Evaluation Manual
for the Authorisation of biocides

General Introduction E.M. biocides

Biocides

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ctgb

Board
for the authorisation
of plant protection products and biocides

Chapter 1 General introduction E.M. biocides
Biocides

Changes made in the Evaluation Manual

General introductionEvaluation Manual Biocides			
Version	**Date**	**Paragraph**	**Changes**
2.0	October 2016		Initial version of this document
2.1	July 2017		Update on links
			The subject on Biocidal products based on micro-organisms has been amended to emphasize that the "Guidance on the Biocidal Products Regulation Volume V, Guidance on Active Micro-organisms and Biocidal Products" describes the procedures following data requirements, hazard and exposure assessment and risk characterisation for all aspects as physical chemical, efficacy, human toxicology, and environment. As the information presented in the introduction of the evaluation manuals is sufficient enough the subject is not described further anymore in the evaluation manual.
			Update of the situation on Disinfection By-Products.
2.2	October 2017	5.8	Inclusion of CA-Nov16-Doc.4.3, Note for guidance on handling 'carriers' in the authorization of biocidal products.

		5.9	Inclusion of ECHA documents with harmonised sentences for SPCs ('Frequently used sentences in the SPC and translations' and 'SPC AVKs translations')
2.3	January 2018	5.4	Addition of the Recommendation of the BPC Working Groups with regard to *in situ* generated active substances.
2.4	May 2018	5.10	Addition of the way forward described in the minutes of the 70th CA-meeting (March 2017) on linking biocidal label claims and the product authorization.
2.5	July 2018	New paragraph 5.11	Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

1. INTRODUCTION

The general introduction of the present Evaluation Manual provides background information on the Biocidal Products Regulation (BPR) for products based on active substances already approved as well as active substance approval, and the Dutch transitional law for products based on active substances that are still under review. This general introduction chapter explains the differences between both legislations and makes clear under which legislations products must be notified. Specific details on legislation and information requirements are described in the BPR and transitional parts of this evaluation manual. The specific NL information requirements or NL aspect specific assessments is described in the NL-part of the current evaluation manual.

The BPR-part furthermore provides generic information about legislation, information requirements, and assessments. Furthermore, new elements (as e.g. Biocidal Product Families and Comparative Assessment) concerning the technical and scientific assessment described in the BPR not pertained to a specific aspect as physical chemical, efficacy, human toxicology, and environment are described in a separate paragraphs.

2. LEGISLATION

Whether an application for authorisation of a biocidal product will be assessed according to the BPR or according to transitional legislation in The Netherlands depends on the active substance(s) in the product. All applications for authorisation of biocidal products based on (an) approved active substance(s) (included on the Union list of Approved Active Substances) are assessed according to the BPR and are first processed by ECHA. Since 1 September 2013, an application for authorisation of a biocidal product or renewal of an authorisation under Biocidal Products Regulation (EU) 528/2012must be submitted through the information system (R4BP3) provided by the European Chemicals Agency (ECHA). For active substances with a low-risk profile which are included on Annex I of the Biocidal Products Regulation (not to be confused with Annex I of the Directive) an application for a simplified authorisation can be.

Applications for authorisation of a biocidal product based on active substances that are not yet approved and still under review for the relevant product type must be submitted under transitional legislation to the competent authority in the Member State concerned (if applicable). Products having both approved and non-approved substances must be evaluated under the transition law as well. In The Netherlands products must be notified to the Ctgb and products are subsequently assessed according to the Wgb (Dutch law on plant protection products and biocides) considering national specific elements.

2.1. EU/NL framework

In general, in the European context, active substances are assessed to determine at least one realistic safe use within each product type for which authorisation is requested. According to the Biocidal Products Regulation, 22 product types are distinguished (see paragraph 6 of this chapter). The website EC Public Health identifies all the active substances that are being assessed in this European review programme and for which product type(s) they are being assessed.

The specific NL information requirements or exposure and risk assessments (national specific elements), described in the NL part of the BPR Evaluation Manual, is reverted to where no EU procedure has been laid down or where specific national information requirements are necessary.

The responsibility for establishing and maintaining the specific national framework for the assessment of biocides lies with the Ctgb.

Biocidal products
The situation is now as follows:

- European harmonized methodologies and appointments are implemented as much as possible by The Netherlands.
- For methodologies and agreements not yet harmonized, The Netherlands adheres to those methods that have been used until now. These are the national interpretation of gaps used by the Ctgb until a harmonized methodology is adopted in the EU.
- If a harmonized methodology or appointment has been established but The Netherlands has good reasons to deviate, Ctgb adopts a national specific derogation. That derogation shall be notified to the EU.
- If a national specific element is defined in Dutch legislation, then the responsibility for nationally specific derogation is not taken by the Ctgb but by the Dutch government.

