EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	REFIT evaluation in view of the obligation stemming from Article 117(4) of Regulation (EC) No 1907/2006 for the Commission to report by 1 June 2017 on the implementation of REACH.		
LEAD DG – RESPONSIBLE UNIT	GROW D1 / ENV A3	**DATE OF THIS ROADMAP**	18/ 05 / 2016 Modified : 23/05/2016 Only concerns update of links pp.5-6
TYPE OF EVALUATION	Evaluation Ex post Mixed	**PLANNED START DATE** **PLANNED COMPLETION DATE**	On-going since Q1 / 2013 Q2 / 2017
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

The EU Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) has been in force since June 2007. The 2017 evaluation of the operation of REACH (REACH report 2017) is part of the reporting on the implementation of REACH, to be carried out every five years by Member States, the European Chemicals Agency (ECHA) and the Commission to monitor progress in the achievement of the objectives of Regulation. Regular monitoring and reporting provides information to identify needs for adjustment and to propose recommendations to improve the implementation of the Regulation or the need to consider modifications.

The REFIT evaluation will cover the five compulsory evaluation criteria (effectiveness, efficiency, relevance, coherence and EU added value) and put emphasis on potentials for burden reduction and simplification.

(A.2) Justification

According to Article 117(4) of REACH, the Commission has to report on the functioning of REACH every five years, starting from 1 June 2012. Therefore, there is a legal obligation for the Commission to report again by 1 June 2017.

Furthermore, Article 138 of REACH further specifies some elements that are relevant for the report,

EU chemicals legislation is essential to protect human health and the environment and has brought considerable cost savings to businesses operating in the Single Market. However, small companies find it difficult and costly to understand and comply with some of the requirements. These concerns have been addressed through a series of actions announced in the Commission Report on the Review of REACH (COM(2013)49). The effect of these measures and the impacts on stakeholders, in particular SMEs will be addressed by this REFIT evaluation and any residual unnecessary administrative burdens will be identified.

Since 2013, the knowledge base on chemicals has evolved significantly. This REFIT evaluation will assess whether REACH is fit to tackle evolving issues such as nanomaterials, cumulative effects, endocrine disruptors and other emerging issues.

The Commission announced in the Commission work Programme 2016 the intention to carry out a REFIT evaluation of REACH. Applying the five general evaluation criteria efforts will be made to identify burden reduction potentials and simplification, coherence and consistency between Occupational Health and Safety legislation and REACH will be considered.

B. Content and subject of the evaluation

(B.1) Subject area

REACH is the cornerstone of EU chemicals legislation, setting harmonised rules for the registration, evaluation, authorisation and restriction of chemicals in the EU. In force since 2007, REACH also established the European Chemicals Agency (ECHA), based in Helsinki.

(B.2) Original objectives of the intervention

The objectives of REACH are to ensure a high level of protection of human health and the environment, including the promotion of alternative methods to animal testing for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing the competitiveness and innovation.

In addition, REACH should contribute to the fulfilment of the World Summit on Sustainable Development 2020 goals.

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

Protection of human health and the environment.

REACH merged the previously different Regulations, Directives, Communications and Recommendations governing so-called new and existing chemicals into one unified systematic registration system, ensuring that the same obligations apply to both groups of chemicals.

In line with the polluter pays principle, REACH shifted the burden of proof by making industry responsible for safety, extending the responsibility along the supply chain. The registration system introduced requirements to make sufficient information available about the properties of so-called existing chemicals (i.e. those already on the market in 1981) in order to conduct risk assessments and introduce risk reduction measures where so required for hazardous substances. Health and environment benefits should arise from the application of appropriate risk reductions measures.

The registration requirements, including the testing requirements, depend on the proven or suspected hazardous properties, on uses, exposure and volumes of chemicals that are produced or imported. All chemicals placed on the market in volumes at or higher than 1 tonne per company per year have to be registered and special attention is given to long-term and chronic effects at the higher tonnages.

REACH puts the obligation on economic operators placing on the market hazardous substances and in particular when so doing in higher volume (above 10 t/y) to apply a consistent and comprehensive approach to risk management in the chemical safety assessment (CSA) and to document the results in the chemical safety report (CSR) and the safety data sheet (SDS), containing also recommendations regarding the safe use of those chemicals which downstream users then must follow.

REACH provides that ECHA and the Member States can evaluate the information submitted by companies, examine the quality of the registration dossiers and the testing proposals contained therein.. Registrants may be required to submit further information on the substance to clarify whether a given substance constitutes a risk to human health or the environment. Dossier evaluation aims at checking that industry is meeting its obligations and prevents unnecessary testing.

