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Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment

This document is an attempt to provide guidance in the interest of consistency. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.
This document will be reviewed in 2 years in the light of experience.

1. Scope of this document

This document follows up from the discussions at the 89th Competent Authority meeting in September 2020 in relation to the proposal to bridge the assessment of endocrine disrupting (ED) properties of non-active substances (so-called "co-formulants") in biocidal products with the integrated regulatory strategy under Regulation (EC) No 1907/2006 (REACH).

2. Background

Paragraph 8(a) of Annex VI of the BPR establishes that the evaluating body must, when evaluating a biocidal product, take into consideration other relevant technical or scientific information which is reasonably available to him with regard to the properties of a biocidal product, its components, metabolites or residues. In accordance with Commission Delegated Regulation (EU) 2017/2100[1] specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) and in line with document CA-March18-Doc.7.3.b-final[2], the evaluating Member State needs to conclude whether the biocidal product should be considered to have ED properties, based on the existing knowledge and available scientific information[3]. This involves considering the ED criteria for both the active substances and the non-active substances included in the biocidal product.

While the ED properties of the active substances are evaluated under the approval procedure, the ED properties of the non-active substances are assessed at the product authorisation stage. Based on the available information, the following conclusions can be drawn from the assessment of the non-active substances included in the biocidal product:

(i) There are no indications of ED properties;

(ii) The non-active substance is an ED and has already been identified as having ED properties by other regulatory bodies at EU level (e.g. REACH, BPR, PPP[4]);

(iii) The non-active substance has indications of ED properties that would require further assessment.

For the non-active substances having indications of ED properties, the key objective is to ensure that they are further investigated in order to establish whether they do actually have ED properties. Non-active substances included in biocidal products may also be used in many non-

[1] Commission Delegated Regulation (EU) 2017/2100 was published on 17 November 2017 (http://eur-lex.europa.eu/eli/reg_del/2017/2100/oj) and is applicable as of 7 June 2018.
[2] The document is available at /CircaBC/SANTE/BPR - Public/Library/documents finalised/CA-March18-Doc.7.3b-final- EDs- biocidal products.docx
[3] The guidance for ED assessment under the BPR and PPPR developed by EFSA and ECHA is available at https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311
[4] In case, e.g. the non-active substance is also a biocidal or PPP active substance.

biocidal products and would therefore be subject to screening, assessment and data generation under REACH. In order to avoid duplication of similar evaluating activities and ensure consistency between the possible conclusions on the ED properties under different legal frameworks, it is proposed that the ED properties of non-active substances in biocidal products are scrutinised under the integrated regulatory strategy of REACH (for more details, please see the Annex). This approach is in line with the EU Communication on Chemical Strategy for Sustainability[5], in particular for the coordination and simplifications of actions across legislation ("one substance – one assessment") and the attention to ED chemicals.

Non-active substances are expected to be registered under REACH. The screening of all registered substances under REACH, as well as some non-registered substances (i.e. substances below 1 tonne per year notified for C&L), takes into account structural similarity and information from other relevant sources to identify (i.a.) substances with indication of ED properties and concluding on ED properties. The screening of all registered substances is expected to be concluded by 2027, starting from groups of substances with indications of concerns, so that by the end of 2021 most substances with indications of ED properties are expected to be identified.

A preliminary list of co-formulants being used in biocidal products is being created by extraction from IUCLID biocidal product dossiers[6]. This list (under development) allows the upfront identification of substances used as non-active substances in biocidal products to be taken into account in the REACH screening process when it is concluded that there is a need for further assessment in relation to ED assessment.

When the assessment of biocidal products recognises indications of ED properties for non-active substances, it is already current practice that further assessment and generation of further information is followed up under REACH (e.g. substance evaluation).

3. Proposed way forward for the assessment of ED properties of non-active substances in biocidal products in synergy with REACH

A way forward is proposed to identify by biocides' competent authorities whether a non-active substance has indications of ED properties taking benefit of the integrated regulatory strategy under REACH. Figure 1 shows a schematic representation of subsequential steps to be followed by biocides competent authorities during the evaluation of a biocidal product application in relation to the assessment of ED properties of non-active substances[7]. The steps are described below. Various sources of information are indicated, besides the assessment provided by the applicant that, in principle, should collect already all relevant information.

A. Checking if, based on an EU decision, there has been a conclusion on whether the non-active substance is an ED or not

Step 1: Biocides competent authorities should check in the BPR[8] and PPPR lists[9] and opinions whether the non-active substance fulfils the ED criteria[10].

