

# Guidance on the Biocidal Products Regulation

## Volume II: Efficacy Part A: Information Requirements

Version 2.0  
May 2018



## **LEGAL NOTICE**

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document

### **Guidance on the Biocidal Products Regulation: Volume II: Efficacy - Part A: Information Requirements**

**Reference:** ECHA-18-G-04-EN  
**Cat. Number:** ED-02-18-532-EN-N  
**ISBN:** 978-92-9020-505-0  
**DoI:** 10.2823/510705  
**Publ. date:** May 2018  
**Language:** EN

© European Chemicals Agency, 2018

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:  
<http://echa.europa.eu/contact>.

### **European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland  
Visiting address: Annankatu 18, Helsinki, Finland

## **DOCUMENT HISTORY**

<b>Version</b>	<b>Comment</b>	<b>Date</b>
Version 1.0	First edition	June 2013
Version 1.1	Corrigendum: <ul style="list-style-type: none"><li>- Division of the guidance in the 4 volumes of the new BPR Guidance structure</li><li>- Minor editorial changes</li></ul>	November 2014
Version 2.0	Update to align Part A with Parts B+C: <ul style="list-style-type: none"><li>• Update to Sections 2 and 3 relating to Point 6 of the Annexes II and III;</li><li>• Addition of sections 2.2 &amp; 3.2 - "Point 7 Intended Uses and Exposure" from Volume I Part A, and subsequent update of these sections.</li></ul> Corrigendum: <ul style="list-style-type: none"><li>• In Preface: To update the text to reflect the changes to the structure of the BPR guidance and to align the text with that in the current published Parts B+C for Volumes II, III and IV;</li><li>• In Preface: to add text and links on "Applicability of Guidance";</li><li>• To amend the formatting and numbering of all sections for clarification and to include cross reference to Annex sections</li></ul>	May 2018

## PREFACE

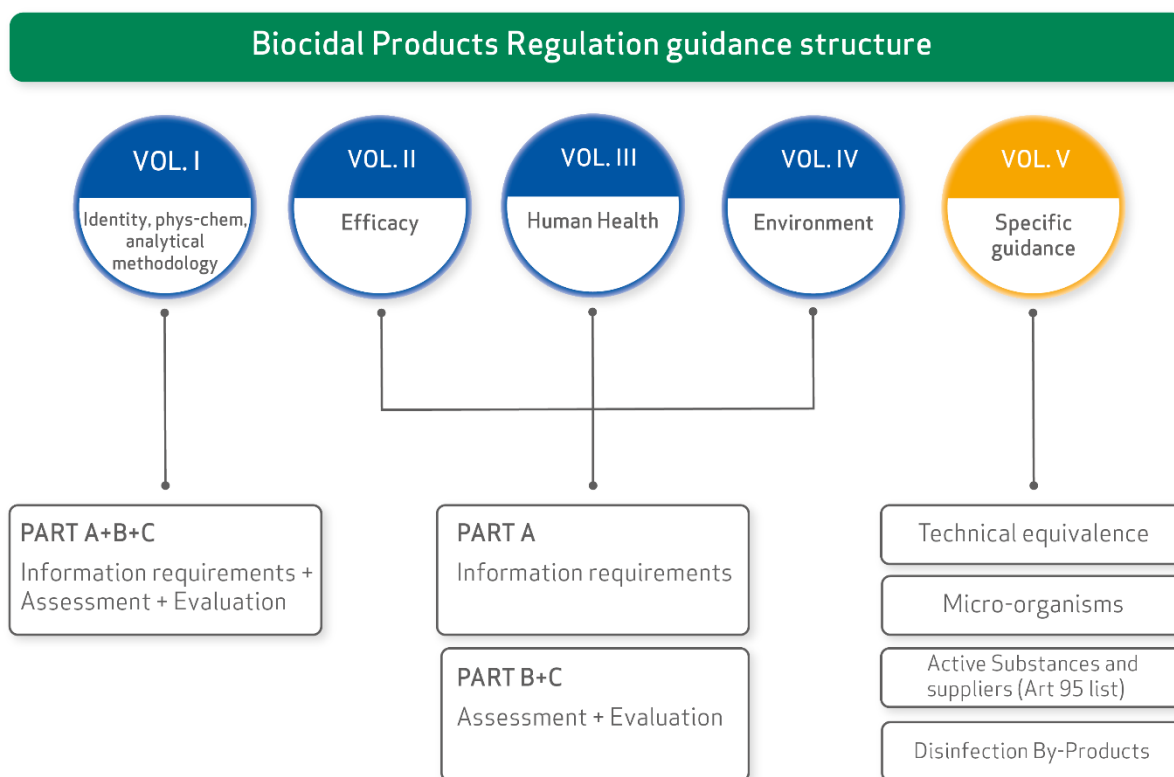
The Guidance on the Biocidal Products Regulation – Part A (information requirements) is to be applied to applications for active substance approval and product authorisation as submitted from 1 September 2013, the date of application (DoA) of the Biocidal Product Regulation (the BPR).

This document describes the BPR obligations and how to fulfil them.

The scientific guidance provides technical scientific advice on how to fulfil the information requirements set by the BPR, how to perform the risk assessment and the exposure assessment for the evaluation of the human health and environmental aspects and how to assess and evaluate the efficacy to establish the benefit arising from the use of biocidal products and that it is sufficiently effective (Parts B & C).

In addition to the BPR guidance, the Biocidal Products Directive (BPD) guidance and other related documents are still considered applicable for new submissions under the BPR in the areas where the BPR guidance is under preparation. Furthermore, these documents are still valid in relation to the applications for active substance approval or applications for product authorisation under the BPD that may still be under evaluation. Also the Commission has addressed some of the obligations in further detail in the Biocides competent authorities meetings documents which applicants are advised to consult. Please see ECHA Biocides Guidance website for links to these documents: [<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>].

The complete guidance series in support of the BPR is shown in the figure below:



**Figure 1: BPR guidance structure**

The BPR guidance was developed based on the Technical Notes for Guidance (TNsG) on data requirements under the previous legislation, the Biocidal Products Directive (BPD). However, the information requirements compared to the BPD have changed in the BPR; the major differences are:

1. The term *information requirement* is used instead of *data requirement*. The new term reflects the fact that applicants do not, in all cases, need to supply data, i.e. information originating from studies but also general information such as addresses and names as well as (quantitative) structure–activity relationship (Q)SAR and so forth.
2. The harmonisation with Guidance from other legal frameworks was a key objective:
  - a. When applicable, endpoint sections entail a reference to a relevant REACH (Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals) Guidance if available;
  - b. When applicable, Guidance from the Plant Protection Products Regulation (PPPR, Regulation (EC) No 1107/2009) – Uniform Principles is referred to.
3. The structure has been modified in accordance with the new BPR Annex structure:
  - a. The core data set (CDS) and additional data set (ADS) are listed in the same section.
  - b. The specific rules for adaptation from standard information requirements (including those given by BPR Annex II and III column 3) are included in the respective endpoint sections, where available.
4. The core data requirements have been modified and certain long term animal studies are only required when necessary.
5. The BPR also allows for a more systematic approach to the adaptation of information requirements based on exposure as well as the use of techniques such as read-across, (Q)SAR and calculation methods.
6. The principle of proposing and accepting adaptations to the information requirements has been formalised and Member States have to inform and, if possible, assist the applicants with their adaptation requests.
7. It is possible to provide a reduced data package on a case-by-case basis when applying for product authorisation, taking into account the nature of the product and the expected level of exposure.

### **Applicability of Guidance**

Guidance on applicability of new guidance or guidance related documents for active substance approval is given in the published document "*Applicability time of new guidance and guidance-related documents in active substance approval*" available on the BPC Webpage<sup>1</sup> [<https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>] and for applicability of guidance for product authorisation, please see the CA-document CA-july2012-doc6.2d (final), available on the ECHA Guidance page

---

<sup>1</sup> Link available under Working Procedures (right column) [<https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>]

[[https://echa.europa.eu/documents/10162/23036409/ca-july12-doc\\_6\\_2d\\_final\\_en.pdf](https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf)].

## Table of Contents

LEGAL NOTICE .....	2
DOCUMENT HISTORY.....	3
PREFACE .....	4
LIST OF ABBREVIATIONS .....	10
1 PART A: INTRODUCTION TO THE GUIDANCE ON INFORMATION REQUIREMENTS ..	12
1.1 GENERAL STRUCTURE OF THE GUIDANCE ON INFORMATION REQUIREMENTS	13
1.1.1 Information requirements in general .....	13
1.1.2 Comparison of BPD-BPR .....	13
1.1.3 Volume II Part A: Document structure .....	15
1.2 GUIDING PRINCIPLES WITH REGARD TO INFORMATION REQUIREMENTS IN	
GENERAL.....	15
1.3 ON THE USE OF ADDITIONAL GUIDANCE DOCUMENTS .....	19
1.3.1 Existing biocides Guidance and other relevant documents.....	19
1.3.2 REACH Guidance .....	19
1.3.3 CLP Guidance.....	19
1.4 GENERAL GUIDANCE ON GENERATING NEW INFORMATION.....	20
1.5 GUIDANCE ON NON-SUBMISSION OF INFORMATION .....	22
1.6 TESTING OF METABOLITES AND TRANSFORMATION PRODUCTS .....	22
1.7 BACKGROUND DOCUMENTS .....	23
1.8 SOURCES OF TEST METHODS AND STANDARDS .....	24
2 PART A: DOSSIER REQUIREMENTS FOR ACTIVE SUBSTANCES.....	26
BPR ANNEX II, TITLE 1, 6 EFFECTIVENESS AGAINST TARGET ORGANISMS .....	26
2.1 POINT 6 EFFECTIVENESS AGAINST TARGET ORGANISMS .....	26
2.1.1 Point 6.1 Function, e.g. fungicide, rodenticide, insecticide, bactericide and	
mode of control e.g. attracting, killing, inhibiting .....	26
2.1.2 Point 6.2 Representative organism(s) to be controlled and products,	
organisms or objects to be protected .....	26
2.1.3 Point 6.3 Effects on representative target organism(s) .....	26
2.1.4 Point 6.4 Likely concentration at which the active substance will be used in	
products and, where appropriate, in treated articles .....	26
2.1.5 Point 6.5 Mode of action (including time delay) .....	26
2.1.6 Point 6.6 Efficacy data to support these claims on biocidal products and,	
were label claims are made, on treated articles .....	27
2.1.7 Point 6.7 Any known limitations on efficacy.....	28
2.1.7.1 Point 6.7.1 Information on the occurrence or possible occurrence	
of the development of resistance and appropriate management	
strategies .....	28
2.1.7.2 Point 6.7.2 Observations on undesirable or unintended side-	
effects, e.g. on beneficial and other non-target organisms .....	29
2.2 POINT 7 INTENDED USES AND EXPOSURE .....	29
2.2.1 Point 7.1 Field of uses envisaged for biocidal products and, where	
appropriate, treated articles.....	29
2.2.2 Point 7.2 Product-type(s) .....	29

---

2.2.3	Point 7.3 Detailed description of the intended use pattern(s) including in treated articles.....	29
2.2.4	Point 7.4 Users, e.g. industrial, trained professional, professional or general public (non-professional) .....	30
2.2.5	Point 7.5 Likely tonnage to be placed on the market per year and, where relevant, for the intended major use categories.....	30
2.2.6	Point 7.6 Exposure data in conformity with Annex VI to this Regulation ..	31
2.2.6.1	Point 7.6.1 Information on human exposure associated with the intended uses and disposal of the active substance.....	31
2.2.6.2	Point 7.6.2 Information on environmental exposure associated with the intended uses and disposal of the active substance .....	31
2.2.6.3	Point 7.6.3 Information on exposure of food producing animals and food and feeding stuffs associated with the intended uses of the active substance.....	31
2.2.6.4	Point 7.6.4 Information on exposure from treated articles including leaching data (either laboratory studies or model data) .....	31
3	PART A: DOSSIER REQUIREMENTS FOR BIOCIDAL PRODUCTS.....	35
	BPR ANNEX III, TITLE 1, 6 EFFECTIVENESS AGAINST TARGET ORGANISMS .....	35
3.1	POINT 6 EFFECTIVENESS AGAINST TARGET ORGANISMS .....	35
3.1.1	Point 6.1 Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting .....	35
3.1.2	Point 6.2 Representative organism(s) to be controlled and products, organisms or objects to be protected .....	35
3.1.3	Point 6.3 Effects on representative target organisms.....	36
3.1.4	Point 6.4 Likely concentration at which the active substance will be used .....	36
3.1.5	Point 6.5 Mode of action (including time delay) .....	36
3.1.6	Point 6.6 The proposed label claims for the product and, where label claims are made, for treated articles.....	37
3.1.7	Point 6.7 Efficacy data to support these claims,.....	37
3.1.8	Point 6.8 Any known limitations on efficacy.....	38
3.1.8.1	Point 6.8.1 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies .....	38
3.1.8.2	Point 6.8.2 Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms .....	39
3.1.9	Point 6.9 Summary and evaluation .....	39
3.2	POINT 7 INTENDED USES AND EXPOSURE.....	39
3.2.1	Point 7.1 Field(s) of use envisaged for biocidal products and, where appropriate, treated articles.....	40
3.2.2	Point 7.2 Product-type .....	40
3.2.3	Point 7.3 Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles .....	40
3.2.4	Point 7.4 User e.g. industrial, trained professional, professional or general public (non-professional) .....	40
3.2.5	Point 7.5 Likely tonnage to be placed on the market per year and where relevant, for different use categories.....	40
3.2.6	Point 7.6 Method of application and a description of this method .....	40
3.2.7	Point 7.7 Application rate and if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes.....	41

3.2.8	Point 7.8 Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human and animal health and the environment .....	41
3.2.9	Point 7.9 Proposed instructions for use .....	42
3.2.10	Point 7.10 Exposure data in conformity with Annex VI of this Regulation .....	42
3.2.10.1	Point 7.10.1 Information on human exposure associated with production and formulation, proposed/expected uses and disposal	42
3.2.10.2	Point 7.10.2 Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal .....	43
3.2.10.3	Point 7.10.3 Information on exposure from treated articles including leaching data (either laboratory studies or model data)..	43
3.2.10.4	Point 7.10.4 Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions.....	43
	REFERENCES AND BACKGROUND DOCUMENTS .....	44
	APPENDIX 1 CHECK LIST FOR EFFICACY TESTS PRESERVATIVES .....	45

## Figures

Figure 1: BPR guidance structure .....	4
Figure 2: Structure of data/information requirements under the BPD and the BPR. ....	14

## Tables

Table 1: Section of Annex II BPR vs BPR Guidance Volume and section number .....	9
Table 2: Section of Annex III BPR vs BPR Guidance Volume and section number .....	9
Table 3 Three-column- structure of BPR information requirements in Annexes II and III of the BPR. ....	14



### **NOTES to the reader:**

When reading this document, please note that the text written in *italics* originates from the BPR or its Annexes.

The numbering of the requirements corresponds to the numbering in the BPR Annexes II and III.

Section Finder: The two tables below relate the sections of the BPR Annexes II and III with the Guidance Volume and section number.



**Table 1: Section of Annex II BPR vs BPR Guidance Volume and section number**

<b>Annex II BPR section</b>	<b>BPR Guidance Volume + section number</b>
1. APPLICANT	Volume I: Section 2.1
2. IDENTITY OF THE ACTIVE SUBSTANCE	Volume I Section 2.2
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES	Volume I Section 2.3
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS	Volume I Section 2.4
5. METHODS OF DETECTION AND IDENTIFICATION	Volume I Section 2.5
6. EFFECTIVENESS AGAINST TARGET ORGANISMS	Volume II: Section 2
7. INTENDED USES AND EXPOSURE	Volume II Section 2.2
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS	Volume III: Section 2.1
9. ECOTOXICOLOGICAL STUDIES	Volume IV: Section 2.1
10. ENVIRONMENTAL FATE AND BEHAVIOUR	Volume IV: Section 2.2
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT	Volume I: Section 2.11
12. CLASSIFICATION, LABELLING, AND PACKAGING	Volume I: Section 2.12

**Table 2: Section of Annex III BPR vs BPR Guidance Volume and section number**

<b>Annex III BPR section</b>	<b>BPR Guidance Volume + section number</b>
1. APPLICANT	Volume I: Section 3.1
2. IDENTITY OF THE BIOCIDAL PRODUCT	Volume I: Section 3.2
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES	Volume I: Section 3.3
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS	Volume I: Section 3.4
5. METHODS OF DETECTION AND IDENTIFICATION	Volume I: Section 3.5
6. EFFECTIVENESS AGAINST TARGET ORGANISMS	Volume II: Section 3.6
7. INTENDED USES AND EXPOSURE	Volume II: Section 3.2
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS	Volume III: Section 3.1
9. ECOTOXICOLOGICAL STUDIES	Volume IV: Section 3.1
10. ENVIRONMENTAL FATE AND BEHAVIOUR	Volume IV: Section 3.2
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT	Volume I: Section 3.11

12. CLASSIFICATION, LABELLING, AND PACKAGING	Volume I: Section 3.12
--	------------------------

## List of Abbreviations

Standard term / Abbreviation	Explanation
(Q)SAR	(Quantitative) structure activity relationship
ADS	Additional data set
ASTM	American Society for Testing and Materials
BPC	Biocidal Products Committee (ECHA body)
BPD	Biocidal Products Directive. Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products
BPR	Biocidal Products Regulation. Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
CAS	Chemical abstract (Service or System)
CDS	Core data set
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytic Council Ltd.
CLP (Regulation)	Classification, Labelling and Packaging Regulation. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of substances and mixtures
DG	European Commission Directorate General
DoA	Date of application
DWD	European Drinking Water Directive (Directive 98/83/EC)
EC	European Communities or European Commission
eCA	Evaluating Competent Authority
EC methods	Test Methods as listed in the Test Methods Regulation
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of (new or notified) Chemical Substances
EN	European norm
EPA (DK, USA)	Environmental Protection Agency (of Denmark, or the United States of America)
EPPO/OEPP	European and Mediterranean Plant Protection Organization
ESD	Emission Scenario Document, Guidance developed under the BPD tailored for biocides
EU	European Union
FPD	Flame photometric detector
g	Gram(s)
GC	Gas chromatography
GLP	Good laboratory practice
ha	Hectare(s)
ISBN	International standard book number
ISO	International Organization for Standardization
ISO (TC, SC, WG)	International Organization for Standardization Technical Committee, Scientific Committee, Working Group
ISSN	International standard serial number
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union for Pure and Applied Chemistry
JRC	Joint Research Centre
kg	Kilogram(s)

**SUPERSEDED GUIDANCE A NEW VERSION IS AVAILABLE**

Standard term / Abbreviation	Explanation
mg	Milligram(s)
MOTA	Manual of Technical Agreements of the Biocides Technical Meeting
MSCA	Member State competent authority
OECD	Organisation for Economic Cooperation and Development
Pa	Pascal(s)
PPPR	Plant Protection Products Regulation. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of concerning the placing of plant protection products on the market
PT	Product-type
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RSD	Relative standard deviation
s	Second(s)
SMEs	Small and medium-sized enterprises
TC	Technical material In accordance with FAO manual (FAO, 2010), TC is usually the final product from preparation of the active substance prior to being formulated into an end-use product. This may contain a stabiliser and/or anti-caking or anti-static agents (if required) but no other additives. TC is usually $\geq 900$ g/kg with solvent(s) removed during synthesis, with only residual amounts remaining (usually $\leq 10\%$ ) and no solvent added subsequently.
Test Methods Regulation	Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation
TGD	Technical Guidance Document (EU, 2003)
TNsG	Technical Notes for Guidance
UN	United Nations
VDI	Verein Deutscher Ingenieure (The Association of German Engineers)
WHO	World Health Organisation

## **1 Part A: Introduction to the Guidance on Information Requirements**

Regulation (EU) No 528/2012 of the European Parliament and of the Council (Biocidal Products Regulation, the BPR) lays down rules and procedures for approval of the active substances in biocidal products at European Union (EU) level and for the authorisation of biocidal products in both Member States and at EU level<sup>2</sup>. The objective of the BPR is to improve the functioning of the internal market on biocidal products whilst ensuring a high level of environmental and both human and animal health protection. In addition, the BPR removes a number of deficiencies that were identified during the implementation of Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products (BPD).

Study data and other information must fulfil the minimum requirements whilst being sufficient to conduct a proper risk and efficacy assessment in order to finally allow for a decision on the suitability of the substance to be approved or, the product to be authorised.

The BPR set out rules on information requirements (especially in Articles 6-8). The information requirements are specified for active substances in Annex II, and for the respective biocidal products in Annex III (in Title 1 of Annex II and III for chemicals and Title 2 of Annex II and III for micro-organisms).

Due to the wide scope of the BPR and the extensive variation of efficacy, exposure and risks of biocidal products, the general rules provided in the BPR and its Annexes have to be specified in order to ensure efficient and harmonised day-to-day implementation of the regulation. The aim of the Guidance is to provide detailed and practical direction on which study data and other information should be submitted, when applying for approval and authorisation according to the BPR. The requirements outlined in this Volume are also applicable for the simplified authorisation procedure, i.e. those products that fulfil all conditions of the requirements listed in Article 25 of the BPR.

It should be noted that only chemical biocidal products (Title 1 of Annex III to the BPR), including treated articles, and chemical active substances (Title 1 of Annex II to the BPR) are covered by the present document. Guidance on the information requirements for micro-organisms will be available separately in Guidance on micro-organisms (Volume V). Guidance on substances of concern will be available in Parts B+C of Volumes III and IV.

Several documents published by the Commission and ECHA have been used as a basis for the information requirements presented; see section 1.3 of the BPR Guidance, Volume I, Part A: Information Requirements.

This Guidance is primarily addressed to applicants, seeking approval of an active substance and for authorisation of a biocidal product, who submit information to the Member State competent authorities (MSCA). The MSCAs task is then to validate and evaluate the application, (adequacy and relevance) of the submitted information.

---

<sup>2</sup> The terms 'EU' or 'Community' used in this document cover the EEA States. The European Economic Area is composed of Iceland, Liechtenstein, Norway and the EU Member States.

## **1.1 General structure of the guidance on information requirements**

### **1.1.1 Information requirements in general**

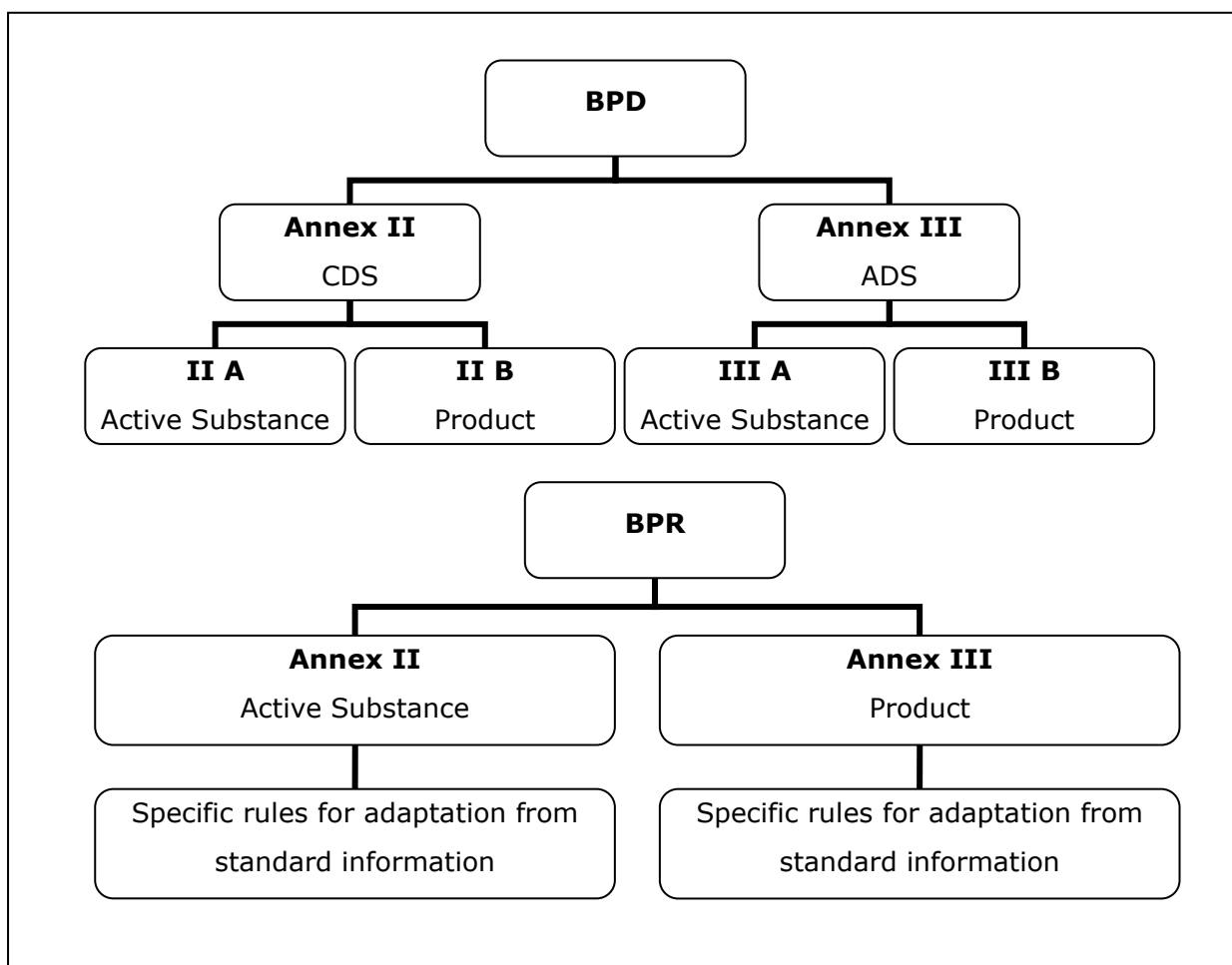
The information requirements as described in the BPR, are two-tiered:

- I. The core data set (CDS) is mandatory for all product-types. This information always has to be submitted, unless the rules for adaptation of standard information are applicable (see below),
- II. The additional data set (ADS) might be required to perform the risk assessment under the following conditions (To Note: ADS is not applicable for Efficacy data requirements):
  - a. ADS information on physical chemical properties, methods of detection and identification and on the toxicological profile is required depending on the intrinsic properties of the active substance or the biocidal product,
  - b. ADS information on the ecotoxicological properties and the environmental fate and behaviour of the active substance or biocidal product is required depending on the product-type, i.e. the foreseen use and route of exposure,
  - c. ADS information on the ecotoxicological properties and the environmental fate and behaviour might be required to refine the initial risk assessment.

### **1.1.2 Comparison of BPD-BPR**

Figure 2 represents a comparison of the structure of the data requirements or information requirements, respectively, under the BPD and under the BPR.

In the BPD legal text as well as in the TNSG on data requirements (EU, 2008a), CDS and ADS are listed in separate Annexes. In contrast, the BPR text lists both CDS and ADS in the same Annexes, but includes an additional column to indicate if the requirement is ADS (see below). In addition, '*specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates*' represent data waiving possibilities and are listed alongside the respective endpoints in Annexes II and III in the BPR.



**Figure 2: Structure of data/information requirements under the BPD and the BPR.**

Unlike the BPD, the information requirements in Annexes II and III of the BPR are listed in three columns:

- column 1 contains the actual requirements,
- column 2 indicates whether it is a CDS or an ADS,
- column 3 contains waiving statements when applicable (see Table 1). General rules for data waiving can be found in Annex IV of the BPR.

**Table 3 Three-column- structure of BPR information requirements in Annexes II and III of the BPR.**

COLUMN 1	COLUMN 2	COLUMN 3
Information requirement	ADS label or no label (for CDS)	Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates.

### **1.1.3 Volume II Part A: Document structure**

This document (Volume II, Part A) includes general information on information requirements (i.e. applicable to all four volumes) and covers the specific information requirements for efficacy.

There are 3 sections:

**Section 1** contains general guiding principles for information requirements which apply (in general) to all four Volumes.

**Section 2** covers CDS information requirements as listed in Title 1 of Annex II, point 6 "Effectiveness against Target Organisms" and point 7 Intended Uses and Exposure (of the BPR). The section explains the BPR requirements for active substances (chemical substances) and contains references to relevant test methods and further guidance. For example, it offers guidance on which test is the most suitable for specific cases. In addition, the section contains the *specific rules for adaptation from standard information*, where applicable. These *waiving* rules are generally accepted, scientifically or technically justified exemptions to the information requirements.

**Section 3** provides CDS information requirements as listed in Title 1 of Annex III, point 6 "Effectiveness against Target Organisms" and point 7 Intended Uses and Exposure (of the BPR). The section explains the BPR requirements for biocidal products (chemical products) and contains references to relevant test methods and further guidance. Similar to Section 2, it also contains references to relevant test methods and explains the Annex III requirements. It also lists the *specific rules for adaptation from standard information*.

## **1.2 Guiding principles with regard to information requirements in general**

The following guiding principles reflect the general guidance on information requirements which apply to all four volumes, as provided in the BPR.

1. **The common core data set (CDS)** forms the basis of the requirements. In general, it is regarded to be a **minimum set** required for all substances and product-types.
2. **The additional data set (ADS)** includes supplementary information requirements. These are indicated in column 2 in the BPR Annexes. This information may be required depending on **the characteristics** of the active substance and/or the product-type and on the expected exposure of humans, animals and the environment. The product's use or application method needs to be taken into account under both the proposed normal use and a possible realistic worst case situation (Article 19(2) of the BPR).
3. **The adaptation of information requirements** outlined throughout this Guidance is possible in certain cases for both CDS and ADS. For example, some of the toxicological information requirements may be adapted occasionally when the exposure is limited or when other product-type-specific factors apply; or for the efficacy for new products with uses, mode of action or application technique that is not covered by the guidance, other efficacy tests than stated in the requirements can be more suitable. Sufficient and acceptable justification needs to be provided for the adaptation. In addition, the inherent physical and chemical properties of the substance or the product may justify waiving of some information requirements. The guidance on General Rules for the Adaptation of the Data Requirements is under development by the Commission and will be made available accordingly. Until then please refer to Chapter 1 Section 1.4 of the TNsG on Data Requirements (EU, 2008a). REACH, Guidance on QSARs and

grouping of chemicals could also be useful *Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals*.

4. The information requirements have been specified in as much detail as possible. However, in certain cases, **expert judgement** by the applicant and by the competent authority (CA) may be necessary in order to assess, for instance, whether an additional study is needed or on which organism or under which conditions a test should be performed. The applicant should propose the initial expert judgement, which is then examined during the evaluation. In making the decision as to whether additional testing is justified, the benefit for the risk assessment (including intended use), the compatibility with accepted risk assessment rationales, and the feasibility of the required tests may have to be considered. When providing an expert judgement one must, when relevant, take into account both the proposed normal use and a possible realistic worst case situation. Expert judgement decisions should be scientifically justified and transparent. In certain cases, the final decision on information requirements is made by the Biocidal Products Committee (BPC). Special attention is required in cases where there are endpoints of concern and clearly defined or standardised methods are lacking. Here, the applicant is obliged to investigate if relevant methods are applicable. New test methods are continuously being developed and it is the applicant's duty to be up-to-date with the state of science regarding test methods.
5. It is always the **applicant who is responsible** for the submission of the data. All data provided in the application must always be supported by study reports, other data or a letter of access. The information submitted by the applicant on both active substances and biocidal products, and also on substances of concern present in the biocidal product must be sufficient for conducting a risk assessment and an efficacy assessment, and decision-making both at EU level and on the level of the individual Member States. The applicant should consult a CA as to which data should be submitted. This will allow for proper risk mitigation measures to be decided upon if an active substance is likely to fail the criteria for entry into the *Union list of approved active substances* or if a product is likely to fail the criteria to be authorised at national or EU level.
6. The data submitted by the applicant will form the basis for classification and labelling according to the CLP Regulation (harmonised classification in case of active substances and self-classification in case of biocidal products). The active substances may be subject to harmonised classification for the first time or the data can be used to review a previous harmonised classification.
7. The data and test requirements should suit the individual circumstances and thus make it possible to assess the risks and efficacy under a range of conditions. The following parameters should be taken into account when preparing the application for authorisation:
  - a. The characteristics of the application technique,
  - b. The user type (e.g. professional or non-professional users), and
  - c. The environment, in which the product is intended to be used or into which the product may be released.
8. Article 62 (1) of the BPR states that *In order to avoid animal testing, **testing on vertebrate animals** for the purposes of this Regulation shall be undertaken **only as a last resort**. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.* Concerning the latter, further detailed rules are provided in Article 62 (2) of the BPR. The data generated and collected under



other legislative regimes, especially under Council Regulation (EU) No 544/2011, Council Regulation (EC) No 1907/2006 and Council Regulation (EC) No 1272/2008 should be used, taking into account the rules on data protection. Sharing of vertebrate data submitted under the BPD or BPR is mandatory.

9. With regard to **data sharing**, for guidance see the ECHA Biocides Guidance webpages and the reference to the REACH Guidance on data sharing established by ECHA (in accordance with Regulation 1907/2006 (REACH) and the Explanatory Note clarifying which chapters are of relevance to the applicants under Biocidal Products Regulation (EU) No528/2012 (BPR), [<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>].
10. For renewal of a product authorisation the applicant must submit **all relevant data required under Article 20 of the BPR, that it has generated since the initial authorisation**. This requirement corresponds to the obligation to submit any new data after the authorisation has been granted (Article 13(2) of the BPR). This only applies to data that were generated by the applicant and not any other data that may be available. For example, if several reports on similar studies are available to the applicant they should all be submitted to allow a more sound risk assessment with, among others, assessment of inter-species variability. An exception to this rule, is for resistance when all available data including a literature search, should be provided. The additional data should be of an acceptable quality (see Annex IV, point 1 of the BPR).
11. Point 8 (a) of Annex VI to the BPR states that for the evaluation of a biocidal product, the evaluating CA *shall take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues*. This means that Member States and other stakeholders should also submit relevant data to the evaluating CA, which is reasonably available to them but which has not been available to the applicant. The applicant is not responsible for this additional information. The applicant, however, is responsible to search for data from all sources which he or she may reasonably be expected to have access to.
12. Public literature data can be used in the assessment if the following conditions are fulfilled:
  - a. The data comply with the BPR Annex II, III introduction points 5-9.
  - b. The identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the substance addressed in the application.
  - c. The reporting of the study allows evaluation of the quality of the study.If conditions a-c are met the applicant can claim that adequate data is publicly available. Providing that the quality of public data fulfils the criteria, it can be used as key studies.
13. There must be at least one key study or an accepted waiving justification for each CDS endpoint given in the BPR Annexes II and III (and for each PT if more than one PT is applied for). The same applies to ADS endpoints in the BPR Annexes II and III, depending on the product-type (in the case of ecotoxicology endpoints and environmental fate and behaviour) and on intrinsic physical-chemical or toxicological properties of the substance or the product, respectively. A key study is the critical study for a certain endpoint and has to be reliable and adequate to use for the risk assessment and efficacy assessment. For criteria on the selection

