EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries		
LEAD DG – RESPONSIBLE UNIT	GROW/D.2 & ENV/A.3	**DATE OF THIS ROADMAP**	18/05/2016
TYPE OF EVALUATION	Fitness Check	**PLANNED START DATE**	March 2015
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This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

The aim of this fitness check ("FC") is to assess whether the current legislative framework for chemicals, as outlined in the scope in Section C below, is fit for purpose and delivers as intended/expected. It shall:

- assess the overall **effectiveness**, **efficiency, relevance, coherence,** and **EU added value** of this legislative framework, including the procedures to implement the framework;
- identify possible excessive regulatory burdens, overlaps, inconsistencies, obsolete measures and gaps in the legislative framework;

The results of this FC, together with the forthcoming REACH Report in 2017 and the completed and ongoing studies (listed in Section D.2), will provide an overall picture of the effectiveness, efficiency, relevance, coherence, and EU added value of EU chemicals legislation that will form the basis of a stock-taking report on the regulatory fitness of chemicals legislation as foreseen in the Commission Communication on REFIT in 2014[1].

According to the Communication 'Better regulation for better results – An EU agenda' COM(2015) 215, this FC will identify possible further burden reduction actions.[2]

(A.2) Justification

In December 2012, the European Commission announced the launch of the Regulatory Fitness and Performance Programme (REFIT)[3]. Its aim is to have in place a simple, clear and predictable framework for business, workers and citizens, so that the policy objectives set are achieved and the benefits of EU legislation are enjoyed at lowest cost and with a minimum of regulatory burden. Among the tools used under REFIT are fitness checks, comprehensive policy evaluations designed to ascertain whether the regulatory framework for a policy sector is fit for purpose.

A second communication related to REFIT ("Results and next steps") released in October 2013[4] identified a number of policy areas, in which a regulatory fitness check should be conducted. One of these areas is *"the most*

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook', COM(2014)368, 18 June 2014.

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Better regulation for better results - An EU agenda'; COM(2015) 15, 19 May 2015.

[3] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'EU Regulatory Fitness', COM(2012) 746 final, 12 December 2012.

[4] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Regulatory Fitness and Performance (REFIT): Results and Next Steps', COM(2013) 685 final, 2 October 2013

relevant chemicals legislation not covered by REACH as well as related aspects of legislation applied to downstream industries".

In addition, in the Commission Communication "Commission follow-up to the 'TOP TEN' Consultation of SMEs on EU Regulation",[5] SMEs were reported to "have concerns about the complexity and cost of information obligations, inconsistent application by Member States and a lack of coherence with specific chemicals legislation such as Restrictions of Hazardous Substances (RoHS), biocides, endocrine disruptors and Toy Safety". Some of these concerns are being addressed in the follow up to the REACH Review. The issues regarding the choice of risk management measures and the coherence between pieces of legislation are the focus of this FC.

The continued interest in chemicals is reflected in the 2014 REFIT communication[6] which underlines our commitment to make further efforts at the EU level to facilitate the implementation of legislation on chemicals and to reflect on specific areas where rules can be simplified and burdens reduced.

B. Content and subject of the FC

(B.1) Subject area

General considerations

Chemicals are omnipresent in society, contributing considerably to achieving our high living standard. Chemicals are present in almost every product used by a consumer, in almost every building or construction, and forms part of almost every production process, be it food, electronics, toys, clothes or industrial machines. This omnipresence shows how dependent a modern prosperous society is on chemicals but also that the exposure and hence potential human health and environment risks are manifold and multifaceted.

The European Union chemicals *acquis* has developed over the past 50 years, balancing the need of society to continue to use chemicals and thereby contributing to prosperity, whilst safeguarding society against the potential human health and environment risks arising from that very use. Its development started in 1967 with the adoption of a Directive that harmonised the Member State rules for classification, packaging and labelling of chemical substances across the then European Economic Community. This enabled the free circulation of chemicals, without the need to re-classify, re-package and re-label the chemical product when being traded across national borders and established a Community wide harmonised system of communicating hazards to the users of chemicals, thus enabling them to take appropriate safety measures. The European Union chemicals *acquis* has now developed into a comprehensive system of over 100 pieces of primary legislation.

The legislative framework for chemicals comprises both chemicals legislation in the strict sense of the word – directly regulating chemical substances and mixtures– and related legislation, e.g. regulating conditions, under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, in which chemicals are used (this includes consumer articles, for which certain requirements exist in product-specific legislation, although the use and presence of hazardous chemicals in many articles is not systematically regulated).

The development of this framework has been continuous and has been built on the experiences obtained and the approaches developed. Yet there has not been a comprehensive assessment across the European Union chemicals *acquis* to ascertain if it still meets its primary aims; to ensure that both the European citizen benefits from a high level of protection for humans and the environment and that the EU internal market in chemicals functions well. Meeting these aims should stimulate innovation and boost competitiveness. It has also not been fully evaluated if it does so efficiently and coherently while remaining relevant in addressing stakeholders needs.

Moreover, as announced in the Circular Economy Action Plan, the Commission is working on assessing the interaction between waste, products and chemicals legislations (in order to facilitate the traceability of chemicals in the recycling process and limit unnecessary burden for recyclers). The fitness check will also provide essential input to this assessment.

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Commission follow-up to the "TOP TEN" Consultation of SMEs on EU Regulation', COM(2013) 446 final, 18 June 2013.

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook', COM(2014)368, 18 June 2014

Risk management of chemicals

There are several elements of the risk management process for chemicals, typically starting with the identification of hazards of a chemical substance or mixture and ending with risk management measures to control any risks determined by the intrinsic hazards and the exposure in a concrete use or application. The extent to which the steps below are present in the risk management process depends on the specific pieces of legislation.

A hazard is determined by the intrinsic properties of the substance or mixture, i.e. whether its characteristics can lead to health and environmental damages. These intrinsic properties are identified using information generated through testing or epidemiological studies.

Hazard identification may occur in both horizontal and sectoral legislation. A key horizontal regulation that mandates the identification of hazards is the CLP Regulation[7], which upon identification also classifies these hazards as health hazards, physical hazards or environmental hazards. Those hazard classes are based on the UN Globally Harmonized System of Classification and Labelling of Substances and Mixtures (GHS). In addition to the hazard classification under CLP, other legislation may foresee other hazard classifications, such as the criteria in the Plant Protection Products Regulation for the classification of substances as persistent organic pollutants (POP), persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) properties, the identification of substances of having endocrine disrupting properties or other substances with equivalent levels of concern.[8,9]

Depending on the nature and dimension of hazards and the exposure situations involved, risk management measures are taken directly based on the identified hazard classification using generic risk considerations justifying a direct risk management consequence, or based on a specific risk assessment.

Direct mechanisms applying measures to classified substances based on generic risk considerations without further specific assessment of the risk may be justified by specific considerations, such as the characteristics of the hazard, the vulnerability of certain parts of the population (e.g. children), non-controllable or widespread exposure.

Examples of risk management and communication measures based on generic risk considerations include coverage of industrial sites by the Seveso Directive, labelling requirements under CLP, EU Ecolabel eligibility under the Ecolabel Regulation and cut-off criteria under the Plant Protection Products Regulation.

A specific risk assessment assesses the probability of occurrence of an adverse effect on man or the environment resulting from a given exposure to a chemical or mixture. The assessment takes into account both the hazards and the potential specific exposures of humans and the environment. An example of legislation providing for such specific risk assessments is the Cosmetics Regulation as regards CMR[10] categories 1A, 1B and 2 substances.

In addition, in some cases, risk management measures may take into account other factors, such as socio-economic considerations and the precautionary principle.[11]

Risk management measures require the analysis of a complex set of considerations that need to be balanced against each other with a view to an optimal outcome, ensuring an appropriate protection from risks and the functioning internal market, and also encouraging innovation and the competitiveness of European companies.

[7] GHS is implemented in accordance with the 'building block approach'. The harmonised elements of the GHS may be seen as a collection of building blocks. Countries are free to determine which of the building blocks will be applied in different parts of their systems. However, where a system covers something that is in the GHS, that coverage should be consistent. See GHS section 1.1.3.1.5.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, Annex II, section 3.7.

[9] CLP Article 53(2) states that Member States and the Commission should *"promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN"*. According to Recital 75, *"Subject to developments at UN level, the classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances should be included in this Regulation at a later stage."*

[10] Carcinogenic, Mutagenic and Toxic to Reproduction.

[11] Communication from the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1 final.

(B.2) Original objectives of the intervention

Typically, the overarching general objectives of chemicals legislation and other related legislation can be summarised as follows:

- ensure a high level of protection of human health and the environment
- ensure the efficient functioning of the internal market
- enhance competitiveness and innovation[12,13]

As for any EU intervention, the legislation should allow for a predictable, clear and proportionate legislative framework.

Specific pieces of legislation may have more specific objectives, such as:

- controlling the use of and/or exposure to hazardous substances by identifying and managing & communicating their risks
- giving appropriate incentives to develop suitable alternatives and to substitute hazardous chemicals where better alternatives exists
- reducing the number of animals used for testing chemicals
- ensuring coherent and effective implementation of the Union's obligations under international agreements
- increasing the free movement of specific products
- encouraging improvements in the safety and health of workers at work
- ensuring a high level of protection of animal health
- utilising natural resources prudently and rationally

Some of the related legislation within the scope of this fitness check may also include objectives that concern other policy areas, such as ensuring agricultural productivity and sustainability or promoting products that have a high level of environmental performance.

(B.3) How the objectives were to be achieved

Resources and mechanisms – according to legal base

The above-mentioned general objectives are typically achieved through the following mechanisms in chemicals legislation:

- Step 1: hazard identification (e.g. CLP hazard classification or identification of PBT/vPvB or substances of equivalent concern, identification of hazardous substances in the workplace under the OSH Directives)
- Step 2: consideration of risks based on:
  - Generic risk considerations
  - Specific risk assessment
- Step 3: defining risk management measures, considering hazard, possible exposure and/or socio-economic factors (this is not applicable in all cases) based on Step 2.

Some legislation may omit some of the above-mentioned steps or implement an iterative process of certain steps if needed.

Outputs – according to legal base

The relevant outputs are appropriate risk management measures on specific uses of chemicals (either at EU or national level, depending on the legal base), which include:

- risk management on packaging of hazardous chemicals
- authorisations (with conditions)
- restrictions on use/manufacturing/placing on the market
- bans on use/manufacturing/placing on the market
- hazard and risk communication, including labelling
- prevention of major accidents and the limitation of their consequences
- other risk management and risk mitigation measures

Results

The expected results, depending on the legislation, include the following:

- relevant information on hazardous chemicals to users
- better protection of users, citizens and the environment from the adverse effects of hazardous chemicals
- lower rates of health incidents, illness, and environmental pollution
- substitutions or phase-out of hazardous chemicals

[12] See COM(2001) 88 final, White Paper, Strategy for a future Chemicals Policy, 27 February 2001, p. 5.
[13] Some legislation within the scope of the fitness check may place a particular emphasis on one of these general objectives.

- preserving the essential uses of chemicals e.g. to prevent or control a serious danger to human health, animal health or the environment or in case of a disproportionate impact on society when compared to the above mentioned risks
- harmonised rules for manufacture/use/placing on the EU market

Impacts

Depending on the pieces of legislation concerned, the expected impacts include:

- higher protection of health and the environment
- better functioning of the internal market
- preserving growth and competitiveness
- encouraging innovation
- improving the safe use of chemicals for society
- more jobs and social cohesion

External factors

- Member States activities (national actions, initiatives, enforcement, practices, etc.)
- Market trends
- International regulatory instruments for chemicals (both bilateral and multilateral, e.g. UN GHS)

Some of the related legislation within the scope of this FC may not entirely follow the intervention logic listed above, but contain some provisions on chemicals and thereby partially contribute to the chemicals framework and its objectives.

