change:

- Measures regarding climate change mitigation and achieving the international agreed warming limit level; measures affecting adaptation needs of developing countries.

2. HOW TO ASSESS THE IMPACTS ON DEVELOPING COUNTRIES

The scope and depth of the analysis will be determined, on a case-by-case basis, by the likely impacts of the proposed action.

When the screening process indicates that impacts on developing countries will be significant, consulting with developing countries stakeholders will be the main means to collect information. While the principles and requirements remain those of the 'better regulation' guidelines and relevant tools, the mechanisms need to be adapted to the reality of contexts, particularly for least-developed countries. While the lead DG will define the content of the consultation in cooperation with the interservice coordination group (ISCG), EU Delegations will define the most appropriate consultation activities and mechanisms⁴⁷⁷. While some stakeholders can be reached online, information will be mostly collected through direct consultations (e.g. interviews, workshops, meetings and seminars).

⁴⁷⁷ For details/examples see Tool #51 (*Consulting stakeholders*)

External expertise can be used to complement the consultation process, to gather evidence and conduct a more detailed, substantial and quantified analysis or/and qualitative analysis of the impacts of the EU policy proposed options⁴⁷⁸.

It is also important to consider factors potentially playing a role in the final negative/positive impact (e.g. other international actors, etc.) and determine whether it would be transitory or permanent. Furthermore, qualitative estimate of the main political risks should be provided (possible sources include comments/criticism on this or similar policy/measure by the European Parliament, the Council or civil society).

2.1. Guiding questions for a targeted consultation and/or qualitative and quantitative assessments

The table below presents the list of potential impact areas that should be screened to identify the most relevant impacts for subsequent, more detailed analysis. The guiding questions can also be considered when carrying out a targeted consultation and/or qualitative assessment⁴⁷⁹.

Category of impact	Potential impact areas and guiding questions
Economic impacts	Which developing countries are producing (and exporting to the EU) the goods/services affected? Are these least developed countries?
	What is the impact on proportion (esp. in value) of the trade between these developing countries and the EU, in particular regarding the trade balance of developing countries?
	What is the likely impact on price volatility?
	What are the impacts on proportion between the purchase of raw materials and finished products from developing countries?
	What are the impacts on domestic sectors development and infant industries?
	What is the impact on the competitiveness of exporters in developing countries in terms of intended or unintended trade barriers?
	What are the impacts on the initiative on intellectual property rights, standards, and technology and business skills in developing countries and on their capacity to trade their goods (towards the EU or among themselves)?
	What is the impact on food security for local population (e.g. by affecting the price of commodities or food in world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on the different population groups (urban vs. rural, small-vs. large-scale farmers and their livelihood)?
	What are the impacts on international and domestic investment flows (outflows and inflows including FDI) in the developing countries?

⁴⁷⁸ A qualitative analysis/overview of the impact of EU policy options on developing countries is a valid approach, especially when proceeding to a fully-fledged quantitative assessment is cumbersome (due to lack of data) or not proportionate (because the cost incurred in gathering such data would not be justified in the light of the magnitude of the initiative's likely impact).

⁴⁷⁹ These guiding questions could also support stakeholders in their analysis when participating in public or targeted consultations.

	What are the impacts on the private sector in developing countries (including competitiveness, access to finance, access to market)?
Social impacts ⁴⁸⁰	What are the impacts on labour market, e.g. quantitative impact on employment level, impact on the quality of employment (respect of labour standards, impacts on different groups of workforce – low-skilled vs. high-skilled workforce, wages, working conditions, discrimination, exploitation)?
	What are the impacts on main stakeholders and institutions affected by the proposal?
	What is the impact on poverty levels ⁴⁸¹ and income inequality in developing countries?
	What are the impacts on gender equality and on the most vulnerable groups of society, including persons with disabilities ⁴⁸² ?
	What is the impact on human rights ⁴⁸³ in the development countries?
	What is the impact on migrants, refugees, and other forcibly displaced populations? What is the impact on migration and mobility in developing countries (rural-urban or international)? What is the impact on EU aid allocation to developing countries (conditionality)?
	What is the impact on food security for the local population (e.g. by impacting on price of commodities or food on world and regional/local markets or by limiting access to land, water or other assets)?
	What is the impact on different population groups (urban vs. rural, small- vs. large-scale farmers)?
	What is the impact on health systems at the regional and local level, in particular from a health security perspective and more generally from a human development one?
	What is the impact on the state's capacity to procure security to the population in the whole territory and its borders? What is the impact on cybersecurity?
Environmental impacts ⁴⁸⁴	How does it impact ecosystems (terrestrial, marine)?
	What is the impact on emission targets in developing countries?
	What is the impact on chemicals authorisation as well as on use and waste management?
	What is the impact on green economy development (e.g. on the adoption of green/circular practices) both globally and in partner countries?
	What is the impact on the low carbon technology transfer and its availability in developing countries?

⁴⁸⁰ See Tool #30 (*Employment, working conditions, income distribution, social protection and inclusion*)

⁴⁸¹ Those people that stay below the poverty line

⁴⁸² When analysing the impacts on persons with disabilities, consider the UN Convention on the Rights of Persons with Disabilities, to which the EU is a party (for example: accessibility of persons with disabilities to buildings, transport infrastructure and on-line services; access to employment and education; reduction of poverty; and deinstitutionalisation process).

⁴⁸³ See Tool #29 (*Fundamental rights, including the promotion of equality*)

⁴⁸⁴ For additional information see Tool #57 (*Methods to assess costs and benefits*) and Tool #36 (*Environmental impacts*)

	What is the impact on the biodiversity (mono-cropping, deforestation) and global or local food security?
	What is the impact on the management and use of natural resources, e.g. minerals, timber, water, land, etc.?

For qualitative assessments, a comprehensive literature review can provide the necessary elements for the assessment of the expected effects, which can be corroborated by means of focus groups or interviews.

2.2. Quantitative assessment

Whenever stakeholder consultation and/or qualitative assessment may indicate that a detailed, substantial and quantified analysis is advisable (e.g. for new regulatory proposals that substantially affect a specific production in developing countries), the analysis should be supported by detailed quantitative data to establish a causal link between the policy option and its impact and analytical tools that entail modelling techniques⁴⁸⁵.

No single analytical approach is recommended given the broad range of policy options that might need to be considered and the constraints on human and financial resources that might be available for the assessment. Moreover, several analytical/methodological approaches have been used in the past for similar types of policy option and each gives satisfactory results. More of different analytical tools can be used together to cover various elements at stake, with possibility of their combination. The various analytical approaches include:

- **Econometric analysis:** Gravity models have been widely used for estimating the impact of trade and non-trade barriers to trade (e.g. standards).
- **Computable General Equilibrium (CGE) models:** There are several well-established CGE models that can be used to yield results in ex-ante assessments. Results obtained from such models capture relations between different macro indicators providing full scale information on given economy be it on national or regional level. Widely used GTAP8 model serves in simulating world trade and production providing for assessment of likely impacts on economic performance after introduction of certain measure (change in tax rates, price levels, investment activity, consumption patterns, production technology, etc.)^{489,486}. For examples, see Box 2.

Box 2. Example of a modelling study

The CEPR Study used to simulate the likely effects of the Transatlantic Trade and Investment Partnership (TTIP) on the EU, which is based on the so-called GTAP8 model, is a good illustration of modelling studies that can potentially be used in impact assessments⁴⁸⁷. This is a well-established Computable General Equilibrium model to analyse tariff and non-tariff barriers to trade. If this model were to be applied to an appropriate level of aggregation (i.e. various groups of developing countries or, in special circumstances, individual developing countries), isolating trade diversion effects from other effects and substantiating important

⁴⁸⁵ For the list of plausible models see Tool #61 (*Simulation models*)

⁴⁸⁶ For a detailed description of the GTAP8 see, for instance, Aguiar, Angel H., McDougall, Robert A., and Narayanan, G. Badri (ed.), (2012), "Global Trade, Assistance, and Production: The GTAP 8 Data Base", Center for Global Trade Analysis, Purdue University

⁴⁸⁷ See http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

assumptions on other indirect effects towards the developing countries, it could prove to be a reliable tool for an assessment of the likely effects on developing countries. The responsible DGs could explore the opportunity of co-operating with the JRC to establish a sound application of this methodology to analyse and measure the impact of the proposed policy measures on the developing countries.

3. FOSTERING POLICY COHERENCE FOR DEVELOPMENT AND ASSESSING MITIGATING MEASURES

Choosing the appropriate policy option for reducing negative impacts in developing countries, while seeking positive synergies, is markedly important for the particularly vulnerable economies. From an array of mitigating measures those most effective for developing countries should be chosen.

Box 3. Examples of used mitigating measures

- The Common Agricultural Policy (CAP) post-2013 Regulation was accompanied by an evaluation framework to measure ex-post the performance of the CAP with the EU development cooperation objectives. This monitoring was based on appropriate indicators to provide a consistent and dynamic picture of performance of the CAP vis-à-vis its stated development objectives.
- When the Economic Partnerships Agreements were negotiated, several mitigating measures were envisaged, including:
 - At least 80% of customs import duties would be phased out by African Caribbean Pacific (ACP) Group of States over 12 years; following negotiations, the period was extended to 15 years (in some cases to 20 or even 25 years) and in one case a lower 75% threshold was accepted.
 - All export duties/taxes should be phased out; following negotiations, it was accepted that existing duties/taxes may continue, and new ones introduced in specific cases for development reasons, including industrial development, infant industry protection, and food security, environmental or fiscal reasons.
 - Exceptional difficulties should be dealt with traditional safeguard clauses: after negotiations, specific provisions were added to protect infant industries, food security and rural development, and bilateral safeguard clauses were provided for in cases of import surges from the EU, with lower triggers than those of multilateral safeguards under WTO rules.

4. INFORMATION SOURCES AND BACKGROUND MATERIAL

Examples of sources of information already available and on databases than can support the analysis of the different dimension of the IA on Developing Countries.

- **Tool knowledge already available.** To identify and obtain existing relevant sectoral studies, the lead service should contact in priority the DGs INTPA, RTD and JRC. Commissioning an expert study on given subject might also be an option (contact DG INTPA for available experts and use of relevant framework contracts). In addition,

relevant ex-post evaluations, previous impact assessments covering similar countries/sectors as well as provision of literature review can serve as good starting point.

- **Databases to support economic and social assessments.** The most comprehensive database in terms of coverage of cross-country, cross-time information on developing countries currently publicly available is the World Development Indicator database (WDI), which contains useful information on several dimensions of poverty (economic, protective, political, and human socio-cultural). As regards data on international prices, they can be found on the International Comparison Programme (ICP).⁴⁸⁸
- **Databases on Trade and FDI flows.** EUROSTAT, via the COMEXT database, has also extensive data on imports and exports of goods with developing countries. The UN COMTRADE can also be used to gather import data for the EU, as opposed to the actual export data from the developing countries (which can prove to be a great advantage as import values for developing countries are generally more reliable than export values. The UNCTAD and OECD have databases regarding foreign direct investments and DG TRADE also developed a market access database. The DAC OECD database reports complementary information on this. In terms of data on the measurement of standards/NTMS, the FP7 NTM project can be helpful.
- **Databases to support the environmental assessment.** As regards the environmental impacts on developing countries, relevant data can be found at the [United Nations Framework Convention on Climate Change](#), the [Convention on Biological Diversity](#), [Global Climate Change Alliance](#) and the [Forest Law Enforcement, Governance and Trade](#).

5. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Contribution to the international 100bn USD commitment on climate related expending • Official development assistance as share of gross national income • EU financing to developing countries <i>UN indicators:</i> • Proportion of domestically generated resources allocated by the government directly to poverty reduction programmes • Proportion of government recurrent and capital spending to sectors that disproportionately benefit women, the poor and vulnerable groups • Total official flows (official development assistance plus other official flows) to the agriculture sector • Whether or not legal frameworks are in place to promote, enforce and monitor equality and non-discrimination on the basis of sex	   

⁴⁸⁸ The ICP is a worldwide statistical exercise established at the end of the 1960s. Its objective is to compare the GDP of various economies to "... determine their relative size, productivity and material well-being". This comparison is done using purchasing power parities.

Relevant SDG indicators	SDGs
• Proportion of countries with systems to track and make public allocations for gender equality and women's empowerment • Total resource flows for development, by recipient and donor countries and type of flow (e.g. official development assistance, foreign direct investment and other flows) • Mobilized amount of United States dollars per year between 2020 and 2025 accountable towards the \$100 billion commitment • Number of least developed countries and small island developing States that are receiving specialized support, and amount of support, including finance, technology and capacity-building, for mechanisms for raising capacities for effective climate change-related planning and management, including focusing on women, youth and local and marginalized communities • Foreign direct investment (FDI), official development assistance and South-South cooperation as a proportion of total domestic budget • Volume of remittances (in United States dollars) as a proportion of total GDP • Total amount of approved funding for developing countries to promote the development, transfer, dissemination and diffusion of environmentally sound technologies • Worldwide weighted tariff-average	  

TOOL #36. ENVIRONMENTAL IMPACTS

1. INTRODUCTION

Environmental impacts are changes in the state of the environment due to anthropogenic activities (such as the use of resources or activities causing pollution) that may also affect human health.