The BPR delineates the space that Member States have for specific derogations. The grounds on which a Member State may derogate from the conditions of the authorisation to recognize is explicitly defined in Article 37 of the BPR:

- The grounds for derogation of article 37, paragraph 1 are:
  - the protection of the environment;
  - public policy or public security;
  - the protection of health and life of humans, particularly vulnerable groups, or of animals or plants;
  - the protection of national treasures of artistic, historic or archaeological value;
  - the target organisms are not present in harmful quantities.
- Article 37 paragraph 4: the Member State may refuse authorisation for animal welfare reasons for PT 's 15 (Avicides), 17 (Piscicides) and 20 (vertebrates other than rodents).

Where article 19(1) point b stipulates that it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;
(ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
(iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
  — the fate and distribution of the biocidal product in the environment,
  — contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
  — the impact of the biocidal product on non-target organisms,
  — the impact of the biocidal product on biodiversity and the ecosystem;

Where article 19(2) stipulates that the evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

(a) realistic worst case conditions under which the biocidal product may be used;
(b) the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

(c) the consequences of use and disposal of the biocidal product;
(d) cumulative effects;
(e) synergistic effects.

Where article 19(5) stipulates that notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.

In general the starting points for decision making as regards the effects on humans and the environment are presented in the Common Principles (Annex VI to BPR 528/2012). In summary, in relation to the criteria set out in points (iii) and (iv) of Article 19(1)(b), the evaluating body shall combine the conclusions arrived at for the active substance(s) and the substances of concern to produce overall summary conclusions for the biocidal product itself. A summary of the conclusions in relation to the criteria set out in points (i) and (ii) of Article 19(1)(b) shall also be made.

The evaluating body shall, on the basis of the evaluation carried out in accordance with the Common Principles (Annex VI to BPR 528/2012), come to a conclusion as to whether or not it is established that the biocidal product complies with the criteria laid down under point (b) of Article 19(1).

Active substances
According to the BPR528/2012 article 4 an active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 (exclusion criteria) may only be approved for an initial period not exceeding five years.

2.2. Transitional legislation frame work

The goal of the EU framework is to ensure that the legislation pertaining to biocidal products in the various member states is completely harmonised by 2024(1). This means that, until 2024, national legislation can remain in force for biocidal products based on existing substances (i.e. substances in biocidal products which were already on the market before 14 May 2000) not yet included on the Union list of Approved Active Substances or Annex I of the BPR (512/2012).

For products containing such existing substances that have not yet been approved, transitional legislation in The Netherlands applies and the procedure of the transitional legislation frame work should be followed.

[1] At first, this was intended to be 2010, but the transition period has been extended to 2024. This is due to delays in the European evaluation programme for all active substances. Originally, a period of 10 years was scheduled for that purpose, but this turned out to be too short in practice. By 2024, all existing substances must have been reviewed.

There is no transition period for biocidal products based on new substances. These must be evaluated in accordance with the rules of the Biocidal Products Regulation without any delay, and products based on such new substances cannot be registered until the active substance has been approved. In case the active substance has not been included in the European review programme an application for authorisation of this product cannot be submitted. First, a dossier for the active substance should be submitted and the substance must be approved.

3. INFORMATION REQUIREMENTS

The EU-part and NL-part of the BPR Evaluation Manual together with the Transitional Legislation (TL) Evaluation Manual describes the information requirements and how the data submitted is evaluated in the EU/NL framework under BPR 528/2012 and in the TL framework under Wgb 2007 (2011); art. 49 and Bgb and Rgb).

The BPR Evaluation Manual (EU or NL) describes the procedures following the information requirements as laid down in BPR 528/2012 Annex II and Annex III (title I chemical substances) for active substances and for products respectively . These information requirements apply for active substances submitted after 1 September 2013 (see CA-March14-Doc.4.1 Final Principles for substance approval.doc available on the CIRCABC Public Biocides Regulation Page (on CIRCABC Public Biocides Regulation Page (Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings).

Biocidal products based on micro-organisms

The technical advice on the information requirements for micro-organisms in accordance with Annex II, Title 2 and Annex III, Title 2 of the BPR for micro-organisms for all aspects as physical chemical, efficacy, human toxicology, and environment are listed in the Guidance on the Biocidal Products Regulation Volume V, Guidance on Active Micro-organisms and Biocidal Products for which 2.1 (March 2017) is the current version. The guidance is published on ECHA's website under the BPR regulation. No additional information requirements for product authorisation are obligated by the Ctgb. Because the assessment contains at least the core data set (CDS), a valid Letter of Access to the relevant dossier is sufficient to fulfil the information requirements unless additional information requirements are listed in the BPR opinion and/or product specific parameters are required.