C. Scope of the FC

(C.1) Topics covered

The FC will consist of the following:

1. Mapping out links between the various hazards identified and the risk management measures taken as a consequence in downstream legislation on the basis of generic risk considerations

This will include an analysis of the hazard identification and classification provisions in the CLP regulation, and of the inter-linkages of these provisions with risk management measures provided for in the same piece of legislation or in another piece of legislation (e.g. provisions communicating hazards to users of chemicals and setting specific legal requirements on risk management of chemicals).

The same analysis should be performed for any provision identifying or categorizing hazard of chemicals that is provided for in pieces of legislation other than the CLP Regulation (e.g. the criteria for PBT/vPvB substances under the Biocidal Products and REACH Regulations, the identification of hazardous substances in the workplace under the OSH Directives).

2. Mapping out the links between the specific risk assessments and the risk management measures taken as a consequence

This will include an analysis of the specific risk assessment provisions and of the inter-linkages of these provisions with risk management measures provided for in the same piece of legislation or in another piece of legislation.

3. Examining the overall effectiveness, efficiency, relevance, coherence and EU added value of the hazard identification/generic risk considerations and specific risk assessment procedures (on their own but also compared to one another)

This will require examining the various procedures to identify hazard or specific risks provided for in EU chemicals legislation. Once the various procedures are described, their merits and shortcomings should be analysed on their own but also by comparison to one another following the FC criteria listed in section C.2 below.

4. Examining the overall effectiveness, efficiency, relevance, coherence and EU added value of the two risk management approaches adopted in the chemicals legislation, i.e. (i) risk management based on generic risk considerations and (ii) risk management based on specific risk assessment (on

their own but also compared to one another)

This will require examining the two approaches to adopting risk management in EU chemicals legislation. The two approaches' merits and shortcomings should be analysed on their own but also by comparison to one another following the FC criteria listed in section C.2 below.

The FC will also address potential missing links between chemicals management legislation and identified hazard or hazard classes based on generic risk considerations, e.g. cases in which a direct or indirect link between a risk management measure and an identified hazard via generic risk consideration may be warranted.

5. Analysing the coherence of the legislative approach and procedures regarding hazard identification, generic risk consideration, specific risk assessment or risk management measures.

This will include an analysis of the manner in which a given chemical is treated throughout the EU chemicals legislation and whether the various provisions applying to it provide for consistent definitions and coherent measures (i.e. measures adapted to the substance and the context). For instance, PBT substances are mentioned in several pieces of legislation and guidance documents, with various consequences attached to the qualification of PBT. The FC would, in this case, aim at determining whether the definition of PBT substances is identical in all pieces of legislation (or whether some differences are justified) and whether the consequences in each piece of legislation are coherent given the properties of the substance and the context of its use.

The list below contains legislation that falls within the scope of the fitness check. This list may be revised based on input received during the public commenting period. Whilst the fitness check covers any aspects of this legislation related directly to chemicals, it does not aim to evaluate, in its entirety, each individual piece of legislation.

The REACH Regulation is generally outside the scope of this exercise, as it has been evaluated as part of the REACH Review. Independently of the fitness check, DG Internal Market, Industry, Entrepreneurship and SMEs (GROW) and DG Environment (ENV) are currently following up the conclusions of the latest REACH Review. This work, which itself is also included on the REFIT Scoreboard, includes addressing problematic interfaces between sector-specific Union legislation and the REACH Regulation, as well as identifying burdens for SMEs. Moreover, the next REACH Report foreseen under Article 117(4) of the REACH Regulation is due in 2017 and will be prepared in parallel with this FC. Nevertheless, given the importance of hazard identification and classification criteria in this FC, Annex XIII to the REACH Regulation covering PBT and vPvB criteria will exceptionally be covered by this exercise.

