Explanatory note to a review report

**Introduction**

It is very likely that changes have occurred to the use, the available technology or the socio-economic situation of the authorisation holder or other actors in its supply chains during the review period of an authorisation. These changes may have resulted in narrowing of the scope of the use applied for. For example, it is possible that a suitable alternative has become available for part of the sectors covered in the original application for authorisation[[1]](#footnote-2) or that the technical constraints to use the alternatives by the customers have been removed (e.g. by changing the specifications). The Commission’s decision may have included specific conditions for the authorisation or the review report.

All changes are expected to be reflected in the review report to be submitted, should the authorisation holder wish to continue the use of the substance after the expiry of the review period. The authorisation holder needs to demonstrate how it has searched for or implemented alternatives, and, considering the provisions of Article 60(10) of REACH, describe how the exposures have been reduced. The authorisation holder should also outline what changes have taken place related to the use itself and to the socio-economic impacts related to the continued use of the substance.

**The purpose of the explanatory note**

The purpose of the explanatory note is to make it clear to the reader what progress the authorisation holder has made, in terms of risk control and substitution, and what other factors relevant to the authorisation have changed since the application for authorisation was submitted and the authorisation was granted.

**Documentation of the changes that took place**

Please only identify or list the changes since the submission of the application for authorisation. The detailed description, discussion and impact should be presented in the relevant assessment reports for each use applied for.

**IMPORTANT!** Please indicate where in the assessment reports more information can be found (e.g. refer to the respective pages or sections in the assessment reports).

Enclosure: The format of the Explanatory Note.

**Version 1.0**

**May 2017**

Format for

Explanatory note to a review report

**Legal name of**

**authorisation holder(s):** *[Legal name(s) of authorisation holder(s)]*

**[Name of the applicant:]** *[Only if Legal entity change has taken place]*

**Authorisation number:** *[Include authorisation number]*

**Submitted by:**  *[Legal name of submitting authorisation holder]*

**Substance:**  *[Include Annex XIV substance name, EC and CAS number]*

**Use title:**  *[Include full use title]*

*[This format is for one use. If an application or a review report has several uses, separate notes need to be prepared]*

**Use number:** *[Include the number for this use as stated in section 3.10 of the
 IUCLID application for authorisation dossier under the "Use concerned by the request" field]*

**Date** *[Date of the note]*

1. **The scope of the use**

*Instruction:*

*If the scope of your use has changed please explain what is different and describe succinctly why this took place to help the reader to understand. In particular be clear if the scope is*

*(i) narrower (e.g. because alternatives have been adopted for some ‘sub-uses’) or
(ii) split (because you want to provide more specific description of the use).*

1. **Chemical Safety Report (CSR)**

*Instruction:*

*If you made changes to the CSR please describe the most relevant ones. These may comprise the change of the volume of the substance used, number of sites, contributing scenarios and workers, duration and frequency of exposure, RMMs and OCs, exposure/emissions assessment methodology (monitoring methodology and modelling).*

*If the Commission’s decision contained conditions or monitoring arrangements please identify clearly where in the CSR you have demonstrated compliance with them.*

*If you were subject to* ***enforcement*** *activities by the Member State Competent Authority related to your use please tell when this took place and what the main outcome was. Please add a possible report of this as an annex to the CSR.*

1. **Analysis of Alternatives (AoA)**

*Instruction:*

*If you made changes to the AoA please describe the most relevant ones. These may comprise the identification of new alternatives, the suitability of alternatives, R&D activities or substitution timelines.*

*If the Commission’s decision contained conditions please identify clearly where in the AoA you have demonstrated compliance with them.*

1. **Socio-economic Analysis (SEA; if relevant)**

*Instruction:*

*If you made changes to the SEA please describe the most relevant ones. These may comprise changes to the non-use scenario, the costs of continued use, the benefits of continued use or the justifications for the length of the review period.*

*If the Commission’s decision contained conditions please identify clearly where in the SEA you have demonstrated compliance with them.*

1. Please note that the widening of the scope, to include use/s not included in the application, would necessitate submission of the new application for authorisation for the new use [↑](#footnote-ref-2)