Direct environmental impacts (so climate impacts, loss of biodiversity, resource use, etc.) have secondary (indirect) impacts on the economy and wider social wellbeing. Environmental impacts often affect not just the environment but through it:

- human health through impacts to our physical condition and well-being;
- economic activity through changes to production and services;
- social aspects through e.g. poverty alleviation and wealth distribution.

The 'better regulation' guidelines commit us to analysing the environmental impacts of all policies in a proportionate manner and following the 'do no significant harm' principle. This includes the identification of impacts, and, as far as possible, the quantification of positive and negative environmental impacts. This tool explains how to identify environmental impacts and is an introduction to Chapter 8 that provides approaches for determining their significance and trade-offs.

2. THE EU GREEN DEAL AND 'DO NO SIGNIFICANT HARM' PRINCIPLE

EU actions and policies should pull together to help the EU achieve a successful and just transition towards a sustainable future, in line with the objectives of the **European Green Deal**. Evaluations and impact assessments also systematically assess the relevance and coherence of current legislation with new priorities. To this end:

- **Stakeholder consultations** should explicitly cover environmental aspects where relevant. This can be done either with a reference in the 'call for evidence' and/or a set of questions in the public consultation or with targeted consultations reaching specific groups of stakeholders.
- **Evaluations** should look at whether the evaluated legislation or programmes had some impacts on the environment. This can concern either direct impacts or possible (in)coherence with overarching environmental goals (such as the European climate law) or (in)consistencies with other policies targeting the environment. All evaluations should ask the following evaluation questions:
 - Are there any identified issues that significantly harm the environment?
 - Is there any incoherence with the climate law?
 - If so, how they could be removed or minimised?

If the evaluation found that there could be potentially significant negative effects on the environment, but data were not available to quantify or fully assess the significant harm, the evaluation should conclude on the limitation of methodology, qualitatively

present the significant adverse effects, and include in the lessons learned the issues identified and the lack of data.

- **Impact assessments** should be clear if there will be environmental impacts, and what the trade-offs are between the environment and other objectives. This element should be clearly identified in the report and the proposal in the following way.

It is paramount that the options are consistent with the environmental objectives of the European Green Deal. In particular, the climate law⁴⁸⁹, states *“The Commission shall assess the consistency of any draft measure or legislative proposal, including budgetary proposals, with the **climate-neutrality objective** set out in Article 2(1) and the 2030 and 2040 targets before adoption, and include this analysis in any impact assessment accompanying these measures or proposals, and make the result of that assessment public at the time of adoption. The Commission shall also assess whether these draft measures or legislative proposals including budgetary proposals, are consistent with ensuring **progress on adaptation** as referred to in Article 5. In making its proposals, the Commission shall endeavour to align them with the objectives of this Regulation. In any case of non-alignment, the Commission shall provide the reasons as part of the assessment referred to in this paragraph.”* In cases when significant environmental harm cannot be avoided, options could include mitigating or compensatory actions. In any case, the analysis of options (in particular, the preferred option) should always clearly present the environmental assessment to allow for an informed policy decision.

The following, non-exhaustive list of questions helps to check the consistency of the legislative proposal with the ‘do no significant harm’ principle, when relevant.

- Does the policy have impact on any of the objectives of the European Green Deal?
- Are the options consistent with the objectives of the European Green Deal, including climate neutrality?
- Do the options consider all environmental impacts? What are the trade-offs? Are the global, non-EU environmental impacts considered?
- Do the options include incentives for cleaner production or consumption (e.g. information, market-based instruments, polluter pays principle)? Is the creation of new markets considered, allowing for the pricing of resources previously considered as without value, including instruments such as cap-and-trade schemes (e.g. ETS)?
- Is mitigation of possible negative environmental impacts considered? Has adaptation to changing environmental circumstances been considered?
- When relevant, are options analysed based on sector-specific resource modelling or a life-cycle assessment (see Tool #66) along the whole value chain? Have re-use, recycling, cascading uses, and circular economy been considered? Can less resource intensive alternatives lead to the same outcome?
- Will the options also limit or prevent environmental damage in the future with a rapidly changing context?

⁴⁸⁹ Regulation (EU) 2021/1119 of 30 June 2021 establishing the framework for achieving climate neutrality (European Climate Law)

- Do the options increase the EU’s leverage to improve the environmental practices of the trading partners?

A specific section of the preferred option chapter should transparently report if there are decisions that will cause significant environmental harm because of concerns over the costs of mitigation, or trade-offs between different environmental aspects (e.g. trade-offs between enhanced battery capacity for electro-mobility and the use of toxic and/or environmental damaging substances to obtain the enhanced capacity). These impacts should be transparently reported.

- The **explanatory memorandum** accompanying all legislative proposals and delegated acts will include a specific section explaining how each initiative upholds the ‘do no significant harm’ principle. An illustrative example of this can be found in the European Commission Proposal for a Regulation concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) 2019/1020, (COM(2020) 798/3)⁴⁹⁰.

3. WHAT ARE THE RELEVANT ENVIRONMENTAL IMPACTS?

3.1. Principles of environmental analysis

The identification of the likely significant environmental impacts is followed by a deeper assessment. The assessment can be qualitative if quantitative data are not available or not fully available.

Analysis of environmental impacts is often best done through a multi criteria analysis⁴⁹¹ (a pure cost-benefit or cost-effectiveness analysis is often difficult to be performed due to the character of impacts). This involves⁴⁹²:

- identifying the full extent of environmental impacts (what impacts are significant?);
- quantifying those impacts where possible (for example, km² of land converted, tons of waste or emissions and identify where they occur;
- monetising the costs and benefits of those impacts where possible.

3.2. What environmental impacts can be distinguished?

Tool #18 includes an identification of the main environmental areas on which a policy could have an impact. These can be overlapping and linked, e.g. a circular economy approach will normally reduce climate impacts. The different impacts of any option concern changes in the state of:

- climate;
- air quality;
- water quality and quantity;
- biodiversity;
- soil quality or resources and land use change or degradation;
- waste production and recycling;

⁴⁹⁰ [Proposal for a Regulation on batteries and waste batteries](#)

⁴⁹¹ https://europa.eu/capacity4dev/evaluation_guidelines/wiki/multi-criteria-analysis-0

⁴⁹² See Tool #62 (*Multi-criteria decision analysis*)

- zero pollution and toxicity;
- efficient use of resources (renewable & non-renewable);
- contribution to circular economy;
- the likelihood or scale of environmental disasters;
- international environmental impacts.