CHEMICALS LEGISLATION AND RELATED LEGISLATION

Below is a non-exhaustive list of the main legislation relevant to this FC. If impacts or coherence issues of other EU legislation on the functioning of the chemicals legislation (also from the perspective of the downstream user) are noted, they may be assessed. This list may also be adapted in order to reflect revisions to existing legislation.

1) Legislation covering hazard identification and classification

- Classification, labelling and packaging (Regulation No (EC) 1272/2008)
- Plant protection products (Regulation (EC) No 1107/2009)
- Biocidal products (Regulation (EU) No 528/2012)
- REACH, Annex XIII (Regulation (EC) No 1907/2006)
- Inland transport of dangerous goods (Directive 2008/68/EC)
- Chemical Agents (Directive 98/24/EC), Asbestos (Directive 2009/148/EC), Carcinogens and mutagens at work (Directive 2004/37/EC)

2) Legislation covering risk management measures[14]

Worker safety and transport legislation

- Inland transport of dangerous goods (Directive 2008/68/EC)
- Carcinogens and mutagens at work (Directive 2004/37/EC)
- Young people at work (Directive 1994/33/EC)
- Pregnant workers (Directive 1992/85/EEC)

[14] Risk management measures are defined in a broad manner as any step towards reducing the risk of a chemical to health or environment to an acceptable level, e.g. not only bans or restrictions of use, but also communication measures, emission limits or residue limits.

- Signs at work (Directive 92/58/EEC)
- Chemical Agents (Directive 98/24/EC)
- Asbestos (Directive 2009/148/EC)

Environmental protection legislation

- Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
- Waste framework (Directive 2008/98/EC) and List of Waste
- Waste shipments (Regulation (EC) No 1013/2006)
- Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
- Water Framework (Directive 2000/60/EC)
- Urban Waste Water (Directive 91/271/EEC)
- Marine Strategy Framework (Directive 2008/56/EC)
- Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
- End of life vehicles (Directive 2000/53/EC)
- Batteries (Directive 2006/66/EC)
- Packaging and Packaging Waste (Directive 94/62/EC)

Chemicals control legislation

- Biocidal products (Regulation (EU) No 528/2012)
- Plant protection products (Regulation (EC) No 1107/2009)
- Export and import of hazardous chemicals (Regulation No 649/2012)
- Persistent organic pollutants (Regulation (EC) 850/2004)
- Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
- Residues of pesticides (Regulation (EC) No 396/2005)

Product controls

- EU Ecolabel (Regulation (EC) 66/2010)
- Safety of toys (Directive 2009/48/EC)
- Cosmetic products (Regulation (EC) No 1223/2009)
- Detergents (Regulation (EC) No 648/2004)
- Drinking Water (Directive 98/83/EC)
- Fertilisers (Regulation (EC) No 2003/2003)[15]
- Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)[15]
- Aerosol dispensers (Directive 75/324/EEC)
- Explosives (Directive 93/15/EEC)
- Pressure equipment (Directive 2014/68/EU)
- Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
- General Product Safety (Directive 2001/95/EC)

3) Supporting legislation

- Test methods (Regulation (EC) No 440/2008)
- Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
- Protection of animals used for scientific purposes (Directive 2010/63/EU)

Wherever Framework Directives are listed, the scope also includes Specific Directives (Daughter Directives) insofar as they are relevant.

[15] Some relevant legislation has recently been recast or is currently undergoing a revision (e.g. fertilisers, medical devices). The ex post analysis of such recent or future legislation (replacing existing instruments) will therefore be limited to relevant aspects only (notably mapping and analysing the links). The analysis will take due account of the impact assessments and political decisions underlying these revised pieces of legislation.

