

**OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT
COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL
UPDATE FOR THE YEARS 2015-2017
ADOPTED ON 4 FEBRUARY 2015**

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 Member State 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).

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 third draft CoRAP annual update for years 2015-2017, the same selection criteria were applied as for the second draft CoRAP and its second annual update.

More details 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.

Third draft CoRAP update for years 2015-2017:

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 2015-2017 which was submitted 17 October

2014 to the MSs. At the same time, the draft CoRAP update for years 2015-2017 was submitted also to the MSC for opinion.

The procedure foreseen in Article 45(3) of REACH (more than one MS having expressed an interest in evaluating the same substance) was not triggered for the draft CoRAP update for the years 2015-2017.

Process for adoption of the opinion

At its 37th meeting (15-18 September 2014) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (a total of 9 MSC members, alternates and experts) in order to develop an opinion on the draft CoRAP annual update for the years 2015-2017.

On 17 October 2014 the draft CoRAP update for years 2015-2017, including 134 substances with justifications, was submitted to the MSs and to the MSC and a non-confidential version of the draft CoRAP update was published on the ECHA homepage on 30 October. The third draft CoRAP update for the years 2015-2017 was then introduced to the Committee in its 38th meeting (28-29 October 2014), where the Committee provided its first comments. Consequently, the CoRAP working group distributed the 65 new substances among themselves for further scrutiny.

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 the years 2015-2017 (confidential version), dated 15 October 2014
- Justification documents (JD) on each substance suggested for evaluation

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 26 November. This draft opinion and explanatory annex were discussed at the 39th MSC meeting on 8-12 December 2014. It was decided that the MSC members could further comment on the documents until 9 January 2015. There were no specific MSC comments. Therefore an updated draft opinion which was provided by the Rapporteur to the MSC on 21 January 2015 for discussion/adoption at the 40th MSC meeting (3-5 February 2015), took into account only JD updates received from the MS. On 04 February 2015 the document was discussed at the 40th MSC meeting and some late changes were introduced. The rapporteur presented an updated version on 04 February 2015 which was adopted by the MSC.

The draft CoRAP update for years 2015-2017 and focus of the opinion

1. Old CoRAP entries

The MSC used the previous MSC opinion on the final CoRAP update adopted in February 2014 and the input from MSs to express its opinion on the substances already on the CoRAP as adopted in February 2014.

The MSC notes that some changes were made in years of evaluation.

The Finnish entry resin acids and rosin acids, hydrogenated, esters with pentaerythritol (HRPE) (1); resin acids and rosin acids, hydrogenated, esters with glycerol (HRGE) (2) (EC 264-848-5 (1); 266-042-9 (2)) was separated into two entries: resin acids and rosin acids, hydrogenated, esters with pentaerythritol (HRPE) (1) (EC 264-848-5 (1)) and resin acids and rosin acids, hydrogenated, esters with glycerol (HRGE) (2) 266-042-9 (2)) with a footnote indicating joint evaluation.

In addition following changes of exiting entries were done: change of evaluating member state from Germany to United Kingdom for entry naphthalene (CAS 91-20-3, EC 202-049-5) as well as removal of 1-chlorooctane (CAS 111-85-3 EC 203-915-5), planned to be evaluated in year 2016 by Germany, as a recent dossier was updated and there is no more initial PBT/vPvB concern.

The respective JDs were updated for two substances already on the CoRAP as adopted in February 2014. The updated JDs were assessed with the selection criteria as explained above and it was concluded that the changes made do not affect the general conclusion to support their inclusion in the CoRAP. Remarks for single substances were included in the relevant column of the Annex to Opinion.

For all other substances already in the CoRAP as adopted in February 2014, there were no indications on the need to re-evaluate the justification documents to decide on the appropriateness of the inclusion of the substance in the updated CoRAP.

2. New CoRAP entries

The MSC used the confidential draft CoRAP update for the years 2015-2017 and the justification documents as a basis to express its opinion on the single substances.

