Public Consultation in relation to the REACH REFIT evaluation

Fields marked with * are mandatory.

1) Purpose and Context of the Consultation

a) The REACH REFIT evaluation

REACH[1] is the European Regulation for the Registration, Evaluation, Authorisation and Restriction of chemicals (EC) No 1907/2006. It is the main EU law on chemicals, covering substances on their own or in mixtures or in articles for industrial, professional or consumer use[2].

The European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs and DG Environment) is conducting an evaluation of the REACH Regulation as part of the regular reporting obligation to monitor progress in the achievement of the objectives of the Regulation according to Article 117 (4) of REACH. 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.

This evaluation is part of the Commission's Regulatory Fitness and Performance Programme (REFIT) [3] and will cover the five compulsory evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value, including examining the potential to improve the way in which it delivers on its objectives and the potential for burden reduction and simplification.

The roadmap[4] for the REACH REFIT evaluation outlines the objectives, scope and key evaluation questions to be addressed in the evaluation. Furthermore, the consultation strategy[5] for the REACH REFIT evaluation provides additional details about the consultation objectives, activities and tools planned, including the present open online public consultation.

The objective of the public consultation is to obtain stakeholder views on the general approach to the 2017 REACH REFIT evaluation and to collect stakeholder views on strengths and weaknesses of REACH as well as any potentially missing elements. The responses will be taken into consideration in the preparation of the Commission Staff Working Document, presenting the results of the REACH REFIT evaluation and the Commission general report on the functioning of REACH addressed to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

The current open online public consultation is part of a broader stakeholder consultation strategy which includes also an SME panel circulated through the Europe Enterprise Network. Please note that the results may also be used in the context of other studies in the chemicals field.

** The consultation will last for 12 weeks. Responses to the public consultation must be submitted by 28 January 2017. **

b) Structure of this questionnaire

The questionnaire has four parts and you may choose which parts (or questions) you answer depending on your interest and level of familiarity with the REACH legal text and its implementation:

Part I – General Information about respondents (compulsory)

Part II - General Questions for respondents interested in REACH, but who may not be familiar enough with the legal text and provisions to answer more detailed questions (compulsory)

Part III – Specific Questions which require more in-depth knowledge and experience in dealing with the REACH Regulation (optional)

Part IV – Additional Comments

You may interrupt your session at any time and continue answering at a later stage. Once you have submitted your answers online, you can download a copy of the completed questionnaire.

To facilitate the preparation of your contribution, a pdf version of the questionnaire is available here.

In view of the limited resources for translation as well as the specialised nature of the topic and technical terminology involved in this consultation, the questionnaire is available in English, German and French. Individual replies may be provided in any EU language.

Privacy Statement: The information you provide will be used strictly in accordance with the provisions of Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The content of your contribution and identity will be published on the Internet, unless you ask to remain anonymous.

Disclaimer: This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties. The suggestions contained in this document do not prejudge the form or content of any future proposal by the European Commission.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December
2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) OJ L 396, 30.12.2006

[2] http://ec.europa.eu/growth/sectors/chemicals/reach/

http://ec.europa.eu/environment/chemicals/reach/reach_en.htm

[3] http://ec.europa.eu/smart-regulation/index_en.htm

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf

[5] http://ec.europa.eu/DocsRoom/documents/17785/attachments/1/translations/

2) Questionnaire

Part I – General Information about Respondents (compulsory)

1. Please indicate your name or the name of your organisation.

* Your name or name of the organisation/company:

Confederation of Industry of the Czech Republic

Contact name (for organisations):

Jaroslav Suchý

Transparency Register ID number (for organisations):

(If your organisation is not registered in the transparency register, you have the opportunity to <u>register</u> <u>now</u>. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and as such, will publish it separately.)

