

**OPINION OF THE MEMBER STATE COMMITTEE ON THE DRAFT
COMMUNITY ROLLING ACTION PLAN (CoRAP) ANNUAL
UPDATE FOR THE YEARS 2019-2021**

ADOPTED ON 06 FEBRUARY 2019

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 2019-2021, 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:

https://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf/67441c3c-75be-4ecd-992e-b90ab2041805

Draft CoRAP annual update for the years 2019-2021:

Based on the agreed selection criteria and a screening process, ECHA and the MSs proposed substances that could be included in the CoRAP. MSs also proposed substances that were not included in the 2018 screening process. Substances for which the MSs indicated an interest for evaluation were then included in the draft CoRAP update 2019-2021 which was submitted on 27 September 2018 to the MSs. At the same time, the draft CoRAP update 2019-2021 was

submitted also to the MSC for its opinion. In this draft CoRAP update 20 new substances were included and 11 substances were withdrawn.

After mentioned submission, ECHA received from MSCAs late proposals for the inclusion of four additional substances in the draft CoRAP update 2019-2021. ECHA supported the respective proposals and has therefore decided to amend the draft CoRAP update 2019-2021. Following this decision, on 22 October 2018 an amended draft CoRAP update 2019-2021 was submitted to the MSC for their opinion as well as to MSs. In this amended draft CoRAP update 24 new substances were included and 11 substances were withdrawn.

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 2019-2021.

Process for adoption of the opinion

At its 60th meeting (14 June 2018) the MSC appointed a Rapporteur and a Co-Rapporteur to prepare the Committee's draft opinion on the draft CoRAP annual update for the years 2019-2021 and on any Article 45(5) proposals from Member States to add substances to the CoRAP outside this round. In order to provide support to the Rapporteur/Co-Rapporteur in this task, MSC appointed a Working Group (made up of 7 MSC members and experts including the Co-Rapporteur) by written procedure on 24 September 2018.

On 27 September 2018 the draft CoRAP update 2019-2021, including 107 substances with justifications, was submitted to the MSs and to the MSC. A non-confidential version of the draft CoRAP update was published 10 October 2018 on the ECHA homepage. The draft CoRAP update 2019-2021 was then introduced to the Committee in its 61st meeting (10-11 October 2018), so the Committee could provide its first comments. Consequently, the CoRAP working group distributed among themselves for further scrutiny the 20 substances that are new additions to the draft CoRAP and 6 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)
- The submission letter,
- ECHA's draft CoRAP update for the years 2019-2021 confidential version, dated 27 September 2018 and public version dated 10 October 2018,
- Justification documents (JD) on each substance suggested for evaluation

- Template for justifying the withdrawal of a substance from CoRAP.

The justification document template 'withdrawal' was submitted to MSC for the first time and it is targeted towards evaluating MS (eMS)s who requested to withdraw substances that are already on the CoRAP prior to the start of evaluation. Such eMSs were required to fill in this template to provide reasons for reconsidering the relevance of the concerns that lead the substance to be placed on the CoRAP, with the aim of publishing this document on the website.

Due to the late proposals for the inclusion of 4 additional substances in the draft CoRAP update 2019-2021, on 22 October 2018 ECHA submitted an amended draft CoRAP update 2019-2021 to the MSC as well as to MSs. In this amended draft CoRAP update 24 new substances were included and 11 substance were withdrawn. The CoRAP working group distributed among themselves for further scrutiny additional 4 new substances.

In the update ECHA submitted to MSC the following documents:

- The submission letter.
- ECHA's amended draft CoRAP update for the years 2019-2021 public version dated 22 October 2018.
- ECHA's amended draft CoRAP update for the years 2019-2021 Confidential version,
- Justification document (JD) of the newly added substance resorcinol,
- JD for the one group of three substances – hydrofluoroethers.

The Rapporteur provided a draft opinion with explanatory annex to the MSC on 29 November 2018. In this draft 111 substances, 24 new and 87 existing, were included. 11 substances were removed from the list on request of the evaluating MS before referral of the draft CoRAP. This draft opinion and explanatory annex were discussed at the 62nd MSC meeting on 10-14 December 2018. It was decided that the MSC members could further comment on the documents until 17 January 2019. *No specific MSC comments were given.* An updated draft opinion with Annex with 111 substances was provided by the Rapporteur to the MSC on 24 January 2019., The documents were discussed at the 63th MSC meeting (5-7 February 2019) and some late changes introduced. The (amended) opinion was adopted by the MSC on 6 February 2019.

The draft CoRAP annual update for years 2019-2021 and focus of the opinion

1. Existing CoRAP entries

The MSC used the previous MSC opinion on the draft CoRAP update 2018-2020, which was adopted by MSC in February 2018, and any new input from MSs to express its opinion on the substances already on the CoRAP 2018-2020 update, as adopted by ECHA in March 2018.