(C.2) Issues to be examined

With a view to its overall aim as set out in Section A1 above the FC will address the following questions related to effectiveness, efficiency, relevance, coherence, and EU added value of the legislative framework:

Effectiveness:

- To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?
- What are the consequences or effects (whether socio-economic, environmental or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?
- What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?
- To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedure)?

Efficiency:

- What are the costs and benefits associated with the implementation of the legislative framework for chemicals?[16] To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits? A specific focus will be given to SMEs.
- What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

Coherence:

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

Relevance:

- To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)
- To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?
- To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

EU added value

- What is the added value of regulating the risk management of chemicals at an EU rather than at national level?

(C.3) Other tasks

N/A

[16] Please note that costs and benefits of the legislative framework will generally be assessed in qualitative terms; quantification, as well as an international comparison will be done wherever possible.

D. Evidence base

(D.1) Evidence from monitoring

While most legislation includes specific monitoring provisions (e.g. regular reporting on CLP enforcement measures under CLP Article 46), there are no monitoring provisions for the legislative framework as a whole.

(D.2) Previous evaluations and other reports

The Commission concluded a review of the REACH Regulation in 2013. While the REACH Regulation itself is outside the scope of this exercise (as described above in section C.1), the REACH Regulation is a key component of the legislative framework for chemicals, requiring the submission of registration dossiers, including hazard and exposure data as well as voluntary risk management measures, and allowing for the restriction or authorisation of chemicals based on their risks and considering socio-economic aspects. Therefore, some of the outcomes of the REACH Review may be relevant for this fitness check and, conversely, the fitness check may identify issues with relevance for the REACH Regulation.

In 2012, the Commission conducted the fitness check of EU fresh water policy[17] which included the Water Framework Directive, the Ground Water Directive, the Directive on Environmental Standards, the Urban Waste Water Directive, the Nitrates Directive and the Floods Directive. Some of the outcomes may be relevant for this fitness check too. Other relevant exercises include ongoing fitness checks of EU legislation on occupational health and safety at work (OSH), food law, EU Ecolabel, a concluded fitness check on five waste stream directives[18] and on-going or planned evaluations of the drinking water directive, the toy safety directive, detergents regulation and plant protection products legislation. This FC will not duplicate this work. Instead where appropriate, the findings from those exercises will feed this FC.

Other relevant on-going studies include the study of the cumulative costs impact for the chemical industry and the study on the calculation of the benefits of chemical legislation for human health and the environment.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

Information on the implementation and application of the legislation will be gathered through the various supporting studies.

(D.4) Consultation

This fitness check is supported by a consultation strategy, encompassing the following consultation tools: an open public consultation, an SME Panel, targeted interviews, a stakeholder workshop, expert group discussions with competent authorities and a Eurobarometer. These consultation tools will collect input from stakeholders such as public authorities, companies in both the chemicals industry and downstream industries, industry associations, workers employed by the aforementioned industries, trade unions, NGOs, consumer associations, academia and research/educational institutes, and citizens. Data will be collected regarding the effectiveness, efficiency, coherence, relevance and EU added value of the legislative framework, as well as any cases of excessive regulatory burden that it entails. The open public consultation was launched in March 2016 and is running for a period of 12 weeks (see Your Voice in Europe website: http://ec.europa.eu/yourvoice/consultations/index_en.htm). The targeted interviews will be conducted as part of the supporting studies (listed below).

(D.5) Further evidence to be gathered

Two main studies are or will be conducted to gather evidence in support of the fitness check:

- Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation (GROW)
- Additional study in support of the fitness check (ENV)

In addition, the following on-going studies will also provide relevant data:

- Study on the assessment of the cumulative cost impact for the chemical industry (GROW)
- Study on the international comparison of cumulative regulatory costs for the chemical industry (GROW)
- Study on the calculation of the benefits of chemical legislation for human health and the environment (ENV)

E. Other relevant information/ remarks

N/A

[17] http://ec.europa.eu/environment/water/blueprint/fitness_en.htm

[18] The waste fitness check is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014SC0209&from=EN