The enabling conditions to meet the objectives of the above-mentioned areas include:

- ensuring effective and efficient implementation of Union legislation on environment and climate;
- strengthening the integrated approach to policy development and implementation, including the link to social objectives;
- mobilising sustainable investments from public and private sources;
- ensuring that environmental policies and action are based on the best available scientific knowledge.

3.3. Key questions to identify potential impacts

First, what are the potential environmental impacts of the existing policy intervention (evaluation) or policy options (impact assessment) that need to be assessed? For evaluations this step is informed by impacts identified in the prior impact assessment or accompanying documents of the legislation or policy to be evaluated. However, possible unintended or unknown impacts could have occurred.

As a rule, environmental impacts occur both in the short term and in the long term. The immediate impact on the environment can be negligible, but the effect can be quite significant if the impact takes place over a longer period (the cumulative effect). The impacts can be interlinked and can be of different magnitude. They can be of local or of transboundary nature. Once the potential impacts are clear, a deeper assessment may need to follow (see section 4 below).

There are several **overarching questions** to consider:

- Is there a market failure linked to externalities (so polluters do not pay for the damage they do)? For example, does the policy affect economic incentives for reduction of greenhouse gases (e.g. first and second round incentives and price signals under the EU's emission trading system)?
- Is there a market failure linked to environmentally harmful subsidies that encourage pollution?
- What is the role of environmental technology and innovation in the problem and solving it?
- Are there issues related to implementation and enforcement of existing environmental legislation?

Moreover, the following, non-exhaustive questions can help identify potential direct or indirect impacts:

Climate change

- Does the policy contribute to the achievement of the 2030 climate target of at least 55% net greenhouse gas emission and the climate-neutrality objective by 2050?
- Does the policy affect the emission of ozone depleting substances (CFCs, HCFCs etc.)?
- Does the policy affect our ability to adapt to climate change? How does the policy affect our adaptive capacity, resilience, or vulnerability for climate change?
- Does the policy allow to increase carbon removals or preserve carbon stocks?
- Does the policy improve climate mainstreaming into other policy goals?
- With a view to achieving climate neutrality, i.e. equalisation of emissions and removals of greenhouse gases by 2050, does the policy ensure that no additional carbon lock-in is created?
- Does the policy create risks for climate resilience as referred to in Tool #14 (*Risk assessment and management*)?

Air quality

- Does the policy have an effect on emissions of harmful air pollutants that might lead to deterioration in the environment (crop yields, soil, forests or rivers etc.), affect human health, and damage buildings and cultural heritage?

Water quality and resources

- Does the policy decrease or increase the quality or quantity of freshwater and groundwater?
- Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)?
- Does it affect drinking water resources, and in particular their quality?

Biodiversity

- Does the policy affect natural capital and the ecosystem services?
- Does the policy reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)?
- Does it affect protected or endangered species or their habitats or ecologically sensitive areas?
- Does it affect the integrity and the conservation measures of Natura 2000 sites and for example split the landscape into smaller areas or in other ways affect migration routes, ecological corridors, or buffer zones?
- Does the policy affect the scenic value of protected landscape?

Soil quality and land use change and degradation

- Does the policy affect soil quality and result in a loss of soil carbon stocks, decline of soil biodiversity, compaction, sealing, landslides, acidification, contamination, salinisation or erosion?
- Does it lead to loss of available soil (e.g. through building or construction works i.e. land sealing) or increase the amount of usable soil (e.g. through land decontamination)?
- Does the policy lead to land use change, land take and bring new areas of land ('greenfields') into use for the first time?
- Does it affect land designated as sensitive for ecological reasons?
- Does it lead to degradation of land?

Waste production and recycling

- Does the policy affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of, or recycled?

Zero pollution and toxicity

- Is the product toxic? At what levels? Is it (bio)degradable? Does it accumulate in the bodymass?
- What are the sectors? Are there any non-toxic substitutes?

Efficient use of resources (renewable & non-renewable)

- Does the policy affect the use of renewable resources (fish, etc.) and lead to their use being faster than they can regenerate?
- Does it reduce or increase use of non-renewable resources (groundwater, minerals, etc.)?
- Does the policy affect the energy intensity of the economy?
- Is there a risk of a 'rebound effect' (e.g. improvement in resource efficiency is offset by an increase in consumption)?
- Is there an impact on the supply chain for key resources?

Circular economy

- Does the policy aim at maintaining the value of products, materials, and resources (understood as durability, reparability, reusability, or recyclability) for as long as possible by returning them into the product cycle at the end of their use, while minimising the generation of waste?
- Does the policy lead to verifiable additional sustainable production and consumption?
- Does the policy change the relative prices of environmentally friendly and unfriendly products?

- Does the policy promote or restrict environmentally (un)friendly goods and services through changes in capital investments, loans, insurance services, etc.?
- Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?

The likelihood and scale of environmental risks

- Does the policy affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions?
- Does it affect the risk of unauthorised or unintentional release or proliferation of organisms or products that might have an environmental impact (such as invasive species)?

International environmental impacts

- Does the policy have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?
- Does the policy promote the EU's sustainability objectives in third countries (Green Deal diplomacy)?

Environment and fairness

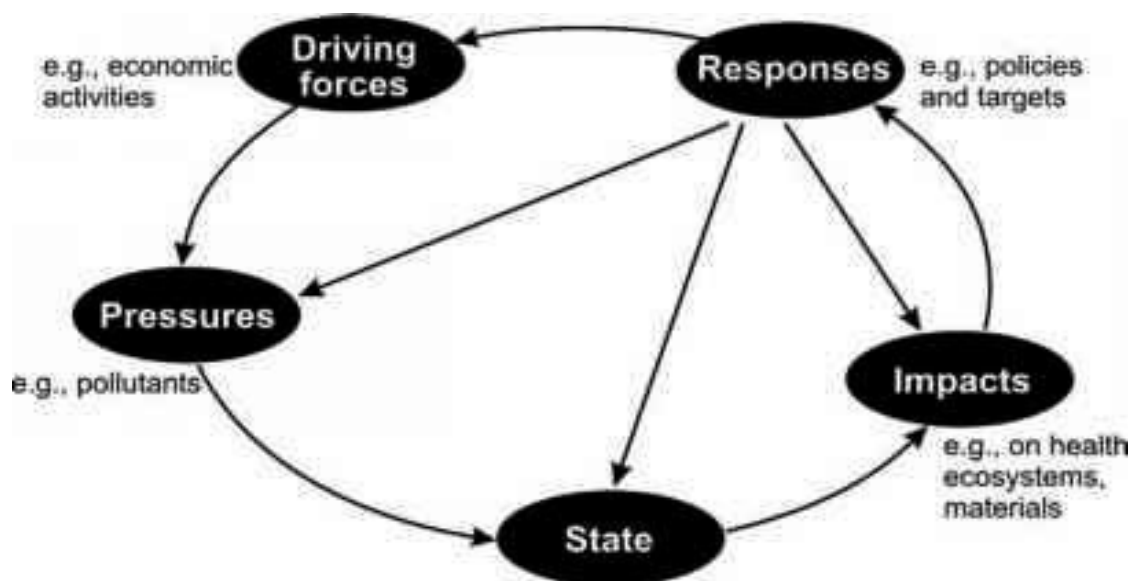
- Is the environmental policy socially just?
- Does the policy reduce social and regional inequalities with respect to environmental and health risks, and access to eco-system services?
- Does the policy disproportionately burden certain citizens (e.g. low-income or rural)? Are the benefits of the policy evenly distributed?

4. ASSESSMENT OF ENVIRONMENTAL IMPACTS

4.1. The DPSIR framework

DPSIR (drivers, pressures, state, impact and response model of intervention) is a causal framework for describing the interactions between society and environment – human impact on the environment and vice versa because of the interdependence of the components.

The DPSIR framework has been widely adopted by the European Environment Agency (EEA), an EU decentralised agency, acting as an integrated approach for reporting, e.g. in the EEA's State of the Environment Reports. The framework gives a structure to present the indicators needed to inform policy makers on environmental quality and the resulting impact of the political choices. According to the DPSIR framework there is a chain of causal links starting with 'driving forces' (economic sectors, human activities) through 'pressures' (emissions, waste) to 'states' (physical, chemical, and biological) and 'impacts' on ecosystems, human health and functions, eventually leading to political 'responses' (prioritisation, target setting, indicators). The mapping and assessment of ecosystems and their services (MAES) initiative is a collaboration between the European Commission, the EEA and Member States, which is based on the DPSIR framework.



4.2. Understanding market failures in the environment

Market failure occurs when the price mechanism fails to account for all the costs and benefits necessary to provide and consume a good. In the real world, it is not possible for markets to be perfect due to inefficient producers, externalities, environmental concerns, and lack of public goods. An externality is an effect on a third party which is caused by the production or consumption of a good or service, without being considered by the producer or consumer. Externalities can be positive (external benefit) or negative (external cost). The result is that producers or consumers do not behave in the socially most optimal way. Many (environmental) policies try to correct these externalities. Tools #13 (*How to analyse problems*) and #16 (*How to identify policy options*) explain how these market failures can be addressed in impact assessments.

A first example of market failures causing environmental damage is when economic actors are not fully accountable for the negative environmental externalities (or damage) their actions cause. Economic instruments (e.g. taxes) are often proposed as a solution to 'internalise' these externalities. A particular example of this is the **polluter pays principle**, where those who produce pollution should bear the costs of managing it to prevent damage to human health or the environment. For instance, a factory that produces a potentially poisonous substance as a by-product of its activities is usually held responsible for its safe disposal. The polluter pays principle is part of a set of broader principles to guide sustainable development worldwide. The polluter pays principle is included in the Treaties. Article 191(2) TFEU, "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on ... the polluter should pay*".

A second example of market failures in the environment is, the common case, when there is an **absence of market prices** for the environmental goods or services. The lack of market prices for environmental services does not mean that these goods have no value. Monetisation of environmental goods helps to create incentives to avoid environmental damage. Valuation techniques to assess the costs of environmental damage and benefits of environmental services are set out in Tool #57 (*Methods to assess costs and benefits*).

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

- [International resource panel website](#)
- [European Environment Agency](#)
- [Mapping and Assessment of Ecosystems and their services](#)
- [Natural Capital Accounting](#)
- [REGIO guidelines on CBA](#)
- [Taxonomy Regulation](#)
- [Handbook on the external costs of transport](#)

6. RELEVANT SDG INDICATORS

To track progress in this field, the SDG indicators below can be a useful methodology, though the list should not be considered exhaustive.

Relevant SDG indicators	SDGs
<i>EU indicators:</i> • Area under organic farming • Ammonia emissions from agriculture • Exposure to air pollution by particulate matter • Population having neither a bath, nor a shower, nor indoor flushing toilet in their household • Population connected to at least secondary wastewater treatment • Biochemical oxygen demand in rivers • Nitrate in groundwater • Phosphate in rivers • Water exploitation index • Primary & final energy consumption • Energy productivity • Share of renewable energy in gross final energy consumption • Energy dependence • Share of busses and trains in total passenger transport • Settlement area per capita • Recycling rate of municipal waste • Consumption of hazardous and non-hazardous chemicals • Resource productivity and domestic material consumption (DMC) • Average CO2 emissions per km from new passenger cars • Circular material use rate • Generation of waste excluding major mineral wastes • Greenhouse gas emissions • Greenhouse gas emissions intensity of energy consumption • Global mean ocean surface acidity • Estimated trends in fish stock biomass • Assessed fish stocks exceeding fishing mortality at maximum sustainable yield (Fmsy) • Surface of marine sites designated under NATURA 2000 • Bathing sites with excellent water quality • Share of forest area • Surface of terrestrial sites designated under NATURA 2000 • Soil sealing index • Estimated soil erosion by water • Common bird index • Shares of environmental and labour taxes in total tax revenues	       

Relevant SDG indicators	SDGs
<i>UN indicators:</i> • Prevalence of moderate or severe food insecurity in the population, based on the Food Insecurity Experience Scale (FIES) • Proportion of agricultural area under productive and sustainable agriculture • Number of plant and animal genetic resources for food and agriculture secured in either medium- or long-term conservation facilities • Proportion of local breeds classified as being at risk, not at risk or at unknown level of risk of extinction • Mortality rate attributed to household and ambient air pollution • Proportion of population using safely managed drinking water services • Proportion of population using (a) safely managed sanitation services and (b) a hand-washing facility with soap and water • Proportion of wastewater safely treated • Proportion of bodies of water with good ambient water quality • Level of water stress: freshwater withdrawal as a proportion of available freshwater resources • Change in the extent of water-related ecosystems over time • Proportion of population with primary reliance on clean fuels and technology • Renewable energy share in the total final energy consumption • Energy intensity measured in terms of primary energy and GDP • International financial flows to developing countries in support of clean energy research and development and renewable energy production, including in hybrid systems • Passenger and freight volumes, by mode of transport • CO2 emission per unit of value added • Ratio of land consumption rate to population growth rate • Proportion of urban solid waste regularly collected and with adequate final discharge out of total urban solid waste generated, by cities • Annual mean levels of fine particulate matter (e.g. PM2.5 and PM10) in cities (population weighted) • Total expenditure (public and private) per capita spent on the preservation, protection and conservation of all cultural and natural heritage, by type of heritage (cultural, natural, mixed and World Heritage Centre designation), level of government (national, regional and local/municipal), type of expenditure (operating expenditure/investment) and type of private funding (donations in kind, private non-profit sector and sponsorship) • Number of countries with sustainable consumption and production (SCP) national action plans or SCP mainstreamed as a priority or a target into national policies • Material footprint, material footprint per capita, and material footprint per GDP • Domestic material consumption, domestic material consumption per capita, and domestic material consumption per GDP • Number of parties to international multilateral environmental agreements on hazardous waste, and other chemicals that meet their commitments and obligations in transmitting information as required by each relevant agreement • Hazardous waste generated per capita, and proportion of hazardous waste treated, by type of treatment • Number of companies publishing sustainability reports • National recycling rate, tons of material recycled • Number of countries implementing sustainable public procurement policies and action plans • Amount of fossil-fuel subsidies per unit of GDP (production and consumption) and as a proportion of total national expenditure on fossil fuels • Number of countries that have communicated the establishment or operationalization of an integrated policy/strategy/plan which increases their ability to adapt to the adverse impacts of climate change, and foster climate resilience and low greenhouse gas emissions development in a manner that does not threaten food production (including a national adaptation plan, nationally determined contribution, national communication, biennial	  