Prior to the referral of the draft CoRAP update 2019-2021 to MSC the following changes took place to some of the existing CoRAP entries. The JDs were updated for 7 substances already on the CoRAP as adopted in March 2018. The changes cover adding and/or deleting some part(s) of the initial grounds of concern or a change in substance identity or tonnage band. In addition JDs for 4 substances were updated due to hand overs from UK to another MS. 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. The changes for single substances were included in the relevant column of the Annex to the Opinion.

11 of the existing entries have been withdrawn upon requests of an eMSCA with justification provided in the withdrawal documents. These are: 4,4'-Methylenediphenyl diisocyanate, oligomeric reaction products with butane- 1,3-diol, 2,4'- diisocyanatodiphenylmethane, 2,2'-oxydiethanol and propane-1,2-diol (EC 500-415-1 old/ 701-276-1 new); 1-isocyanato-2(or 4)-(4-isocyanatobenzyl)benzene and their reaction products with (methylethylene)bis(oxy)]dipropanol and butane-1,3-diol and propylene glycol (EC 701-029-8); (1-methylethyl)-1,1'-biphenyl (EC 247 -156-8), diiron tris(sulphate) (EC 233-027-9); 10-undecenyl 2-cyano-3,3-diphenylpropenoate (EC 700-604-0); Trimethyloctadecylammonium chloride (EC 203-929-1); Oximino Silanes Category (EC 218-747-8, EC 245-366 4); Disodium 4,4'-bis[(4,6-dianilino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate (EC 205-117-2); Piperonylbutoxide (EC 200-076-7) and Dinitrogen tetraoxide (234-126-4). MSC has no comments on the justifications as provided, and can support their withdrawal.

For the other substances already in the CoRAP, as adopted in March 2018, there were no indications of 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. MSC can support their postponement.

The MSC notes that 42 changes were made in the year of evaluation at the time of referral of the draft CoRAP update 2019-2021. For only one substance (Triclocarban EC 202-924-1) the evaluation was brought forward whilst for the rest the evaluation year was postponed. The reasons for postponement were to wait for the results of ongoing compliance checks/testing proposals, or of substance evaluation of similar substances and, for two eMS, reduced resources. After referral another substance had its evaluation brought forward, Bis(4-chlorophenyl) sulphone (EC 201-247-9), making the total number of changes in evaluation year being 43.

2. New CoRAP entries

The MSC used the confidential draft CoRAP update 2019-2021 and the justification documents as a basis to express its opinion on the single (new) substances.

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 stated in the justification document¹?
- 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 (2019-2021). The following information is specified for each of the substances:

1. Expected evaluation year
2. Whether year of evaluation has changed (existing entries)
3. Evaluating MS
4. EC number
5. CAS number
6. Substance public name
7. Initial grounds of concern
8. Member State contact details
9. Source (whether it is a new or an old entry)
10. Legal basis for the proposal (Art. 44 or 45 REACH)
11. Tonnage band disseminated
12. Selection criteria met for the substance²
13. Statement if the grounds of concern match with the rationale in the Justification Document
14. Conclusion of the MSC on the application of the selection criteria

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

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.

MSC Opinion on the draft CoRAP annual update for years 2019-2021

For some substances, the MSC working group requested updates of the justification documents mostly to solve some inconsistencies. Special consideration was given to the substance Resorcinol (EC 203-585-2). Finland concluded the first substance evaluation of this substance in October 2017 with no further action as described in SEV conclusion and RMOA documents. France requested the substance to be reinserted into CoRAP for the same endocrine disruption concern due to the changes in circumstances described in the justification document. It is noted that evaluation and regulation of endocrine disruptors and suspected endocrine disruptors are a priority for the French Authorities. This substance was included in the French National Strategy for Endocrine Disruptors.

The MSC working group is of the opinion that the conclusion that no action needs to be taken under SEV by one MSCA does not prevent another MS from requesting the substance to be reinserted in the CoRAP, even if the available information on that substance has not changed. Since no draft decision was issued by Finland, France has had no opportunity in the SEV process to formally react (using Proposals for Amendments) to Finland's assessment. Therefore MSC working group is of the opinion that the substance Resorcinol (EC 203-585-2) can be reinserted in the CoRAP update.

For all substances on the draft CoRAP update 2019-2021 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.

Due to ongoing compliance checks (CCH) and testing proposal examinations (TPE) however, evaluations may be postponed later or may not be needed due to the results of the CCH/TPE.

Therefore, based on the outcome of the assessment of the justification documents with the selection criteria as explained above, the MSC supports the draft CoRAP annual update for the years 2019-2021 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 2019-2021 including criteria used for the proposal (grounds for concern/selection criteria met), legal basis and conclusion of MSC on application of selection criteria. This table reflects the changes described in this opinion.