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785320514128-81
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* Country:

Czech Republic

* E-mail address

jsuchy@spcr.cz

* 2. Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution:

(Please note that regardless the option chosen, your contribution may be subject to a request for access to documents under <u>Regulation 1049/2001</u> on public access to European Parliament, Council and Commission documents. In this case the request will be assessed against the conditions set out in the Regulation and in accordance with applicable <u>data protection rules</u>)

- My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
- My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication
- I do not agree that my contribution will be published at all

* 3. We might need to contact you to clarify some of your answers. Please state your preference below:

- I am available to be contacted
- I do not want to be contacted

* 4. Please indicate whether you are replying to this questionnaire as:

- A citizen
- A business
- A non-governmental organisation (NGO)
- A consumer association
- An industry association
- A trade union
- A government or public authority
- An intergovernmental organisation
- Academia or a research or educational institute
- Third country private organisation
- Third country public authority
- Other (please specify)

* 4.2. Business or industry association - fields of interest or activity(ies) - multiple choises possible (the letters in brackets correspond to NACE codes)

- Agriculture, forestry and fishing (A)
- Mining and quarrying (B)
- Manufacture of food products (C10)
- Manufacture of beverages (C11)
- Manufacture of tobacco products (C12)
- Manufacture of textiles (C13)
- Manufacture of wearing apparel (C14)
- Manufacture of leather and related products (C15)
- Manufacture of wood and of products of wood and cork except furniture (C16)
- Manufacture of paper and paper products (C17)
- Printing and reproduction of recorded media (C18)
- Manufacture of coke and refined petroleum products (C19)
- Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)
- Manufacture of pesticides and other agrochemical products (C20.2)
- Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)
- Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)
- Manufacture of other chemical products (C20.5)
- Manufacture of man-made fibres (C20.6)
- Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)
- Manufacture of rubber and plastic products (C22)
- Manufacture of other non-metallic mineral products (C23)
- Manufacture of basic metals (C24)
- Manufacture of fabricated metal products, except machinery and equipment (C25)
- Manufacture of computer, electronic and optical products (C26)
- Manufacture of electrical equipment (C27)
- Manufacture of machinery and equipment (C28)
- Manufacture of motor vehicles, trailers and semi-trailers (C29)
- Manufacture of other transport equipment (C30)
- Manufacture of furniture (C31)
- Manufacture of games and toys (C32.4)
- Manufacture of medical and dental instruments and supplies (C32.5)
- Other manufacturing (excluding manufacturing of toys or medical and dental instruments) (C32)
- Electricity, gas, steam and air conditioning supply (D)
- Water supply; sewerage; waste management and remediation activities (E)
- Construction (F)
- Wholesale and retail trade (G)
- Transporting and storage (H)
- Professional, scientific and technical activities (M)
- Other (please specify)

5. Please indicate the level at which your organisation is active:

- Local
- National
- Accross several countries (e.g. Scandinavia)
- 🔘 EU
- Global

Part II – General questions (compulsory)

This part is intended for all respondents interested in REACH, including those who may not be familiar enough with the legal text to answer more detailed questions.

6. To what extent do you think REACH is achieving the following objectives?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
*a) Improve protection of consumers	0	O	0	۲	0	0
*b) Improve protection of workers	0	O	O	۲	0	0
*c) Improve protection of the environment	0	O	0	۲	0	0

*d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)			۲	۲		O
*e) Enhance competitiveness and innovation	0	O	۲	©	0	۲
*f) Promote alternative methods to animal testing for hazard assessment of chemicals	0	0	0	۲	0	٢

7. To what extent do you think REACH is delivering the following results?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
*a) Generation of data for hazard /risk assessment	0	©	O	O	۲	0

*b) Increase in information on chemicals for risk management	0	0	0	©	۲	٢
*c) Increase in information exchange in the supply chain	0	O	0	۲	0	O
*d) Improvement in development and implementation of risk management measures	0	O	O	O	۲	۲
*e) Shifting the burden of proof from public authorities to industry	0	O		O	۲	O
*f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)	0	O	۲	۲	0	O
*g) Promoting the development, use and acceptability of alternatives to animal testing	0	O	0	۲	0	O

*h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing	0	O		۲	0	O
*i) Dissemination of information on chemicals for the general public	0	O	0	©	۲	0

8. The various processes of REACH (e.g. registration, evaluation) are expected to generate data that can be used by public authorities to adopt adequate risk management measures under REACH or in other EU legislation. To what extent do you think that the data generated are adequate for adopting the following measures?