Low risk active substances

Active substances for Annex I of the BPR are identified as presenting a low risk/low concern. At the ECHA website an amendment is provided for the data requirements for these substances for all aspects. Information on the former information requirements is laid down in Biocides Directive 98/8 for active substances and products.

Note further that at the ECHA website transitional (REACH) guidance on data sharing is available for use until they are incorporated into the BPR guidance structure.

The TL Evaluation Manual describes the information requirements for products. In general for all aspects comparable information requirements as already available in the EU-part, and in the NL part of the BPR Evaluation Manual are used. A separate application form is available on the Ctgb website explaining the minimum data that should be submitted.

For some aspects data filing requirements will not be assigned to applicants. Applicants retain the right to voluntary submit a data dossier, because new information requirements for applications will have a transitional period. For the different aspects, specific situations are described in the relevant chapters.

4. ASSESSMENTS

The described assessment in the EU-BPR Evaluation Manual can be used for both the approval procedure for the active substances as well as for the authorisation procedure for products based on approved substances. NL specific approaches that should be taken into account in the assessment for active substances and products for the Dutch market are described in the NL-BPR Evaluation manual. So, the NL procedure for evaluation of a substance or product, described in the NL part, is reverted to where no EU procedure has been laid down or where a specific assessment is necessary.

An EU Evaluation Manual for the Authorisation of Biocidal Products (EU EMPA CA-May13-Doc.6.2.d) has been developed for this purpose and was intended for experts working on the dossier evaluation of biocidal products under Directive 98/8/EC at the Competent Authorities of their EU Member State. Although this EU Evaluation Manual for the Authorisation of Biocidal Products has been written for product authorisation under the European Biocidal Products Directive (98/8/EG), the information in this manual may also be useful as background information because the different aspects of a risk evaluation are elaborated in more detail and can be used as guidance for specific aspects of biocide dossier evaluation under the BPR 528/2012.

Biocidal products based on micro-organisms

The technical advice on the hazard and exposure assessment and the risk characterisation and the evaluation of the active substances and biocidal products in accordance with Annex II, Title 2 and Annex III, Title 2 of the BPR for micro-organisms for all aspects as physical chemical, efficacy, human toxicology, and environment are listed in the 'Guidance on the Biocidal Products Regulation Volume V, Guidance on Active Micro-organisms and Biocidal Products'" for which 2.1 (March 2017) is the current version. The guidance is published on ECHA's website under BPR regulation. No specific approaches for product authorisation are obligated by the Ctgb.

The TL Evaluation Manual describes the methods necessary to be used in the assessment. In general for all aspects the same methods as already available in the EU-part, and in the NL part of the BPR Evaluation Manual are used. However, for some aspects available methods will not be immediately included in the assessment, because in some cases there is a transitional period.

5. NEW ELEMENTS CONCERNING THE SCIENTIFIC ASSESSMENT DESCRIBED IN THE BPR AND RELEVANT FOR TWO OR ALL ASPECTS

In the information document Technical Agreements for Biocides (TAB adapted frequently) agreements of the Working Groups of the Biocidal Products Committee (WGs) are provided in concise format. In this document, the technical and scientific WG agreements are covered to create a general database of questions where an agreement has already been reached. The general relevance is focused on methodological decisions with respect to risk assessment and questions on the implementation and interpretations of the Biocides Regulation 528/2012.

Besides the guidances on the BPR and the document TAB agreements there are also relevant CA documents that should be used for the scientific assessment for the different aspects. A list of finalised CA documents is available on the CIRCABC Public Biocides Regulation Page (Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings). New (BPR) elements concerning the technical and scientific assessment not pertained to a specific aspect as physical chemical, efficacy, human toxicology and environment are

described beneath (e.g. BPF, SoC etc). The relevant CA documents per aspect are presented for that specific aspect.

5.1. Biocidal product family (BPF)

The new definition of a BPF in Article 3(1)(s) of the BPR refers to a group of products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy. Hence this means that products within a BPF, in addition to having different composition, can be intended for different uses, including different user categories, and also responding to different risk or efficacy levels.

In order to clearly define what is exactly authorised within a BPF, the authorisation, on the basis of the conclusions of the risk and efficacy assessment leading to acceptable uses, shall provide information in a structured way. In this context, the concept of "meta SPC" has been introduced.Further detailed information about the practical approach for the implementation of the new concept of BPF based on the updated provisions of the Biocidal products Regulation is described in the following CA-document-Nov14-Doc.5.8 - Final.rev3 - Implementing the new BPF concept which is available on the CIRCABC Public Biocides Regulation Page (see Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings). .