The confidential draft CoRAP update table was extended in order to provide information for every substance inter alia on the tonnage band, the reflection of the MSs' justification for the selection as indicated in the justification documents (selection criteria met, initial grounds of concern) and to express the MSC conclusion for every substance on whether or not 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 (2015-2017). The following information is specified for each of the substances:

1. Expected evaluation year
2. Evaluating MS
3. EC number
4. CAS number
5. Substance name
6. Initial grounds of concern
7. Source (whether it is a new or an old entry)
8. Member State contact details
9. Legal basis for the proposal (Art. 44 or 45 REACH)
10. Tonnage band
11. Selection criteria met for the substance¹

¹ Based on the document „Selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria)“.

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:

- Does the ground of concern given in the draft CoRAP update match with the justification stated 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 Article 45(5) is used as legal basis to propose the substance, does the justification document describe a risk based concern?
- Are there any other relevant inconsistencies between the justification document and the draft CoRAP update?

The MSC used the documents listed in Section 1. The justification documents and the draft CoRAP update for years 2015-2017 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 justification document. Remarks for single substances were included in the relevant column of the Annex to Opinion.

MSC Opinion on the draft CoRAP update for years 2015-2017

The MSC checked the justification documents for each of the new entries and found out that in order to take final decision more than half of JDs of all proposed substances had to be either corrected or updated (e.g. more detailed explanations regarding the initial concern should be provided). JDs were then updated by the MSs accordingly providing a basis for the Rapporteur to conclude on the substances.

Some substances proposed for CoRAP were evaluated under the previous legislation 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (EC 201-236-9); phenol (EC 203-632-7); tris(2-chloro-1-methylethyl) phosphate (TCPP) (EC 237-158-7) and zinc oxide (EC 215-222-5). The MSC acknowledges that for each of them sufficient justification for re-evaluation was given in JDs.

The MSC also acknowledges some changes made in years of evaluation. Most changes were already introduced in the draft CoRAP update for years 2015-2017 sent to the MSs and MSC on 17 October 2014.

In addition the Netherlands extended the scope of evaluation for tetrapropylenebenzene (EC 246-772-4) based on the CCH outcome. France proposed later in the process to add a new substance, tert-butyl-4-methoxyphenol.

For three substances EC 444-340-1 (name confidential); polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane (No EC number); tert-butyl-4-methoxyphenol (EC

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

246-563-8), only hazard related selection criteria but no exposure or risk related selection criteria are listed in the JD.

The MSC notes for two German substances EC 444-340-1 (name confidential) and polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane (No EC number) that the hazard - based criteria are fulfilled but none of exposure-based criteria of "2011 CoRAP selection criteria" are selected in Chapter 5.2 of their JDs. However, the MSC acknowledges that exposure to the environment is identified as initial ground of concern in Chapter 5.3 of both JDs. However there are sufficient grounds to consider that these substances may also constitute a risk for the environment. In addition, Germany notified these two substances in accordance with Article 45(5) of REACH Regulation as a national priority for evaluation.

The MSC notes for tert-butyl-4-methoxyphenol (EC 246-563-8) that the hazard - based criteria are fulfilled but none of exposure-based criteria are selected in Chapter 5.2 of the JD. However, the MSC acknowledges that wide dispersive use, consumer use as well as exposure of the sensitive populations are identified as initial ground of concern in Chapter 5.3 of the JD. Furthermore, the evaluation of this substance has been proposed as the outcome of a French risk management option analysis. Therefore the legal basis for the substance to be included in CoRAP is Article 45(5) of REACH Regulation.

The MSC had to discuss if the justifications for these three substances is in line with Article 44 (or 45) REACH and considered it sufficient to support their inclusion in the CoRAP. For all other substances on the draft CoRAP update for the years 2015-2017 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.

In conclusion , based on the outcome of the assessment of the justification documents with the selection criteria as explained above, the MSC supports the draft CoRAP update for the years 2015-2017 and agrees that all the substances included shall be evaluated by the MSCAs in the next three years under the condition that the above mentioned points are clarified.

Annex

Table of substances on the draft CoRAP update for years 2015-2017 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria