

OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL UPDATE FOR YEARS 2013-2015

ADOPTED ON 6 FEBRUARY 2013

Introduction

According to Article 44 of Regulation (EC) No 1907/2006 (REACH) the Agency shall compile a draft Community Rolling Action Plan (CoRAP) for three years based on prioritising criteria of Article 44(1) that are further developed in cooperation with the Member States (MSs). The Member State Committee (MSC) shall provide an opinion on ECHA's draft CoRAP.

The relevant Article 44 (2) states:

"[...] The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 76(1)(e) (hereinafter referred to as "the Member State Committee") and shall publish the plan on its website, identifying the MS who will carry out the evaluation of the substances listed therein as determined according to Article 45."

For the draft annual updates to the CoRAP, Article 44(2) of REACH states:

"[...] the Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year."

(Details of the process timelines can be seen in the section below).

2012 CoRAP selection criteria:

According to Article 44(1) the Agency shall develop in cooperation with the MSs criteria for prioritising substances for substance evaluation (SEv). Prioritisation shall follow a risk based approach. Article 44(1a-c) further defines these criteria.

For this first draft CoRAP annual update for years 2013-2015, the same selection criteria were applied as for the first draft CoRAP.

More detail on the selection criteria to prioritise substances for Substance Evaluation can be found on the ECHA website on:

http://www.echa.europa.eu/documents/10162/17221/background_doc_criteria_ed_32_2011_en.pdf.

First draft CoRAP update for years 2013-2015:

Based on the agreed selection criteria, ECHA and the MSs proposed substances that could be included in the CoRAP. MSs proposed substances also based on other specific risk-based concerns. Substances for which the MSs indicated an interest for evaluation were then included in the draft CoRAP update for years 2013-2015 which was submitted on 12 October 2012 to the MSs. At the same time, the draft CoRAP update for years 2013-2015 was submitted also to the MSC for opinion.

The procedure foreseen in Article 45(3) of REACH was not triggered for the draft CoRAP update for years 2013-2015.

Process for adoption of the opinion

At its 25th meeting (19-21 September 2012) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of 7 MSC members, alternates and experts) in order to develop an opinion on the draft CoRAP annual update for years 2013-2015.

On 12 October 2012 the draft CoRAP update for years 2013-2015, including 116 substances with justifications was submitted to the MSs and to the MSC and a non-confidential version of the draft CoRAP was published on the ECHA homepage. The first draft CoRAP update for years 2013-2015 was then introduced to the Committee in its 26th meeting (23-24 October 2012), where the Committee provided its first comments. Consequently, the CoRAP working group distributed the 63 new substances among themselves for further scrutiny and requested information from the relevant MSs on changes for the 53 substances already included in the first CoRAP as adopted in February 2012.

For the preparation of its opinion the Committee has been provided with the following documents:

- Background document to the decision of the Executive Director of ECHA, ED/32/2011, Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria)
- ECHA's draft CoRAP update for years 2013-2015 (confidential version) dated 11 October 2012
- Annex to ECHA's draft CoRAP update for years 2013-2015.
- Justification documents on each substance suggested for evaluation.

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 29 November 2012. This draft opinion and explanatory annex were discussed at the 27th MSC meeting on 13 December 2012. It was decided that the MSC members could further comment the documents until 9 January 2013. There were no specific comments, but for some substances new information came to the attention, which is now included in the draft opinion with explanatory annex. This new information was provided by the Rapporteur to the MSC on 25 January 2013 for discussion/adoption at the 28th MSC meeting. On 6 February 2013 the document was discussed at the 28th MSC meeting and some late changes were introduced. The rapporteur presented an updated version on 7 February 2013 which was adopted by the MSC. It was also agreed that the publication of the first annual CoRAP update and the MSC opinion would take place on 20 March 2013.

The draft CoRAP update for years 2013-2015 and focus of the opinion

1. Old CoRAP entries

The MSC used the previous MSC opinion on the final CoRAP adopted in February 2012 and the input from MSs to express its opinion on the substances already on the CoRAP as adopted in February 2012.

For this draft CoRAP update for years 2013-2015 there were no indications on the need to re-evaluate the justification documents for the substances already on the CoRAP as adopted in February 2012 to decide on the appropriateness of the inclusion of the substance in the updated CoRAP.

However, due to the format change of the justification documents the elements of concern were brought forward in another and clearer way than last year providing that some elements were subsequently changed/added in the annex to the opinion. Also, a harmonisation exercise took place during the writing of this year's opinion to solve inconsistencies between last year's opinion and new information in this year's updated justification documents.

For some of the substances it was noticed that new information has affected their inclusion in the draft CoRAP update. These specific substances are discussed in the 'MSC opinion on the draft CoRAP update for years 2013-2015' part of this document.

