Evaluation Manual for the Authorisation of biocides

Active substance approval and product authorisation under BPR

Biocides

version 3.6; January 2023

ctgb

Board
for the authorisation
of plant protection products and biocides

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Biocides

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Changes made in the Evaluation Manual

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Version	**Date**	**Paragraph**	**Changes**
2.0	October 2016		Initial new version
2.1	June 2017	2.2	TAB for physchem added published in December 2016
		4.1	Adding of article 62 of the BPR, i.e. to avoid animal testing
		4.2	More explanation for the use of SCOEL and Dutch reference values in the SoC approach.
		4.3	Final guidance on DBPs January 2017
		4.1	Document Dermal absorption of PT21 active substances
		4.4	Document ADI and ARfD derivation for biocidal active substances
2.2	November 2017	2.3	Harmonized pack sizes rodenticides added

		3.1	Technical Agreements on Biocides is included for efficacy (published August 2017)
		3.2	Update on status Volume II Efficacy Part A is included
		3.3	Volume II Efficacy Part B/C: Efficacy Assessment and Evaluation is included (version 1.0, published February 2017)
		4.4	Human health risk assessment reference to volume III adjusted
2.3	January 2018	2.3	Harmonised minimum pack sizes rodenticides added
3.0	January 2019		All links and guidance versions are checked and updated if required New parts A, B and C are included at the different sections Referred to general introduction SoC section for SoC criteria Referred to general introduction DBP section for DBP assessment. Referred to general introduction ED section for ED assessment. For efficacy new part II A and part II B/C guidances were published. For efficacy all part II B/C appendices except for the label claims matrix have been incorporated into the new part II B/C guidance document. For efficacy the chapter on PT5 was updated in part II B/C. The Technical Agreements Biocides (TAB) for efficacy is now a separate document. The efficacy TAB has also been updated with new items (room disinfection and textile disinfection).
3.1	August	2.4	Implementation of agreement from CG-30 on simplified procedures
3.2	November 2020	3.1, 3.3.3	Technical Agreements on Biocides (TAB) is updated for efficacy with new items (published July 2020).
		3.3	Status of PT19 guidance update was updated. PT14 footnote reference was updated. EN599-1 Annex A reference was updated.
3.2	March 2021	2.1.1 2.1.2 2.1.3	Implementation of CA-July19-Doc.4.1-rev.2 on the product authorization of *in situ* generated substances.
		5.5	Implementation of the new TAB (ENV) including update of the hyperlinks. Notes on the applicability of TAB-entries are added as well as additional information on SimpleTreat.

		Chapter 4. Human Health, all sections	General revision/update, textual and hyperlinks.
3.3	July 2021	3.3.3.	Included reference to: Harmonized approach to determine worst-case (or a representative) test product for efficacy core assessment for disinfectant Biocidal Product Family
		5.5 (added between 5.4 and 5.6)	Warning sentence for Bees
3.4	February 2022	5.5 (adjusted)	Adjusted the previous change (Warning sentence for Bees) in line with the conclusion at the Working Group.
3.5	October 2022	4.1 and 5.1	Inclusion of reference to in situ generated a.s. and products
3.6	January 2023	4	Delete references to specific information in several documents agreed at WG HH/CA/CG documents(is now covered in new section 4.7) and general textual updates
		4.4	Implementation of CA-June22-Doc4.8
		4.7	New section on other available guidances
		2	Several textual improvements
		5	References to specific information in several documents agreed at WG ENV/AHEE/CA/CG documents deleted (is now covered in new section 5.7) and general textual updates in line with chapter 4 (HH) made.
		5.4	Implementation of CA-June22-Doc4.8
		5.7	New section on other available guidances

1. INTRODUCTION EU FRAMEWORK

The present document describes processes, methodology, and legislation applied by the Ctgb regarding authorisation of biocidal active substances and biocidal products according to the Biocidal Product Regulation (BPR). It concerns notification and assessment of biocidal products containing active substances that are approved as a biocide in Europe and notification of new active substances. The EU-part of the evaluation manual is not applicable for biocidal products based on existing substances not yet included on the Union list of Approved Active Substances or Annex I of the BPR (512/2012). Notification of these products will be done according to the Transitional Legislation (TL). General information on the BPR an transitional law is found in the general introduction.

2. PHYSCHEM

2.1. Information requirements for active substances and biocidal products

2.1.1 General data requirements

The information requirements regarding the physchem assessment are explained in Volume I - Part A, B and C. The information requirements are two-tiered. The core data set (CDS) is mandatory for all product types and should always be submitted. The additional data set (ADS) must be submitted when required by the intrinsic properties of the active substance or biocidal product, when required by the foreseen use and route of exposure, or when the initial risk assessment must be refined.

The Ctgb follows the BPR regarding information requirements and has not defined additional requirements. Note that the assessment report should also contain the CDS for the active substance. A letter of access to the relevant active substance dossier(s) is often sufficient, unless additional information requirements are listed in the BPC opinion and/or product specific parameters are necessary.

2.1.2 Guidance on authorization of active substances generated *in situ*

The *in situ* active substances are a specific case which are not addressed in detail within the BPR nor in the general data requirements. The BPC working groups have drafted recommendations to address the data requirements, which can be found on the ECHA site here.

Currently, the exact requirements for *in situ* generated active substances and their precursors are dealt with on a case-by-case basis. Generally, the annex II requirements apply to precursors and the substances generated, but depending on the nature of the precursor and substance generated, the BPC Working Group APCP can be requested to exempt applicants from providing certain data related to identity, physical and chemical properties and analytical methods, when appropriate. This should be discussed with the evaluating competent authority (eCA). See also paragraph 2.2 on the BPC working group agreements.

2.1.3 Guidance on product authorization of active substances generated *in situ*

In addition to the general data requirements for the authorization of biocidal products for specific situations guidance is available. For the assessment of biocidal products based on the concept of in situ generation of active substance, the document CA-July19-Doc.4.1rev.2 (Management of product authorisation for in situ cases) is available. This document describes four major types of IGS (*in situ* generation systems) and how these case types are to be dealt with.