Relevant SDG indicators	SDGs
update report or other) • Number of least developed countries and small island developing States that are receiving specialized support, and amount of support, including finance, technology and capacity-building, for mechanisms for raising capacities for effective climate change-related planning and management, including focusing on women, youth and local and marginalized communities • Index of coastal eutrophication and floating plastic debris density • Proportion of national exclusive economic zones managed using ecosystem-based approaches • Average marine acidity (pH) measured at agreed suite of representative sampling stations • Proportion of fish stocks within biologically sustainable levels • Coverage of protected areas in relation to marine areas • Number of countries making progress in ratifying, accepting, and implementing through legal, policy and institutional frameworks, ocean-related instruments that implement international law, as reflected in the United Nations Convention on the Law of the Sea, for the conservation and sustainable use of the oceans and their resources • Sustainable fisheries as a proportion of GDP in small island developing States, least developed countries, and all countries • Forest area as a proportion of total land area • Progress towards sustainable forest management • Proportion of important sites for terrestrial and freshwater biodiversity that are covered by protected areas, by ecosystem type • Proportion of land that is degraded over total land area • Coverage by protected areas of important sites for mountain biodiversity • Mountain Green Cover Index • Red List Index • Proportion of traded wildlife that was poached or illicitly trafficked • Progress towards national targets established in accordance with Aichi Biodiversity Target 2 of the Strategic Plan for Biodiversity 2011–2020 • Proportion of countries adopting relevant national legislation and adequately resourcing the prevention or control of invasive alien species Official development assistance and public expenditure on conservation and sustainable use of biodiversity and ecosystems	

TOOL #37. CUSTOMS ENFORCEMENT OF SECTORAL PROHIBITIONS AND RESTRICTIONS AT EU BORDERS

1. INTRODUCTION

The EU Customs Union is the operational arm of many EU policy measures at the Union borders: it controls goods arriving from third countries before they can enter the EU market or other movements of goods such as exports or transit. This applies not only to financial measures⁴⁹³ but also to 'sectoral legislation' aimed at protecting a variety of public interests such as health, safety, security, environment, cultural goods, intellectual property, or sanctions imposed in the framework of the Common Foreign and Security Policy (CFSP). Authorities responsible for the controls of Prohibitions & Restrictions (P&R) at EU external borders are designated by Member States and are in most cases Customs. As of April 2021, more than 300 pieces of EU legislation linked to Prohibitions & Restrictions⁴⁹⁴ require enforcement at EU borders. This already presents a huge workload for Customs even considering that controls are primarily risk-based.

Enforcement of Prohibitions & Restrictions may equally have significant impacts on economic operators. On the one hand, they may represent an additional cost⁴⁹⁵ as they must comply with numerous and sometimes complex legislation when declaring goods at EU borders, such as complying with product requirements, providing specific documentation or certificates. On the other hand, an ineffective enforcement of Prohibitions & Restrictions at EU borders may also have significant economic impacts on EU businesses as it may distort competition by putting EU economic operators at a disadvantage *vis-a-vis* non-EU economic operators not abiding to EU legislation.

This tool concerns the part of the 'sectoral legislation' requiring enforcement by Customs Authorities (hereinafter Customs) at the Union's external borders which is usually referred to as Prohibitions & Restrictions. It should be applied only for those cases involving P&R (entry, release for free circulation, exit, export or transit of goods or their placement under another customs procedure).

2. SCREENING OF OPTIONS AGAINST CUSTOMS' MANDATE

Options involving a role for Customs in the enforcement of P&R measures at the EU borders should be consistent with the mission and practices of customs authorities.

As shown in Box 1, customs need to enforce a multitude of sectoral legislation, while not being specialists. Therefore, they need clear instructions in the sectoral legislation. In consequence, the impact assessment should consider options that are viable from a customs perspective and that allow for an effective and efficient enforcement at EU borders.

⁴⁹³ Customs and trade measures cover among other customs duties, quotas, commercial policy measures, fishery conservation and management measures. For customs and trade legislation see Tool #27 (*External trade and investment*)

⁴⁹⁴ DG TAXUD is developing with the help of the lead DGs an integrated list of Prohibitions and Restrictions

⁴⁹⁵ In international rankings most EU Member States are listed as [best places to import goods into \(no cost](#), which is very good) but this is probably by comparing them to other countries; in reality all compliance bears a cost. An [OECD paper](#) assessing 5000 traded goods and 80 countries estimates that the ad valorem equivalent of a non-tariff measure (P&R), that is the proportional rise in the domestic price of the goods to which it is applied, can be as high as 15.9%; it is clearly not the case for the EU (because domestic goods would not allow such surge in prices) but this illustrates that the cost of compliance is non-negligible.

Box 1. Key provisions of the Union Customs Code⁴⁹⁶

Mission of customs authorities

According to [Article 3](#), “Customs authorities shall be primarily responsible for the supervision of the Union’s international trade, thereby contributing to fair and open trade, to the implementation of the external aspects of the internal market, of the common trade policy and of the other common Union policies having a bearing on trade, and to overall supply chain security. Customs authorities shall put in place measures aimed, in particular, at the following:

- (a) protecting the financial interests of the Union and its Member States;
- (b) protecting the Union from unfair and illegal trade while supporting legitimate business activity;
- (c) ensuring the security and safety of the Union and its residents, and the protection of the environment, where appropriate in close cooperation with other authorities; and
- (d) maintaining a proper balance between customs controls and facilitation of legitimate trade.”

