

Case Id: 175a1994-8e01-48ff-bf39-005958127354

REACH authorisation: Public consultation on streamlining and simplification of the REACH authorisation application procedure for applications concerning uses of substances in low volumes and on a one-time extension of transitional arrangements for uses of substances in legacy spare parts

Fields marked with * are mandatory.

All your answers to questions in sections 2, 3 and 4, are intended to be published on the web, together with some of your personal data (please read the [specific privacy statement](#) before answering the following questions). Please note that answers to questions 1.2 to 1.4 will not be published.

*How would you like your contribution to appear?

- Under the name supplied** (I consent to the publication of all the information in my contribution, and I declare that none of it is subject to copyright restrictions that would prevent publication)
- Anonymously** (I consent to the publication of all the information in my contribution, except my name/the name of my organisation, and I declare that none of it is subject to copyright restrictions that would prevent publication)
- I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account. In any case, the contribution will be subject to the rules on access to documents, Regulation (EC) No 1049/2001)

1. Respondent's information

*1.1. Your full name:

Ninja Reineke

*

1.3. I'm replying as a(n):

- a. Individual citizen
- b. On behalf of an organisation

*

1.3.b.1 If replying on behalf of a(n) organisation/association/authority/company/body, please provide the name:

CHEM Trust

*

1.3.b.2. Is your organisation listed in the EU transparency register?

- a. Yes
- b. No
- c. Do not know

*

1.3.b.2.a. Please specify identification number:

27053044762-72

*1.3.b.3. Please specify the organisation you represent:

- i. Public authority
- ii. Private company
- iii. Non-Governmental Organisation
- iv. Trade union
- v. Industrial or trade association
- vi. Academic/Research institution
- vii. Other

*

1.4. Your country:

UK

2. Part I of the Public Consultation: Streamlining and simplification of applications for authorisation for uses of substances in low volumes

2.1. Do you consider that the level of detail and documentation required in applications for authorisation for uses of a substance in low volumes should be lower than required in normal circumstances? Please justify your reply.

- a. Yes
 b. No

Justification:

The aim of the REACH authorization process is the gradual replacement of substances of very high concern with alternative substances and technologies where available. There is no tonnage threshold foreseen for an SVHC authorization in REACH. This is based on the general principle that a continued use of an SVHC requires a special permission, otherwise the use has to be discontinued. In cases where the risks have been demonstrated to be adequately controlled or no safer alternatives exist and the socio-economic benefits outweigh the risks, an application will usually be granted.

This mechanism was chosen by the legislators for providing a business incentive for innovation and substitution because a company's decision on whether to substitute or to apply for an authorization will often depend on a cost comparison of these options.

In CHEM Trust's view there is the danger that reducing the application requirements for "low volume substances" will partly remove this incentive and result in a greater use of SVHCs instead of the development of safer alternatives. Moreover, reducing the level of documentation will also increase the difficulties for the ECHA committees and the Commission to decide whether authorisations should be granted or refused. Judging from the experiences with authorization applications so far one of the problems was that the uses applied for were much too broad and the information provided often too general. These are points that should be addressed with better guidance and improved communication rather than eliminating important elements from the authorisations application (such as the risk characterization for indirect exposure to humans via the environment).

We also wonder:

- Are there any Commission estimates for the expected SVHC volume remaining on the market if these simplified procedures were implemented?
- Did the Commission look into the negative implications for those companies that have already invested in replacing SVHCs and developed alternative technologies?

2.1.a. What is the maximum volume per legal entity which could be considered as "low volume" for the purposes of applications for authorisation? Please justify your reply.

- a. Below 10 kg
 b. Below 100 kg
 c. Other

Please specify:

Justification:

It is unclear what the underlying basis for these two volume levels is. The Commission consultation paper simply states these proposed volumes "appear reasonable". From our perspective this does not provide a sufficient justification.

Moreover, SVHC chemicals in small amounts will be handled by very different companies (small, large, specialized, generalists) in very different sectors and the resulting risks of using SVHCs will always depend on the specific conditions of use.

We therefore doubt this general approach of "low volume" makes sense, in particular considering that a large number of "simplified applications" will lead to higher overall volumes. Implementing these proposals will give the signal to the market that replacement of SVHCs is not such a priority after all.

2.2. In order to ensure that the simplified authorisation application for uses in low volumes is not misused, it should apply only to applications for authorisation for the applicant's own uses, and the maximum volume allowed should constitute the maximum total limit for all the applicant's uses of the same substance. Are these criteria to frame the low volume application requirements clear and practicable?

- a. Yes
 b. No

Justification:

The criteria appear rather unworkable and cannot prevent misuse. Are these proposals really addressing the right issues, given

the current problems and flaws around the whole authorization process? (for our general criticism see here: <http://www.chemtrust.org.uk/replacing-chemicals-with-safer-alternatives-or-protecting-dirty-industry/>)

2.3. The simplified authorisation application for uses in low volumes should exclude cases where potential exposure of consumers to the substance may occur as in those cases the assessment of the exposure and the risk may require more detailed information in a normal application. Therefore the simplified procedure should not apply to uses of a substance when the presence of that substance in mixtures or articles intended for consumers (above 0.1% concentration w/w) cannot be excluded. Is this criterion clear and practicable?