	1 Not useful at all	2 Slightly useful	3 Somehow useful	4 Substantially useful	5 Very useful	Do not know / not applicable
*a) REACH authorisation	0	O	O	۲	0	0
*b) REACH restriction	0	0	0	۲	0	0
*c) Consumer protection legislation concerning chemicals in articles (e.g. cosmetics, toys, food packaging)	O	O	O	O	۲	O
*d) Environmental legislation (e. g. Seveso, Industrial Emissions Directive)	0	O	0	۲	0	٢

*e) Harmonised Classification & Labelling	0	O	0	۲	0	©
*f) Occupational Exposure Limits (OEL) in the context of worker protection legislation	O		۲	O	0	O

9. To what extent do you agree with the following statements in relation to the European Chemicals Agency (ECHA)?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
*a) ECHA has handled the registrations of chemical substances effectively (i.e. support for registrant, access to IT tools)	O	O	©	O	۲	O
*b) ECHA has established a strong and trustful relationship with its stakeholders	0		©	0	۲	O

*c) ECHA has contributed to reducing the impact of REACH on SMEs	0	0	0	۲	۲	0
*d) ECHA's activities and guidance have facilitated an innovation- friendly framework	O		۲	0	۲	0
*e) ECHA has been successful in facilitating the implementation of the last resort principle concerning animal testing.	O		۲	۲	۲	۲

This part contains more detailed questions related to the five evaluation criteria and to REACH procedures.

You may further explain your answers at the end of the consultation.

Part III. A

Effectiveness

The following questions explore the extent to which the objectives of the REACH Regulation have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

10. In your view, to what extent have the REACH Regulation and its various chapters been implemented successfully?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
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Registration	۲		0	0	۲	O
Data-sharing and avoidance of unnecessary testing			0	©	۲	O
Information in the supply chain	0	O	O	۲	0	0
Evaluation – dossier	0	0	O	۲	0	0
Evaluation – substance		0	0	۲	0	۲
Authorisation	۲		۲	0	0	0
Restriction	0		۲	0	0	0
Overall implementation of REACH		O	O	۲	0	O

11. Do you agree that the REACH legal text presents requirements regarding the following chapters in a clear and predictable manner?

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
Registration	O	O	O	۲	O	0
Data-sharing and avoidance of unnecessary testing	0	O	©	۲	©	0
Information in the supply chain	0	0	O	۲	0	0
Evaluation – dossier	0	0	©	۲	0	۲
Evaluation – substance	0	0	O	۲	0	0
Authorisation	0	0	۲	0	0	0
Restriction	O	O	۲	۲	O	0

12. In your view, to what extent are the following elements of REACH working well?

	1 Not well at all	2 Rather not well	3 Neutral	4 Rather well	5 Very well	Do not know / not applicable
Transparency of procedures	O	©	O	۲	O	0
Speed with which hazards/risks are identified	0	©	O	۲	0	0
Speed with which identified risks are addressed	O	©	O	O	0	0
Time to allow duty holders to adapt	0	O	۲	0	O	0
Predictability of the outcomes	0	©	۲	O	©	0

13. Please identify unintended effects of REACH, indicating whether you consider those to be positive or negative. Please provide evidence to quantify such effects or a qualitative description.

(max. 5.000 characters)

Registration costs are higher than expected- especially the generation data, IT reguirements and also administrative costs connected with managing the SIEFs. Some SMEs finished their activities because of these high costs. Authorisation costs are also higher than expected- high authorisation fee and very costly and complex preperation of the application with negative impact on the competitiveness of companies and whole sectors.

14. In your view, to what extent are the following elements of REACH enforcement satisfactory?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicable
Overall REACH enforcement in the EU	0	0	O	۲	0	O
REACH enforcement at Member States level	0	۲	0	۲	0	O
REACH is enforced uniformly across the EU	0	0	۲	0	0	O

Prioritisation of enforcement activities at EU level (by Forum)	0	O	©	0	۲	0
Communication on enforcement activities from Member States and Forum	O		0	۲	O	0

14.1. If you answered 3 or less for any of the above, please explain how the relevant aspect of REACH enforcement could be improved.

(max. 5.000 characters)

Enforcement efforts should be increased across the EU. According to our information, in some MS are enforcement activies very low. Comparable enforcement efforts in all MS are essential. Enforcement effords should be more focused on importer of chemicals.