- of key studies and further information, see Parts B+C of each Volume for Efficacy, Human Health and Environment. A study with a reliability indicator of 3 or 4 cannot be a key study and can be used only as supportive information.
14. When more than one adequate study is available, expert judgement should be used to decide whether mean or median values should be used instead of the result of a single key study. If there is divergent data from acceptable studies, a study summary should be provided for all these studies. The study summary of each study must be presented in the IUCLID file.
  15. It is always possible to require additional information or studies if this is considered to be necessary for a proper risk assessment, efficacy assessment and decision making. The need for additional studies may be justified either by e.g. the properties of the chemical (i.e. hazard) or by the predicted exposure. In Article 8(2) of the BPR it states that *where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly*. In that case, the stop-the-clock rule is applied. Data may also be required for a **substance of concern** present in the biocidal product other than the active substance. Similarly for a **co-formulant**<sup>3</sup> to demonstrate that it cannot be considered an active substance. However, the detailed requirements are left mainly to be judged on a case-by-case basis and if the outcome of the applicant's assessment indicates a need for more data, the applicant should already consider further studies.
  16. Point 11 of Annex VI to the BPR states that *During the process of evaluation, applicants and the evaluating bodies shall **cooperate** in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment*. BPR Specifically SMEs should be allowed extensive guidance from the competent authorities in order to be able to fulfil the obligations laid down in the BPR.
  17. For the approval of the active substance a specification of the active substance will need to be derived. *This specification must be representative for the manufacturing process as well as for the (eco)toxicological batches tested or, in other words, the reference source would be the source for which the (eco)toxicological data submitted cover the specification. Therefore it needs to be ensured that all impurities in the proposed specification are considered in the environmental fate and (eco)toxicological studies (batches used for the environmental fate and (eco)toxicological studies may contain impurities at levels equal or higher than the proposed specifications or it can be justified why some impurities in the proposed specification are not covered by these studies).*

---

<sup>3</sup> For more information see [Technical Agreement for Biocides](https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups) [<https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups>]

## 1.3 On the use of additional Guidance documents

### 1.3.1 Existing biocides Guidance and other relevant documents

Part A for each of the four Volumes of the BPR Guidance replaces the TNSG on Data Requirements in support of the BPD (EU, 2008a).

In addition to the BPR guidance, Biocidal Products Directive (BPD) guidance and other related documents are still considered applicable for new submissions under the BPR in the areas where the BPR guidance is under preparation. Furthermore these documents are still valid in relation to the applications for active substances for Annex I inclusion or applications for product authorisation under the BPD that may still be under evaluation. Also the Commission may have addressed some of the obligations in further detail in the Biocides competent authorities meetings documents which applicants are advised to consult. These documents are available via a "related link" on the ECHA BPR webpage [<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>]

This BPD Guidance and relevant documents should be utilised notwithstanding the references to the BPD and without prejudice to the scientific content. The BPD Guidance and related documents consist of:

- Emission Scenario Documents (ESD) which represent the main guidance to estimate the amount of substances released into the environment,
- Technical Guidance Document (TGD) which forms the basis for the exposure- and risk assessment of both active substances and products,
- Technical Notes for Guidance (TNSG) which deal specifically with biocides and BPD implementation,
- The Manual of Technical Agreements (MOTA) which contains decisions from Biocides Technical Meetings on the technical aspects of the risk assessment (EU, 2011a). The MOTA represents a living document, which is constantly updated. Comments from the MOTA are included in this Guidance where considered appropriate,
- Technical Agreements for Biocides (TAB) which provides the agreements of the Working Groups of the Biocidal Products Committee (WGs) in a concise format,
- EU Evaluation Manual for the Authorisation of Biocidal Products (EU, 2012a).

### 1.3.2 REACH Guidance

In addition, REACH Guidance represents a major guidance source. The REACH Guidance should be taken into account for the evaluation of biocides, where relevant and indicated. The use of REACH Guidance is recommended for a number of endpoints with the intention of facilitating a harmonised approach. ECHA Guidance can be obtained from the ECHA website: <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

### 1.3.3 CLP Guidance

In addition, the Guidance on the Application of the CLP Criteria (ECHA) represents an additional guidance source. This guidance document is a comprehensive technical and scientific document on the application of the CLP Regulation. ECHA Guidance can be obtained from the ECHA website: <https://echa.europa.eu/guidance-documents/guidance-on-clp>.

## 1.4 General guidance on generating new information

If new tests are performed in order to fulfil the data requirements, the following principles have to be followed:

According to point 5 (Methods of Detection) of Annex II and Annex III of the BPR, as a general principle, tests *shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008*. These methods ("EC methods") are based on methods recognised and recommended by international bodies, in particular OECD. In the event of a method being inappropriate or not described, *other methods shall be used which are scientifically appropriate*. Their use needs to be justified. Recommended test methods are listed in the endpoint sections.

According to point 6 (Effectiveness against Target Organisms) of BPR Annexes II and III, tests *'should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU'*.

Furthermore, point 6 of BPR Annexes II and III explains that *'Tests performed should comply with... in the case of ecotoxicological and toxicological tests, good laboratory practice... or other international standards recognised as being equivalent by the Commission or the Agency.'* At the moment there are no "other international standards" considered equivalent to GLP. Ideally, tests are carried out in accordance with Good Laboratory Practice (GLP) or similar quality assurance systems (ISO), although this is not mandatory for efficacy tests.

In addition, point 6 of BPR Annexes II and III declares that *'Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.'* The test methods for the physico-chemical properties are described in the Test Methods Regulation (EC No 440/2008), whereas preferred tests for the purposes of physical hazard classification are referred to in Part 2 of Annex I to CLP Regulation, via references to the UN Recommendations on the Transport and Dangerous Goods, Manual of Test and Criteria, UN-MTC (UN, 2009). The testing according to international standards should be interpreted as testing carried out by laboratories complying with a relevant recognised standard (e.g. ISO/IEC 17025, ISO 9001).

However, most of the methods listed in the Test Methods Regulation *'are developed within the framework of the OECD programme for Testing Guidelines, and should be performed in conformity with the principles of Good Laboratory Practice, in order to ensure as wide as possible 'mutual acceptance of data'*. From 1 January 2014, new tests for physical hazards must be carried out in compliance with a relevant recognised quality system or by laboratories complying with a relevant recognised standard as stipulated by Article 8(5) of the CLP Regulation. Where relevant recognised standards for testing are applicable, the use of the most recent updates is advised, for example the EN and ISO standards.

Where test data exist that have been generated before the DoA of the BPR by methods other than those laid down in the Test Methods Regulation, the adequacy of such data for the purposes of the BPR and the need to conduct new tests according to the Test Methods Regulation must be decided on a case-by-case basis. Amongst other factors, the need to minimise testing on vertebrate animals needs to be taken into account (Article 90(2) of the BPR). Such a decision should first be proposed by the applicant when collecting data for the application and then evaluated by the competent authority when checking the completeness of the application and approving the justification provided for such a case. If a test has been performed, that does not comply with the Test Methods Regulation, the nature of the differences must be indicated and justified. The same applies to deviations from the test protocol used. The test protocol should be provided in full unless there is sufficient detail in the test report.

In certain cases, testing can be replaced by modelling using (Q)SAR, Quantitative Structure Activity Relation. *Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals.*

As a general rule, tests on the active substance should be performed with the substance as manufactured. For some of the physical and chemical properties' tests, a purified form of the substance is being tested, which is indicated by footnote 2 in Annex II column 1 of the BPR, in other cases, the applicant is free to choose between testing on either purified form or the form as manufactured as indicated by footnote 1 in Annex II column 1 of the BPR. The "Active substance as manufactured" is the active substance in its natural state or as obtained by a production process. This includes any additive necessary to preserve the stability of the products and any impurity deriving from the process used. It excludes, however, any solvent which may be separated without affecting the stability of the substance or changing its composition. Furthermore, the identity, purity and the impurities of the substance have to be defined and to be comparable with the substance subject to the application.

In order to implement the three R's, Replacement, Refinement and Reduction of animals in research, the following should be taken into account when planning new tests: If there is an established EC test method or OECD test guideline for a given purpose, for example testing of acute oral toxicity, and in addition one or more alternative methods which may equivalently be used, the test method that requires a lower number of test animals and/or causes less pain should be used. A number of alternative tests either not using test animals or reducing the number of test animals are under development and when endorsed, these tests are preferred when new tests have to be performed.

A substance which is approved as an active substance (included in the *Union list of approved active substances*) should be related to the active compound in the formulation. This means that a case-by-case decision must be taken by the evaluating CA on the name to be given to the active substance. This could be for example simple ions or different molecular structures, precursor/activator, or unstable/breakdown active components, or multiple component products. The specifications of the used material need to be described in detail (point 7 of Annex II to the BPR) i.e. a brief description of the composition for all batches used in tests is needed. Where testing is done using an active substance the material used should be of the same specification as that which would be used in the manufacture of preparations to be authorised except where radio labelled material is used. All batches of a substance or a product used for testing should be representative of typical commercial material for which the approval is applied for and within the production concentration range. If for any test the composition of the substance or product is different from that quoted for commercial material, full details must be provided. Certain exceptions on this general rule are provided in the Guidance. When the long term stability is in doubt, the composition should be determined before testing. Where appropriate, details of the stability of the substance in any vehicle used during testing should also be specified. For certain tests (e.g. some physico-chemical tests) there are specific requirements for purity of the active substance.

In addition, the specific guidance provided in the relevant test guidelines should always be followed. For instance, guidance on when the testing of transformation products instead of the active substance is relevant may be found in the test guidelines concerned.

Some active substances may have characteristics that impede testing or limit the methods that can be used. Substances, which are difficult to test, need special attention (OECD, 2000a). The difficulties may arise from the chemical nature of the substance (e.g. insoluble substances, metals, complex mixtures of chemicals, oxidising substances

or surface active compounds (surfactants)). Further difficulties may be owing to the activity of the substance.

Where studies are conducted using an active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using the active substance as manufactured unless it can be justified that the test material used for the purposes of testing and assessment is technically equivalent. In cases of uncertainty, appropriate bridging studies must be submitted to serve as a basis for a decision on the possible need to repeat studies. The test guidelines usually include guidance on the limitations of the method or give detailed guidance on how the method should be modified when testing chemicals with specific characteristics. Separate Guidance documents may be available for specific testing situations. For instance, Guidance on intermediate compounds has been published *Guidance on intermediates*. The Guidance provided in the Technical Guidance Document concerning risk assessment of new and existing substances Part II (EU, 2003) should also be followed when designing the testing strategy for substances that are difficult to test.

The test results must be reported properly and according to the guidelines used. The study summaries and full study reports of all key studies should be included in the data forwarded to the CA. Relevant analytical raw data should be provided on request. For example, individual data points should be provided in addition to mean values and calibration equations should be provided to allow a suitable evaluation of the study by an assessor.

### **1.5 Guidance on non-submission of information**

The guidance text to be provided in this section is under development by the Commission and will be made available accordingly. Until then please refer to Chapter 1 Section 1.4 of the TNsG on Data Requirements (EU, 2008a).

### **1.6 Testing of metabolites and transformation products**

For the efficacy aspects of metabolites or transformation products, they are included in the test relevant for the use of the active substance and the biocidal product. Metabolites or transformation products should not be tested separately for efficacy.

For the toxicology aspects of metabolites and transformation products, the possibility of the formation of metabolites not investigated by the usual testing must be taken into account. See section on metabolism studies in mammals in Volume III .

For environmental aspects, metabolites relevant for the risk assessment can be distinguished as:

- Major metabolite:
  - formed in amounts of  $\geq 10\%$  of the active substance at any time of the degradation studies under consideration, or
  - the metabolite appears at two consecutive sampling points at amounts  $\geq 5\%$ , or
  - at the end of the study the maximum of formation is not yet reached but accounts for  $\geq 5\%$  of the active substance at the final time point;
- Minor metabolite: all metabolites not meeting the above criteria;
- Ecotoxicologically relevant metabolite: any minor or major metabolite which e.g. poses a comparable or higher hazard than the active substance.

In general, an environmental risk assessment for the relevant compartments needs to be performed for all major metabolites. However, as a first step a semi-quantitative

assessment of these metabolites using the available data and expert judgement to fill data gaps may be sufficient. A quantitative assessment should be performed on a case-by-case basis.

If there is any reason for concern, a risk assessment also needs to be performed for those ecotoxicologically relevant metabolites which are minor metabolites.

## **1.7 Background documents**

### **Legal texts**

For the detailed legal texts (plus amendments and annexes, when applicable) cited in this guidance document and listed below in this section, please visit the eur-lex bibliographic website: <http://eur-lex.europa.eu>. or ECHA website: <http://echa.europa.eu/regulations/biocidal-products-regulation/legislation>

### **Regulations**

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; (*REACH*)

Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); (Test Methods Regulation)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; (CLP Regulation).

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; (PPPR).

Commission Regulation (EU) No 1152/2010 of 8 December 2010 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products; (BPR).

Commission Regulation (EU) No 487/2013 of 8 May 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

**Directives**

Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States.

Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances.

Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market; (BPD).

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption; (The Drinking Water Directive (DWD)). Consolidated version 2009-08-07.

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy; (The EU Water Framework Directive, WFD). Consolidated version 2009-06-25.

Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice; (GLP).

Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances; (GLP).

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration; The Groundwater Directive.

Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council; The Priority Substances Directive.

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

**Decisions**

2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

**1.8 Sources of test methods and standards**

AFNOR Standards can be purchased from the website of AFNOR, the French Institute for Standardisation (<http://www.afnor.org/en/>).

ASTM Standards may be obtained from the American Society of Testing Methods, West Conshohocken, Pennsylvania, USA (<http://www.astm.org>).



BSI Standards can be purchased from the website of BSI, the English Institute for Standardisation (<https://www.bsigroup.com/#>).

CEB Methods can be purchased from the website of AFPP, the French Association for plant protection (<http://www.afpp.net/>).

CIPAC methods may be purchased from the Collaborative International Pesticides Analytical Council (<http://www.cipac.org>).

DIN Standards can be purchased from the website of DIN, the German Institute for Standardisation (<http://www.din.de>).

DVG Standards can be purchased from the website of DVG, the German Veterinary Medical Society (<http://www.desinfektion-dvg.de>).

EC methods are published in the Official Journal of the European Union. The testing methods are described in the Test Methods Regulation (Regulation (EC) No 440/2008). They are regularly updated with new methods introduced as required..

EPPO Guidelines may be obtained from the Secretary of the European and Mediterranean Plant Protection Organisation (EPPO), Paris, France (<http://www.eppo.int/>).

European Standards (CEN standards), transposed as national standards, can be purchased from National Members and Affiliates of the European Committee for Standardisation (CEN). Contact information for CEN National Members and also draft European Standards may be obtained from the CEN Central Secretariat, Brussels, Belgium (<http://www.cen.eu>).

ISO International Standards: orders should be addressed to the ISO member bodies (non-USA users, if subscribing to Internet from a USA-based provider, should consult the ISO member list for ordering ISO standards in their country) which are normally the primary ISO sales agents, or for customers in countries where there is no member body, to the ISO Central Secretariat, Geneva, Switzerland (<http://www.iso.org/iso/store.htm>).

OECD test methods can be obtained directly via their internet address ([http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals\\_chem\\_guide\\_pkg-en](http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en)).

US EPA Office of Prevention, Pesticides, and Toxic Substances Test Guidelines can be obtained from the EPA website (<http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>).

VAH Standards can be purchased from the website of VAH, the German Association for Applied Hygiene (<http://www.mhp-verlag.de/en/home>)

VDI Guidelines can be obtained from the website of VDI, The Association of German Engineers (<http://www.vdi.de>).

WHO guidelines for efficacy testing can be obtained from WHO website (<http://www.who.int/whopes/guidelines/en/>).

## 2 Part A: Dossier Requirements for Active Substances

### BPR Annex II, Title 1, 6 Effectiveness against target organisms



#### **NOTE to the reader:**

The following section headings include a reference to the relevant section/point in the BPR Annex for ease of cross reference.

#### **2.1 Point 6 Effectiveness against target organisms**

Efficacy data are a fundamental component in the regulatory management and decision making process for active substances. Efficacy data are required to establish the benefit arising from the use of the active substance in biocidal products and must be balanced against the risks their use poses to man and the environment.

Approval of an active substance will only be granted according to Art. 4 (1) of the BPR if a representative biocidal product containing the active substance fulfils the minimum requirements in the active substance part of Volume II Parts B+C. Thus, the data provided must show the efficacy of an active substance used in biocidal products or, where such claims are made, in treated articles. The information given according to BPR Annex II point 6 on the effectiveness and intended uses of the active substance must be sufficient to permit an evaluation of the representative biocidal product. It is particularly important that efficacy tests on a representative product reflect the use conditions given for the active substance. When active substances are used in treated articles, use conditions often differ widely. In this case it can be meaningful to reflect different use-conditions by submitting different efficacy tests with the example product. Furthermore, efficacy studies must establish that the concentration of the active substance used for the risk assessment is a relevant and efficacious concentration for the use(s) intended.

The efficacy studies with the representative biocidal product should generally be carried out in accordance with section 3.1 (of this guidance). If the information requirements differ for active substance approval, this is indicated below.

The information must include, for every product type separately.

##### **2.1.1 Point 6.1 Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting**

Please follow guidance in Section 3.1.1.

##### **2.1.2 Point 6.2 Representative organism(s) to be controlled and products, organisms or objects to be protected**

Please follow guidance in Section 3.1.2.

##### **2.1.3 Point 6.3 Effects on representative target organism(s)**

Please follow guidance in Section 3.1.3

##### **2.1.4 Point 6.4 Likely concentration at which the active substance will be used in products and, where appropriate, in treated articles**

Please follow guidance in Section 3.1.4.

##### **2.1.5 Point 6.5 Mode of action (including time delay)**

Please follow guidance in Section 3.1.5.

### **2.1.6 Point 6.6 Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles**

Point 6.6 of Annex II to the BPR refers to " (...) *any available standard protocols, laboratory tests or field trials used including performance standards where appropriate*".

During the review of an active substance at the active substance approval stage, both the efficacy of the active substance itself and of a representative biocidal product containing that active substance are assessed.

Information, in the form of studies or justifications, must be provided to support the requirements set out in sections 3.1.1 to 3.1.5 of this guidance.

The information for the submission of efficacy data given in sections 3.1.6 and 3.1.7 of [this guidance](#) is also relevant for active substance approval. Please note: the SPC mentioned in section 3.1.6 is not relevant for active substance approval. Please provide the information in IUCLID instead.

#### **2.1.6.1 Efficacy of the active substance**

During the active substance approval stage, the efficacy of the active substance itself must be demonstrated.

This is normally done by carrying out testing using the technical active substance, or a simple dilution of the active substance in water or an appropriate matrix. The testing is carried out without other substances present which may affect the efficacy.

The efficacy studies submitted on the active substance should be capable of demonstrating the innate activity of the active substance against representatives of the proposed target organisms at the concentration relevant for the risk assessment.

For that purpose, innate activity of an active substance could be defined as the capacity of an active substance to provide an effect on one or more target organisms relevant to the use being considered.

Generally, efficacy data are generated from laboratory tests, are performed by the applicant. Nevertheless, efficacy data from literature could also be acceptable if the application rate, target organisms, area of use and the identity of the active substance is described and are relevant (for general requirements to be fulfilled by literature see point 12 in section 1.2 of the BPR Guidance Volume I, Part A: Information Requirements). For example, if cited literature is used to support a preserving effect it must also show that untreated test specimens supported growth. When curative effects are claimed the cited literature must demonstrate the efficacy of the active substance according to the requirements per PT. The use of cited literature should be agreed between the applicant and the evaluating CA (eCA) on a case by case basis.

If no efficacy tests with the active substance itself are available, tests carried out with a formulated product may be acceptable where a suitable justification is provided by the applicant addressing the possible influence of co-formulants on the efficacy. If the co-formulants used potentially have biocidal activity, it is essential to demonstrate that the efficacy is due to the active substance and not to the co-formulants, e.g. a test should be performed with all co-formulants but without the active substance.

#### **2.1.6.2 Efficacy of the representative biocidal product at the active substance approval stage**

Although approval for the Union list is primarily concerned with the active substance, efficacy data is also required for a representative product to demonstrate that the active substance is capable of producing an effect on the target organism when included in a formulated product.

Ideally efficacy data on an existing biocidal product should be submitted. If this is not possible, data on a “dummy product<sup>4</sup>” could be acceptable to demonstrate that the active substance is capable of producing an effect on the target organism in a relevant formulation.

As the intention of the evaluation is to demonstrate the efficacy of the active substance in a formulation, it is important that testing, as far as possible, be carried out on a formulation which only contains a single active substance.

Efficacy data packages for formulations containing two or more active substances are not fully suitable for determining the activity contribution from the active substance under evaluation. For that reason great attention should be paid to justify the contribution of the active substance under evaluation to the total efficacy of the product. Information about the mode of action/function of the other active substances present in the product is also requested. For more details please refer to Volume II parts B+C, section 4.3.

The evaluation of the effectiveness of the representative product at the stage of active substance approval is not as detailed as that carried out for product authorisation.

Nevertheless, the level of efficacy (e.g. the kind of activity “curative” or “preventive”) have to be consistent with the uses claimed and fulfil the minimum requirements mentioned in the active substance part (Guidance on the BPR: Volume II, Parts B+C).

### **2.1.6.3 Approval of the active substance**

Where the innate activity of both the active substance and representative biocidal product against the target organisms has been demonstrated, a recommendation can be made for approval of the active substance.

Where the level of activity demonstrated for the representative biocidal product would not normally be considered high enough for a product authorisation, the applicant should justify why the levels of activity noted should be considered acceptable (e.g. where there only is a dummy product containing only the active substance under consideration, or where the active substance will always be used in combination with one or more other active substances).

Where the applicant provides an acceptable justification, approval of the active substance should still be recommended and the efficacy more fully addressed at the product authorisation stage.

It is not necessary to demonstrate efficacy against all of the claimed target organisms at the active substance approval stage. However, approval will only be granted for use against those organisms for which efficacy has been demonstrated. Additional target organisms may be added at product authorisation, but must be supported by suitable efficacy data.

### **2.1.7 Point 6.7 Any known limitations on efficacy**

Please follow guidance in section 3.1.8.

#### **2.1.7.1 Point 6.7.1 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies**

Please follow guidance in section 3.1.8.1.

---

<sup>4</sup> A “dummy product” is a product that is not fully formulated. It is not intended to be placed on the market. For more information please consult section 4.4 of the *Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C)*

### **2.1.7.2 Point 6.7.2 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms**

Please follow guidance in section 3.1.8.2.

## **2.2 Point 7 Intended uses and exposure**

### **2.2.1 Point 7.1 Field of uses envisaged for biocidal products and, where appropriate, treated articles**

The intended and potential use should be indicated together with the fields of use. For active substance evaluation at least one realistic use per PT should be given. Additional uses may be identified and supported at product authorisation stage.

The information on the intended use should be in accordance with the uses presented in section 2.1.1 of this guidance (BPR Point 6.1) and should be sufficient to allow an approximate and realistic estimation of human and environmental exposure to the product or treated article, respectively under conditions reflecting a representative use. Additionally, it should be sufficient to allow an approximate and realistic estimation of the efficacy of the active substance/biocidal product.

The uses intended should be relevant to the product type(s) under consideration.

Uses taking place outside the EU should be disregarded. Any operation carried out with a view to exporting the biocidal product or the treated article outside the EU should also be disregarded.

### **2.2.2 Point 7.2 Product-type(s)**

The intended product-type(s) as listed in Annex V to the BPR should be indicated.

### **2.2.3 Point 7.3 Detailed description of the intended use pattern(s) including in treated articles**

Provide a detailed description of the overall use patterns linked to the fields of use intended. Use means all operations carried out with a biocidal product, including storage, handling, mixing and application.

The information on the intended use in accordance with BPR Point 6.1 (see section 2.1.1 of this guidance) should be sufficient to allow efficacy evaluation and an approximate but realistic estimation of human and environmental exposure to the active substance under realistic worst case conditions and for an evaluation of the use-conditions under which the biocidal product is intended to be used.

The following product-type-specific guidance should be followed if applicable:

- For disinfectants state the area of use e.g. 'surface disinfection in hospitals and other health care institutions', instead of only 'surface disinfection'.
- For material preservatives information on the type of matrices should be given. Furthermore information on ageing, weathering etc. which could limit efficacy should be given.
- For material preservatives of product-types 6, 7, 9, and 10, the different environments in which the material treated with the product is intended to be used should be indicated (e.g. indoors or outdoors, in cattle sheds, preserved material used in contact with drinking water or food storage).

- For product-type 8, the use classes, (as defined in the standard EN 335-1 Durability of wood and wood-based products. Definition of use classes - Part 1: General), in which wood treated with the product is intended to be used should be indicated for wood preservatives. For uses not described in this standard, such as curative or antisapstain products, see also Volume II, Parts B+C: PT 8.
- For product-type 21, in addition to the fields of use, specify also if the product or treated article, respectively, is intended to be used in marine environments, in brackish water and/or in fresh waters. The uses should also distinguish between for example, aqua-culture, buoys and other small static objects, sluice doors, harbour constructions, oil rigs, inlet pipes of cooling water systems, marine sensors, ships' hulls (e.g. deep sea, coastal, inland waterway vessels), etc.
- For treated articles, intended and/or potential uses which show a specific exposure pattern or specific use-conditions should be listed, even if they belong to the same product-type (e.g. use for antimicrobial treatment of underwear, use for treatment of food containers, etc.). If necessary, the applicant should suggest use-categories which include similar exposure patterns, and/or similar use-conditions relevant for efficacy.

#### **2.2.4 Point 7.4 Users, e.g. industrial, trained professional, professional or general public (non-professional)**

Indicate users with the help of the user categories<sup>5</sup> :

- Industrial user: user involved in manufacturing, handling and/or packaging of actives or products at industrial sites (e.g. handling of in-can preservatives);
- Trained professional: professional user using end-products outside industry in the course of their professional activities and have extra-training or certification process (e.g. handling of avicides and piscicides);
- Professional user: professional user using end-products outside industry, but in the course of their professional activities (e.g. handling of preservatives in liquid-cooling and processing systems);
- General public (non-professional user): member of the population or citizen that make a private use of a biocidal product at a workplace or at home (consumer) (e.g. handling of disinfectants for water beds or mosquito repellents).

Users outside the EU should be disregarded.

#### **2.2.5 Point 7.5 Likely tonnage to be placed on the market per year and, where relevant, for the intended major use categories**

An estimate of the quantity of the active substance placed, or to be placed, on the EU market by the applicant (i.e. imported or produced) per year. The quantities for biocidal use and in which product-type(s) should be given, and where relevant for the intended major use categories, within each product-type. The quantities for use other than as a biocide should be indicated, if available. In case of the renewal of approved active substances, tonnage data should cover the last three years. For new substances not previously marketed, production plans covering three years after authorisation should be provided.

---

<sup>5</sup> See also for additional information the Note for guidance (CA-May16-Doc.5.4.a- Final) User categories of anticoagulant rodenticides: common understanding and adaptation to national situations in case of mutual recognition - [/CircaBC/SANTE/BPR - Public/Library/documents finalised](#)

## **2.2.6 Point 7.6 Exposure data in conformity with Annex VI to this Regulation**

The principles of the exposure assessment, as outlined in Annex VI to the BPR on the common principles for the evaluation of dossiers for biocidal products points 32-34, and 45 should be taken into account when assessing the exposure associated with the uses and disposal of an active substance. According to Annex VI, an exposure assessment needs to be carried out for human and environmental populations for which exposure to a biocidal product occurs or can reasonably be foreseen.

For further guidance on exposure assessment on active substances, see Parts B+C - Evaluation and Assessment of Volumes III and IV of the BPR Guidance.

### **2.2.6.1 Point 7.6.1 Information on human exposure associated with the intended uses and disposal of the active substance**

The provided information should be sufficient to allow an approximate but realistic estimation of human (occupational and consumer) exposure associated with the proposed/expected uses and disposal of an active substance. The prediction of the exposure levels should also describe a realistic worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modelling.

### **2.2.6.2 Point 7.6.2 Information on environmental exposure associated with the intended uses and disposal of the active substance**

The provided information should be sufficient to allow an approximate but realistic estimation of environmental exposure associated with the proposed/expected uses and disposal of an active substance. The prediction of the exposure levels in all relevant environmental compartments and respective biota should also describe a realistic worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modelling.

### **2.2.6.3 Point 7.6.3 Information on exposure of food producing animals and food and feeding stuffs associated with the intended uses of the active substance**

To estimate exposure of food producing animals follow the Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (see Volume III Parts B+C Section 6).

### **2.2.6.4 Point 7.6.4 Information on exposure from treated articles including leaching data (either laboratory studies or model data)**

Articles treated with or incorporating biocidal products can lead to consumer and environmental exposure if chemical constituents of the biocidal product are released in any way from these types of articles. Exposure from treated articles during service life may in some situations be the most significant exposure to the active substance (and to substance(s) of concern in the case of product authorisation applications). Specifically, articles consisting of different types of polymers can be used in a large range of consumer applications, which makes the exposure situation very complex. The diversity of applications has consequences both for the exposure of consumers and the environment. For consumers, possible worst case exposure scenarios have to be defined. Then, applications leading to simultaneous consumer exposure within a certain timeframe have to be modelled. For the environment, emissions from uses with similar exposure patterns (e.g. down the drain, direct exposure to soil, etc.) should be summed

up for the respective compartment. When treated articles are imported into the EU, the only possible way to carry out a risk assessment is by active substance evaluation. It is therefore important that the applicant for an active substance approval describes the intended or potential uses in a way as detailed as possible so that the appropriate exposure scenarios can be applied. Here it is noted that the applicant may not always have this detailed knowledge, in particular with regards to treated articles imported into the EU.

The applicant submitting an application for approval of an active substance (or for authorisation of a biocidal product to treat an article) which is intended to be used in biocidal products to treat an article must submit an exposure assessment. The assessment can be based on model calculations with well supported default values and/or measured laboratory leaching values, or based on the results of an exposure study. For several product-types, information on leaching will be required as listed in Volume IV Parts B+C (section 2) on product-type-specific data requirements on the foreseeable route of entry into the environment based on the intended use.

It has to be decided on a case-by-case basis how detailed the exposure assessment has to be: i.e. whether all intended uses in treated articles need to be covered or not. Here a balance has to be found between the ability of the applicant to obtain all the relevant information to carry out a detailed exposure assessment, the requirements for the approval process and the relevance of each use in relation to the foreseen exposure.

The need for additional data needs to be judged on a case-by-case basis. The REACH Guidance on exposure assessment on treated articles (ECHA) is very comprehensive and can be applied in many cases. The OECD Guideline document on how to write emission scenarios for the life-cycle step service life (OECD, 2008a) can also be useful.

#### **2.2.6.4.1 Environment**

Depending on the use, either the tonnage approach or an approach in which leaching rates are determined from the treated article is required for the calculations. If the tonnage approach is not used, information on the likely application rate must be stated for the most relevant uses and modes of application. Generally, a detailed quantitative description of the fields of use intended should be given to allow for a realistic worst-case estimation of environmental exposure of the active substance (or any substances of concern for applications for product authorisation). When using the tonnage approach, it may be necessary to allocate a certain percentage of the overall tonnage to certain uses if such uses have a different exposure profile. Information on the estimated service life time of the treated article and possible reapplications, if relevant, is required.

In general, a tiered approach should be followed for leaching rate determination:

- Tier 1: worst-case assumption where 100% of the active substance (and for product authorisation applications – if present in the biocidal product – the substance(s) of concern). The life time can be different and depends on the product-type and use of the treated article.
- Tier 2: validated laboratory leaching test. The uncertainty of using a laboratory test to predict environmental concentrations should be addressed by using an assessment factor.
- Tier 3: semi-field tests or field studies. The duration of the field- or semi-field study should reflect the exposure situation and enable an extrapolation to the service life of the treated article.

The service life time of an article can be different and depends on the product-type and use of the treated article. For polymers, default values for the life times of different consumer articles are given in the OECD Emission scenario document on plastic additives (OECD, 2009a). For wood preservatives, the service life time of treated timber is defined



by the mode of application and the use classes (OECD, 2009b). Guidance on extrapolation of leaching rates for life time calculations can be found in the Emission Scenario Document for product-type 8 (OECD, 2000b).

For polymers, it has to be taken into account that leaching rates can vary quite significantly depending on the type of polymer (polyethylene leaches less than polyamide), the type of application (incorporation or coating) and of the use (a regularly washed textiles leaches much more than a kitchen worktop). This observation will apply for many other types of treated articles. For wood preservatives, no reliable method exists to predict the leaching rate based on physico-chemical properties and therefore leaching studies are normally required.

For some product-types like e.g. PT 1, 2, 4, 7, 9, and 10, the biocidal product is often added as a premix concentrate to a surface treatment system or a polymer. The surface treatment system or the polymer may subsequently be applied to a surface and/or incorporated into the matrix from which leaching of the active substance(s) (and possibly substances of concern) will take place. As these surfaces/matrices may have many different characteristics, it is important that the applicant submits data for the leaching behaviour of different types of surfaces/matrices which are likely to cover the worst-case leaching behaviour. The emissions during service life are considered to be diffuse emissions that usually cause exposure on a wider scale compared to local emissions. Possible environmental emissions from articles treated with the same active substance and similar exposure patterns should be summed up. Uses within the same exposure pattern can be summarised to simplify the aggregated exposure assessment.

#### Further Guidance:

- ECHA REACH Guidance on information requirements and chemical safety assessment. Chapter R.17: Estimation of exposure from articles (ECHA);
- Guidance note on leaching rate estimations for substances used in biocidal products in PT 07, 09 and 10 (EU, 2010b);
- Workshop on determination of the leaching rate from treated wood to the environment (EU, 2005b);
- OECD Test Guideline 313 Estimation of Emissions from Preservative - Treated Wood to the Environment;
- OECD Series on Testing and Assessment Number 107 Preservative- treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground; ENV/JM/MONO(2009)12 (OECD, 2009b);
- CEN/TS 15119-2 (2012): Durability of wood and wood-based products - Determination of emissions from preservative treated wood to the environment - Part 2: Wooden commodities exposed in Use Class 4 or 5 (in contact with the ground, fresh water or sea water) - Laboratory method;
- CEN/TS 15119-1 (2008): Durability of wood and wood-based products - Determination of emissions from preservative treated wood to the environment - Part 1: Wood held in the storage yard after treatment and wooden commodities exposed in Use Class 3 (not covered, not in contact with the ground) - Laboratory method.

#### **2.2.6.4.2 Human Health**

In a tier 1 exposure estimation, the chemical composition of the article is used to assess whether the total amount of the active substance (or substances of concern in case of product authorisation applications) present in the article may exceed the AEL or

reference value. In a tier 2 assessment, exposure estimations may be refined by data obtained in e.g. leaching tests. Such tests must be conducted in appropriate media (for example, artificial sweat, saliva, etc.). They should also be specific for the intended material (for example type of polymer), use situation (for example mouthing, wearing on the skin), consistency of the article (for example, hard, smooth or porous) and duration of exposure. It is also important to obtain leaching rates during the service life of an article because in many cases articles give a high level of exposure during the first period of use and a lower level of exposure after repeated uses.