REACH also aims at managing hazardous substances while ensuring the efficient functioning of the EU internal market:

- The authorisation procedure aims to assure that the risks from Substances of Very High Concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternatives or technologies where these are economically and technically viable.
- The restriction process addresses unacceptable risks to human health or the environment posed by certain substances and requiring Union-wide action. The manufacture, use or placing on the market of those substances on their own, in mixtures or in articles may be restricted or even banned, if necessary.

Harmonisation of the internal market.

REACH aims at fully harmonising the chemicals legislation at Union level. This was implemented by choosing a Regulation based on the EC Treaty provision on harmonisation of legislation as the legal form of REACH, which ensures uniform application in all Member States, by establishing a central Agency (ECHA) to do most of the scientific and technical work and by establishing detailed rules for allowing marketing and use of substances in the EU.

Enhancing competitiveness and innovation.

The Regulation was designed to be a major factor in shaping the innovative behaviour of firms in the chemical industry as it terminated the disadvantages of the previous system for new chemicals by raising the registration threshold to 1 tonne per year and company (compared to 10 kg before) and by requiring the same amount of data for existing chemicals. REACH should therefore promote the competitiveness of the chemical industry and encourage innovation, by facilitating the development of safer chemicals, in particular chemicals aimed at replacing SVHCs.

To ensure proportionality, the system provides for a tiered approach (information requirements depend on volume of marketed substance) and staggered registration deadlines (high volume and the most dangerous chemicals were registered in the first registration deadline in 2010, followed by medium volume substances in 2013 and lower volume substances in 2018).

Promotion of non-animal testing.

Registrants are obliged to systematically collect all available information to promote non-animal testing and only where this information is insufficient to fulfil the information requirements a test should be considered. Furthermore most testing involving animals needs prior approval by ECHA and legal possibilities to use alternative methods to fill information gaps (e.g. through read across) were introduced.

Separately the Commission has committed itself to stimulate and fund the development of new non-animal test methods.

C. Scope of the evaluation/FC

(C.1) Topics covered

The REACH report 2017 will focus on certain elements of REACH, in particular those that have emerged or developed substantially after the 2013 REACH review. Thus, the report will focus mainly on the period 2010-2016, and will assess REACH's contribution to meeting the World Summit Sustainability Development (WSSD) 2020 goals and the Sustainable Development goals, as these objectives frame the subsequent detailed analysis. The results of the REACH Evaluation will feed into the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP).

The following aspects will be part of this evaluation:

I. Main issues resulting from the information obtained from regular reports from Member State Competent Authorities and ECHA submitted according to Article 117 of the Regulation, which cover the implementation of all REACH processes and enforcement. Member State reports provide an overview of the functioning of REACH in the territories of the 28 EU Member States and the EEA countries, including also information on their enforcement activities. ECHA's reports provide an overview of the operation of REACH, including information on joint submission of information by multiple registrants (Article 11) and the state of implementation of use of non-animal testing. These reports will allow monitoring the practical implementation of REACH and how it contributes to the protection of health and the environment in all EU Member States.

Furthermore, Article 138 of the REACH Regulation specifies some elements that are relevant for the general REACH report, namely registration requirements for 1 – 10 tonnes substances, including the CSA and CSR obligation for substances that are carcinogenic, mutagenic or toxic to reproduction - CMRs category 1A or 1B.

II. The status of implementation of the work launched as a follow-up to the 2013 REACH review and the actions that the Commission, ECHA, the Member States, and, where relevant, stakeholders have already implemented or are implementing in that context. This will include significant legislative and policy developments since 2013:

- Implementation of the SVHC roadmap
- Streamlining of the restriction procedure

III. Ongoing implementation work planned by 2017 (will be reported on only but not subject to ex post-evaluation)

- Implementation work on registration (including data sharing) and authorisation requirements with a view to improve effectiveness and lessen the administrative burden stemming from the Regulation.