For specific provisions with regard to authorization of products, please refer to the implementing regulations and assessment reports, published within the scope of the active substance approval. These documents can be obtained on the ECHA website via the active substance database.

2.2. BPC working group agreements

Agreements within the BPC Working Group APCP (identity, physical and chemical properties and analytical methods) are published in the Technical Agreements on Biocides (TAB). The TAB includes relevant technical agreements made at the BPC Working Groups and, as the Working Groups were previously known, the Technical Meetings. The link to the TAB can be accessed through the Working Groups portal. The TAB includes agreements on both active

substance data as biocidal product data.

It should be noted that there are also other sources for guidance which may have a direct or indirect impact on the requirements relating to identity, physical and chemical properties and analytical methods (e.g. Competent Authority meetings (CA) or the Coordination Group(CG). Documents finalised in the CA can be found on CIRCABC (link).

2.3. Harmonized pack sizes rodenticides

For the first renewal of the anticoagulant rodenticides the pack sizes of anticoagulant ready for use bait products are harmonized. The pack sizes can be found in the implementing regulations of the active substances for non-professional users and in the harmonised sentences to be used in the different sections of the SPC for anticoagulant rodenticides for professional users (see CA-Nov16-Doc.4.1.b - Final - harmonised sentences SPC AVKs . The minimum pack size for professional/trained professional users is 3 kg. The maximum pack sizes for the general public (non-professional users) are dependent on whether it concerns a first or second generation anticoagulant, the target species and the bait type (see also summary below). Please note that pack sizes for contact formulations (e.g. foam) are not harmonized.

First-generation anticoagulants (chlorophacinone, coumatetralyl, warfarin)

Professional/trained professional users: minimum pack size 3 kg

General public:
Products shall only be supplied with a maximum quantity of bait per pack of:

Target species	Bait type	Maximum quantity of bait per pack (g)
mice only	grain, pellet or paste	250
	wax block	500
rats only or mice and rats	grain, pellet or paste	750
	wax block	1,500

Second-generation anticoagulants (brodifacoum, bromadiolone, difenacoum, difethialone, flocoumafen)

Professional/trained professional users: minimum pack size 3 kg

General public:
Products shall only be supplied with a maximum quantity of bait per pack of:

Target species	Bait type	Maximum quantity of bait per pack (g)
mice only	grain, pellet or paste	50
	wax block	100
rats only or mice and rats	grain, pellet or paste	150
	wax block	300

2.4. Specific provisions for simplified procedures with regard to shelf-life

At the Coordination Group meeting number 30 (July 2018, agenda item 7.2e), it was agreed that a shelf-life study, as outlined in the ECHA Guidance on the Biocidal Products Regulation, part B , point 3.6.4, is not required if efficacy data performed using a fresh and an aged sample (e.g. 2 year old product, stored in appropriate commercial packaging) shows

that the product is still efficacious after storage.

This exemption only applies to authorizations of products or families applied for using the simplified procedure as outlined in chapter V of the BPR (articles 25 - 28).

Still, for enforcement purposes, a validated analytical method for determination of the content of the active substance in the product(s) is always required, even in the case efficacy data is used to address the shelf-life.

3. EFFICACY

3.1. Introduction Efficacy

This chapter describes the assessment of the efficacy of an active substance for placement of this active substance on the Union list and the assessment of a biocide for product authorisation.

In the last decades guidance on the efficacy evaluation has been developed, partly under the BPD, partly as transitional guidance[1] and part is still under development. All this guidance will be combined in one guidance document for the BPR: Volume II Efficacy of the Guidance on biocide legislation. There are some appendices to this guidance which are not included in the guidance itself. The reason for this is the possibility to update them regularly, without going through the whole procedure of updating Volume II Efficacy.

This Volume II Efficacy consists of two parts, Part A and Part B/C. In addition specific guidance that is not (yet) included in Volume II Efficacy Part B/C on the information requirements for humaneness and resistance .

In addition to the guidance document relevant technical agreements (e.g. specific testing requirements) made at the BPC Working Groups are published on the ECHA website. Those technical agreements are included in the Technical Agreements on Biocides (TAB) on the public part of the S-CIRCABC website, which now also includes agreements of the EFF (efficacy) Working Group.

3.2. Volume II Efficacy Part A: Information Requirements.

This guidance describes the information requirements for active substances and biocidal products in accordance with the Title 1 of Annex II and III of the BPR. Volume II Efficacy Part A was published 23-05-2018 on the ECHA website under *Guidance on biocides legislation*.

This guidance provides an explanation on the different data that is required. This is very general, more detailed guidance on the efficacy data (testing, minimum requirements, criteria, etc.) are described in Volume II Efficacy Part B/C.

3.3. Volume II Efficacy Part B/C: Efficacy Assessment and Evaluation.

This guidance (version 3.0) was published April 2018. Volume II Efficacy Part B/C contains general chapters on efficacy evaluation for active substance approval and product authorisation and chapters per PT, where the PT specific requirements and norms and criteria for assessment are described. Please note that several chapters on specific PTs were already published as transitional guidance[2]. For these chapters the date of endorsement/publication which is given below is leading and not the publication date of Part B/C.

Below some explanation is given per chapter of the guidance. In those cases where the guidance is under development and not published yet, applicants can contact the Ctgb

[2] A "Transitional Guidance" is a guidance document that has been initiated under the "old" Biocidal Products Directive and has been finalised before the Vol II part B/C was fully developed. These documents are now all included in Vol II part B/C. Transitional guidance is EU guidance and has nothing to do with transitional legislation in NL.

Service desk (servicedesk@ctgb.nl) for the latest version of the guidance that they seek.

3.3.1 Part B/C general (Chapter 1-3)

Three general chapters contain a general introduction, information on label claims, and general considerations for the development and reporting of efficacy data. Although these are not basically different from the approach taken in former guidance documents, it is a bit more explicit.

3.3.2 Active substance approval (Chapter 4)

This chapter contains the general principles for efficacy evaluation of active substances, and highlights some specific cases (active substances which are not intended to be used in isolation, dummy products, and treated articles). The approach as was taken and refined over the years for the active substance that have been approved so far is described in this chapter.

In this chapter no PT specific guidance is given, only some general guidance per main group. It is assumed that similar tests can be used for the active substance as for the product. Therefore, all the PT specific information is given in the chapters on product authorisation.

3.3.3 Product authorisation (Chapter 5)

This chapter contains a general introduction, a section on product families (efficacy testing for a family, influence of efficacy on deviation in *meta*-SPC's; section 5.2), and a section on treated articles (section 5.3). This last section gives information on materials and articles which contain an active substance. Per 13th of January 2021 a harmonized approach to determine a worst-case test product to be taken into account for efficacy testing for a disinfectant biocidal product family is decribed in this document.

Under this chapter sections per PT or groups of PT's are included.

All appendices, except for the appendix on claims matrices for PT's 1-4 and treated artciles, have been included in Volume II part B/C. This appendix can be found on the ECHA website at the page of the Working Group – Efficacy.

Disinfectants (Section 5.4)
This section contains a **general introduction** which was published 31-5-2016. An earlier version of this section was published in May 2013 (CA-May13-Doc.6.2b).

PT1-4
This section (5.4.1-5.4.4) contains guidance on the efficacy evaluation of products in PT 1, 2, 3, and 4 which was published 31-5-2016. An earlier version of the section on PT2 was published in May 2013 (CA-May13-Doc.6.2b).

Please note that additional information on disinfection of rooms, textile and packaging before filling, on devices generating the active substances by electrolysis, on co-formulants being a potential active substance in disinfectant products, on limited virucidal activity, on efficacy testing of stored disinfection products during shelf life, on differentiation of target organisms by contact time and dosage (PT4), on applicability of Phase 2, step 2 tests for different surface applications methods and on differentiation of virucidal claims for hard surface

disinfection is described in the Technical Agreements on Biocides (TAB).

PT5
This section (5.4.5) contains guidance on the efficacy evaluation of products in PT5. This section has been updated from version 2.0.

Please note that additional information on devices generating the active substances by electrolysis, on co-formulants being a potential active substance in disinfectant products, on efficacy testing of stored disinfection products during shelf life and on EN 1276 and EN 14476 test requirements for PT 5 active chlorine-based disinfectants is described in the Technical Agreements on Biocides (TAB).

Materials and Articles Treated to Protect Humans or Animals
This section (5.4.6) contains guidance on the efficacy evaluation of materials and articles with claims to protect humans or animals.

Preservatives
A general chapter on preservatives was published as transitional guidance 28-5-2014. This chapter is updated and incorporated in the section on preservatives in *Volume II Efficacy Part B/C (section 5.5.1-5.5.5)*. This section contains a section on **wet-state preservation** which gives a general view on testing preservatives in PT6, 11, 12, and 13. A section **curative treatments** gives a general view on testing preservatives which claim to have a curative effect. A section **protection of solid material** gives a general view on testing preservatives in PT7, 9, and 10.

Please note that additional information on growth quantification or determination of filamentous fungi, on relevant test bacteria for preservatives and on tiered approach to testing preservatives is described in the Technical Agreements on Biocides (TAB).

PT6
This section (5.5.6) contains guidance on the efficacy evaluation of products in PT6. This section was published February 2017.

PT 7 & 9
This section (5.5.7) contains guidance on the efficacy evaluation of products in PT7 and PT9. This section was published February 2017.

PT 8
This section (5.5.8) contains guidance on the efficacy evaluation of products in PT8 which was endorsed and published as transitional guidance on 31-3-2015. After publication a few issues were identified (requirements for a general claim against wood boring beetles and barrier treatment against *Serpula lacrymans* is a preservative treatment and not a curative treatment). These updates are included in *Volume II Efficacy Part B/C* (February 2017).

After publication of *Volume II Efficacy Part B/C* an additional appendix on "Annex A of EN-599" was developed to provide additional explanation about changes in formulation of PT8 products and whether new biological testing is needed. The final version is included in Appendix 12 of *Volume II Efficacy Part B/C* (April 2018).

In section, 5.5.8.2.2.3: the footnote added in version 2.0, (footnote 28) has been moved to the beginning of the section because it applies to Use Class 1 as well as Use Class 2. It is now footnote 24.

PT 9
This section (5.5.9) only contains a reference to section 5.5.7 where guidance on efficacy evaluation of products in both PT7 and PT9 is given.

PT 10
This section (5.5.10) only contains a reference to the General sections 1-3 and the preservatives general sections (5.5.1-5.5.3). This section is under development. No draft version is available or foreseen in the near future. As long as no PT10 specific guidance is available the general guidance on preservatives and in particular the section **protection of solid material** should be used as guidance for PT10 products.

PT 11
This section (5.5.11) only contains a reference to the General sections 1-3 and the preservatives general sections (5.5.1-5.5.3). This section is under development. The first draft version is foreseen in 2019 and might be published on the ECHA website under Ongoing guidance consultations. As long as no PT11 specific guidance is available the general guidance on preservatives and in particular the section **wet-state preservation** should be used as guidance for PT11 products.

PT 12
This section (5.5.12) only contains a reference to the General sections 1-3 and the preservatives general sections (5.5.1-5.5.3). This section is under development. The first draft version is foreseen in 2019 and might be published on the ECHA website under Ongoing guidance consultations.

As long as no PT12 specific guidance is available the general guidance on preservatives and in particular the section **wet-state preservation** should be used as guidance for PT12 products.

PT 13
This section (5.5.13) contains guidance on the efficacy evaluation of products in PT13. This section was published 31-5-2016.

Pest control
This section (5.6) contains a general introduction on pest control. This section is under development. No draft version is available or foreseen in the near future.

PT 14
This section contains guidance on the efficacy evaluation of products in PT14 which was endorsed February 2009 and after major revision again published in December 2016.

As there are still many discussions on the paragraph on resistance and since there is no clear way forward, this part of the PT14 guidance is marked as ‘under review’ (footnote 31).

Please note that information on applications for major changes with lower concentration of an active substance is described in the Technical Agreements on Biocides (TAB).

PT 15, 16, & 17
This section (5.6.3) contains guidance on the efficacy evaluation of products in PT15, 16 & 17. This section is under development. No draft version is available or foreseen in the near future. As long as no PT15, 16 & 17 specific guidance is available, the general principles as described in the first chapters should be used as guidance for PT15, 16 & 17 products.

PT 18 and 19 on arthropods
This section (5.6.4) contains guidance on the efficacy evaluation of products in PT18 and 19 on arthropods which was endorsed December 2012 and published as transitional guidance on 16-9-2016.

Please note that additional information on semi-field tests for insecticides against crawling and flying insects intended to be used in aircrafts, on the shelf life of PT18 bait products and on efficacy requirements for an insecticide to be used in stables (PT18) is described in the Technical Agreements on Biocides (TAB).

After endorsement/publication several data gaps and a few issues were identified with respect to the PT19 guidance included in the published guidance and were discussed in a dedicated Efficacy workshop on repellents in June 2016. It was decided that in the future revision of this guidance, PT18 and PT19 guidance should be separated and guidance should be developed/revised for some arthropods. This revision will be discussed in a dedicated workshop in December 2017, an updated final version of the PT19 guidance is expected to become available in 2021. For arthropods for which no specific guidance is available, the general principles as described in the PT18/19 guidance should be used.

Please note that for repellents against mosquitoes that it is agreed among MSs that **arm-in-cage tests are worst case for mosquitoes and are always needed and that field tests are not mandatory**, but can be provided as additional information.

PT 19 non-arthropods
This section (5.6.5) contains guidance on the efficacy evaluation of products in PT19 on non-arthropods. Please note that the final version of the PT19 guidance update (expected to become available in 2021) will not include specific guidance for product to be used against non-arthropods. As long as no PT19 non-arthropods specific guidance is available, the general principles as described in the General sections 1-3 and the general introduction of the PT18/19 guidance on arthropods should be used as guidance for PT19 non-arthropods.

PT 20
This section (5.6.6) only contains a reference to the General sections 1-3. This section is under development. No draft version is available or foreseen in the near future. As long as no PT20 specific guidance is available, the general principles as described in the General sections 1-3 should be used as guidance for PT 20 products.

Humaneness
This section (5.6.1) is under development. No draft version is available or foreseen in the near future. In this section reference is made to TNsG on Product Evaluation (section 6) where some general guidance can be found. Humaneness criteria are relevant for biocides in the Pest Control PTs14, 15, 17, 19 (repelling or attracting vertebrates) and PT 20.

Other biocidal products

PT 21
This section contains guidance on the efficacy evaluation of products in PT 21 which was endorsed and published as transitional guidance on 28-5-2014.

PT 22
This section (5.7.2) contains guidance on the efficacy evaluation of products in PT 22 which was endorsed and published as transitional guidance on 12-8-2014.

Resistance and cross-resistance

This section (3.2) is under development. No draft version is available or foreseen in the near future. According to the BPR (Article 19(1)(b) criterion ii and common principles point 50 and 75 in Annex VI) biocidal products should cause no unacceptable effects on the target organisms, including unacceptable resistance or cross resistance. This criterion is relevant for biocides of all product types.

Where relevant, an evaluation on the possibility of the development by the target organism of resistance or cross-resistance to an active substance in the biocidal product shall be made.

Where the development of resistance or cross-resistance to the active substance in the biocidal product is likely, the evaluating body shall consider actions to minimise the consequences of this resistance. This may involve modification of the conditions under which an authorisation is given. However, where the development of resistance or cross- resistance cannot be reduced sufficiently, the evaluating authority shall conclude that the biocidal product does not satisfy criterion (ii) under point (b) of Article 19(1).

Guidance on the assessment of resistance and cross-resistance is currently not included in Volume II Efficacy Part B/C. Reference is made to the TNsG on Product Evaluation (section 6) where some general guidance can be found.

4. HUMAN HEALTH

Starting points for the evaluation of dossiers for biocidal products as regards the effects on humans are presented in the Common Principles (Annex VI to BPR 528/2012). In summary, in each of the areas where risk assessments have been carried out, the results for the active substance shall be combined together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects. For biocidal products containing more than one active substance, any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

4.1. Information requirements for active substances and biocidal products

The information requirements are laid down in Annex II and III of the BPR and are further explained in Volume III - Part A with regard to human health. The information requirements are two-tiered. The core data set (CDS) is mandatory for all product types and has always to be submitted. The additional data set (ADS) must be submitted when required by the intrinsic properties of the active substance or biocidal product, when required by the foreseen use and route of exposure, or when the initial risk assessment must be refined. Volume III only deals with chemical a.s or chemical biocidal products, guidance on the information requirements for micro-organisms is available separately in Guidance on micro-organisms (Volume V).

A general Introduction to guidance on the Biocidal Products Regulation, which is applicable to all four volumes (Physchem, Eff, HH and Env) is available. This document gives general background information as well as on the principles to be used for generating (new) information. Note also that the Ctgb highly value the purpose of article 62 of the BPR, i.e. to avoid animal testing. Therefore the applicant should have submitted a written request to the Agency to allow them to check whether such tests have already been submitted in connection with a previous application.

The biocidal product can also be generated in situ (second indent art. 3 (1)). The *in situ* active substances/products are a specific case which are not addressed in detail within the BPR nor in the data requirements. According to the commen principles (Annex IV, point 6 and 14), the risk assessment should also includes the possible risks from the precursor(s). The BPC working groups have drafted recommendations to address the data requirements, which can be found on the ECHA site here. Several documents on in situ are endosed at CA meetings (link, see folder finalised in situ). The CA also decided that if the in situ biocidal product of an IGS fulfils any of the criteria listed in Article 19(4), the in situ biocidal product should not be authorised for the use by the general public.

Currently, the exact requirements for *in situ* generated active substances and their precursors are dealt with on a case-by-case basis. Generally, the Annex II requirements apply to precursors and the substances generated, but depending on the nature of the precursor and substance generated, the BPC Working Group can be requested to exempt applicants from providing certain data related to human health, when appropriate. This should be discussed with the evaluating competent authority (eCA).

The Ctgb follows the BPR regarding information requirements and has not defined additional requirements. Note that the assessment report for the active substance contains at least the CDS. A letter of access to the relevant active substance dossier(s) is therefore often sufficient for evaluating a biocidal product, unless additional information requirements are listed in the BPR opinion and/or product specific parameters (e.g dermal absorption) are

necessary.

4.2. Information requirements for substances of concern

Some biocidal product may contain asubstance of concern (SoC) regarding the human health. For the criteria of SoC, please be referred to the General introduction, section 5.3: Substance of concern or to the Guidance on the BPR: Volume III Human Health, Part B&C Assessment& Evaluation, Annex A and and CG45 for on Harmonized approach to consider a co-formulant as a substance of concern (SoC) based on its workplace exposure limits.
In general, a full quantitative risk assessment should be performed using for substances that lead to classification in band C and for substance where an European Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set. The risk characterisation needs to be performed for the same exposure scenarios as for the risk characterisation of the exposure to the active substance. In the Netherlands a full quantitative risk assessment needs to be performed for substances for which community workplace exposure limits exists (=publieke grenswaarde), (see SER lijst and Arbeidsomstandighedenregeling).

4.3. Information requirement for disinfection by-products (DBPs)

DBPs formed by DBP forming active substances (e.g. reactive chlorinated/brominated substances, peroxides etc.) will be considered during product authorisation from January 2019 and onwards. For the guidance for DBP, please be refered to the General introduction, section 5.7: Disinfection By-Products.

In January 2017 the final guidance on Disinfection By-Products was made available on the ECHA website (Volume V Specific Guidance, Guidance on Disinfection By-Products). This document summarises background information and provides a strategy for the human health risk assessment of DBPs. This document provides a scientific and pragmatic strategy for the risk assessment of disinfection by-products (DBPs) in the context of authorisation of halogenated biocidal products in swimming-pool water under European legislation. The risk assessment is based on a set of known marker DBPs, using consensus health-based limit values and published, modelled or measured DBP concentrations under described conditions.

Measurements of concentrations of DBPs after biocide use in swimming-pools are needed to perform the risk assessment. Relevant concentration data may be gathered from available literature. Where needed actual measurements should be performed. Simulation studies or modelling can be used to derive realistic worst case formation levels.

The present guidance focuses on PT2 in swimming-pool water for which human exposure was considered most relevant while discussing the exposures to DBPs (PT2 swimming water, PT11/12). Other PTs for which a DBP-assessment may be needed are PT1, PT4 and PT5, followed by PT3, PT11 and PT12. It is recommended to further investigate the applicability of the present guidance to these PTs.

4.4. Information endocrine disruption (ED)

Endocrine disrupting properties for active substances and biocidal products need to be considered from 7th June 2018 and onwards. For the guidance for ED, please be refered to the General introduction, section 5.12: Endocrine disruptors or information included at the ECHA webpage (Volume V Specific Guidance, Guidance for identification of endocrine

disruptors).

An ED screening needs to be performed for all co-formulants and disinfection by-products (DBPs, see CA-March21-Doc.5.2_final) formed in accordance with the procedure agreed at the CG in March 2019 and at the CA in March 2021.

The results should be reported clearly in the PAR, see CG-50 2022-05 for practical information for applicants on how to perform the assessment of ED properties of a biocidal product.

According to CA-June22-Doc.4.8, a substance identified as endocrine disruptor, and contained in a biocidal product, should be present in a concentration higher than or equal to 0.1% w/w for triggering its identification as SoC for the assessment of this biocidal product. However, where a biocidal product contains several substances in individual concentrations lower than 0.1% (w/w) which are identified as ED, but the sum of their concentrations is higher than or equal to 0.1% (w/w), they should be considered as SoC.

4.5. Human health risk assessment

In general the Guidance on the BPR: Volume III Human health, Part B+C: Assessment and Evaluation (active substances and product authorisation which fall under the BPR legal frame) plays a key role in the Human Health risk assessment. This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and product authorisation which fall under the BPR legal frame with respect to Human Health risk assessment. The latest version is available on the ECHA's website. The applicant must apply the most recent version for their risk assessment and all additional agreements as listed in section 4.7.
Furthermore, instructions for the evaluation of toxicity studies are given in the Guidance on the BPR: Volume III Human Health, Part B&C Assessment& Evaluation. This evaluation leads for each study and for each sub-aspect to a toxicologically based endpoint, and finally to the toxicological profile of a substance. In Chapter 1 of the Guidance on the BPR: Volume III Human Health, Part B&C Assessment & Evaluation the hazard identification is described. In chapter 2 the hazard characterisation is described.

The estimation of human exposure is a fundamental element of the risk assessment process and requires quantification of the levels of exposure for both users of the biocidal product and others who may be exposed following its use.

For each of the identified populations that are likely to be exposed to the biocidal product, it needs to be defined what type of exposure is expected. The type of exposure expected for each of the identified exposed populations should be characterised as primary (direct) or secondary (indirect). **Primary exposure** to biocidal products occurs to the individual who actively uses the biocidal products, i.e. the user. The user may be a professional at work or a non-professional. Professional users differ from non-professional users in a number of aspects and a distinction between the two is necessary in exposure assessments.

Secondary exposure is exposure that may occur during or after the actual use or application of the biocidal product. There can be three main categories that need to be considered as being potential source of secondary (indirect exposure). These are environmental sources from the point of view of treated areas with biocidal products (e.g. a room fumigated with a biocidal product, swimming pool treated with disinfectants), treated articles and dietary exposure sources (covering potential of exposure via consumption of

food where residues of biocidal products may be present).

Not all tasks that may be carried out with biocidal products are covered with suitable experimental exposure data or databases/approaches. In such cases suitable information on exposure is required (to be provided by industry to the evaluating CA) to build a risk assessment to indicate appropriate safety for humans during use. The general principles for drawing up exposure estimates are given in the Guidance on the BPR: Volume III Human Health, Part B&C Assessment & Evaluation available on the ECHA website at Guidance on biocides legislation. This Guidance provides technical advice on how to perform the hazard assessment and exposure assessment and risk characterisation for biocidal active substances and products with respect to human health risk assessment. The Guidance on Exposure Assessment (Chapter 3) should be read together with the Biocides Human Health Exposure Methodology (also available on the ECHA website Ad hoc Working Group - Human Exposure in which the actual estimation of exposure, additional technical guidance on types of generic models, calculations and default parameters are provided. Furthermore the Ad hoc Working Group on Human Exposure supports the Biocidal Products Committee and its Working Groups (especially the Working Group on Human Health) with issues related to human exposure to biocides, including among others:

- Technical or scientific matters as well as generic or specific methodological issues
- Harmonisation of the approach for assessing human exposure to biocides
- Implementation of the strategies of biocides exposure assessment
- Identification of the needs to revise the existing guidance documents on human exposure to biocidal products and contribution to the revision, where appropriate

As a result, opinions of the human exposure expert group and the recommendations of the ad hoc working group on human exposure were developed and available on the ECHA website Ad hoc Working Group - Human Exposure a link is included to the Recommendations of the Ad hoc Working Group on Human Exposure (HEAdhoc) and to the Opinions of the Human Exposure Expert Group (HEEG), the human exposure expert group under the BPD (see ECHA website: HEEG opinions)

In general, for many applications of biocidal products, harmonised assessment approaches have been agreed, which should be followed when appropriate for the application to be assessed. Besides these harmonised approaches, other models for exposure assessment exist and may be used in cases where no suitable harmonised approach exists.

Thus, when choosing a model for exposure estimation, the following ranking shall be observed:

1. Recommendations of the Ad hoc Working Group on Human Exposure (HEAdhoc) (see ECHA website: HEAdhoc recommendations)
2. Opinions of the Human Exposure Expert Group (HEEG) (see ECHA website: HEEG opinions)
3. Models and defaults formerly presented in the Technical Notes for Guidance (TNsG) and the respective User Guidance and now included in Biocides Human Health Exposure Methodology (see link to the word document ECHA website Ad hoc Working Group - Human Exposure)
4. Other Models, e.g., generic models, ConsExpo (webbased version: ConsExpo Web, RISKOFDERM, Advanced Reach Tool (ART) etc.

Any deviation from this ranking should be justified.

Besides the guidances on the BPR and the document TAB agreements there are also relevant documents agreed at WG/CA/CG/ documents that should be used for the risk assessment. A list including hyperlinks is given in section 4.7.

For determining the dermal absorption, the “EU guidance document on dermal absorption” (EFSA Journal 2012;10(4):2665 or EFSA Journal 2017;15(6):4873 depending on the date of submission of the dossier) should be used as a guideline. For biocidal products under the BPR from March 2020 and onwards, only EFSA 2017 guidance must be used. However, if applicable to your product, the default values of the EFSA 2017 can be used before the indicated time. Otherwise, EFSA 2012 needs to be considered. For active substance dossiers EFSA 2017 guidance needs to be used, as this guidance needs to be considered from September 2018 and onwards. It is noted that in the SCoPaFF an addition to the 2017 guidance is endorsed: SANTE/2018/10591 rev.1,24 October 2018. In this SANTE document the definition of concentrate and in-use dilution is set as follows:

1. A "concentrate" when the active substance is present in the plant protection product at a concentration higher than 50 g/L (or 50g/Kg or 5%);
2. A "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).

4.6. Indirect Exposure and Risk assessment

As stated in the Guidance on the BPR: Volume III Human Health, Part B&C Assessment & Evaluation (Guidance on the BPR: Volume III Human Health, Part B&C Assessment & Evaluation) indirect exposure of humans via the environment may occur by consumption of food (e.g. fish, crops, meat and milk) and drinking water, inhalation of air and ingestion of soil.

With regard to dietary exposure, the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood) supports the Biocidal Products Committee and its Working Groups (especially the Working Group on Human Health) with issues related to human exposure to biocides through food: see ECHA website: ARTFood.

1. Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods Non-professional Uses: see BPR guidance Vol. III HH, part B+C, Chapter 5).
2. Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Professional Uses : see draft at ECHA website: ARTFood.
3. Estimating Livestock Exposure to Biocidal Active Substances : see BPR guidance, Guidance on the BPR: Volume III Human Health, Part B&C AssessmentGuidance on the BPR: BPR guidance Vol. III HH, part B+C, Chapter 6).
4. Estimating indirect exposure via food by using insect repellants: see draft at ECHA website: ARTFood..

If residues in food could occur due to the use of biocidal product, a dietary risk assessment need to be performed. It may be possible that the above list of guidances may not cover all possible scenarios. A case-by case approach needs to be considered in those cases.

In chapter 6 of the BPR guidance Vol. III HH, part B+C reference is made to the interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials (CA-March17-Doc.7.6.c-final) and to the EMA-CVMP guidance document “Guideline on Risk characterisation and assessment of maximum residue limits (MRL) for biocides” (EMA/CVMP/SWP/90250/2010).
The interim approach, based on a step-wise procedure and the current knowledge and data, is proposed to help deciding in which situations and/or under which conditions it is necessary to establish limits for residues of biocidal active substances. The EMA-CVMP guidance

presents the approach taken in the MRL evaluation of pharmacologically active substances included in biocidal products for use in animal husbandry and to provide guidance on the type of data required in relation to the dietary risk assessment and MRL evaluation.

For active substance approval , the following provision should be included in section 2.4 of the BPC opinion if relevant: “An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs”.

The Ctgb assesses human health risks entirely according to the latest agreed versions of the Guidances. As long as there is no agreed guidance, the conclusion on dietary risk assessment will not affect the approval of the active substance. Having a preliminary exposure estimation to residues in food and feed and dietary risk assessment at the active substance approval phase would serve the purpose of providing useful information for the product authorisation phase.