5.2. Candidates for substitution / Comparative assessment

The objective of this provision in the BPR is to identify substances of particular concern to public health or the environment and to ensure that these substances are phased-out and replaced by more suitable alternatives over time.

The criteria are based on the intrinsic hazardous properties in combination with the use. An active substance will be considered as a candidate for substitution if any of the following criteria are met:

- It meets at least one of the exclusion criteria.
- It is classified as a respiratory sensitiser.
- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use.
- It meets two of the criteria to be considered as PBT.
- It causes concerns for human or animal health and for the environment even with very restrictive risk management measures.
- It contains a significant proportion of non-active isomers or impurities.

Since harmonised classification is a key element in the exclusion criteria and therefore for the assessment of whether an active substance is a candidate for substitution, the ECHA secretariat will aim to ensure cooperation between the Biocidal Products Committee and the Risk Assessment Committee (RAC).

Similarly, the PBT properties of an active substance also need to be assessed when deciding whether an active substance is a candidate for substitution. Therefore, the ECHA secretariat will also aim to ensure cooperation among the BPC and the ECHA PBT expert group.

If during the approval process of an active substance, the evaluating competent authority identifies an active substance as a potential candidate for substitution, this will be listed in the conclusions of its evaluation. In such cases, ECHA will initiate a public consultation on alternatives.

Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal. If the active substance meets one or more exclusion criteria, it will only be approved for five years.

Authorisation of products containing a candidate for substitution
In accordance with Article 23(1) of the BPR, the receiving competent authority or, in the case of an evaluation of an application for a Union Authorisation (UA), the evaluating Competent Authority (eCA), shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a BP containing an AS that is a candidate for substitution (CFS) in accordance with Article 10(1) of that Regulation. This also applies to the applications for product authorisation referred to in Article 91 of the BPR.
The product will only be authorised if there are no better alternatives.

As required by Article 24 of the BPR, the Commission has drawn up Technical Guidance Notes (TGN) to facilitate the implementation of Chapter VII and, in particular, Article 23(3) Further detailed information about the practical approach for the implementation of the new concept of Comparative Assessment is described in the following CA-documents CA-May15-Doc.4.3.a - Final - TNG on comparative assessment and CA-March14-Doc.5.4 Final-comparative_assmt_consolidated_version.doc which are available on the CIRCABC Public Biocides Regulation Page (see for the CA finalised documents Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings).

5.3. Substance of concern

A substance of concern (SoC) is defined in Art 3(f) of Regulation (EU) No. 528/2012/EC or the Biocidal Product Regulation (BPR) as follows:.

> *'substance of concern' means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.*
> *Such a substance would, **unless there are other grounds for concern**, normally be:*
> - *a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or*
> - *a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,*
> - *a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;Note that the information requirements for PBT assessment is available in chapter R.11: PBT assessment*

Therefore, Substances of Concern (SoC) are co-formulants in biocidal products, in addition to the active substance, which can pose a potential risk for humans and the environment. The Biocidal Products Regulation states explicitly that SoCs must be included in the risk

assessment.

Further general information about the assessment of SoCs is described at the Ctgb website. There is a guidance document on the assessment of SoCs for the human health risk assessment and for the environmental risk assessment. The SoC guidance for human health toxicology is described in CA-Nov14-Doc.5.11 – SoC guidance_final.doc also present on the CIRCABC Public Biocides Regulation Page (see for the CA finalised documents Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings).

SoC guidance for environment is still under discussion, but in the intermediate time the Ctgb considers it important that the applicant submits relevant information/data for all substances of concern in their product to quantify the environmental risk for the intended uses.

Co-formulants that have been approved or are being assessed in the Review Programme for another product type (PT) than the product type that is applied for, must also be considered as an SoC from the moment onwards that the draft Assessment Report for the other product type has been published.

5.4. In situ generated active substances

Biocidal active substances are called in situ generated active substances if they are generated from one or more precursors at the place of use. The approval of such substances requires evaluation of the generated active substance and of the precursor(s) it is generated from, in the context of each product type(PT).

The documentation, including notes for guidance, is made available by ECHA on their website.