A special case of treated articles are food contact materials, which must also undergo a dietary risk assessment (see data requirements in Annex II 8.16 and Annex III 8.8, 8.9 and 8.10). For this, the Guidance listed below is available.

In a real life situation, daily exposure to different articles treated with the same active substance may occur. Consequently, an aggregated exposure assessment may be necessary. Uses with the same exposure pattern can be summarised to simplify the aggregated exposure assessment. If an active substance is used in a large number of different consumer articles, it is likely that a consumer is exposed from multiple uses. To reflect this in an exposure assessment, it may be considered as a first step to compare the acute exposure of single characteristic uses to a chronic AEL value.

#### Further Guidance:

- TNSG on Human Exposure to Biocidal Products (EU, 2007). This document contains some models for exposure scenarios from treated articles in section 2.6.9. For scenarios not covered by the available models, the general principles for secondary exposure assessment in the document should be followed in order to build scenario-specific models;
- Guidance for Food Contact Materials (Commission Regulation (EU) No 10/2011). This regulation defines test conditions for migration studies. The migration studies give amounts of substances in food or per surface area. Consumer exposure is then calculated using the migration results and assuming a 60kg person consuming 1kg of food in contact with 6.0dm<sup>2</sup> FCM in a day. The EFSA Note for Guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation (EFSA, 2008) is currently under revision and should be consulted when finished for current body weight and food intake default values. It should be noted that only plastic materials are covered by the regulation. Other materials should be assessed in line with the principles for plastic materials;

Suitable exposure assessment models for specific scenarios available from other sources may be used for the assessment of treated articles, e.g. a generic risk assessment model for insecticide treatment of mosquito nets and their subsequent use (WHO, 2004).

## **3 Part A: Dossier Requirements for Biocidal Products**

### **BPR Annex III, Title 1, 6 Effectiveness against target organisms**

 **NOTE to the reader:**

The following section headings include a reference to the relevant section/point in the BPR Annex for ease of cross reference.

#### **3.1 Point 6 Effectiveness against target organisms**

Authorisation will only be granted according to Art. 19 (1) b of the BPR if a biocidal product is sufficiently effective. Thus, the data provided must show the efficacy of a biocidal product or, where such claims are made in treated articles. The intended function and the given use conditions must be reflected in the efficacy tests.

The efficacy assessment of a biocidal product is based on substantiating the efficacy claims made for a product. The assessment is made on the product and its instructions and conditions of use.

All requirements regarding efficacy outlined below equally apply also to the simplified authorisation procedure (Article 20(1)(b) of the BPR).

For each product type and use area separately, the following information (sections 3.1.1 to 3.1.9) must be included.

##### **3.1.1 Point 6.1 Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting**

It is often necessary to describe the function of the biocidal product in more detail, particularly if use in treated articles is intended. In many cases it is not sufficient to refer only to terms (e.g. bacteriostatic, fungicidal, attracting) although they provide useful clarification within the overall description. The function should be described in terms of a problem formulation: which problem is caused by the unwanted organism? How does the biocidal treatment prevent or solve the problem? It is hereby often essential to describe the conditions of use and the type of material which is to be protected. Use conditions and materials can often vary greatly and in this case it is necessary to define the use conditions and materials for which the biocidal product is supposed to be effective.

In case of articles where the protection of humans or animals is intended, it is even more crucial to describe the problem and the protection goal to describe the function. This is a necessary precondition to evaluate the efficacy of such treatment.

##### **3.1.2 Point 6.2 Representative organism(s) to be controlled and products, organisms or objects to be protected**

For an organism to be controlled provide both the common name and the scientific name when possible and also the sex, strain and stadia where relevant and appropriate. In cases where groups of organisms are to be controlled, generic names that are representative of the group must be indicated (e.g. bacteria, flying insects, animal fouling).

For groups that are not specifically addressed in BPR Guidance: Volume II (Parts B+C), it may be useful to provide examples of relevant species within the stated group.

If relevant, indicate in which parts of EU the organisms to be controlled exist.

List the products, organisms or objects which are to be protected and against which organisms or group(s) of organisms. Make it clear whether humans or animals must be protected.

### **3.1.3 Point 6.3 Effects on representative target organisms.**

The effects on the target organisms required for the claimed efficacy should be described and specified for each use and method of application if these have different effects. For microorganisms, it needs to be indicated whether the intended effect is biostatic or biocidal for each use.

The dependence of the effect on the concentration of the active substance should be indicated.

### **3.1.4 Point 6.4 Likely concentration at which the active substance will be used**

The likely use concentrations of active substance(s) and applied dose rate of product should be stated for each use and method of application. When a dose range is suggested an explanation should be given when to use the lower or upper limit. It should be indicated and justified if the use concentrations are different in different parts of EU and whether they should be different in different materials, for different use-conditions, etc.

The dose rate used in the efficacy assessment and risk assessment should be consistent. When a dose range is suggested efficacy should be demonstrated at the lower limit.

### **3.1.5 Point 6.5 Mode of action (including time delay)**

The mode of action in terms of the biological, biochemical and physiological mechanisms and biochemical pathways involved should be stated.

Information on time delay should be included, where applicable.

Where it is expected that there is a time delay before the effects start, information should be provided to address this, for example insect growth regulators (e.g. larvicides) that take some time to manifest their effect (e.g. on adult population of flies and mosquitoes). Also conditions that influence on efficacy (of disinfectants or preservatives), like temperature, humidity and other should be added. Where available, the results of experimental studies must be reported.

Where it is known that in order to exert its intended effect the active substance must be converted into a metabolite or degradation product following application or use of a preparation containing it, justification should be submitted for why this metabolite or degradation product is not considered to be the active substance. In addition, available information relating to the formation of reactive metabolites or reaction products must be provided. This information must include:

- The chemical name, empirical and structural formula, molecular mass, and CAS and EC (EINECS, ELINCS or No Longer Polymers list) numbers if available;
- The processes, mechanisms and reactions involved;
- Kinetic and other data concerning the rate of conversion and if known the rate limiting step; and
- Environmental and other factors effecting the rate and extent of conversion.

Indicate also if the actual active substance is the result of a combined action of different products, when such a combination is necessary to achieve the intended effect (i.e. *in situ* generated active substance).

### **3.1.6 Point 6.6 The proposed label claims for the product and, where label claims are made, for treated articles**

The directions for use and the claims made for the biocidal product are included in a summary of the biocidal product characteristics (SPC) in accordance with Article 22(2) (BPR).

A label claim is information which is provided to the user which describes the biocidal effects that will result from using a biocidal product under its normal conditions of use (i.e. when it is used at the recommended dose/application rate, by the recommended application method(s) and in the appropriate areas, etc.). The product label can only include claims that are in line with the authorised uses, as given in the SPC<sup>6</sup>.

Label claims should be as specific as possible, or if more general claims (such as “fast acting”) are made, then they should be further clarified in the PAR where possible (e.g. “fast acting – acts within 5 minutes”). If no clarification is provided, the evaluating Competent Authority should ask the applicant to specify the claim. A judgement as to what a normal user would reasonably expect from the claim should be made. The evaluation should be made according to this claim and the directions for use should be taken into account.

Please also refer to the specific section for the different PTs in Vol II, parts B+C of the efficacy guidance (e.g. Appendix 1 and 4 for disinfectants, chapter 5.5.6.1 for wood preservatives, chapter 5.7.1.1.7 for antifoulings, chapter 5.6.2.4.1 “Norms and criteria” for rodenticides) to understand which requirements and pass criteria apply for certain claims. For preservatives, it needs to be made clear whether the claims refer to curative or preservative effects. Marketing statements that are not related to the biocidal function (e.g. new fragrance, better formula) are not subject to the efficacy evaluation and should not be stated in the product application. The claims demonstrated become part of the products authorisation.

### **3.1.7 Point 6.7 Efficacy data to support these claims,**

Point 6.7 of Annex III to the BPR states that [...] *including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant.*

Volume II, Parts B+C provide further elaboration in this area, including treated articles. Product-type-specific guidance where available can be found in Parts B+C. Applicants are advised to check for the future availability of new guidance.

The applicant must demonstrate that the biocidal product or treated article is effective and suitable for its intended use when applied according to its instructions for use. This can be confirmed by provision of data that may include laboratory studies, simulated-use or semi-field test data or other relevant study data, provided that the test conditions reflect instructed conditions of use.

For field studies the extent of the information required will vary depending on the product-type and proposed use pattern. The data provided should include all appropriate information that is necessary for an evaluation of the reported results. This generally includes information on the harmful organism (e.g. relevance to the Member State in which authorisation is sought) and relevant case-dependent information which can include meteorological parameters (e.g. mean temperatures and rainfall), location

---

<sup>6</sup> See also: European Commission Note for Guidance Linking biocidal label claims and the product authorisation CA-March17-Doc.4.3 – Final

details or physico-chemical parameters of the system in which the biocidal product is used.

For laboratory studies and field studies, practical aspects of designing and performing tests on efficacy are described in the product-specific parts of Parts B+C.

The test method should measure a response and, as appropriate, an endpoint relevant to the label claims. The method should employ an untreated control. However, this may not be always possible for field studies.

Appendix 1 of this guidance provides a check-list for preservatives for the suitability of the planned or submitted test.

Where earlier formulations of the product/treated article or other products/treated articles containing the same active substances are cited as supporting evidence, all relevant formulation details must be provided and the relevance of this evidence to the current formulation must be fully justified, preferably through bridging efficacy studies.

The tests (and data generated) should be based on sound scientific principles and practices. Although GLP is not required for efficacy studies, testing should be carried out in accordance with a relevant quality standard, e.g. ISO 17025<sup>7</sup>, ISO 9001<sup>8</sup> or GLP . More detailed guidance on appropriate test methods is provided in Volume II Parts B+C .

### **3.1.8 Point 6.8 Any known limitations on efficacy**

Provide possible restrictions or recommendations concerning the use of the product in specific environmental or other conditions. State possible factors that can reduce the efficacy, for instance hot, cold or humid environments or the presence of other substances, in addition to the reasons for these. State if the product cannot be mixed or used consecutively with, for example, other biocidal products or detergents, or if the use of the product with other biocidal products is recommended.

#### **3.1.8.1 Point 6.8.1 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies**

Provide information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies, including also cross-resistance. This information must be submitted even where it is not directly relevant to the uses for which authorisation is sought or to be renewed (e.g. different species of harmful organism), as it may provide an indication of the likelihood of resistance development in the target population.

Where there is evidence or information to suggest that in commercial or experimental use the development of resistance is likely, evidence must be generated and submitted as to the sensitivity to the substance on the part of the populations of the harmful organism concerned. In such cases a management strategy designed to minimise the likelihood of resistance or cross-resistance developing in target species must be provided. This should include possible recommendations concerning the avoidance of the continuous use of the product to prevent the development of resistant strains in addition to the reasons for these. It may be acceptable to make a reference to the CAR, however if more recent or relevant information on the product is available this should be

---

<sup>7</sup> General requirements for the competence of testing and calibration laboratories

<sup>8</sup> Quality management systems – requirements.

provided. This is addressed in the TNSG on product evaluation (EU, 2008c) Appendix 6.2<sup>9</sup>.

### **3.1.8.2 Point 6.8.2 Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms**

Provide observations on undesirable or unintended side effects. Provide observations such as on adverse reaction to fastenings and fittings used in wood following the application of a wood preservative, corrosion risk on sanitary fittings following application of disinfectants, etc. Provide information on effects on beneficial and other non-target organisms, only as far as this is not covered under Volume IV Sections 2 and 3.

Provide information on unnecessary suffering and pain for target vertebrates, where relevant (PT14, 15, 17, 19, 20).