15. Have you, in the past 5 years, experienced a REACH inspection/control or have your products been controlled for REACH compliance? - To be answered only by companies (REACH dutyholders).

- Yes
- No
- I don't know

Efficiency

The following questions explore the costs and benefits of implementing the REACH Regulation. The legislation was designed to deliver benefits in terms of protection of human health and the environment, better functioning of the EU internal market (e.g. facilitating trade between EU Member States) and fostering competitiveness and innovation of EU industry (e.g. better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

16. In your view, how significant are the following benefits generated for society by the REACH Regulation?

	1 Not significant at all	2 Rather not significant	3 Neutral	4 Rather significant	5 Very significant	Do not know / not applicable
Reducing the exposure of citizens in general to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	۲			۲		٢

Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.		۲	٢	٢
Reducing damage to the environment and to eco- systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up contaminated land, etc.		۲	O	

Encouraging research and innovation, generating new jobs, and improving the competitiveness of EU manufacturing industry by encouraging /supporting a shift towards green, sustainable chemistry and a circular economy			۲			
Stimulating competition and trade within the EU single market	۲	0	0	۲	0	O

Stimulating international trade between the EU and other countries	0	0	۲	©	©	0
For businesses: Increasing the confidence of your clients /customers in your products	O		۲	O	©	O

17. In your view, to what extent are the costs linked to the following REACH chapters (for society, companies, public authorities, etc.) proportionate to the benefits (for society, companies, public authorities, etc.) achieved?

	1 Not at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not know / not applicable
Registration	O	O	O	۲	0	0
Information in the supply chain (e.g. eSDS - extended Safety Data Sheets)	0	©		۲	0	0
Evaluation - dossier	0	©	۲	O	0	0
Evaluation - substance	0	©	O	۲	O	0

Authorisation	O	0	۲	©	0	0
Restriction	0	0	۲	©	0	0
Requirements for substances in articles	۲	۲	۲	©	۲	0

18. Is the level of the fees and charges paid to ECHA as provided by the Fee Regulation (Commission Regulation (EC) No 340/2008), still adequate?

	Yes	No, it is too high	No, it is too low	l don't know
Fee for registration	O	۲	0	0
Fee for authorisation	O	۲	0	0
Fee for appeal	0	۲	0	0

19. Do you believe that there are areas where the REACH Regulation could be simplified or made less burdensome?

- Yes to a large extent
- Yes but only to a minor extent
- No
- I don't know

If yes, you may provide ideas, preferably substantiated with quantitative evidence or qualitative information, at the end of the questionnaire.

Relevance

The following questions explore the extent to which REACH is consistent with current needs.

20. Do you believe that the REACH Regulation addresses the key issues in relation to the management of chemicals?

- Yes to a large extent
- Yes but only to a minor extent
- 🔘 No
- I don't know

If you answered no, you may provide detailed comments at the end of the questionnaire.

21. How suitable do you consider REACH to be to deal with the following emerging

issues?

	REACH is the most suitable EU legal instrument to address the issue	REACH should only play a secondary role and the issues should be addressed by specific legislation	REACH is not a suitable instrument and should not address the issue at all	Do not know / Not applicable
Nanomaterials	۲	0	0	0
Endocrine disruptors	۲	0	O	0
Substances in articles	۲	0	0	0
Combination effects of chemicals	۲	0	0	0
Extremely persistent substances	۲	0	0	0

Coherence

22. Please tell us to what extent you agree or disagree with the following statements:

	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly agree	Do not know / not applicable
The different chapters (e.g. registration, authorisation, restriction,) in REACH are applied in a coherent manner (e.g. there are no contradictions, inconsistencies)	O	O		۲	O	0

The different chapters in REACH (e.g. registration, authorisation, restriction,) are applied in a coherent manner (e. g. there are no contradictions, inconsistencies, they are complementary) in relation to other EU legislation (e.g. worker protection legislation, consumer protection legislation, environmental legislation)				۲		
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The implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH	O	۲		
The implementation of the SVHC Roadmap, including the RMOA, contributes to coherent implementation of REACH in relation to other EU legislation (e.g. there are no contradictions, inconsistencies, they are complementary)	٢	۲		

22.1. If you disagree with one or more of the statements above, where do you consider coherence should be enhanced?

(max. 5.000 characters)