- If Yes, the non-active substance is considered as an ED and the biocidal product will be considered to have ED properties and the evaluating body must also apply the regulatory

[5] COM(2020)667 final
[6] CG-41-2020-15 AP 7.3 Inventory of the c-f from IUCLID.
[7] Further information on the non-active substances can also be found in the substance infocards and brief profiles published on the ECHA website: https://echa.europa.eu/information-on-chemicals.
[8] https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
[9] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
[10] It may happen that biocidal or plant protection active substances are used as non-active substances in biocidal products.

consequences related to ED properties[11].

- If No, proceed to Step 2.

Step 2: Biocides competent authorities should check if the non-active substance is included in the list[12] of substances of very high concern (SVHC) due to ED concern (according to Article 57(f) and Article 59(1) of the REACH).

- If Yes, the non-active substance is considered as an ED and the biocidal product will be considered to have ED properties and the evaluating body must also apply the regulatory consequences related to ED properties[11].
- If No, proceed to Step 3.

Step 3: Biocides competent authorities should check if the non-active substance is a food/foodstuff material according to the definition of "food" within Regulation (EC) No 178/2002[13,14].

- If Yes, the non-active substance does not have indications of ED properties.
- If No, proceed to the next step.

B. Checking if there are any relevant assessments under REACH

Step 4: Biocides competent authorities should check the Activities Coordination Tool (ACT)[15]. ACT shows all REACH and CLP regulatory activities for the substances such as classification and labelling (CLH) proposals, SVHC proposals, hazard assessment activities (including ED), Community Rolling Action Plan (CoRAP) for substances under evaluation and dossier evaluation.

In the following cases the non-active substance has indications of ED properties currently under assessment, including, when necessary, the generation of further data:

- there is a SVHC proposal for ED;
- the non-active substance is included in the CoRAP list due to ED concern;
- substance evaluation is ongoing to clarify ED concern;
- the non-active substance is under dossier evaluation or substance evaluation for ED related endpoints to clarify ED concern[16].

If none of the above-mentioned conditions is met, Biocides competent authorities should check whether the non-active substance has been screened. If the non-active substance has been screened and the screening outcome is "No action" or the hazard assessment conclusion is that there are no indications of ED concern, it is possible to conclude that there are no indications of ED properties. Otherwise, the screening outcome may identify indications of ED properties requiring further action under REACH.

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[11] Articles 5(2), 19(4), 22(2)(e), 23, 25(b) or 42 of the BPR, as well as the relevant provisions in Annex VI to the BPR (for example point 48) that are linked to the ED properties of the product or its components.
[12] Available on the ECHA website at https://echa.europa.eu/candidate-list-table.
[13] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178)
[14] This is in line with the Coordination Group meeting agreements (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants_final and CG-41-2020-03 AP 16.5 ED co-formulant_assessment by MS_vf_PUBLIC).
[15] ACT is accessible at: https://interactportal.echa.europa.eu/
[16] Indications of the concerns behind the requests will be available in ACT. If the compliance check (CCH) follow-up has clarified ED properties, the non-active substance would be flagged for substance evaluation (SEV) or risk management proposal under ACT.

The substances with ongoing or past screening within a group of substances are visible in ACT under the "RMOA" column with the planned next regulatory action indicated (when defined) and a report providing the whole plan for the group and related substances. The report also includes conclusions on indications of ED properties.

C. Checking if there are other indications of ED properties

If checking the status under REACH was not sufficient to conclude, Biocides competent authorities should consider to conclude primarily based on the information provided by the applicant and indications from the classification e.g. whether the non-active substance has harmonised or self-classification under CLP for hazards relevant for potential ED properties e.g. reproductive toxicity, STOT RE (e.g. thyroid, adrenals, pancreas) and carcinogenicity (e.g. uterus, mammary glands, testis). If no indications are identified so far under REACH and CLP, neither from the information in the application and from the classification, it can be concluded that there are no indications of ED properties. If the substance is registered under REACH, either it has been screened or is expected to be screened within a few years by also taking into account structural similarities with known ED substances (group approach), which may have revealed less apparent evidences of ED. Clear indications of ED, especially for high tonnage substances, were already searched in the annual screening performed in the past under REACH based on IT algorithms and, if confirmed by the subsequent expert check, the substance should be in the process of assessment or at least scheduled for a priority screening.

D. Optional step: further assessment by Biocides competent authorities

Biocides competent authorities could check, e.g., US databases (ToxCast, EDSP), literature search and structural similarities with ED substances. These indications should normally not be considered in isolation, but in a Weight of Evidence (WoE) approach.

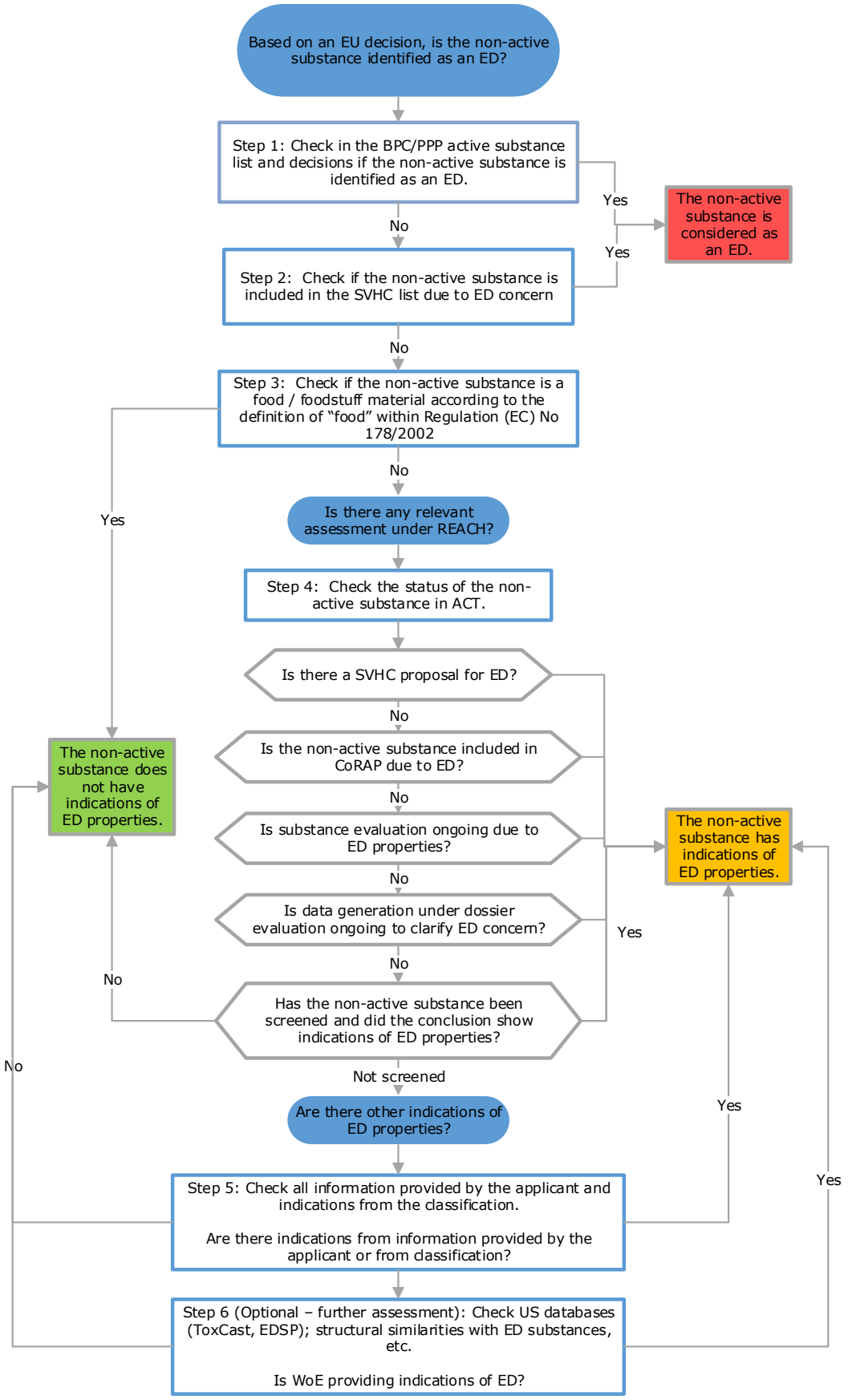

Figure 1 Flowchart for the assessment of ED properties of non-active substances in biocidal products

4. Follow-up in case the non-active substance has indications of ED properties

In line with the current practice, in case there are indications that the non-active substance may have ED properties, normally there is not sufficient time to verify it in the frame of the biocidal product authorisation process. The Biocides competent authority can authorise the product, if the procedure cannot be concluded before the legal deadline for product authorisation[17]. The non-active substances contained in biocidal products are used in many mixtures and articles. The assessment of one (or more) non-active substance is proposed to be generally further assessed in the frame of REACH (or BPR or PPPR if the non-active substance is an active substance with no decision yet on ED). Once the conclusion regarding ED properties of this non-active substance is available, the applicant must inform the evaluating Biocides competent authority / reference Member State pursuant to Article 47 of the BPR. If needed, the conditions of authorisation shall be revised in accordance with Article 48 of the BPR.

The Biocides competent authority can follow-up as described below.

In case the substance is already undergoing assessment under REACH, the evaluating competent authority should inform ECHA and the REACH competent authority in charge of the substance evaluation, that the substance is used as a biocidal non-active substance and what could be the regulatory consequences should it be confirmed ED.

The timelines to conclude on ED properties will vary depending on the type of assessment. Substance evaluation would require at least 2 years, plus the time for experimental testing (1-3 years, as well as the follow-up assessment period of the evaluating MSCA - up to 12 months) to conclude. The confirmation in the SVHC list may be concluded in about one year.

In case the Biocides competent authorities find indications of ED properties for substances that are still awaiting the REACH screening, they should inform ECHA[18] that the substance is used as a biocidal non-active substance (although it can be already known from the co-formulant list). This might only be relevant for ED indications identified according to Step 5 or the optional Step 6 in Figure 1. If the REACH screening identifies indications of ED properties, follow-up actions will take place under REACH.

Biocides competent authorities can check the schedule for REACH screening in the Rolling list of groups[19]. The Rolling list shows all substances in all the groups generated so far for screening under REACH and also the tentative schedule for screening, as well as whether there are alerts (generally based on structural similarities, to be verified and not yet to be considered as indications) for specific concerns (e.g. CMRS or ED) requiring attention in the screening. The prioritisation in the time schedule takes already into account any alert for concern.

If it is considered urgent, Biocides competent authorities should consult with their REACH competent authority about the possibility of volunteering to perform the screening and assess the substance, together with similar substances in the group, earlier than the current plan.

In case the substance is not registered, the substance and dossier evaluation processes under REACH do not apply. However, the substance may be notified in the C&L inventory (and self-classified) and could already be included together with structurally similar substances in any of the groups planned for screening under REACH.

Biocides competent authorities are advised to consult in ACT the progress of the assessment under REACH, in order to verify whether the ED concern for the non-active substance has been removed. This is particularly relevant for the renewal stage of a product authorisation.

[17] Please refer to document CA-March18-Doc.7.3.b-final for further details.
[18] Biocides competent authorities can inform by email ECHA (via Biocides@echa.europa.eu).
[19] This can be checked under the "Screening" tab in the Interact Portal. The rolling list of substances can be downloaded in MS Excel format.

Annex: Integrated regulatory strategy under REACH

ECHA has developed an integrated regulatory strategy[20] that brings together the various regulatory processes and provides support to authorities to address substances of concern as quickly as possible to conclude which substances:

(i) are of high priority for regulatory risk management;

(ii) need more data for a judgement to be made; or

(iii) are currently of low priority for further work,

and to have all registered substances allocated to these pools by 2027, as indicated in the Action Plan[21] set in 2019. The integrated regulatory strategy under REACH is presented in the infographic available on the ECHA website[22].

To speed up the identification of chemicals that need regulatory action, REACH authorities address groups of structurally related substances rather than single substances (so called grouping). The groups of substances are primarily formed based on:

- structural similarity, using the substance identity information in registration dossiers and C&L notifications; and
- read-across and categories, using information received in registration dossiers from industry and external sources.

Structurally similar substances are identified from all the registered substances (the chemical universe). Also notified (non-registered) substances are later included in the groups of structurally related substances to prevent regrettable substitution when some group member is confirmed to need regulatory risk management (such as SVHC identification based on ED properties).

By end of 2021, ECHA expects to have placed the majority of the higher volume REACH registered substances in groups, as well a significant part of the lower volume substances. The rest of groups will be created later but because of this grouping and extensive screening activities performed in the past the rest of registered substances is not likely to contain many substances with concern triggers for further actions. All the groups will queue for assessment to be done at the latest by the end of 2027.

Once the grouping is done, substances belonging to the groups will be assessed mostly by ECHA (a few groups will be assessed by MSCAs). ECHA, the Member States and the European Commission have developed the approach to assess the groups by teams of substance identity, (eco)toxicologist and exposure/risk management experts. The teams consider information from REACH registrations and other sources as well as evidence from structural relations. Based on the screening they conclude on hazard (including ED) and exposure potential, with consideration of the regulatory measures already in place. Evidences of ED for biocidal products normally trigger further assessment as they are normally associated with relevant exposure.

As a result, substances are allocated to the appropriate pools, indicated above, within the chemical universe and later to different REACH and CLP processes. According to the pool, the substances, either individually or as a group, are subject to assessment/data generation or risk management processes under REACH, CLP or other legislative framework (including actions under BPR for product authorisation).

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[20] Further details available at: https://echa.europa.eu/substances-of-potential-concern

[21] https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

[22] https://echa.europa.eu/irs-infographic