The first guidance concerns CA-May12-Doc.6.2a and relates to the definition of in situ generated active substances. In CA-March15-Doc.5.1- Final - Substances generated in situ.doc further guidance is given for the management of in situ generated active substances. A similar document was prepared for the case of ozone in CA-May15-Doc.5.1.a - Final - Ozone.doc with the final Managements of in situ generated active substances in the context of the BPR. In CA-Sept15-Doc.5.1.b Final the Management of in situ generated active substances in the context of the BPR for free radicals is described. A final version of this guidance is included in CA-May16-Doc.5.1 the guidance on information requirements for free radicals generated in situ from ambient air or water is described (see for the CA finalised documents Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings).

In the BPC Working Groups, a recommendation (*In situ* generated active substances – Risk assessment and implications on data requirements for active substances generated *in situ* and their precursors) was drafted with regard to the technical requirements on *in situ* generated substances and the definitions used.

5.5. Nanomaterials

Nanomaterials are chemical substances or materials that are manufactured and used on a very small scale. Their structures range from approximately 1 to 100 nm in at least one dimension.

Nanomaterials have unique and more pronounced characteristics compared to the same material without nanoscale features. Therefore, the physico-chemical properties of nanomaterials may differ from those of the bulk substance or particles of a larger size.

Nanotechnology is rapidly expanding. A large number of products containing nanomaterials are already on the European market (e.g. batteries, coatings, anti-bacterial clothing, cosmetics, food products). Nanomaterials offer technical and commercial opportunities, but may pose risks to the environment and raise health and safety concerns for humans and animals. Although there are no explicit requirements for nanomaterials under REACH or CLP, they meet the regulations' substance definition and therefore the provisions apply. Further general information is described on the ECHA website (nanomaterials).

5.6. Disinfection By-Products

By using (predominantly halogenated biocidal products Disinfection By-Products (DBPs) can be formed. DBPs could cause a risk for human health and environment. In January 2017 European Chemicals Agency (ECHA) made the final guidance on Disinfection By-Products available, being in force from January 2019. The guidance focuses on three product types: disinfection of swimming-pool water and waste water (PT2), cool water (PT11) and at the production of paper (PT12). This means that the applicants have to submit risk assessments for these product types.

The guidance on Disinfection By-Products provides a strategy for the human health and environmental risk assessment of DBPs to the applicants and the competent authorities. The human health risk assessment is based on a set of known marker DBPs, using consensus health-based limit values and DBP concentrations. The guidance focuses on PT2 in swimming-pool water for which human exposure was considered most relevant while discussing the exposures to DBPs. The environmental risk assessment is predominantly focused on the determination of the risks of DBPs directly or indirectly present in surface water. That focus is relevant for applications for product types PT2, PT11 and PT12.

Further general information is described on the ECHA website in the guidance on Disinfection By-Products (see ECHA website BPR Regulation, Guidance documents).

Disinfection by-products may also be relevant for other biocides than halogen-containing biocides, like in situ generated free radicals.

5.7. Treated articles

The Regulation contains provisions which apply both to biocidal products and to any articles that have been treated with or incorporate a biocidal product. In particular, articles can only be treated with active substances that have been approved in the EU for that purpose. This is a significant change to the previous scheme, where articles imported from non-EU countries were permitted to have been treated with substances that are not allowed in the EU.

Further detailed information about the practical approach for the implementation of the concept of treated articles based on the updated provisions of the Biocidal products Regulation is described in the following CA-document which is available on the public part of the European database CA-Sept13-Doc.5.1.e(Rev1)- treated articles guidance doc and CA-May15-Doc.6.1 – Final – Labelling of TAs.docx. CA-Sept13-Doc5.1g and CA-Jul13-Doc.5.1.g contains some background and Q&A on this issue (see for the CA finalised documents Circabc public > categories > European Commission > Health and Food Safety>Biocides – BPR 528/2012 – Public > Library > Documents finalised at CA meetings).

5.8. Products based on carriers

Certain products are not treated articles, but are biocidal products in the form of an article as defined by the REACH regulation, with a primary biocidal function. Examples are

impregnated wipes, fly stickers and moth cassettes.

Considering Regulation 1272/2008/EC does not provide for classification and labelling of articles, a note for guidance (CA-Nov16-Doc.4.3) was endorsed by the 67th CA in November 2016, to deal with 'handling "carriers" in the authorisation of biocidal products'.

The document provides guidance on what to regard as part of the product's composition, classification and labelling and information requirements.

5.9. Harmonised sentences SPC

To promote the use of harmonised terms and sentences in the SPC, two documents are available on the ECHA website. These documents are the results of two ECHA Working Parties held in 2015/2016. These harmonized sentences should be used on the SPC when applicable, modification of the sentences can only be done if the application or situation is such that the harmonized sentences do not apply.

