



Bridging the endocrine disruptor assessment of biocidal non-active substances with UK and EU REACH screening and assessment

September 2023

This document is an attempt to provide guidance in the interest of consistency. Please note, however, that the GB authority and applicants are not legally obliged to follow the approach set out in this document, since only the courts can give authoritative interpretations on the contents of the law.

This document may be periodically reviewed in the light of experience.

Document history

Version	Comment	Date
1.0	First edition	October 2022
2.0	Removal of the requirement for applicants to provide a literature review for non-target organisms. Minor updates to formatting of footnotes. Links to external websites updated.	September 203

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Scope of this document

This document proposes a way forward 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).

This guidance is for applicants wishing to place biocidal products on the GB and NI market. The guidance broadly corresponds with that developed by ECHA (the European Chemicals Agency)¹ and incorporates GB requirements.

This guidance is considered supplementary to CA-March18-Doc.7.3.b-final²; the ED assessment of biocidal products should still be performed according to CA-March18Doc.7.3.b-final. However, where indications of ED properties are identified for any co-formulant, from information from authorities and bodies across the globe, including those related to the EU, this will be addressed through the UK REACH processes.

¹ [CA-March-21-Doc.4.3 Final Bridging Biocides with REACH](#)

² The document is available [on CircaBC](#)

Background

Paragraph 8(a) of Annex VI of the GB Biocidal Products Regulation 528/2012 (GB 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 with regard to the properties of a biocidal product, its components, metabolites or residues. Regulation (EU) 2017/2100³ continues to apply in GB, specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under GB BPR. In conjunction with document CA-March18-Doc.7.3.b-final, this guidance sets out the approach applicants and the GB authority (HSE) should follow when determining the potential endocrine disrupting properties of biocidal products using existing knowledge and available scientific information⁴. 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 the GB authority (e.g. under UK REACH, GB BPR, GB PPP⁵) or by other regulatory bodies (e.g. at EU level or other international body);
- iii. The non-active substance has indications of ED properties, from information from authorities and bodies across the globe, 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-biocidal products and would therefore be subject to screening, assessment and data generation under UK and EU 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 nonactive substances in biocidal products are scrutinised under the integrated regulatory strategy of UK and EU REACH (for more details, please see the [Annex](#)).

³ [Commission Delegated Regulation \(EU\) 2017/2100](#) was published on 17 November 2017 and is applicable as of 7 June 2018.

⁴ The guidance for ED assessment under the BPR and PPPR developed by EFSA and ECHA is available [on the EFSA online library](#)

⁵ In case, e.g. the non-active substance is also a biocidal or PPP active substance.

Non-active substances are expected to be registered under UK and EU REACH. The screening of all registered substances under EU 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 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 high concern, so that by the end of 2027 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 in the EU by extraction of information from IUCLID biocidal product dossiers⁶. This list (under development) allows the upfront identification of substances used as non-active substances in biocidal products for which a further ED assessment is required which should be addressed by the EU REACH screening process. However, this list may not be made publicly available by ECHA. In addition, an equivalent list will not be created in GB.

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

⁶ CG-41-2020-15 AP 7.3 Inventory of the c-f from IUCLID.

Way forward for the assessment of ED properties of non-active substances in biocidal products drawing on UK and EU REACH

A way forward is proposed, for applicants and the GB authority to follow, to identify whether a non-active substance has indications of ED properties, taking benefit of the integrated regulatory strategy under UK and EU REACH. Figure 1 shows a schematic representation of the subsequential steps to be followed by applicants and the GB authority, during the evaluation of a biocidal product application, in relation to the assessment of ED properties of non-active substances⁷. 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 a GB or EU decision, there has been a conclusion on whether the non-active substance is an ED or not

Step 1:

Applicants should check in the GB and EU BPR⁸ and GB and EU PPPR lists⁹ and opinions whether the non-active substance fulfils the ED criteria¹⁰.

- If the non-active substance fulfils the ED criteria, it 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 properties¹¹.
- If divergence in GB and EU lists and opinions exist, relevant conclusions must be applied to the biocidal product according to where authorisation is being sought (GB only, GB&NI or NI only applications).
- If the non-active substance does not fulfil the ED criteria, proceed to Step 2.

⁷ Further information on the non-active substances can also be found in the substance infocards and brief profiles published [on the ECHA website](#)

⁸ [Biocidal Products Committee opinions on active substance approval](#) and [BPR active substance lists for GB and NI](#)

⁹ [EU pesticides database](#) and [Active substances approved for use in pesticides - HSE](#)

¹⁰ It may happen that biocidal or plant protection active substances are used as non-active substances in biocidal products.

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.

Step 2:

Applicants should check if the non-active substance is included in the UK and EU list¹² of substances of very high concern (SVHC) owing to ED concern (according to Article 57(f) and Article 59(1) of REACH).

- If the non-active substance is included in both lists, the non-active substance is considered 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 properties¹¹.
- If the non-active substance is included in the EU but not the GB list, the GB authority will consult UK REACH team colleagues to confirm that the EU decision is not supported in the UK or if action is planned under UK REACH. Relevant conclusions must be applied to the biocidal product according to where authorisation is being sought (GB only, GB&NI or NI only applications).
- If the non-active substance is not included in both lists, proceed to Step 3.

Step 3:

Applicants should check if the non-active substance is a food and/or foodstuff material according to the definition of “food” within Regulation (EC) No 178/2002^{13,14}.

- If the non-active substance is a food and/or foodstuff material, it is assumed that the non-active substance does not have indications of ED properties of concern.
- If the non-active substance is not a food and/or foodstuff material, proceed to the next step.

¹² [ECHA candidate list of substances of very high concern for authorisation](#) (for NI applications). [UK REACH candidate list of substances of very high concern \(SVHCs\) for authorisation](#) (for GB applications). Both lists must be checked for GB&NI applications.

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

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).

B. Checking if there are any relevant assessments under UK and EU REACH

Step 4:

Applicants should check the EU Public Activities Coordination Tool (PACT)¹⁵. PACT provides an overview of the substance-specific activities that Authorities are working on under the EU REACH and CLP regulations. It also provides up-to-date information on the activities planned, ongoing or completed by ECHA and/or EU Member State Competent Authorities for a given substance in the following areas:

- Data generation and assessment – dossier evaluation, substance evaluation, informal hazard assessment (PBT/vPvB/ED).
- Assessment of regulatory needs (ARN).
- Regulatory risk management – harmonised classification and labelling (CLH), SVHC identification, restriction.

Applicants should also check the UK REACH candidate list of substances of very high concern.

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

- there is a proposal for identification as a SVHC for ED properties under UK or EU REACH;
- the non-active substance is included in the CoRAP (in the EU) or Rolling Action Plan (RAP) (in GB) for ED concern;
- substance evaluation is ongoing in the GB or EU to clarify ED concern;
- the non-active substance is under dossier evaluation or substance evaluation in the GB or EU for ED related endpoints to clarify ED concern¹⁶.

If none of the above-mentioned conditions is met, applicants should check whether the non-active substance has been screened (under UK and EU REACH). 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, 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 EU REACH.

¹⁵ [EU Public Activities Coordination Tool \(PACT\)](#)

¹⁶ Indications of the concerns will be available in PACT or the RAP. 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.

It is noted that substances with ongoing or past screening within a group of substances are visible in:

- PACT under the 'Regulatory risk management' column
- ECHA's 'Assessment of regulatory needs list'¹⁷
- HSE's UK REACH webpages¹⁸

Where the planned regulatory action is indicated for each substance or group of substances, a conclusion on ED properties is also generally presented.

C. Checking if there are other indications of ED properties

If checking the status under UK and EU REACH was not sufficient to conclude, applicants should consider potential ED indications from the classification e.g. whether the non-active substance has EU harmonised (for NI applications), GB mandatory (for GB applications) 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 of ED properties are identified from the UK and EU REACH and CLP processes, other sources of information or from the classification of the substance, it can be concluded that there are no indications of ED properties. If the substance is registered under EU REACH, either it has been screened or is expected to be screened (by also taking into account structural similarities with known ED substances) within a few years. Clear indications of ED, especially for high tonnage substances, were already searched in the annual screening performed in the past under EU REACH based on IT algorithms. If these indications were confirmed by the subsequent expert check, the substance should be in the process of assessment or at least scheduled for a priority screening.

In addition to checking the status of non-active substances under UK and EU REACH, for GB applications, the GB authority will consult UK REACH team colleagues to check for any additional activities planned or being undertaken under UK REACH beyond those conducted by the EU.

D. Further assessment by the applicant

The applicant should check other possible sources of information, for example, US databases (ToxCast, EDSP) and structural similarities with established ED substances. These indications should normally not be considered in isolation, but in a Weight of Evidence (WoE) approach.

¹⁷ [ECHA's 'Assessment of regulatory needs list'](#)

¹⁸ [HSE's UK REACH webpages](#)

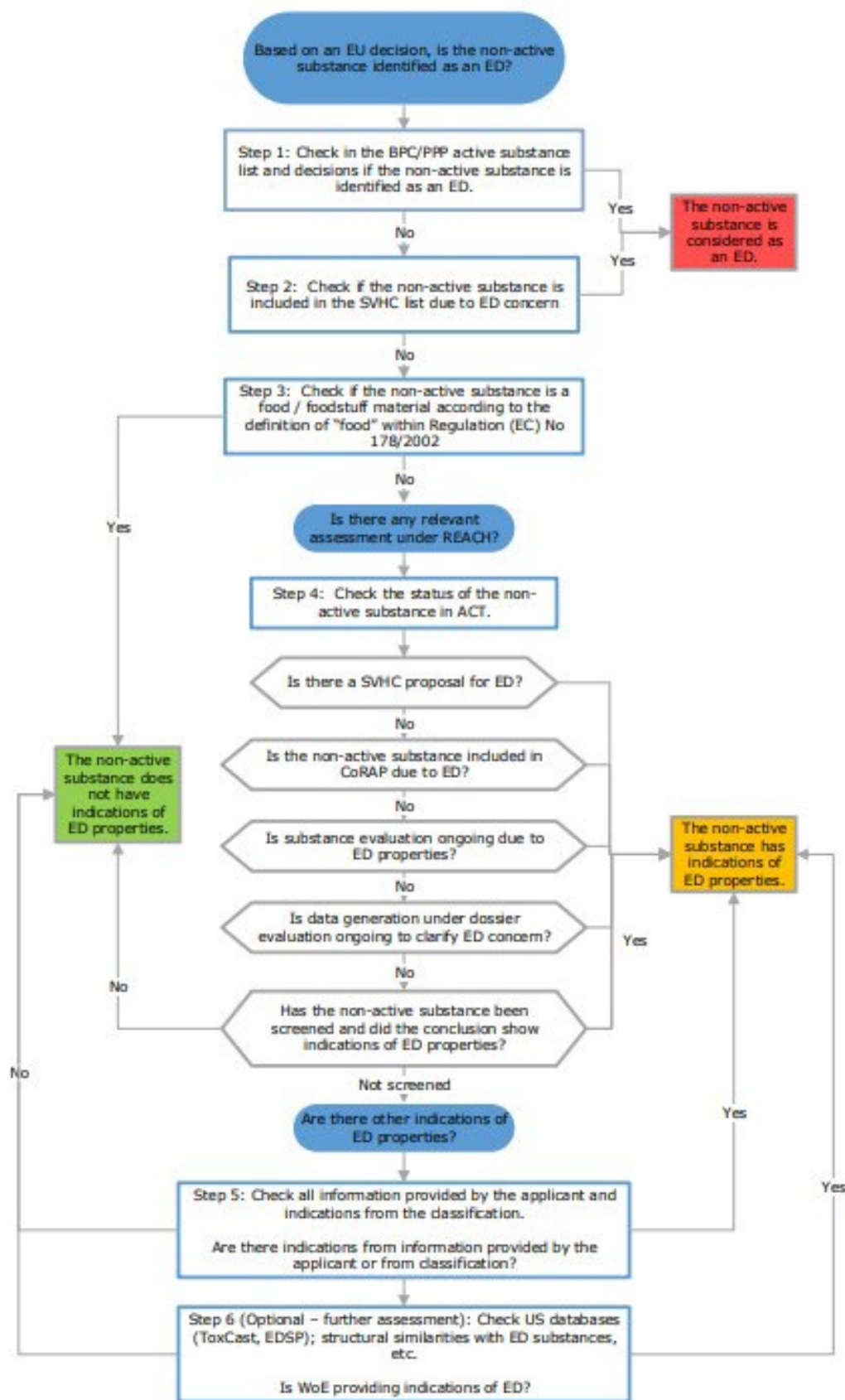


Figure 1. Flowchart for the assessment of ED properties of non-active substances in biocidal products. (Note: this flowchart is also applicable to GB applications but should be read in conjunction with the modified text in this document)

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

In line with current practice, in case there are indications that the non-active substance may have ED properties, normally there is not sufficient time to ascertain them during the biocidal product authorisation process¹⁹. The GB authority can authorise the product, if a full evaluation (including generation of more data) cannot be finalised before the legal deadline for product authorisation²⁰.

The non-active substances contained in biocidal products are used in many mixtures and articles. It is proposed that for non-active substances with indications of ED properties, these are further assessed in the frame of EU REACH (or BPR or PPPR if the non-active substance is an active substance with no decision yet on ED). If a concern is raised about a non-active substance under UK REACH, it would be considered for prioritisation, alongside other substances and activities, and included in the UK REACH Work Programme. Once the conclusion regarding ED properties of this non-active substance is available, the applicant must inform the GB authority pursuant to Article 47 of the BPR. If needed, the conditions of authorisation shall be revised in accordance with Article 48 of the BPR.

Applicants and the GB authority can access ECHA's Community Rolling Action Plan (CoRAP)²¹, which lists substances, the grounds for concern, and evaluation and conclusion documents. The GB authority can follow-up EU CoRAP evaluations as described below.

In case the substance is already undergoing assessment under UK or EU REACH, the GB authority will liaise with UK REACH team colleagues. The Authority will inform UK REACH team colleagues that the substance is used as a biocidal non-active substance.

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) before a conclusion is reached. SVHC ED listing may be concluded in about one year.

¹⁹ Further testing of non-active substances in relation to indications of ED properties is not required for product authorisation.

²⁰ Please refer to document [CA-March18-Doc.7.3.b-final](#) for further details.

²¹ [ECHA's Community Rolling Action Plan \(CoRAP\)](#)

In case the substance has indications of ED properties but is not currently undergoing assessment under UK or EU REACH, the GB Authority will liaise with UK REACH team colleagues.

In case the substance is not registered, the substance and dossier evaluation processes under UK and EU REACH do not apply. However, the substance may be notified in the EU 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 EU REACH.

Annex: Integrated regulatory strategy under REACH

Information on the integrated regulatory strategy under EU REACH is available in CA-March-21-Doc.4.3²².

HSE will continue to develop its UK REACH activities, as set out annually in the UK REACH Work Programme²³. Information on regulatory activity taking place under UK REACH is published on the HSE website.

²² [CA-March-21-Doc.4.3 Final Bridging Biocides with REACH](#)

²³ [UK REACH Consolidated Reports and Work Programmes](#)



Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit [the HSE website](#).

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