Evaluation Manual for the Authorisation of biocides

Active substance approval and product authorisation under BPR

Biocides

version 2.2; November 2017

ctgb

Board for the authorisation of plant protection products and biocides

Active substance approval and product authorisation under BPR
Biocides

Changes made in the Evaluation Manual

Evaluation Manual Biocides Active substance approval and product authorisation under BPR			
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

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

The information requirements regarding the physchem assessment are explained in Volume I - Part A for which 1.1 (November 2014) is the current version. 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. It is self-evident that the ADS should focus on the information requirements needed for the specific case.

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, unless additional information requirements are listed in the BPR opinion and/or product specific parameters are necessary.

2.2. BPC working group agreements

In December 2016, ECHA published a new version of the Technical Agreements on Biocides (TAB) on their website, which includes relevant technical agreements made at the BPC Working Groups and, as the Working Groups were previously known, the Technical Meetings. In addition to the TOX and ENV chapters, agreements with regard to the APCP (identity, physical and chemical properties and analytical methods) are now available as well.

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 BPC opinions on the application for renewal of the approval of the active substances. The minimum pack size for professional/trained professional users is 5 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 5 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 5 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

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 humaneness and resistance is given.

In addition to the guidance document relevant technical agreements made at the BPC Working Groups are published on the ECHA website. August 2017, ECHA published a new version of these Technical Agreements on Biocides (TAB) on their website, which now also includes agreements of the EFF (efficacy) Working Group. The following items were added:

1. Disinfection of packaging before filling
2. Devices generating the active substances by electrolysis
3. Co-formulants being a potential active substance in disinfectant products
4. Insecticide against crawling and flying insects intended to be used in aircrafts
5. Limited virucidal activity
6. PT14: applications for major changes with lower concentration of an active substance
7. Shelf life of PT18 bait products

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 28-11-2014 on the ECHA website under *Guidance on biocides legislation*. The ECHA Secretariat plans an update of Part A to bring it in line with the recently published Parts B/C of Volume II (Assessment and Evaluation). An updated version is expected in March 2018.

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 1.0) was published February 2017. 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

[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

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 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.

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

Some of the appendices belonging to the PT specific guidance are only incorporated in Volume II part B/C as a link. These appendices can be found on the ECHA website at the page of the Working Group – Efficacy. These appendices might be updated more often than Volume II part B/C.

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).

Appendix 1 (Claims Matrix PT 1-4) and Appendix 4 (Overview of standards, test conditions,

transitional legislation in NL.

and pass criteria of the TG on Efficacy Assessment for PT 1-5) of this guidance are not included in the guidance itself, only a link to the location is given.

Please note that additional information on disinfection of packaging before filling, devices generating the active substances by electrolysis, co-formulants being a potential active substance in disinfectant products and limited virucidal activity 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 is under review. The draft to PEG (Partner Expert Group) version of this section can be found at the ECHA website under Ongoing guidance consultations and will be discussed by the PEG in November 2017. The final version is expected in February 2018 and will then replace the current section 5.4.5.

Please note that additional information on devices generating the active substances by electrolysis and on co-formulants being a potential active substance in disinfectant products 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.

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. A draft version of this appendix can be found under Ongoing guidance consultations. A final version is foreseen November/December 2017.

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.

PT10
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 2018 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 2018 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.

PT13
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 33).

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).

PT15, 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.

PT18 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 and on the shelf life of PT18 bait products 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 draft version is expected in 2018 and might be published on the ECHA website under Ongoing guidance consultations. 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.

PT19 non-arthropods
This section (5.6.5) contains guidance on the efficacy evaluation of products in PT19 on non-arthropods. This section is under development and will be discussed in a dedicated workshop in December 2017. A first draft version is expected in 2018 and might be published on the ECHA website under Ongoing guidance consultations. 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.

PT20
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 PT20 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 PT20.

Other biocidal products
PT21
This section contains guidance on the efficacy evaluation of products in PT21 which was endorsed and published as transitional guidance on 28-5-2014.