Customs role with regards to Prohibitions and Restrictions

When it comes to the enforcement of P&R at entry into and exit from the EU customs territory, [Articles 134 and 267](#) of the Union Customs Code foresees that, while they are under customs supervision, the goods “shall be subject to such prohibitions and restrictions as are justified on grounds of, inter alia, public morality, public policy or public security, the protection of the health and life of humans, animals or plants, the protection of the environment, the protection of national treasures possessing artistic, historic or archaeological value and the protection of industrial or commercial property, including controls on drug precursors, goods infringing certain intellectual property rights and cash”.

Cooperation and information exchange between customs and competent authorities and risk analysis

Effective control at EU borders requires cooperation between competent authorities and customs. [Article 47](#) of the Union Customs Code provides the general framework for such cooperation but the sectoral legislation needs to include provisions on the concrete interaction between customs and competent authorities which are adapted to the specificities of that legislation.

Furthermore, risk analysis is an important part of controls at EU borders. For risk analysis, the Customs Risk Management System allows among others to exchange relevant risk information between Customs in all Member States. Some sectoral legislation also lays down the principle of common risk analysis at the EU level. However, as Customs are only generalists, it is paramount to rely also on the expertise of sectoral authorities. The sectoral legislation should thus make explicit the form and scope of exchanges of risk information as well as the means of communication.

Framework and scope of customs enforcement at EU borders

Where Customs plays a role in the enforcement of sectoral legislation, this should precisely

⁴⁹⁶ Regulation (EU) 952/2013 laying down the Union Customs Code and its delegated and implementing acts

lay down its interactions with other framework or specific legislation and its exact scope. For example, when a sectoral legislation relates to product requirements, it should make explicit whether the framework legislation on product compliance (Regulation (EU) 2019/1020) applies in full or whether specific provisions for enforcement at the EU borders are included in the specific legislation, which should accordingly be dealt with as a *lex specialis*. Recital 6 of Regulation 2019/1020 indicates that: *"If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation."*

In this regard, certain basic questions should systematically be considered when designing the options involving P&R measures:

- Does the option allow for a proper balance between customs controls and facilitation of legitimate trade? In other words, can the objective sought be attained by using different, more efficient, means?
- To render controls at EU border as effective as possible, has the option envisaged provisions related to cooperation between competent authorities and customs?
- Have you considered the possible compatibility of options with a horizontal legal framework for enforcement (see point 4)?

3. HOW TO ASSESS ECONOMIC IMPACTS OF SECTORAL POLICY ON CUSTOMS ENFORCEMENT OF PROHIBITIONS & RESTRICTION

Before designing new policy proposals or amending/revising already existing legislation with new provisions relating to entry, release for free circulation, exit, export or transit of goods, or their placement under another customs procedure, there is a need to assess the impacts of sectoral legislation on its enforcement at EU borders.

For this purpose, the following questions may provide guidance:

- 3.1. Does the new policy proposal require enforcement at EU borders?
 - If so, does it require enforcement at import, at export or both at import and export or under other customs procedures (e.g. transit, customs warehouse, inward processing)?
 - What type of protection should the measure provide (prohibition, restriction, technical requirement)?
 - If a measure is envisaged, how will it be managed (by requiring a licence/permit/certificate, due diligence, other?)

Customs enforces sectoral legislation by performing documentary checks that include the customs declarations and the supporting documents (certificates, licences, authorisations), in particular those required by the sectoral legislation, as well as by doing physical or laboratory controls on the goods themselves. Customs controls are based primarily on risk analysis, which allows selecting for control those consignments that present a higher risk of non-compliance. As the selection relies almost exclusively on IT processing of the customs declaration, the latter needs to contain all the necessary information and the necessary IT systems and interfaces shall be foreseen for an efficient and effective

enforcement. However, the customs legislation⁴⁹⁷ provides only a horizontal framework for customs enforcement of Prohibitions & Restrictions (see [Articles 134 and 267](#) above). The sectoral legislation should therefore lay down any specific requirement necessary for customs enforcement and then only its practical implementation will be coordinated with the customs processes and systems. This applies at distinct levels:

- First, the sectoral legislation should normally link any measure applicable at EU borders to the customs classification, thereby allowing for an easy identification of the goods and the applicable measures. Concretely, Customs identify goods via a code system ([6 digit HS, 8 digit CN or 10 digit TARIC](#)) that allows for a quick and precise identification of the goods and serves also as a gateway to the relevant control measures ([TARIC measures](#)).
 - Second, where necessary, the sectoral legislation should lay down all necessary requirements. For example, if customs have to check the existence of certificates or licences, the sectoral legislation should request economic operators to submit such supporting documents together with their customs declaration.
- 3.2. Will the new legislation require a new or upgraded IT systems or interfaces to:
- manage the implementation of the requirements at EU borders (e.g. setting up a new IT system or scaling up an existing system with new modules, new connectivity with other systems)? As long as this new/upgraded IT system is not available, will the new legislation be enforced efficiently and effectively enough? If yes, how?
 - monitor the trade at EU borders (e.g. setting up a new IT system or scaling up an existing system with new modules, new connectivity with other systems)?

Enforcement of sectoral legislation at the EU borders and cooperation between customs and competent authorities in the specific sectoral domain relies largely on IT systems. Their availability and interconnection are essential for an efficient and effective enforcement of Prohibitions & Restrictions.

The EU Single Window environment for customs is a digital solution for the exchange of electronic information between different sectoral authorities and customs. It enables the automated verification by customs of the non-customs regulatory formalities, managed in the Union non-customs systems, which are referenced in the customs declaration as evidence of compliance (e.g. certificates, authorisations, licences) and as well as quantity management⁴⁹⁸.

The Commission proposal on the EU Single Window Environment for Customs⁴⁹⁹ envisages also the business-to-government component, i.e. possibility for economic operators to fulfil customs and non-customs formalities via a single channel.

The possible incorporation of the sectoral measures in the EU Single Window Environment for Customs solution should be subject to the assessment of time needed for the development of the IT systems and the assessment of the related costs.

⁴⁹⁷ Regulation (EU) 952/2013 laying down the Union Customs Code and its delegated and implementing acts

⁴⁹⁸ The EU Customs Single Window Certificates Exchange System (EU CSW-CERTEX) introduced new functionalities, such as quantity management. The monitoring and managing the quantity of goods authorised by partner competent authorities in accordance with Union non-customs legislation is based on the information provided by customs authorities on the clearance of related consignments.

⁴⁹⁹ The EU Single Window Environment for Customs | Taxation and Customs Union; Subject to the approval of the legislative proposal, such channel would be enabled by 2031.

- 3.3. Does the enforcement of the new measure apply on the entire EU customs territory, or should exceptions apply?