IV. Further detailed topics to be covered will include:

- Assessment of the benefits of chemical legislation on human health and the environment as well as socio-economic benefits
- Assessment of the achievements made regarding the use of alternative test methods and non-test methods in REACH and in general
- Perception of chemical safety by citizens
- Support measures to assist SMEs (e.g. information concerning the use of EU funding programmes, guidance through the Europe Enterprise Network (EEN))
- Progress in the registration process, results of 2013 registrations and preparations for the 2018 deadline
- Review of the obligations on registration requirements for low tonnage (1-10 t/y) substances in relation to the REACH objectives
- Review of the obligations on the need, if any, to register certain types of polymers in relation to the REACH objectives
- Consideration of substance identity issues
- Assessment of the optimisation of substance evaluation
- Activities to improve the implementation of the requirements related to extended Safety Data Sheets (eSDS)
- Assessment of the costs and benefits of authorisation
- Interface with other legislation (including in particular the coherence between REACH and the occupational safety and health – OSH – legislation, coherence with legislation on waste as well as other relevant developments since 2013)
- Monitoring of enforcement of REACH via a new indicator system (and a public consultation on enforcement)
- Assessment of the impact of REACH on innovation, competitiveness and SMEs
- Assessment of the impact of REACH on the international competitiveness of the EU chemicals industry and selected Downstream User sectors
- Evaluation of ECHA and its Committees
- Information on substances in articles
- Review of Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency

The following topic may also be included (subject to further reflection on how to assess them):

- Ability of REACH to tackle nanomaterials, cumulative effects of chemicals, endocrine disruptors and other emerging issues

(C.2) Issues to be examined

The Commission will examine effectiveness, efficiency, proportionality, coherence, relevance and EU added value of the provisions of the REACH Regulation, focusing on the elements set out in the previous section.

Effectiveness

1. To what extent does REACH meet its objectives?
2. What have been the effects of REACH (whether socio-economic, environmental or health-related, both positive and negative), including also effects not originally planned?
3. What factors (including external ones) influenced the observed effects and to what extent?
4. To what extent is REACH contributing to meeting the World Summit Sustainability Development 2020 goals?

Efficiency

1. What are the costs and benefits associated with the implementation of REACH? To what extent are the costs proportionate to the benefits achieved?
2. What are the key drivers for those costs and benefits? What factors influenced the efficiency with which the accomplishments of REACH were attained?
3. Was the distribution of costs proportionate between the different stakeholders (e.g. larger companies vs SMEs, or among different industrial sectors)? To what extent are there unnecessary burdens on stakeholders?
4. How are costs distributed among public authorities at EU and national levels?
5. What aspects of REACH (including procedural aspects) are the most efficient and what are the least efficient (including the development of scientific opinions, work of scientific committees, urgency procedures, etc.)? Are there case studies demonstrating highly efficient or inefficient working of REACH processes? Are there differences in efficiency between Member States (both in terms of delivery of objectives and the costs of doing so)?

Coherence

1. To what extent are the different work processes, including their output, in REACH interacting in a coherent manner?
2. The REACH review 2013 examined the coherence of REACH with other chemical legislation. To what extent have inconsistencies, contradictions or missing links with other EU chemical legislation been addressed through REACH implementation after 2013?
3. To what extent is REACH coherent with international efforts, including chemical legislation in third countries?

Relevance

1. To what extent is REACH capable of adapting to evolving needs (e.g. through adaptations to technical and scientific progress)?
2. To what extent is REACH relevant to the EU and its citizens?
3. To what extent is REACH capable of taking into account health, consumer concerns, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?

EU added value

1. What is the additional value of regulating the risk management of chemicals at EU rather than at Member State level?

(C.3) Other tasks

The Commission report will also provide a synthesis of National Reports submitted according to Article 117 (1) as well as reports from the European Chemicals Agency (ECHA), submitted according to Article 117 (2) and (3).

D. Evidence base

(D.1) Evidence from monitoring

Evidence for this evaluation is collected through:

- Information obtained from Member States and ECHA reports on the functioning of REACH which are to be delivered regularly in accordance with Article 117 of the Regulation:

  - ECHA's report on the status of the implementation and use of non-animal test methods and testing strategies to generate information required by REACH.
  - Member States' reports on the operation of REACH in their territories, including evaluation and enforcement.
  - ECHA's report on the operation of REACH, including information on joint submission of data for registration.

- REACH Report 2013 and follow-up work.

- Implementation reports related to the SVHC roadmap.

