Public Consultation in relation to the REACH REFIT evaluation

A copy of the on-line Questionnaire sent by the Swedish Chemicals Agency enlarged with explanations to some provided answers.

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

Fields marked with * are mandatory.

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:

Swedish Chemicals Agency

Contact name (for organisations):

Alicja Andersson

Transparency Register ID number (for organisations):
(If your organisation is not registered in the transparency register, you have the opportunity to register now. 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.)

*Country:

Sweden

*E-mail address:

alicja.andersson@kemi.se

*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 Regulation 1049/2001 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 data protection rules)

- 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)

***4.1. Replying as - Other, please specify**

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	2 Slightly	3 Somewhat	4 Substantially	5 Very	Do not Know/

	at all				much	Not applicable
*a) Improve protection of consumers				X		
*b) Improve protection of workers				X		
*c) Improve protection of the environment				X		
*d) Free circulation of chemicals on the internal market (Reduce barriers to trade in chemicals across borders within the EU)				X		
*e) Enhance competitiveness and innovation			X			
*f) Promote alternative methods to animal testing for hazard assessment of chemicals				X		

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				X		
*b) Increase in information on chemicals for risk management				X		
*c) Increase in			X			

Information exchange in the supply chain						
*d) Improvement in development and implementation of risk management measures				*X*		
*e) Shifting the burden of proof from public authorities to industry				*X*		
*f) Fostering innovation (e.g. substitution of SVHCs, development of new substances)			*X*			
*g) Promoting the development, use and acceptability of alternatives to animal testing			*X*			
*h) Implementation of the 3Rs (replacement, reduction and refinement) in relation to the use of animal testing			*X*			
*i) Dissemination of information on chemicals for the general public					*X*	

Further comments:

1. Communication in the supply chain is an extremely important point, and in theory Reach really provides the means for this exchange (e.g. SDS with exposure scenarios, consortia formation, and assistance from ECHA). However, in practise the implementation has only begun, and all stakeholders (and especially industry) need to focus on promoting the information exchange. Furthermore, the implementation of the provisions on SVHC substances in articles is slow.
2. It is difficult to monitor and report the progress of innovation. Identification of SVHC and harmonised classification seem to be strong driving forces for the industry to substitute and work with innovations. It has been recognised from enforcement in Sweden that SVHCs and Annex XIV substances are substituted. However, we do not know to what extent the industry substitutes instead of applying for authorisation. We call, therefore, for studies that indicate whether this actually occurs the way we assume/expect.

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 at all	2 Slightly	3 Somewhat	4 Substantially	5 Very much	Do not Know/ Not applicable
*a) REACH authorisation			*X*			
*b) REACH restriction			*X*			
*c) Consumer Protection legislation Concerning chemicals in articles (e.g. cosmetics, toys, food packaging)			X			
*d) Environmental legislation (e. g. Seveso, Industrial Emissions Directive)			**X**			
*e) Harmonised Classification & Labelling				X		
*f) Occupational			**X**			

Exposure Limits (OEL) in the context of worker protection legislation						

Further comments:

This question can be interpreted in different ways. Our interpretation is that the data generated are adequate but rarely sufficient for adopting the measures.
For RoHS, REACH data is used to some extent. Our own experience from using data from REACH to predict what substances may cause concerns when used in construction products showed that the Reach registrations do provide data on occurrence of substances in construction products ("use category" nr 19). However, this information is usually too general to be used in a development of appropriate risk management measures.

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	No not Know/ Not applicable
*a) ECHA has handled the registrations of chemical substances effectively (i.e. support for registrant, access to IT tools)				**X**		
*b) ECHA has established a strong and trustful relationship with its stakeholders				**X**		
*c) ECHA has contributed to reducing the impact of REACH on SMEs				**X**		
*d) ECHA's activities and guidance have facilitated an innovationfriendly framework				**X**		
*e) ECHA has been successful in facilitating the implementation of the last resort				**X**		

principle concerning animal testing.						

Part III – Specific questions that require more experience with REACH

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
Registration				X		
Data-sharing and avoidance of unnecessary testing			X			
Information in the supply chain			X			
Evaluation – dossier				X		
Evaluation - substance				X		
Authorisation			X			
Restriction			X			
Overall implementation of REACH				X		

Further comments:
"Successful implementation" implies, in our view, that the legal provisions have been implemented according to the intention of the legislation. It also means that the procedures in place work and deliver the expected results. This is not yet the case, but efforts to improve this situation are ongoing. In particular, the quality of the registrations are still far from satisfactory. Further, although the legal text on restriction is very clear and the procedures are transparent, the applied practice that requires too much proof from the dossier submitter makes the implementation less successful. The implementation of authorisation is still ongoing and is struggling with a range of problems, e.g. slow listing of substances in Annex XIV.

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	No not Know/ Not applicable
Registration				X		
Data-sharing and avoidance of unnecessary testing				X		
Information in the supply chain				X		
Evaluation – dossier				X		
Evaluation – substance				X		
Authorisation				X		
Restriction				X		

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				X		
Speed with which hazards/risks are identified			X			
Speed with which identified risks are		X				

addressed						
Time to allow duty holders to adapt				X		
Predictability of the outcomes			X			

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)

We have identified the following negative effects

1. Lower number of submitted proposals for restriction due to the implementation of the REACH provisions, compared to the previous legislation, because it requires too high level of evidence compared to what the legal text stipulates.
2. Unbalance in the level playing field created for the European producers of articles containing substances on Annex XIV compared to importers of similar articles from third countries. In addition, articles from third countries are purchased directly by consumers on line, which according to industry is a growing phenomenon. Since this trade cannot be regulated by REACH there is an increasing risk of exposure to substances that have already been phased out in the EU. (Communication from the Swedish industry stakeholders).