The EU customs borders do not match exactly with the EU borders. The territorial scope of the EU Customs Union is defined in Article 4 of the Union Customs Code⁵⁰⁰. It should be read in conjunction with the UK Withdrawal agreement. UK including Northern Ireland are not part of the customs territory (Article 4 of the Protocol of Ireland/Northern Ireland) but, for goods entering Northern Ireland, EU legislation is applicable (Article 5(3) and (4) and Annex 2 of that protocol). The UK sovereign base areas in Cyprus are part of the customs territory of the Union (Article 2 of the Protocol Relating to the sovereign base areas of the United Kingdom of Great Britain and Northern Ireland in Cyprus). See summary table [here](#).

- 3.4. How severe should the prohibition, restriction or technical requirement be?

In other words, how dangerous would be the introduction in the EU customs territory of a good infringing the new measure, should it not be detected by customs? There are two aspects in connection to this question.

First, sectoral legislation may be complex and require specific facilities, equipment, and staff qualifications. The sectoral legislation should consider such elements and define proper mitigating measures. For example, whereas Customs are present at all EU borders (land, air, sea), it might be opportune to limit the entry into or exit from the EU to certain custom offices that have acquired or can acquire knowledge or expertise with the specific sectoral legislation and have at their disposal the necessary control equipment.

Second, depending on the goods' risk profile, advance cargo information and risk analysis may be required to enable the early identification of threats and help Customs to intervene at the most appropriate point in the supply chain. The EU is implementing a new customs pre-arrival security and safety program, underpinned by a large-scale advance cargo information system – Import Control System 2 (ICS2). The ICS2 will collect data about all goods entering the EU prior to their arrival. Economic operators will have to declare safety and security data to ICS2, through the Entry Summary Declaration. The obligation to start filing such declarations will not be the same for all operators. It will depend on the type of services they provide in the international movement of goods.

4. HOW TO MINIMISE IMPACT ON (CUSTOMS) ENFORCEMENT AT EU BORDERS (MITIGATING MEASURES)

4.1. No involvement of customs in the enforcement at the Union borders

Where no enforcement at the Union borders or Customs involvement are necessary, no impact should obviously be analysed. This may be the case for example for sectoral legislation relating to requirements that could easily be enforced at a point in time when the goods are already made available in the market and for which non-compliance with the requirement would result only in remote risks to the interests at stake.

⁵⁰⁰ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (please ensure that you take the latest consolidated text as there were changes to the customs territory recently, not only in relation to the UK)

4.2. Relying on an existing framework to enforce sectoral legislation at EU borders

An easy way to limit the impacts of enforcement of sectoral legislation at the EU borders is to rely on an existing framework that provides already a collaboration mechanism with Customs. Two comprehensive frameworks are in place in the EU: *the product compliance framework* and *the official controls framework*. If one of these two frameworks provides a sufficient basis for the enforcement and no substantial change is necessary, the impacts on Customs may remain limited and require less effort for effectively implementing the sectoral legislation.

4.2.1. Product compliance framework

Regulation (EU) 2019/1020 applies to all products, whether manufactured or not, also including food and feed, medicines and products of human origin and products of plants and animals relating directly to their future reproduction when the goods qualify also as products.

It lays down rules and procedures to ensure a high level of protection of health and safety, in general and in the workplace, and protect consumers, the environment, public security and other public interest in the EU. As regards enforcement at the EU borders, Chapter VII of the Regulation⁵⁰¹ establishes the framework for controls on products imported into the EU.

4.2.2. Official controls framework

Regulation (EU) 2017/625 lays down the governance of the agri-food chain. As regards enforcement at the EU borders, it establishes an integrated approach to import controls. Common rules apply to controls carried out at borders on animals, products of animal origin, plants and other products and goods that must be checked before they enter the EU. The import control system is risk-based and targeted.

A list of animals and goods subject to systematic controls at the border has been established. Border Control Posts (BCPs) carry out border control tasks. Minimum requirements for facilities, equipment and staff qualifications apply throughout all border control posts.

All consignments to be presented at the border control posts must undergo documentary checks. Identity and physical checks are carried out at a frequency depending on the risk linked to the specific animals or goods. The criteria to determine and modify the frequency of rates has been established by the Commission.

In principle, all controls must be carried out at the border control post where the consignment arrives. However, the Commission is empowered to establish cases and conditions under which deviations from this principle are allowed.

A single standard document, the Common Health Entry Document (CHED), must be used by operators for the prior notification of consignments. It is transmitted to the border control post through a new integrated computerised system for official controls (Integrated Management System for Official Controls, IMSOC⁵⁰²).

The provisions require close cooperation among competent authorities, Customs and other authorities involved in the controls of animals and goods arriving from third countries to ensure timely exchange of relevant information. The Commission is empowered to detail the functioning of such cooperation.

⁵⁰¹ DG TAXUD can provide detailed explanations on the product compliance framework upon request.

⁵⁰² IMSOC allows the integration of all computerised systems (TRACES, RASFF, Europhyt, AAC) to optimise exchange of information, data and documents needed enforce agri-food chain rules.

4.3. Specific enforcement requirements

If the legislation relates to either products or the agri-food chain described above, these respective frameworks normally provide an appropriate and comprehensive organisation for controls on goods entering the Union market. Therefore, it is strongly advised to simply rely on these frameworks as their organisation of controls at the Union borders is already in place and the extension to another sector would be easier and only have limited impacts.

On the contrary, in all cases where:

- the relevant goods do not qualify as products or relate to the agri-food chain, or;
- even if they do, further or other specific provisions relating to the organisation of controls on goods entering the Union market are required,

the impact assessment should consider as a minimum the two following options and analyse their impacts in full coordination with DG TAXUD:

- Option 1: (partial or full) reuse of one of the existing organisations of controls under the frameworks described above;
- Option 2: establishment of a separate organisation of controls at the EU borders with specific provisions.

Specific provisions to consider for Option 2 include:

- control at the Union borders would cover in the first line goods declared for transit, export or any special customs procedure;
- control requires specific facilities, equipment and staff qualifications;
- specific control processes are necessary, such as the systematic involvement of a designated authority to clear each consignment;
- specific exchanges of information between the authorities concerned by the controls;
- specific information shall be provided in the customs declaration and therefore require integration in the customs classification systems for automated checks with specific parameters or databases;
- an authorisation (e.g. license scheme) is required and Customs should control it through automated checks of a sectoral database;
- specific reporting is necessary (e.g. for statistics);
- specific IT tools or interfaces should be used or developed.

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

For further DG TAXUD support, documents and guidance:

- Consult [TAXUD Intracomm pages](#)
- Contact TAXUD by email: TAXUD-PROHIBITIONS-RESTRICTIONS@EC.EUROPA.EU