PT22
This section (5.7.2) contains guidance on the efficacy evaluation of products in PT22 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

4.1. Information requirements for active substances and biocidal products

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 evaluating body shall combine the results for the active substance 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 product containing more than one active substance, any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

The information requirements regarding the human health risk assessment are explained in Volume III - Part A for which 1.1 (November 2014) is the current version. 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. It is self-evident that the ADS should focus on the information requirements needed for the specific case.

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, unless additional information requirements are listed in the BPR opinion and/or product specific parameters are necessary. Not 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.

In addition to information requirements presented in Volume III - Part A the working group on Human Health (BPC WG HH) adopted the document "Dermal absorption of PT21 active substances" in November 2016. The publication date on the ECHA website was 9-12-2016 and Ctgb implemented the document from 9-12-2016.

The document on dermal absorption PT21 describes the practical ways forward in performing and interpreting dermal absorption studies on antifouling products.
At the moment the protocols as given in OECD guidelines 427 (*in vivo*) and 428 (*in vitro*), supported by OECD Guidance Document No. 28 for the conduct of skin absorption studies, are considered appropriate. Furthermore, the general principles as indicated in e.g. ECHA Guidance Vol III Part A: Information requirements and EFSA Guidance on dermal absorption (2012) are followed. However, some of the recommended procedures or general principles are difficult to apply to film-forming antifouling paints. In this document the practical ways forward in performing and interpreting dermal absorption studies on antifouling products, not supported by the protocols and the general principles as indicated are recommended.

4.2. Information requirements for substances of concern

Some biocidal product may contain at least one substance of concern (SoC) regarding the human health, i.e. a co-formulant that triggers the human health classification of the biocidal product. The SoC guidance for human health toxicology is described in CA-Nov14-Doc.5.11 – SoC guidance_final.doc which 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). In general, the risk assessment should be performed using a pragmatic approach based on expert judgement e.g. based on "the worst case exposure scenario for respiratory exposure to the product as a value in mg/m3 product per day and the content of the co-formulant in percentages of the product be used". In the Netherlands a full quantitative risk assessment needs to be performed for substances for which community workplace exposure limits exists, (see SER lijst and Arbeidsomstandighedenregeling).

4.3. Information requirement for disinfection by-products

DBPs at present will not be part of the product authorisation of DBP forming active substances (e.g. reactive chlorinated/brominated substances, peroxides etc.).

In January 2017 the final guidance on Disinfection By-Products was made available on the ECHA website.
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.

It is recommended that industry parties coordinate activities to refine the risk assessment.

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.

The guidance should be used by EU member states (CAs and applicants) from January 2019.

Ctgb will inform the applicant that in case there are no concentration data gathered from available literature available actual measurements or simulation data or modelling approaches should be made available by the applicant to be used in the assessments for product authorisations over 2 years. From January 2019 the data for PT2 (swimming water) and the risk assessment based on these data are compulsory. Moreover, the applicants are asked to further investigate the applicability of the present guidance to other human exposure scenarios in PT2 and other PTs and submit data.

4.4. Human health risk assessment

In general the Guidance on the BPR: Volume III Human health, Part B Risk Assessment (active substances) 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 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 which is currently 2.1 (February 2017) and includes all additional agreements as published in the Technical Agreements on Biocides (TAB). The

TAB is available on ECHA's website as well. Various updates of the Guidance are expected in the near future. These updates concerns textual and explicatory changes as well as inclusion of agreements presented.

Instructions for the evaluation of toxicity studies are given 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). 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

Studies are evaluated by using criteria. 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.

Besides the guidances on the BPR and the document with TAB agreements there are also relevant CA documents that should be used for the assessment of the completeness of the dossier and the derivation of endpoints and limit values. A list of 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) . The relevant CA document for the assessment of the completeness of the dossier and the derivation of endpoints and limit values is presented below :

CA-July13-Doc.6.2.b – Final- approach _dermal_absorption.doc

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 Guidance on biocides legislation 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 Ad hoc Working Group – Human Exposure webpage (see ECHA website Ad hoc Working Group - Human exposure).

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 In addition the excel file containing default exposure data for all PTs developed under the BPD 98/8/EC present on the ECHA website can be used in cases where no default exposure data are available (Excel file containing default exposure data).

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 (HEAd-hoc)
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
4. Other Models, e.g., generic models, ConsExpo, RISKOFDERM, etc.

Any deviation from this ranking should be justified.

Besides the guidances on the BPR and the document TAB agreements there are also relevant CA documents that should be used for the risk assessment. A list of 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) . The relevant CA documents for the risk assessment are presented below (documents related to the BPR from 2013-) :

- CA-May16-Doc.5.4.a - Final- User categories of anticoagulant rodenticides about common understanding and adaptation to national situations in case of mutual recognition
- CA-Sept13-Doc.6.2a - Final.Rev1-sensitisers_PPE.doc about authorisation of biocidal products classified as skin sensitisers requiring PPE for non-professional users

Because for a lot of scenarios there are models/default values missing ECHA recently asked KNOELL consultancy to perform a survey helping drafting a practical manual for the exposure assessment of disinfectant active substances and biocidal products for PT1-5. Although the project performed by KNOELL consultancy has been finished the manual is not available yet.

In addition to the technical advices on how to perform the hazard assessment presented in Volume III - Part B&C the working group on Human Health adopted one important document in November 2016. The working Group on Human Health (BPC WG HH) adopted the document "ADI and ARfD derivation for biocidal active substances". The publication date on the ECHA website was 9-12-2016 and Ctgb implemented the document from 9-12-2016.
The document on ADI and ARfD describes that always an ADI and ARfD should be derived if appropriate information is available, unless it is not scientifically justified (e.g. highly reactive substances where no residues are expected). At the moment the ECHA Guidance Vol III Part B&C (2017) describes that only an ADI and ARfD (if necessary) should be derived if residues in food and feed are expected due to the use pattern of a biocidal product.

4.5. Exposure via environmental sources 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.

There are three more specific areas where estimation of risk via exposure needs to be addressed for specific product types and specific guidance is currently under development. It should however be noted that for use scenarios from additional product types (that are not listed below) dietary exposure may be less likely but still has to be considered on a case-by-case basis.

1. Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods Non-professional Uses.
2. Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses.
3. Estimating Livestock Exposure to Biocidal Active Substances

In the WGIII 2016 meeting has been decided that the Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses together with the Guideline on Risk characterisation and assessment of Maximum Residue Limits (MRL) for biocides- EMA/CVMP/90250/2010 already available on the ECHA ad hoc Working Group – Art food webpage (Artfood) and on the EMEA website (Guideline on Risk characterisation and assessment of MRLs for biocides)) respectively should be used for a preliminary assessment of the transfer of biocidal active substance residue into food and feed if relevant and possible. This preliminary assessment could be included as an annex to the CAR, clearly indicating that the assessment is an eCA proposal. The Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses and the Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Product are not yet agreed upon by the Artfood members and cannot be used by an eCA, yet.

As a result, the following provision should be included in section 2.4 of the BPC opinion on a case by case basis: "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 CA documents that should be used for the dietary risk assessment. A list of 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. The relevant CA document for the dietary risk assessment is presented below:

CA-July13-Doc.5.1.i – FCM_Biocides.doc about the regulation of the use of biocides in food contact materials.

5. ENVIRONMENT

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 for which 1.1 (November 2014) is the current version. 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. It is self-evident that the ADS should focus on the information requirements needed for the specific case.

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) are necessary.

5.2. Information requirements for substances of concern

Some biocidal product may contain at least one substance of concern (SoC) regarding the environment, i.e. a co-formulant that triggers the environmental classification (H400, H410, H411, H412, H413 and/or H420) even without the active substance. 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

Guidance on DBPs is agreed at WG I 2016, but not yet adopted at CA level. This means that DBPs at present will not be part of the product authorisation of DBP forming active substances (e.g. reactive chlorinated/brominated substances, and peroxides).

5.4. 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 applicant must apply the most recent version which is currently 1.0 (April 2015) and includes all additional agreements as published in the Technical Agreements on Biocides (TAB). The TAB is available on ECHA's website as well. Various updates of the Guidance are expected in the near future. These updates concerns textual and explicatory changes as well as inclusion of agreements presented.

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. 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 3.1, but it may be expected that version 4.0 will be adopted soon. 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, version 3.1 is included in the EUSES model which can be downloaded here.

The Ctgb assesses environmental risks entirely according to the latest agreed versions of the Guidance, 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 does 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

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