The first document, 'Frequently used sentences in the SPC and translations' gives frequently used sentences in the free text sections of the SPC and their translation into all EU languages for PT1-5, 8 and 18. The sentences have been grouped according to the relevant SPC field, the product type, and the type of user.

The second document, 'SPC AVKs translations' gives harmonised sentences for PT14 (first renewal). This document provides the translations in all EU languages of the agreed SPC templates for anticoagulant rodenticides for different user categories (general public, professionals and trained professionals). In the CA document (CA-Nov16-Doc.4.1.b - Final - harmonised sentences SPC AVKs.doc) explanation is given how to use the harmonized sentences for PT14 anticoagulants. Please note that in the Netherlands for rodenticides several national specific derogations apply. These derogations are only partly visible in the 'SPC AVKs translations' document[2]. For an overview of national specific derogations in NL, see this link on the Ctgb website.

5.10. Label claims

In the CA meeting 70 (March 2017) concerning linking biocidal label claims and the product authorization:

(1) Regarding product authorisation and MR process, and considering that:
- (a) Section 4 of the SPC lists any authorised uses of a biocidal product, which clearly describe the authorised target organism(s), field(s) of use, application method(s), application rate(s) and frequency and category(ies) of users,
- (b) The label of a biocidal products is not part of the product authorisation,
- (c) Label claims are a communication tool to the end user (e.g. consumer) that might be subject to changes over time and requires some flexibility for companies,
- (d) Including too specific information related to label claims in the SPC might trigger:
  - Applications for a change in order to adapt the product authorisation to any evolution of the label claims,
  - Numerous discussions in MR or UA procedures,

[2] General public: Table 2 and 3 do not apply; Professional users: entire user category does not apply; Trained professional users: Table 3, addendum 1, 3 and 4 do not apply, Table 2 use 2 only applies for rats and not for house mice.

- Some inconsistencies between products authorised under the BPR and existing products placed on the market of MSs according to the transitional rules,

(2) It is agreed that label claims are not reflected in the product authorisation (SPC) and therefore will not be part of the SPC agreement in mutual recognition procedures.

(3) For enforcement purposes, and taking into account that:
   (a) The AH has the legal obligation to ensure that any information provided on the label is compliant with:
      - The provisions in Article 69 of the BPR,
      - The EU's general advertising rules under Directives 2006/114/EC and 89/552/EEC,
   (b) Compliance with such legal obligation should be subject to enforcement and where relevant, to the penalties applicable in each MS,
   (c) When carrying out checks, enforcement authorities may request additional information to the biocides CAs and, where relevant, to the AH,

(4) It is agreed that enforcement of label claims is performed against the information available in the authorised uses of the SPC (e.g. target organisms) first. For example, where:
   (a) The authorised target organisms are unspecific (bacteria, yeast and fungi), only general claims would be consistent with the SPC (e.g. "efficacious against bacteria, yeast and fungi").
   (b) A specific target organism (e.g. S. aureus) is listed in the authorised SPC, a label claim against that specific species would be consistent with the SPC (e.g. "efficacious against S. aureus").

(5) Where relevant (e.g. "marketing" label claims), enforcement can also be based on other information made available to the enforcement authorities (e.g. PAR, technical or scientific publications provided by the AH, etc...) in order to conclude whether those claims are substantiated and compliant with the above-mentioned EU legislation.

5.11. Endocrine disruption

Criteria:
The Commission Delegated Regulation (EU) 2017/21003 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/20124 (BPR) establishes that the ED criteria becomes applicable by 7 June 2018.

According to the Endocrine disruption criteria a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

> a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

[3] Commission Delegated Regulation (EU) 2017/2100 was published on 17 November 2017 (see link for all official languages in official journal: http://eur-lex.europa.eu/eli/reg_del/2017/2100/oj) and is applicable as of 7 June 2018.

[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

c) the adverse effect is a consequence of the endocrine mode of action.

A note agreed by Member States' Competent Authorities for Biocidal and Products presents a proposal for the practical implementation of the ED criteria in the context of active substances and product authorization ([DOC]CA-March18-Doc.7.3b-final- EDs- biocidal products.docx - CIRCABC and [DOC]CA-March18-Doc.7.3a-final- EDs- active ... - CIRCABC - Europa EU). It proposes a specific way forward, depending on whether the applications for authorization are still under evaluation by the evaluating body referred to in Annex VI to the BPR, or whether they are in a later stage of the procedure (but before the product authorization is granted). It also addresses how to deal with already authorized biocidal products. The objective of this draft note is to discuss the proposed way forward with Member States' competent authorities and stakeholders in order to find an agreement.

