

**OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT
COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL
UPDATE FOR THE YEARS 2016-2018**

ADOPTED ON 03 FEBRUARY 2016

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 update, and the Agency shall adopt the final CoRAP update on the basis of this opinion.

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 draft CoRAP annual update for 2016-2018, the same selection criteria were applied as for the previous years.

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/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

Draft CoRAP update for the years 2016-2018:

Based on the agreed selection criteria and a screening process, 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 2016-2018 which was submitted on 15 October 2015 to the MSs. At the same time, the draft CoRAP update for years 2016-2018 was submitted also to the MSC for their opinion.

The procedure foreseen in Article 45(3) of REACH (no agreement when more than one MS having expressed an interest in evaluating the same substance) was not triggered for the draft CoRAP update for the years 2016-2018.

Process for adoption of the opinion

At its 43rd meeting (15-17 September 2015) the MSC appointed a Rapporteur, a Co-Rapporteur and a Working Group (made up of 7 MSC members and experts) in order to develop an opinion on the draft CoRAP annual update for the years 2016-2018.

On 15 October 2015 the draft CoRAP update for years 2016-2018, including 138 substances with justifications, was submitted to the MSs and to the MSC. A non-confidential version of the draft CoRAP update was published 28 October 2015 on the ECHA homepage. The draft CoRAP update for 2016-2018 was then introduced to the Committee in its 44th meeting (27-29 October 2015), so the Committee could provide its first comments. Consequently, the CoRAP working group distributed among themselves for further scrutiny the 53 substances that are

new additions to the draft CoRAP and four substances with updated justification documents that are already in CoRAP.

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 2016-2018 (confidential version), dated 15 October 2015
- Justification documents (JD) on each substance suggested for evaluation

The Rapporteur provided a first draft opinion with explanatory annex to the MSC on 26 November 2015. This draft opinion and explanatory annex were discussed at the 45th MSC meeting on 7-11 December 2015, incl. a closed session for discussion of some specific cases. It was decided that the MSC members could further comment on the documents until 10 January 2016. No specific MSC comments were given. An updated draft opinion Annex was provided by the Rapporteur to the MSC on 20 January 2016, changed following the discussion in MSC-45, or as results of justification documents being updated by MSs (by own initiative or after requests from the WG or ECHA). The documents were discussed at the 46th MSC meeting (2-4 February 2016) and some late changes introduced. The (amended) opinion was adopted by the MSC on 3 February 2016.

The draft CoRAP update for years 2016-2018 and focus of the opinion

1. Existing CoRAP entries

The MSC used the previous MSC opinion on the final CoRAP update adopted in February 2015 and any new input from MSs to express its opinion on the substances already on the CoRAP update as adopted in March 2015.

The JDs were updated for four substances already on the CoRAP as adopted in March 2015. For four other substances the initial ground for concern were changed later in the process by the MSs and those JDs were also updated. The updated JDs and changes in concern 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. Changes for single substances were included in the relevant column of the Annex to the Opinion.

For the other substances already in the CoRAP as adopted in March 2015, there were no indications on changes in concern(s) or available information that should trigger the need to re-evaluate the appropriateness of the inclusion of the substance in the CoRAP update. But due to ongoing compliance checks (CCH), testing proposal examinations (TPE), and changes in national resources, some more evaluations have been postponed.

For 13 existing CoRAP entries the year of evaluation was changed compared to the CoRAP 2015 – 2017 before the draft CoRAP update for 2016 – 2018 was referred to MSC on 15 October 2015.

2. New CoRAP entries

The MSC used the confidential draft CoRAP update for the years 2016-2018 and the justification documents as a basis to express its opinion on the new substances.

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 document¹?

¹ The document „Justification for the selection of a candidate CoRAP substance“ prepared by the Member State planning to evaluate the substance

- 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 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 documents. The confidential draft CoRAP update table was extended in order to provide information for every substance on which selection criteria are met and whether the initial grounds for concern match with the MSs' rationale in the justification documents. It also includes the MSC conclusion for every substance on whether or not the substance should be selected for substance evaluation. The information is presented in the Annex to this opinion.

The Annex consists of a list of the substances to be evaluated for every year in the next three years (2016-2018). 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 public name
6. Initial grounds of concern
7. Source (whether it is a new or an existing entry)
8. Member State contact details
9. Legal basis for the proposal (Art. 44 or 45 REACH)
10. Tonnage band disseminated
11. Selection criteria met for the substance²
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

MSC Opinion on the draft CoRAP update for years 2016-2018

It was discussed whether a risk based concern was sufficiently described for the substance 1,1,1,3,5,5,5-heptamethyltrisiloxane (EC 217-496-1 (UK 2017)). The substance is of national priority with Article 45(5) as legal basis. Based on the given justification, MSC is of the opinion that there are sufficient grounds for considering that the substance might constitute a risk to the environment and therefore supports the inclusion in the draft CoRAP update.

Three newly proposed substances were evaluated under the Existing Substances Regulation programme. For two of the substances (EC-215-175-0 (DE 2018); EC-203-545-4 (LV 2018)) the Risk Assessment Reports (RAR) were concluded in 2008 and justification for re-evaluation is given in the justification documents (JDs). For the third substance (EC-216-133-4 (DE 2018)) the JD was updated with a clearer reference to the RAR and better clarification of the reasons for a new evaluation.

In quite many JDs the MSC WG found some inconsistencies between the boxes ticked in the JDs and the text or between different parts of the JDs. The WG contacted the relevant MSs and asked for corrections and clarifications. The opinion Annex was amended according to the answers received.

For 11 new and four existing entries the initial grounds of concern were changed after the referral to the MSC of the draft CoRAP update, either by adding, removing or correcting a concern. These changes do not influence the prioritisation for inclusion in the CoRAP update.

² 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 even if they are not reflected in the initial grounds of concern.

One new substance, 2,6-di-tert-butyl-p-cresol (EC 204-881-4), was notified by France for 2016 just before MSC-45. The inclusion is supported by the MSC.

Two substances already in CoRAP, 4,4'-ethylidenediphenyl dicyanate (EC 405-740-1 (DE 2016)) and allyl alcohol (EC 203-470-7 (HU 2016)) have been withdrawn based on justification letters from the eMSCA. The selection criteria/risk based approach is no longer met and the withdrawal is supported by the MSC.

For 23 substances the eMSCAs or ECHA in cooperation with eMSCAs have proposed to change the year of evaluation, due to:

- Ongoing SEv for similar substance
- Ongoing CCH/TPE
(waiting for draft decision or results)
(Needing time to clarify whether CCH can give the necessary information to clarify concern, so that SEv is not needed)
- Ongoing appeals
- Resource situation

Among these 23 substances, two were new entries and eight existing entries for which the year was changed after referral to MSC. For the rest (13 existing entries), the year was changed already before the draft CoRAP update 2016 – 2018 was referred to MSC as mentioned in *Section 1. Existing CoRAP entries*, above.

For all substances on the draft CoRAP update for the years 2016-2018, with the changes given above, 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.

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 2016-2018 and agrees that all the 138 (54 new and 84 existing) substances in the list (the two withdrawn not included) shall be evaluated by the MSCAs in the next three years.

Annex

Table of substances on the draft CoRAP update for years 2016-2018 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria.