16 September 2016

Review report of an authorisation

1. Purpose

According to Article 61(1) of the REACH Regulation, authorisations granted are valid until the Commission decides to amend or withdraw them in the context of a review, provided that the authorisation holder (AH) submits a review report at least 18 months before the expiry of the review period. This note[1] outlines the approach to be taken when a review report is submitted to the European Chemicals Agency (ECHA). Specifically, it outlines to what extent the review process and the elements of the review report are identical to an application for authorisation (AfA) and what would be different or new. The approach will be included in the practical guide that ECHA will make public by the end of 2016.

This note does not cover situations mentioned under Article 61(2).

2. Requirements of the REACH Regulation

According to Article 61(1) of the REACH Regulation if the authorisation holder (AH) wants to continue placing the substance on the market and/or using it beyond the expiry date of the review period, he will need to submit a review report[2] 18 months before the expiry of that review period. This is analogous to the latest application date (LAD) in the original application. The procedure for the Commission to amend or withdraw the authorisation is the same, *mutatis mutandis* as for adopting an authorisation decision following an application for authorisation.

According to Article 64(2) of the REACH Regulation ECHA shall make available on its web-site the same information (called broad information on uses) for review of authorisations and timelines as is the case for applications for authorisation. The process, set out in Article 64, applies *mutatis mutandis* for the review of authorisations under Article 61(1).

Article 61(1) states that an AH may submit only the number of the current authorisation, however, subject to the following:

1. AH shall submit an update of the analysis of alternatives (AoA) including information about any relevant R&D activity[3] If the updated AoA shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall also submit a substitution plan, including a timetable for proposed actions by the AH.
2. Where the AH cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis (SEA) contained in the original

[1] This note was subject to comments of the members of ECHA's Committees for Risk Assessment (RAC) and Socio-economic analysis (SEAC) during 7 July and 15 August 2016. These comments have been taken fully into account when the note was finalised between ECHA and the Commission services on 16 September 2016.
[2] Assuming that the applicant wants the authorisation to continue after the date of the time-limited review period.
[3] As appropriate an update of any substitution plan submitted under Article 62(4)(f) should be made.

application.
3. If AH can now demonstrate that the risk is adequately controlled (which was not the case when applying for authorisation), he shall submit an update of the chemical safety report.
4. If any other elements of the original application have changed, the AH shall also submit updates of these element(s).

Applicants, have thus far always submitted a chemical safety report (CSR) with exposure scenarios, an AoA and a SEA. The starting point for the review report is the Commission decision. If the CSR or SEA is updated, information, which had been provided by the applicant after the submission of the original application, should be included in the review report, if still relevant.

Downstream Users (DUs) using a substance in accordance with Article 56(2) of REACH shall notify ECHA about their use under a granted authorisation. ECHA encourages the DUs to also make this information available for the AH, where possible. Further details are available at https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use.

The Commission's decisions granting authorisations have normally included the conditions and monitoring arrangements that ECHA's Scientific Committees[4] had recommended. In some cases[5] the Commission's decision contained additional conditions over and above those recommended by ECHA and in some cases certain recommendations were not taken forward into the decision. ECHA's Committees may have given advice to the AH (in the justification section of the opinion) that was not included in the decision. This advice may be relevant with regard to the review report.

The Commission's decision and the advice from ECHA's Committees may affect the exposure scenarios, the AoA and the SEA (including health or environmental impact).

ECHA has issued the reporting formats for AfA according to Article 111.

In conclusion,

1) AoA:

   AH shall submit an update of the AoA including information about any relevant R&D activity, possible new alternatives and progress made towards substitution by safer alternatives. If the AH had submitted a substitution plan as part of its original application it shall also give an update of it as part of the review report[6].

2) CSR:

   Where there are conditions or monitoring arrangements relating to the management of the risks in the decisions, the AH shall submit an update of the exposure scenarios in his CSR. If no such conditions or monitoring arrangements have been issued, the exposure scenarios are still expected to be updated if there are changes affecting them. Reasons for this are, for instance, i) progress affecting production technologies and thus, the possibilities to reduce exposure (new risk management measures, variations to operational conditions, quantities used etc.) and ii) improved knowledge of exposure levels (e.g. based on additional measurements).

3) SEA:

   As the AoA needs to be updated, the benefits of a granted authorisation may change

[4] Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC)
[5] For instance, the Commission's draft decision on uses of recycled DEHP.
[6] Also, if the AH now concludes there is a suitable alternative available taking into account the elements in Article 60(5), he shall provide a substitution plan.

accordingly. Furthermore, to the extent the exposure scenarios are updated the health or environmental impacts of the granted authorisation may change, too. A SEA has been received thus far in all applications partly also to give the applicant's reasoning for the duration of the review period. For these reasons, the AH may also have to submit an updated SEA if it had been submitted as part of the application.

4) Other elements:

AH shall also submit an update of any other element of the original application that have changed or elements that are required by the conditions or monitoring arrangements of the authorisation decision.

3. Approach

The approach for the preparation, opinion making and decision making related to the review report needs to follow the requirements of the REACH Regulation (see Section 2) whilst being as practical as possible. The approach needs to be implemented in a way that is reasonable for the AH and meaningful for the opinion making of ECHA's Scientific Committees regarding the decision to withdraw or amend the related authorisation by the Commission. Thus, the approach should be such that the AH would update all relevant elements in the review report using the original application, the opinion, the decision and relevant communication made during the opinion and decision making as the basis. Therefore, the following approach is taken regarding the review reports:

1. The AH would update all documents submitted in the original application that have changed. The AoA has to be updated in all cases. The latest format of the AfA should be used to facilitate the opinion and decision making phases. ECHA will issue the formats on its website. The formats for review reports are likely to be the same as the formats for applications.

2. To facilitate public consultation, opinion making and decision making, the AH is requested to submit one additional document: a note explaining briefly what is different in the original application and the review report. The purpose of this explanatory note is to make it clear to all what progress has been made since the original application was made and the authorisation was granted. The note would be merely a reading aide, and would include a reference table of where changes have been made. ECHA will issue a format for this explanatory note on its website.

3. The opinion- and decision-making process set out in Article 64 REACH applies *mutatis mutandis* to the process for reviewing authorisations under Article 61(1).

Annex: Article 61 of the REACH Regulation

Annex

Article 61 of the REACH Regulation

Review of authorisations

1. Authorisations granted in accordance with Article 60 shall be regarded as valid until the Commission decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

A holder of an authorisation granted in accordance with Article 60 shall submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 62(4)(f). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken in accordance with the procedure referred to in Article 64 applied *mutatis mutandis*.

2. Authorisations may be reviewed at any time if:

(a) the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio- economic impact; or

(b) new information on possible substitutes becomes available.

The Commission shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.

3. In its review decision the Commission may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation, if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 60(5) become available. In the latter case the Commission shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of his application or update.

In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality.

4. If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.

5. If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6. If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants [7](1), the Commission shall withdraw the authorisation for that use.

[7] OJ L 158, 30.4.2004, p. 7, corrected in OJ L 229, 29.6.2004, p. 5. Regulation as amended by Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 1).