It should be noted though that Articles 26(3), 30(2), 34(4)[5] and 44(1)[6] of the BPR establish the legal deadlines by which the evaluating body[7] must conclude its assessment of an application for product authorization. Moreover, Article 89(3) provides that, following the approval of a particular active substance, Member States shall ensure that authorizations for biocidal products are granted, modified or cancelled within three years of the date of approval.

Paragraph 8(a) of Annex VI to 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.

Therefore, the evaluating body must consider the ED properties of a biocidal product in any procedure that is still under the evaluation phase. This involves considering the ED criteria for both:

- the active substance(s) included in the product; and
- the non-active substances in the product (so-called 'co-formulants').

A biocidal product will be considered to have ED properties if it contains:

(b) active substance(s) and/or non-active substance(s) having ED properties on the basis of the scientific criteria established by Article 5(3) of the BPR and/or,

(c) active substance(s) and/or non-active substance(s) having ED properties in accordance with Article 57(f) and 59(l) of Regulation (EC) No 1907/2006, and/or,

(d) active substance(s) with an intended biocidal mode of action that consists of controlling target organisms via their endocrine system(s). Such an active substance will have an intended biocidal mode of action consisting of controlling target organisms via their endocrine system(s), for which the information has been submitted in the application for approval as required by point 6.5 of Annex II of the BPR, and for which it is showed that the intended

[5] For procedures of mutual recognition in parallel, before the reference MS sends its assessment report and the summary of biocidal product characteristics (SPC) to the MSs concerned.

[6] For Union authorisation procedures, before the evaluating CA sends the assessment report and the conclusions of its evaluation to the Agency.

[7] I.e. the CA responsible for the evaluation of the application referred to in Articles 26(1), 30(1), 34(1) or 44(1) of the BPR.

biocidal mode of action is sufficiently effective.

Assessment:
ECHA and EFSA developed a scientific guidance to implement the scientific criteria (published on 7 June 2018 at https://www.efsa.europa.eu/en/efsajournal/pub/5311).

This guidance document was written to provide guidance to applicants and assessors of competent regulatory authorities on how to identify endocrine disruptors in accordance with the ED criteria laid down in Commission Delegated Regulation (EU) No 2017/21003 and Commission Regulation (EU) No 2018/6054 for biocidal products (BP) and plant protection products (PPP), respectively. The guidance document describes how to gather, evaluate and consider all relevant information for the assessment, conduct a mode of action (MoA) analysis, and apply a weight of evidence (WoE) approach, in order to establish whether the ED criteria are fulfilled.

All relevant information on endocrine disruption should be reported. Such information can come from regulatory guideline studies, non-guideline investigative studies, public literature, QSAR models, read-across approaches, databases (see Appendix D of the Guidance), epidemiological data, field studies, monitoring data and population modelling.

Part of the Guidance document is an Excel template on how the available information can be reported and analyzed. It is recommended that applicant use this template to gather the relevant information from the available studies. Applicants are asked to submit the filled in template in their substance dossier. The Excel template can be found this link under "Supporting Information".

The conclusions on endocrine disruption should answer the two problem formulations identified within the guidance document:

- Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for humans?
- Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for non-target organisms at population level?

A conclusion should always be drawn for both humans and non-target organisms.

When concluding on ED properties it is important to take the following points into consideration:

(a) It is sufficient that the substance meets the ED criteria for one group of non-target organisms in order to be identified as ED.
(b) Where, based on a sufficient dataset, no 'EATS-mediated' adversity was observed or where endocrine activity was found negative, it is possible to by-pass the MoA analysis and to conclude that the criteria are not met.
(c) Where a MoA is based on 'EATS-mediated' adversity the ED criteria are considered met; unless an alternative non-endocrine MoA is demonstrated and in a comparative analysis found to be the most likely explanation.
(d) Where a MoA is based on 'sensitive to but not diagnostic of EATS' adversity and the MoA supports the biological plausibility of the link between the observed adverse effects and endocrine activity for at least one postulated MoA(s), the substance is considered to meet the ED criteria, unless an alternative non endocrine MoA is demonstrated and in a comparative analysis found to be the most likely explanation.
(e) Where the available information is sufficient to postulate a non-EATS endocrine MoA, it is possible that, the supporting available information would be not sufficient to develop the MoA. In these situations, an analysis of the available testing methodologies should be carried out by the applicant in order to justify that the generation of further scientific information suitable for the identification of a non-

'EATS mediated' endocrine MoA is not feasible based on the available scientific knowledge and that the biological plausibility is highly uncertain, and therefore, a conclusion is currently not possible.