- Interpretation of the WSSD 2020 Chemical Goal and assessment of EU efforts to meet the WSSD Commitment (Final report, June 2013)

- Ongoing thematic studies already commissioned by the relevant units of the Commission :

  - Studies on registration requirements for low tonnage (1 – 10 t/y)
  - Technical assistance related to the review of REACH with regard to the registration requirements on polymers
  - Study to develop EU enforcement indicators for REACH and CLP
  - Study on the impact of REACH on innovation, competitiveness and SMEs
  - Study formulating recommendations based on statistical analysis of Member State reporting according to Article 117(1)
  - Study on impacts of REACH and corresponding legislation in 3rd countries on the international competitiveness of the EU chemicals industry and selected downstream user
  - Cumulative Cost Assessment for the chemicals industry
  - Substance Identity (SID) in REACH: Analysis of SID and substance sameness of complex substances
  - Calculation of the indicators of benefits of chemical legislation on human health and the environment
  - Fitness check on Occupational health and safety

(D.2) Previous evaluations and other reports

An Extended Impact Assessment accompanied the Commission proposal for the REACH Regulation (SEC(2003)1171/3). (http://ec.europa.eu/environment/chemicals/reach/background/index_en.htm and http://ec.europa.eu/DocsRoom/documents/14226/attachments/1/translations/en/renditions/native.

A first interim evaluation was carried out after the first five years of operation of REACH and was published in 2013 (COM (2013) 49 final and SWD (2013) 25 final). The REACH review 2013 was developed on the basis of Member State and ECHA reports, as well as thematic studies carried out by external consultants under the supervision of the relevant units of the Commission (http://ec.europa.eu/environment/chemicals/reach/review_2012_en.htm and by

http://ec.europa.eu/DocsRoom/documents/11981/attachments/1/translations/en/renditions/native

- The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH)
- Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006
- REACH contribution to the development of emerging technologies
- Implementation and enforcement of restrictions in Member States
- Impact of the REACH regulation on the innovativeness of EU chemical industry
- Inspections requirements for REACH and CLP
- Functioning of the European chemical market after the introduction of REACH regulation
- Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps
- Technical assistance to prepare the Commission report on operation of REACH
- Review of the registration requirements for 1 to 10 tonnes substances and polymers
- Assessment of health and environmental benefits of REACH
- Review of EU legislation (REACH) concerning nanotechnology

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

Relevant developments in cases addressed by ECHA's Board of Appeal, infringement procedures, judgments of the Court of Justice of the European Union and enforcement activities of Member States will also be considered in the REACH report 2017.

(D.4) Consultation

The implementation of REACH is already subject to regular and extensive consultation. Consultation takes place in the context of the expert group CARACAL, which advises the European Commission and ECHA on the implementation of REACH and CLP involving experts from Member States and stakeholders. Public consultations on specific matters are also conducted by the ECHA in the context of the preparatory work for the implementation of regulatory action.

The REACH report 2017 consultation strategy aims at gathering additional evidence, data and information linked to the implementation of REACH, including costs, benefits and other effects. Evidence gathered in this context should complement evidence gathered through regular consultation, desk research and analysis of available information (e.g. Member State reports, ECHA reports, other information sources).

The main stakeholders addressed in this consultation are Member State authorities, industry associations, trade unions, civil society organisations and third countries. Efforts are made to ensure a geographical balance and representations of all relevant sectors and interest groups.

Planned consultation activities include:

- Targeted consultations to gather specific evidence through questionnaires, interviews or case studies is carried out in the context of thematic studies (carried out between 2014 and 2016).

- A public consultation is planned to take place in the Q2/Q3 2016 in order to present the approach to the REACH report 2017 and collect views on any potentially missing elements.

- Furthermore, it is planned to obtain specific views on SME relevant issues through the Europe Enterprise Network (EEN) in Q3 2016.

The consultation strategy will be published on a webpage devoted to the REACH report 2017, on the websites of DG GROW and DG ENV.

(D.5) Further evidence to be gathered
Studies planned in the course of 2016 - Cumulative human health and environmental benefits of chemical legislation - Cumulative socio-economic benefits of chemical legislation - Study on the costs and benefits of authorisation - REACH baseline study – 10 years up date - Evaluation of ECHA - Eurobarometer survey on the perception of chemical safety - Reporting on progress at Commission Conference "Towards phasing out animal testing" (follow-up to the European Citizen's Initiative).

E. Other relevant information/ remarks
This evaluation takes place in parallel with the fitness check on the most relevant chemicals legislation (excluding REACH - except for the PBT/vPvB criteria), as well as related aspects of legislation applied to downstream industries and will be carried out in full coordination. There is also an on-going ex-post evaluation of 24 EU Directives in the area of health and safety at work. Together they will serve as an evidence base for the chemicals stock-taking report mentioned in the 2014 REFIT communication[1] and, more generally, for developing by 2018 the nontoxic environment strategy as required by the 7th EAP. A conference with all the relevant stakeholders could be considered after the publication of the REACH report 2017 in order to present the findings of the report and to discuss the next steps and REACH after 2018.

[1] See 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 final, p.12.