EU Added Value

23. To what extent do you consider that taking action through the different chapters of REACH has added value above what could have been achieved through action by Member States alone at national level? (1= no value, 5= a very high value)

	1	2	3	4	5	Do not know / not applicable
Registration	O	O	O	0	۲	©
Data-sharing and avoidance of unnecessary testing	0	O	©	O	۲	©
Information in the supply chain	0	0	O	0	۲	0
Evaluation – dossier	0	0	0	0	۲	0
Evaluation – substance	0	0	0	0	۲	0
Authorisation	0	0	0	0	۲	0
Restriction	0	0	0	0	۲	0

Part III. B

24. In your view, how satisfactory are the following mechanisms and procedures of the REACH Regulation?

	1 Not at all satisfactory	2 Rather unsatisfactory	3 Neutral	4 Rather satisfactory	5 Very satisfactory	Do not know / not applicable
Awareness raising for duty holders on key obligations and deadlines	0	O	0	0	۲	O
Support for preparation of registration dossiers	0	O	0	۲	0	O
Participation in Substance Information Exchange Fora (SIEFs) – data sharing		O	0	۲	O	O

Dossier submission - IT tools		0	0	۲	0	O
Communication of information along the supply chain	©		©	۲	0	O
eSDS - extended Safety Data Sheets	0	0	۲	0	0	©
Notification of SVHCs in articles	0	0	۲	0	0	©
Information concerning presence of SVHCs in articles	0	۲	0	0	0	O
Assessment of testing proposals	O	0	0	۲	0	O

Dossier compliance check	0	۲	0	0	0	0
Enforcement /follow-up of compliance check decisions	O	O	©	۲	O	0
Substance evaluation activities by Member States	0	0	0	۲	0	۲
Identification of relevant SVHCs for the candidate list	Ø	O	O	۲	Ø	0
RMOA (Risk Management Option Analysis) process	O	۲	O	O	O	۲
Prioritisation of SVHCs for authorisation	O	۲	O	0	Ø	0

Amendments to the list of substances subject to authorisation	0	©	۲	0	0	0
Substitution of SVHCs	O	O	۲	©	©	۲
Support for applicants for authorisation	O	©	©	۲	O	O
Assessment of applications for authorisation by ECHA	0	O	0	0	۲	0
ECHA public consultations (e. g. in restriction or authorisation)	O	O	©	۲	O	O

Consideration of the availability and feasibility of alternatives	0	0	۲	0	۲	0
Decision making by Commission on applications for authorisation		O	©	۲	0	۲
Preparation of Annex XV dossiers to propose new restrictions	O	O	۲	0	0	0
Assessment of proposals for new restriction	0	0	0	۲	0	0
Decision making by Commission on new restrictions	O	O	©	۲	0	0

Exemptions for R&D activities	0	0	0	0	۲	0
Reduction of fees for SMEs	0	0	O	0	۲	0
Guidance by ECHA	0	0	O	۲	0	0
Guidance by national authorities	O	©	۲	0	0	0
Guidance by industry associations	0	0	0	0	۲	0
Support provided by Helpdesks	0	0	0	0	۲	0
Operation of the Board of Appeal	0	0	0	0	۲	0

Inspections by enforcement authorities	0	©	۲	O	O	0
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25. If you have any additional comments relevant to this public consultation, please insert them here. You may also upload position papers.

(max. 5.000 characters)

Comment to point 19 : Authorisation process should be simplified and reguested for the "right" substances. Not every substance can be substituted. Use of some substances is essential for some sectors, eg. some substances are used in aviation industry for long time and it is not possible to substitute them without many years of testing of another substances. Use of some substances is unique and highly inovative and advanced (eg. some solvents used in nanotechnologies or energy sector). Authorisation proces could mean end of these advanced uses with negative impact on the EU competitiveness. Authorisation process should take more into account exposure of chemical substances and as a consequence should be lower data reguirements. The role of the RMOA is essential to choose the "right " substances and to augment the predictability of the process.

Please upload your additional document(s) (one by one, any format)

26. Are you interested in being contacted in the context of the ongoing study on the impact of authorisation?



Contact

GROW-ENV-REACH-REVIEW@ec.europa.eu