(f) There may be cases where data are not provided for performing the ED assessment according to this Guidance and this is not considered justifiable. For example, failure to perform the MoA analysis as required, failure to generate the information needed to sufficiently investigate endocrine activity and/or endocrine related adversity (despite the fact that appropriate test methods are available), and failure to provide adequate scientific justifications for omission of information. In all those cases, the assessors shall clearly indicate which missing information should have been provided by the applicant when following the present Guidance and to which extent this information is critical to allow a conclusion to be reached on the ED properties of a substance.

The conclusion on the ED criteria needs to be transparently documented, including the remaining uncertainties.

A conclusion on whether the ED criteria are met should always be drawn with respect to both humans and non-target organisms.

Additional regulatory provisions for endocrine disruptors are covered under REACH (https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/reach_1907_2006_regulation_en.pdf) , the Regulation on cosmetics (https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf) , and under EU legislation on food contact materials (https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en).

The same active substance may be used in biocidal products and plant protection products. Information on EDs submitted for the approval of an active substance under the Plant Protection Products Regulation[8] can also be used by the eCA in the assessments if it would not benefit the applicant, as any available information can be used to reach a conclusion on the properties of biocidal active substances. This is consistent with point 8 of Annex VI (common principles for the evaluation of dossiers for biocidal products) of the BPR stating that the evaluating body shall take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues. The ECHA and the European Food Safety Authority (EFSA) should apply the established procedures in the Memorandum of Understanding of 20 May 2009 to enable ED data submitted to the EFSA on the same substance to be used in evaluating a biocidal active substance and vice versa. While EFSA information can be used as additional information during the evaluation by the eCA and ECHA, it must not be used to replace data (and therefore fill a data gap) which the applicant has an obligation to provide.

This approach of using data or information submitted by an applicant under other EU rules is consistent with the data protection rules in Article 59 of the BPR and Article 59 of the Regulation (EC) No 1107/2009 (plant protection products) as these rules clarify that the data protection applies only to the use of data for the benefit of other applicants under these regulations.

Summary for applicants:

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/114/EEC.

- **Review** the active substances in your products and portfolio in light of the new criteria.
- **Be prepared** to provide more information on the possible endocrine-disrupting properties of your active substance in your application.
- **Consult** the national authority responsible for the evaluation of your active substance before starting to test it to support the identification and assessment of possible endocrine disrupting properties.
- **If your substance has already been approved at EU-level**, note that the European Commission and national authorities are in talks on whether and on what level already approved substances should undergo assessment for endocrine-disrupting properties.
- **Note** that the criteria will also apply to co-formulants, not only active substances.
- **Stay up-to-date** - talk to your national industry association and follow ECHA's news.

6. PRODUCT TYPES IDENTIFIED UNDER THE BPR (ANNEX V OF THE BPR)

MAIN GROUP 1: Disinfectants	
These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.	
Product-type 1:	Human hygiene
	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
Product-type 2:	Disinfectants and algaecides not intended for direct application to humans or animals
	Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.
	Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.
	Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.
	Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.
	Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.
Product-type 3:	Veterinary hygiene
	Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.
	Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.
Product-type 4:	Food and feed area
	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.
	Products used to be incorporated into materials which may enter into contact with food.
Product-type 5:	Drinking water

	Products used for the disinfection of drinking water for both humans and animals.
MAIN GROUP 2: Preservatives	
Unless otherwise stated these product-types include only products to prevent microbial and algal development.	
Product-type 6:	Preservatives for products during storage
	Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.
	Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.
Product-type 7:	Film preservatives
	Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
Product-type 8:	Wood preservatives
	Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product-type includes both preventive and curative products.
Product-type 9:	Fibre, leather, rubber and polymerised materials preservatives
	Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.
	This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
Product-type 10:	Construction material preservatives
.	Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack
Product-type 11:	Preservatives for liquid-cooling and processing systems
	Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.
	Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
Product-type 12:	Slimicides
	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
Product-type 13:	Working or cutting fluid preservatives
	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.
MAIN GROUP 3: Pest control	
Product-type 14:	Rodenticides
	Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
Product-type 15:	Avicides

	Products used for the control of birds, by means other than repulsion or attraction.
Product-type 16:	Molluscicides, vermicides and products to control other invertebrates
	Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.
Product-type 17:	Piscicides
	Products used for the control of fish, by means other than repulsion or attraction.
Product-type 18:	Insecticides, acaricides and products to control other arthropods
	Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
Product-type 19:	Repellents and attractants
	Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
Product-type 20:	Control of other vertebrates
	Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.
MAIN GROUP 4: Other biocidal products	
Product-type 21:	Antifouling products
	Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
Product-type 22:	Embalming and taxidermist fluids
	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.