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

	1 Not at all Satis-factory	2 Rather Unsatis-factory	3 Neutral	4 Rather Satis-factory	5 Very Satis-factory	Do not know / not applicable
Overall REACH enforcement in the EU				**X**		
REACH enforcement at Member States level				**X**		
REACH is Enforced uniformly across the EU				**X**		
Prioritisation of enforcement activities at EU level (by Forum)					**X**	
Communication				**X**		

On enforcement activities from Member States and Forum						

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)

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						**X**

productivity, etc.						
Reducing the exposure of workers to hazardous chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.						**X**
Reducing damage to the environment and to ecosystems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up contaminated land, etc.						**X**
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						**X**
Stimulating						**X**

competition and trade within the EU single market						
Stimulating international trade between the EU and other countries						X
For businesses: Increasing the confidence of your clients /customers in your products						

Further comments:

We assume that the exposure to chemicals has decreased which has generated benefits for the society. We do also assume that these benefits include avoided health care costs, avoided costs of treating contaminated water, etc. We are, however, not able to estimate these benefits semi-quantitatively. We understand that the message from the presentations made at the recent workshop on Cumulative benefits of chemicals legislation (Brussels, 17-18 Jan 2017) implies that it is not yet possible to give detailed answers to the questions above.

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					X	
Information in the supply chain (e.g. eSDS -extended Safety Data Sheets)					X	
Evaluation - dossier					X	
Evaluation - substance					X	
Authorisation					X	
Restriction				X		

Requirements for substances in articles					X	

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	I don't know
Fee for registration				X
Fee for authorisation				X
Fee for appeal				X

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

	Yes to a large extent
X	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?

X	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	REACH should only	REACH is not a	Do not Know/

	suitable EU legal instrument to address the issue	play a secondary role and the issues should be addressed by specific legislation	suitable instrument and should not address the issue at all	Not applicable
Nanomaterials	X			
Endocrine disruptors	X			
Substances in articles	X			
Combination effects of chemicals	X			
Extremely persistent substances	X			

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…)				X		
The different chapters in REACH (e.g. registration, authorisation, restriction,…) are applied in a coherent manner (e.g. there are nocontradictions, inconsistencies, they are complementary…) in relation to other EU legislation (e.g. worker protection				X		

legislation, consumer protection legislation, environmental legislation						
The implementation of the SVHC Roadmap, including the Risk Management Option Analysis (RMOA), contributes to coherent implementation of authorisation and restriction under REACH				X		
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…)				X		

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)

There is a contradiction between the requirements in the conformity check of restriction proposals and applications for authorisations.

See also comment on RMOA in question 24.

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					X	
Data-sharing and avoidance of unnecessary testing					X	
Information in the supply chain					X	
Evaluation – dossier					X	
Evaluation – substance					X	
Authorisation					X	
Restriction					X	

Part III. B

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

	1 Not at all Satis-factory	2 Rather Unsatis-factory	3 Neutral	4 Rather Satis-factory	5 Very Satis-factory	Do not know / not applicable
Awareness raising for duty holders on key obligations and deadlines				**X**		
Support for preparation of registration dossiers				**X**		
Participation in Substance Information Exchange Fora (SIEFs) – data sharing						**X**
Dossier submission – IT tools				**X**		
Communication of information along the supply chain		**X**				
eSDS - extended Safety Data Sheets		**X**				
Notification of SVHCs in articles		**X**				

Information Concerning presence of SVHCs in articles		X				
Assessment of Testing proposals				X		
Dossier compliance check				X		
Enforcement /follow-up of compliance check decisions				X		
Substance evaluation activities by Member States				X		
Identification of relevant SVHCs for the candidate list				X		
RMOA (Risk Management Option Analysis) process						X
Prioritisation of SVHCs for authorisation				X		
Amendments to the list of substances subject to authorisation		X				
Substitution of SVHCs			X			
Support for applicants for authorisation			X			
Assessment of applications for authorisation by ECHA		X				
ECHA public consultations (e. g. in restriction or authorisation)			X			

Consideration of the availability and feasibility of alternatives		**X**				
Decision making by Commission on applications for authorisation			**X**			
Preparation of Annex XV dossiers to propose new restrictions		**X**				
Assessment of proposals for new restriction		**X**				
Decision making by Commission on new restrictions				**X**		
Exemptions for R&D activities			**X**			
Reduction of fees for SMEs			**X**			
Guidance by ECHA				**X**		
Guidance by national authorities						
Guidance by industry associations			**X**			
Support provided by Helpdesks						**X***
Operation of the Board of Appeal		**X**				
Inspections by enforcement authorities						**X***

Further comments:

1. Please note that RMOA development is not a process defined in REACH and therefore considered “not applicable”. We are however in general satisfied with the way RMOAs are presently used.
2. In our opinion, it is essential to support the applicants for authorisation with clear guidance. However, the burden of proof should rest on the applicant.
3. The public consultations for restrictions and authorisations do not trigger submission of information about uses and volumes. The focus on exemptions in the restriction process tends to dilute the effectiveness of the restriction proposals. In both processes it is difficult to encourage stakeholders to send information about available and suitable alternatives.
4. X* Considered “not relevant” for authorities to answer.
5. Regarding the exemptions for R&D activities we have identified problems with the interpretation of the legal text including some of the Q&A published by ECHA that we find not are in line with the legal provisions. We do not agree with the interpretation that all use for analytical purposes should be considered as R&D activity.

Part IV – Additional comments

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)

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

X	Yes
	No