- a. Yes
 b. No

Justification:

This is very difficult to control and illustrates the risks of the simplified authorization application: There are certainly cases where exposure to consumer can be excluded from the outset, but past experience has shown that in many cases the "potential exposure to consumers" has often been significantly underestimated. Detailed analysis and consideration of the various exposure pathways from the specific use in question is required. Indeed this pre-REACH experience was also a reason for establishing an authorization procedure in the first place. There are many other direct and indirect ways of exposing consumers, not only from the presence of substances in "consumer mixtures or articles". Moreover, SVHC exposures to the environment and ecosystems can and should not be neglected.

2.4. In order to illustrate these assumptions and exemplify how a streamlined and simplified authorisation application for uses in low volumes could translate into practice, draft formats for a streamlined and simplified chemical safety report ("CSR"), the analysis of alternatives ("AoA") and the socio-economic analysis ("SEA") are available ([AoA and SEA format - CSR format](#)). The draft formats for uses in low volumes aim at respecting the information obligations set out in Article 62(4) REACH, while illustrating how the specific information requirements provided in Annexes I (CSR template) and II (AoA and SEA template) could be streamlined and simplified and what could be level of details and documentation envisaged in these specific cases.

Please, provide your comments, if any:

2.5. For standard application for authorisation a normal review period of 7 years is the basis for SEAC to start its considerations and examine whether there would be reasons to shorten or prolong it in particular cases. Similar mechanism for setting the review period might also be fixed for low volume authorisations- i.e., setting a normal review period with the possibility of shortening or expanding it based on objective reasons. Any adjustments could, for example, be triggered if so requested and justified by the applicant or be based on information on alternative substances or technologies submitted by third parties via the public consultation. Should a default normal review period with the possibility of shortening or expanding it based on objective reasons be established for authorisation of uses in low volumes?

- a. Yes
 b. No

Justification:

We find the default period of 7 years problematic, for example, given that the purpose of authorisation is to encourage innovation towards safer products, the system should be able to put in place shorter review dates when substitutes are soon to be available. We therefore believe review periods should be given on a case by case basis, depending on the use, function and product cycle in question.

REACH is really needed to clean up the circular economy and to facilitate sustainable recycling, see also our recent blog post: <http://www.chemtrust.org.uk/reach-helps-the-circular-economy-clean-up-facilitating-sustainable-recycling/>

3. Part II of the Public Consultation: Extension of transitional arrangements in REACH authorisation for uses of substances in legacy spare parts

3.1. Definitions: do the following definitions appropriately capture the case of uses of substances necessary to maintain in their function the long-life time and durable articles which are no longer produced?

3.1.a "Spare part": a separate part that can replace a part of an existing article. The article cannot function as intended without that part. The functionality of the article is restored or is upgraded when the part is replaced by a spare part.

- a. Yes
 b. No

Justification:

It is not possible to agree on a definition of "spare part" without having clarity on how "long-life time" and "durable article" will be defined. This would be an important prerequisite given the broad scope of REACH applications. Furthermore, any defin

ition for spare parts used in the context of derogations would have to be very narrow in order to prevent misuse.

3.1.b “Legacy spare part”: spare part intended for an article which was placed on the market and whose production stopped or will stop before the sunset date referred to in Annex XIV of REACH for the substance used in the production of the spare part.

- a. Yes
- b. No

Justification:

This proposed definition could lead to the authorisation of new uses of SVHCs on the market in a simplified procedure. We therefore agree with proposals made by some Member States that the definition needs to contain the condition that the SVHC whose continued use is applied for was already used in the production of the original part.

3.2. “Use of a substance in the production of legacy spare parts”: should this case be extended also to the use of substances (on their own or in mixtures) in the repair and maintenance of articles that are no longer produced (e.g. a paint containing an Annex XIV substance used for the repair of scratches on the surface of articles)?

- a. Yes
- b. No

Justification:

Extending the scope in this way would open up a grey zone which would be very difficult to enforce. There is no reason why Annex XIV substances should be allowed in today's repair and maintenance materials such as paints.

3.3. There are currently 31 substances of very high concern listed in Annex XIV to Regulation (EC) No 1907/2006 (REACH). Are you aware whether any of those substances are used in the production of legacy spare parts or in the repair of articles that will no longer be produced after the sunset date?

Please specify in the table below. To enter data, please click in the cell - the cell is automatically expanding.

Table 1

	Name of substance	Description of use (please specify whether it is used in production of legacy spare parts or in repair of articles)	Annual volumes used (if available)	Time period for which legacy spare parts or repair of articles is to be supplied, for example to enable keeping the functionality of articles for which they are intended
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Additional rows needed?

- Yes
- No

Additional information, if any.

Contact

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