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 Please note that answers to questions 1.2 to 1.4 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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:

Guido Lena

*
1.2. Your e-mail address for correspondence:

g.lena@ueapme.com

*
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:

UEAPME

*
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:

55820581197-35

*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:

Representing companies through numerous Member States

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:

Objectives of REACH are to strengthen competitiveness and the innovation-power of the European economy. At the same time a high level of protection of health and the environment, but also the reduction of animal testing should be ensured. For us the consequences of this is that every decision under REACH always will be a compromise between these objectives. Those have to be measured against one another before a regulatory action is performed. On top of this also the proportionality, a fundamental principal in EU-law, needs to be respected. In our opinion regulating small volumes of substances, especially those, which are crucial in production processes, in our opinion are in direct conflict with the objectives of REACH and the principle of proportionality.

An AfA that is easier to be performed for small amounts of substances (means also exposure can be expected to be low) in our opinion is in line with the systematics of REACH, which tiered registration-approach is clearly exposure/risk-based. Article 55 of REACH gives a frame around substitution. Substitution may be the final aim of authorisation, however, that should not happen at all costs. This in our opinion should be a step-wise process, which considers both risks, the one for health and environment and the one for the economy and the impact on every single involved company. The authorisation should not be a shock-treatment, forcing companies to fundamentally change their activities in timescales of 5 years or even less. In such a short time-period for most SMEs the only option would be to close the existing business. However, this cannot be the answer to improve the situation on the European labour-market and to foster economic growth.

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

Justification:

100 kg seem a fair compromise to us. Nevertheless we need to mention that in some sectors 100 kg may be a big amount, in others this is not the case. However, in the spirit of a workable compromise, we think that 100 kg are an amount that can be easily traced and the exposure can be monitored.

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:

Analytical chemicals (standards) are usually used in very small amounts. In such cases also the DU needs to be covered.

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:

A criterion like "cannot be excluded" is unclear and leaves too much room for interpretations. We suggest choosing a more concrete expression, e.g. "when exposure at foreseeable use cannot be excluded".

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:

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We have no opinion due to lack of experience
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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

2.5.a What should the duration of this normal review period be:

- ( ) a. 7 years
- (●) b. more than 7 years
- ( ) c. less than 7 years

Please specify:

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10 years
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Justification:

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The application of a simplified AfA is very limited and the amounts are
very small. We think that for such cases a longer review period is
justified. Also we consider that the objective of substitution is not -
or not significantly - violated, because where justified, the large
amounts of a SVHC could be removed from the market by not granting a
prolongation of the full AfA. The small amounts covered by the
simplified AfA would then phase-out automatically in the next couple of
years, because one can expect that manufacturing of this substance will
stop once the main tonnage-share cannot be marketed anymore.
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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:

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In our opinion the suggested definition is sufficient
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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:

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In our opinion the suggested definition is sufficient
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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:

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The burden through authorisation requirements is similar relevant in
both cases. For example the problem of not having a breaking-fluid for
an old car is absolutely comparable to the one not having a spare-door.
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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 wether 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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