2. New CoRAP entries

The MSC used the draft CoRAP update for years 2013-2015 and the justification documents as a basis to express its opinion on the single substances.

The draft CoRAP table was extended in order to provide for every substance information i.a. on the tonnage band, the reflection of the MSs' justification for the selection as indicated in the justification documents (selection criteria met) and to express for every substance the MSC conclusion on whether the substance should be selected for substance evaluation. This information is presented in an Annex to this opinion.

The Annex consists of a list of the substances to be evaluated for every year in the next three years (2013-2015). The following information is specified for each of the substances:

1. Substance name
2. EC number
3. CAS number
4. Evaluating MS
5. Year of evaluation
6. Initial grounds for concern identified by ECHA
7. The legal basis of the inclusion (Art. 44(1) or 45(5) REACH)
8. Whether it is a new or an old entry
9. The Member State contact details
10. The tonnage band as disseminated on the ECHA website
11. Selection criteria met for the substance¹
12. Statement if the grounds of concern match with the rationale in the Justification Document
13. Conclusion of the MSC on the application of the selection criteria

The MSC assessed the following questions for each substance on the draft CoRAP update:

- Does the ground of concern given in the draft CoRAP update match with the justification

¹ Based on the document „Selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria)“; all selection criteria identified in the JD were listed here.

given in the justification document²?

- Does the concern given in the justification document fulfil the selection criteria agreed on and which of the selection criteria are fulfilled?
- If Art. 45(5) is used as legal basis to propose the substance, does the justification document describe a risk based concern?

The MSC used the documents listed in Section 1. The justification documents and the draft CoRAP update for years 2013-2015 were assessed based on the above mentioned questions.

The MSC checked the justification documents for each of the new entries and verified which of the agreed selection criteria were met based on the full content of the confidential justification document (not only on the 'grounds for concern' part of the document).

For substances where Article 45(5) was chosen as legal basis, it was examined if the justification document sufficiently describes a risk based approach. If the selection criteria are fulfilled and/or a risk based concern is described, the MSC supports the inclusion of the substance into the CoRAP.

MSC Opinion on the draft CoRAP update for years 2013-2015

The MSC acknowledges that for *1-ethylpyrrolidin-2-one* present on the final CoRAP published in February 2012 for years 2012-2014, based on new information from the MS originally proposing the substance, substance evaluation is not considered necessary anymore. This substance was no longer included in the draft CoRAP update for years 2013-2015 sent to the MSs and MSC on 12 October 2012.

The MSC also acknowledges that for *methyloxirane*, one of the new entries on the draft CoRAP update for years 2013-2015, based on new information from the MS originally proposing the substance, substance evaluation is not considered necessary anymore. This substance was still included in the draft CoRAP update for years 2013-2015 sent to the MSs and MSC on 12 October 2012, but was deleted later on in the process.

In addition, due to an update of the registration dossier for *pin-2(10)-ene*, listed in the draft CoRAP update for evaluation in 2013, the substance identity needs to be further reconsidered. Since this process will not be finalised in time for the adoption of the CoRAP update for years 2013-2015, the substance is for the time being withdrawn from the CoRAP.

For all other substances on the draft CoRAP update for years 2013-2015 the MSC is of the opinion that there are sufficient grounds for considering that the substance might constitute a risk to human health and/or the environment.

The MSC also acknowledges some changes made in years of evaluation and legal basis for substances on the first CoRAP. Most changes were already introduced in the draft CoRAP update for years 2013-2015 sent to the MSs on 12 October 2012. However, for *tetrahydrofuran* and for *diethyl phthalate* the changes in the legal basis and for *1,3,5-*

² The document „Confidential justification for the selection of a candidate CoRAP substance“ prepared by the Member State planning to evaluate the substance

tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione) the change in the year of evaluation (2013 to 2015) were introduced later on in the process.

Also, for one of the old entries, *phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased*, the MSC notes that as a consequence of a compliance check decision, the registrant may in future need to change the identifier of the substance.

Moreover, the MSC notes that for one of the new entries on the CoRAP, *Styrenated Phenol*, the public name was changed to the disseminated name: *Reaction mass of 2,4,6-tris(1-phenyl-ethyl)phenol and Bis(1-phenylethyl) phenol*. In addition, a new entry: *Phenol, styrenated*, EC no. 262-975-0 was added to the draft CoRAP update. These entries may be further revised in the CoRAP update for years 2014-2016, when considering similar substances.

Therefore, the MSC, based on the outcome of the assessment of the justification documents with the selection criteria as explained above, supports the updated³ draft CoRAP update for years 2013-2015 and agrees that all the substances included, shall be evaluated by the MSCAs in the next three years.

Annex

Table of substances on the draft CoRAP update for years 2013-2015 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria.

³ Changes introduced after 12 October 2012