If it is concluded that evaluation is not possible using the information available in the dossier, it may be necessary to postpone the exposure estimation to residue and the dietary risk assessment to product authorisation stage.

Besides the guidances on the BPR and the document TAB agreements there are also relevant documents agreed at WG/CA/CG/ documents that should be used for the risk assessment. A list including hyperlinks is given in section 4.7.

4.7. Other guidances

In addition to guidance volume III A and B+C, several specific documents were addressed in this evaluation manual. In addition, other guidance may clarify some information requirements and/or the scientific background. Please take these into account when an evaluation of a biocidal product is conducted:

- Technical Agreements on Biocides (TAB) containing Working Group agreements (link)
- Documents agreed at WG HH: Working Group - Human health - ECHA (europa.eu) and circabc (link)
- Recommendations of the Ad hoc Working Group on Human Exposure (HEAdhoc), Opinions of the Human Exposure Expert Group (HEEG) and the Biocides Human Health Exposure Methodology provide guidance with regard to the information to be used for assessing human exposure: Ad hoc Working Group - Human Exposure - ECHA (europa.eu)
- Documents prepared by the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood): Ad hoc Working Group - Assessment of Residue Transfer to Food (ARTFood) - ECHA (europa.eu)
- CA meeting documents (link)
- Coordination group public documents (link)

5. ENVIRONMENT

Starting points for the evaluation of dossiers for biocidal products as regards the effects on the environment are presented in the Common Principles (Annex VI to BPR 528/2012). In summary, in each of the areas where risk assessments have been carried out, the results for the active substance shall be combined together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects. For biocidal products containing more than one active substance, combined effects shall also be considered to produce an overall assessment for the biocidal product itself.

5.1. Information requirements for active substances and biocidal products

The information requirements regarding the environmental risk assessment are explained in Volume IV - Part A with regard to environment. The information requirements are two-tiered. The core data set (CDS) is mandatory for all product types and always has to be submitted. The additional data set (ADS) must be submitted when required by the intrinsic properties of the active substance or biocidal product, when required by the foreseen use and route of exposure, or when the initial risk assessment must be refined. Volume IV only deals with chemical a.s or chemical biocidal products, guidance on the information requirements for micro-organisms is available separately in Guidance on micro-organisms (Volume V).

The Ctgb follows the BPR regarding information requirements and has not defined additional demands. Note that the assessment report for the active substance contains at least the CDS. A letter of access to the relevant active substance dossier(s) is therefore often sufficient, unless additional information requirements are listed in the BPR opinion and/or product specific parameters e.g. leaching behaviour (PT06-10, PT21) are necessary.

A general Introduction to guidance on the Biocidal Products Regulation, which is applicable to all four volumes (Physchem, Eff, HH and Env) is available. This document gives general background information as well as on the principles to be used for generating (new) information. Note also that the Ctgb highly value the purpose of article 62 of the BPR, i.e. to avoid animal testing. Therefore the applicant should have submitted a written request to the Agency to allow them to check whether such tests have already been submitted in connection with a previous application.

The biocidal product can also be generated in situ (second indent art. 3 (1)). The *in situ* active substances/products are a specific case which are not addressed in detail within the BPR nor in the data requirements. According to the common principles (Annex IV, point 6 and 14), the risk assessment should also includes the possible risks from the precursor(s). The BPC working groups have drafted recommendations to address the data requirements, which can be found on the ECHA site here. Several documents on in situ are endosed at CA meetings (link, see folder finalised in situ). The CA also decided that if the in situ biocidal product of an IGS fulfils any of the criteria listed in Article 19(4), the in situ biocidal product should not be authorised for the use by the general public.

Currently, the exact requirements for *in situ* generated active substances and their precursors are dealt with on a case-by-case basis. Generally, the Annex II requirements apply to precursors and the substances generated, but depending on the nature of the precursor and substance generated, the BPC Working Group can be requested to exempt applicants from providing certain data related to environmental risk, when appropriate. This should be discussed with the evaluating competent authority (eCA).

5.2. Information requirements for substances of concern

Some biocidal product may contain a substance of concern (SoC) regarding the environment. For the criteria of SoC, please refer to the General introduction, section 5.3: Substance of concern or to the Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Part B&C), Part II chapter 8.

SoCs must be included in the risk assessment and their risks are assessed analogue to the active substance. Therefore, the SoC requires the same core data set as the active substance and depending on the physical-chemical properties, the intended use, and possible higher tier risks assessment one or more information items from the additional data set. It is preferable to refer to an existing dossier if the SoC is notified and/or authorised within the BPR and/or REACH. A valid Letter of Access to the relevant dossier is self-explanatory. Alternatively, endpoints derived using quantitative structure activity relationships (QSARs), taken from public resources (e.g. scientific literature), and/or determined experimentally will be accepted as well, but needs to be evaluated by the Ctgb.

5.3. Information requirement for disinfection by-products (DBP)

DBPs formed by DBP forming active substances (e.g. reactive chlorinated/brominated substances, peroxides etc.) will be considered during product authorisation from January 2019 and onwards. For the guidance for DBPs, please refer to the General introduction, section 5.7: Disinfection By-Products.

In January 2017 the final guidance on Disinfection By-Products was made available on the ECHA website (Volume V Specific Guidance, Guidance on Disinfection By-Products). This document summarises background information and provides a strategy for the environmental risk assessment of DBPs. This document provides a scientific and pragmatic strategy for the risk assessment of disinfection by-products (DBPs).
The environmental risk assessment scheme consists of three steps. The steps should not be seen as consecutive tiers, but should be completed, as required, in order to pass the risk assessment.
Step 1 Worst-case PEC/PNEC calculation for known markers assuming 100% conversion.
Step 2 Chemical assessment (descriptive group parameters).
Step 3 Refined PEC/PNEC assessment for known marker DBPs, appended with WET or other tailor-made studies to cover unknown DBPs.

If a potential risk is identified, a refined exposure assessment should be performed. This can be done by (a combination of) modelling and monitoring approaches. Monitoring in this context does not (only) refer to extended time series over several locations, but also includes “measurements” that relate to more or less project-based sampling campaigns, limited in scale with respect to time and place.

The present guidance focuses on PT2, PT11 and PT12 for which environmental exposure was considered most relevant in view of the extent of DBP formation in combination with emissions to surface water. Other PTs for which a DBP-assessment may be needed are PT1, 3, 4 and 5. It is recommended to further investigate the applicability of the present guidance to these PTs.

5.4. Information endocrine disruption (ED)

Endocrine disrupting properties for active substances and biocidal products need to be considered from 7th June and onwards. substances, peroxides etc.). For the guidance for ED,

please refer to the General introduction, section 5.12: Endocrine disruptors or information included at the ECHA webpage (Volume V Specific Guidance, Guidance for identification of endocrine disruptors).

An ED screening needs to be performed for all co-formulants and disinfection by-products (DBPs, see CA-March21-Doc.5.2_final) formed in accordance with the procedure agreed at the CG in March 2019 and at the CA in March 2021.

The results should be reported clearly in the PAR, see CG-50 2022-05 for practical information for applicants on how to perform the assessment of ED properties of a biocidal product.

According to CA-June22-Doc.4.8, a substance identified as endocrine disruptor, and contained in a biocidal product, should be present in a concentration higher than or equal to 0.1% w/w for triggering its identification as SoC for the assessment of this biocidal product. However, where a biocidal product contains several substances in individual concentrations lower than 0.1% (w/w) which are identified as ED, but the sum of their concentrations is higher than or equal to 0.1% (w/w), they should be considered as SoC.

5.5. Warning sentence for bees

Currently bees are not covered in the risk assessment in line with the guidance on BPR. ECHA and various member states are working on a pollinator guidance. For bees the CA has decided that an interim solution is required (please refer to CA-Dec20-Doc.4.1 Warning sentence and RMM for bees_final.docx), which implies the use of the warning sentence: “This biocidal product contains (active substance name) which is dangerous to bees”. This should be implemented from the date of the CA meeting (14 December 2020). The CA conclusion leaves room for interpretation when the sentence should be applied and it was further discussed at WG ENV level. At WG III 2021 it was concluded that the warning sentence should apply to PT18, PT19 and PT08 products used outdoor (excluding treated wood), when the available (acute) endpoint on bees is below the toxicity threshold of 11 µg/bee.

5.6. Environmental risk assessment

The Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) plays a key role in the environmental risk assessment. This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances with respect to environmental risk assessment. The latest version is available on ECHA’s website. The superseded version can be found on the ECHA website as well. The applicant must apply the most recent version for new applications, which is currently v2.0 (October 2017). The applicant is not required to update dossiers to a newer version of the BPR guidance when those dossiers are under evaluation. It is acceptable to update to a newer version when new insights are described in that version of the BPR guidance.

The latest BPR guidance version includes all additional agreements as published in the Technical Agreements on Biocides (TAB). Please refer to the latest version of the TAB that is available on ECHA’s website. During dossier evaluation, TAB-entries that are applicable will be applied in the risk assessment. New TAB agreements that are not yet applicable can be applied by Ctgb when beneficial for the notification.

Emission scenario documents

Emission scenario documents (ESDs) are used to estimate the initial release of substances from biocidal products (or treated materials) to the environment. ESDs for several product types were developed in the EUBEES I and II projects. In addition, ESDs for some product types were developed by the OECD. All finalised ESDs for biocides are available on ECHA's website, where the ESDs are presented per product type in separate folders. In these folders, relevant additional guidance and information is also presented. For the majority of the intended uses the active substances are released to the sewer and consecutive sewage treatment plant (STP). Here, SimpleTreat is used to calculate distribution over air, sewage sludge, and the aqueous phase, and the amount of active substance that is removed by degradation during sewage treatment. Further distribution into the environment is calculated according to the Guideline based on SimpleTreat outcomes (concentrations in air, sludge, and effluent). The version to be applied is either 3.1 or 4.0. Which version to use is described in the latest TAB. Note that the concentration of suspended solids in the STP's effluent must be manually increased from 7.5 to 30 mg/L when using version 4.0. More information on SimpleTreat is available on the website of the National Institute for Public Health and the Environment (RIVM). Version 4.0 is downloadable from the RIVM-website and included in the latest version of the EUSES model which can be downloaded here.

The Ctgb assesses environmental risks entirely according to the latest agreed versions of the Guidance, TAB, ESD, and SimpleTreat. Where applicable, the risk assessment will be adapted to the specific Dutch situation regarding intended use, national legislations, and/or a specific emission pattern. These adaptations are explained in the NL specific evaluation manual and do not require additional data. Note that the number of agreed ESDs is limited and scenarios for some applications are not available. There are several options how to deal with missing ESDs:

- It may be possible that the intended use has been assessed in a Competent Assessment Report (CAR) or Product Authorisation Report (PAR). In that case the applied methods has more or less been agreed by the BPC Working Groups and are therefore preferable;
- An existing ESD can be applied as a worst-case surrogate;
- If the concerning product has several applications, emission from the foreseen intended use may be covered by another use regarding consumption and emission routes;
- Emission to the environment can be assessed qualitatively if emission to the environment is negligible due to the foreseen use and risk mitigation measures that prevent unacceptable emission to the environment;
- Propose a new scenario in the Product Assessment Report. After national agreement, the Ctgb will initiate an EU consultation to discuss the newly proposed scenario.

Questions regarding scenarios to be applied can be send to the Ctgb service desk.

5.7. Other guidances

In addition to Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances), several specific documents were addressed in this evaluation manual. Other guidance may also clarify some information requirements and/or the scientific background. Please take these into account when an evaluation of a biocidal product is conducted:

- Documents agreed at WG EV:
  Working Group - Environment - ECHA (europa.eu) and circabc (link)

- Recommendations of the Ad Hoc Environmental Exposure WG: Ad hoc Working Group - Environment Exposure - ECHA (europa.eu)
- CA meeting documents (link)
- Coordination group public documents (link)