### **3.1.9 Point 6.9 Summary and evaluation**

The findings on the effectiveness against target organisms (BPR Annex III, Title 1, 6.1-6.8.2) are summarised and evaluated. Describe how the provided tests demonstrate the efficacy against all the target organisms at the use concentration and use conditions instructed (e.g. application method, contact time).

When authorisation is sought for a product family the evaluation should be done per *meta* SPC, not per product.

## **3.2 Point 7 Intended uses and exposure**

The SPC (Summary of the Biocidal Product Characteristics) is the summary document for the biocidal product which contains administrative information, information of product classification and labelling, authorised uses and direction for use. An example of the label and instruction for use must be provided for each application for product authorisation<sup>10,11</sup>. The information indicated on the label, instructions for use<sup>12</sup> and other information sources (e.g. web pages) should be consistent with the information in the SPC.

Based on the conclusions of the efficacy assessment the following information should be included in the Section 4 Authorised uses of the draft SPC: any uses of a biocidal product, which clearly describe the target organism(s), field(s) of use, application method(s), application rate(s), application conditions where relevant (e.g. use under high soiling, at 4°C) and frequency and category(ies) of users. Instructions for use should be given which can be use specific, meta- SPC specific, or general for the whole SPC.

Considering the exposure and risk assessment the draft SPC also includes all risk mitigation measures which should be considered for relevant use of product, particularly of likely direct or indirect effects, resistance, first aid instructions and emergency

---

<sup>9</sup> See "related link" on the ECHA BPR webpage [<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>]

<sup>10</sup> Label(s) must be provided in accordance with Annex III, Section 12 of BPR. Please note that at the same time the biocidal product labels are not part of the product authorisation.

<sup>11</sup> See also Note for guidance (CA-Nov15-Doc.4.2- Final) Submission of example labels, instructions for use, safety data sheets and models or drafts of the packaging, labelling and leaflets within an application for product authorisation - [/CircaBC/SANTE/BPR - Public/Library/documents finalised](#)

<sup>12</sup> Article 69(2) of BPR.

measures to protect environment, also instructions for safe disposal of the product and its packaging and conditions of storage of the product. These instructions should be given which can be use specific, meta- SPC specific, or general for the whole SPC.

### **3.2.1 Point 7.1 Field(s) of use envisaged for biocidal products and, where appropriate, treated articles**

Please follow guidance in section 2.2.1 of this guidance.

### **3.2.2 Point 7.2 Product-type**

Please follow guidance in section 2.2.2 of this guidance.

### **3.2.3 Point 7.3 Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles**

Please follow guidance in section 2.2.3 of this guidance.

### **3.2.4 Point 7.4 User e.g. industrial, trained professional, professional or general public (non-professional)**

Please follow guidance in section 2.2.4 of this guidance.

The description of the user on the authorised label might be different from the user categories described under BPR Point 7.4, due to the national policy and laws.

### **3.2.5 Point 7.5 Likely tonnage to be placed on the market per year and where relevant, for different use categories**

An estimate of the quantity of the product or treated article, respectively, placed or to be placed on the EU market by the applicant (i.e. imported or produced) per year. The quantities for biocidal use and in which product-types, and where relevant, for the intended major use categories within each of the product-types. The quantities for use other than as a biocide should be indicated, if available. In case of the renewal of authorisation, tonnage data should cover the last three years. For new products, not previously marketed, production plans covering the next three years after authorisation should be provided.

Where relevant, this information can be added to the confidential annex of the application.

### **3.2.6 Point 7.6 Method of application and a description of this method**

The method of application of product in different uses should be explained. If the product is to be diluted, this should be stated and recommendations on how to do this should be given (e.g. 3 gram product per 5 litre water). A description of the application technique (e.g. dipping, spreading, spraying, automatic/manual dosing etc.) should be included. If additional substances have to be added to the solution, their dosages must also be given.

If specific technical device will be used together with the product, a description of this device should be provided.

If a device is used to produce the active substance *in situ* and dose it directly, information should be provided on control and safety measures to avoid over and under dosing.



The devices used to generate the active substance *in situ* themselves are not covered by the provision of BPR and consequently are not subject to the authorisation.

### **3.2.7 Point 7.7 Application rate and if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes.**

The recommended dose of the product and the active substance per object should be stated (e.g. per surface area of the material to be protected or as a concentration in a water system).

For disinfectants applied in order to disinfect surfaces, information on the amount of product applied per m<sup>2</sup> should be provided. If the product is to be diluted, the substance used for dilution and the final concentration of the product as well as the active substance in the solution - as a percentage - must be stated.

For product-type 21, the final concentrations of each biocidal component in the antifouling coating layer of the antifouling product and in addition the thickness of the film should also be given.

### **3.2.8 Point 7.8 Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human and animal health and the environment**

Indicate the recommended duration of application and possible re-applications including estimated life-time of the treated article if relevant.

Describe, where relevant, how the applications should differ in different parts of the EU or under otherwise differing use-conditions.

The following product-type-specific guidance should be followed if applicable:

- For disinfectants of Main Group 1, potential information on effects of temperature and humidity on the frequency of application must be supplied where relevant. The contact time needed to provide sufficient efficacy should be stated. The waiting period and, if applicable, the necessity of rinsing or wiping to avoid the presence of unacceptable residues from treated equipment in food or feed products should be given.
- For material preservatives of product-types 6, and 7 to 10, instructions on the minimum drying time or time to reach resistance to leaching (fixation) of the product in the material treated has to be described. Information on the effects of e.g. temperature and humidity on drying or fixation has to be given, i.e. when the treated material is dry enough for safe exposure of humans and the environment. Furthermore, when possible, a qualitative or quantitative method should be stated for determining that the proper drying or resistance to leaching has been achieved.
- For product-types 11 and 12, when used in an open system with process water, information on the minimum dilution or treatment time for the active substance in waste water should be given in order to assure a sufficient degree of degradation

or dilution before it is released to a water course to protect aquatic organisms from harmful effects.

- For pest control products of Main Group 3, for products used in e.g. fumigation, clearance times sufficient to protect bystanders etc. should be given.
- For molluscicides (product-type 16) and piscicides (product-type 17), necessary waiting periods should be given to prevent harm or dislodging of unacceptable residues from treated tanks or basins for e.g. the subsequent batch of aquaculture.
- For product-type 21, instructions on the minimum drying time of the coating and information on the effects of for instance, temperature and humidity on drying have to be given, i.e. it should be indicated when the coating is dry enough to be ready for launching and whether the coating should be washed before launching in order to reduce the primary release into the aquatic environment. Furthermore, a method for ensuring that a proper coating has been achieved should be given.

### **3.2.9 Point 7.9 Proposed instructions for use**

Any instructions for the end user for proper use of the product should be given here.

The applicant should consider and define the parameters necessary for the effective use of the biocidal product, for example where this is relevant for the respective product:

- The methods by which the biocidal product is employed (for example: spray, wipe, disperse);
- The areas where the product should be applied (e.g. insecticide under refrigerator, in the cracks and crevice, with a bandwidth of 20 cm);
- The necessary preparatory measures, e.g. clean surfaces;
- The time that the biocidal product should be allowed to be in contact with the target (for example: minutes, hours, days);
- The frequency of application or re-application;
- The temperature range within which the biocidal product should be used;
- The dose rate;
- The necessary precautionary measures.

### **3.2.10 Point 7.10 Exposure data in conformity with Annex VI of this Regulation**

According to Annex VI on the common principles for the evaluation of dossiers for biocidal products, an exposure assessment needs to be carried out for human and environmental populations for which exposure to a biocidal product occurs or can reasonably be foreseen.

For further guidance on exposure assessment of biocidal products see Parts B+C Evaluation and Assessment of Volumes III and IV of the BPR Guidance.

#### **3.2.10.1 Point 7.10.1 Information on human exposure associated with production and formulation, proposed/expected uses and disposal**

Sufficient information on exposure to the biocidal product likely to occur during the proposed conditions of use must be submitted. The information should include all relevant stages of production and formulation and of use and all possible exposure routes. Actual exposure data and/or calculations using recommended models are

acceptable. Test reports of any studies conducted because an exposure of the biocidal product on humans through the particular route is possible must be submitted. An expert judgment is needed to decide if any other studies are required (see section 1.2, point 4 of the BPR Guidance, Volume I, Part A: Information Requirements). A starting point is assessment of human exposures to biocides, see BPR Guidance, Volume III Human Health Parts B+C.

Please also follow guidance in section 2.2.6.1 of this guidance.

**3.2.10.2 Point 7.10.2 Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal**

Please follow guidance in section 2.2.6.2 of this guidance.

**3.2.10.3 Point 7.10.3 Information on exposure from treated articles including leaching data (either laboratory studies or model data)**

Please follow guidance in section 2.2.6.4 of this guidance.

**3.2.10.4 Point 7.10.4 Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions**

Possible incompatibility with any products or active substances should be mentioned.

## REFERENCES AND BACKGROUND DOCUMENTS

- ECHA. (n.d.). *Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals.*
- ECHA. (n.d.). *Guidance on intermediates.*
- ECHA. (n.d.). *Guidance on the application of the CLP criteria.*
- EU. (2003). *Technical Guidance Document (TGD) on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the.*
- EU. (2008a). *Technical Guidance Document in support of the of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on Data Requirements for active substances and biocidal products. Short title: TNsG Data Requirements.*
- EU. (2008b). *The Technical Notes for Guidance on Dossier preparation including preparation and evaluation of study summaries under Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market. Short title: TNsG on Dossier Preparation of Dossiers and St.*
- EU. (2008c). *TNsG on product evaluation.*
- EU. (2009b). *Technical Notes for Guidance on Product Evaluation Appendices to Chapter 7 Product Type 14 Efficacy Evaluation of Rodenticidal Biocidal Products.*
- EU. (2011a). *Manual of Technical Agreements of the Biocides Technical Meeting (MOTA). Version 4.*
- EU. (2012a). *Technical Notes Guidance EU Evaluation Manual for the Authorisation of Biocidal Products. Short title: Evaluation manual.*
- EU. (2012b). *TNsG on Products Evaluation. (Revised Appendix to Chapter 7) Guidance Efficacy Evaluation of Insecticides PT 18 and 19. Ca-Dec12-Doc 6.a.) <https://circabc.europa.eu/w/browse/9f8f7f60-764b-4833-9989-a3b6d687dcc6>.*
- FAO. (2010). *Manual on the Development and Use of FAO and WHO Specifications for Pesticides, second revision.*
- OECD. (2000a). *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. Series on Testing and Assessment, No 23.*
- OECD. (2007b). *Analysis and Assessment of Current Protocols to Develop Harmonized Test Methods and Performance Standards for the Efficacy Testing of Treated Articles/Treated Materials. ENV/JM/MONO(2007)4.*
- OECD. (2008d). *Guidance document on the evaluation of the efficacy of antimicrobial treated articles with claims for external effects, ENV/JM/MONO(2008)27.*
- OECD. (2012b). *Guidance document for demonstrating efficacy of pools and spa disinfectants in laboratory and field testing. Series on Testing and Assessment No 170. Series on Biocides No 4. ENV/JM/MONO(2012)15.*
- UN. (2009). *Recommendations on the Transport of Dangerous Goods. Manual of Tests and Criteria. ST/SG/AC.10/11/Rev.5. (UN-MTC). New York and Geneva.*

## Appendix 1 Check list for efficacy tests preservatives

Question	Possible answers	Test not acceptable if
Is the identity of the tested BP clear?	+ or -	-
Is the tested product the reference BP/the BP applied for?	+ or -	Usually not if -
Is the tested material relevant for the intended PT and use? <sup>1</sup>	Written justification	Expert judgement
Is the loading/ concentration of the active substance in its matrix ≤ what is stated in the use descriptions?	+ or -	-
Is the test-protocol used relevant for the function of the representative BP/the BP applied for?	Written justification	Expert judgement
Are the tested organisms relevant for the intended use? <sup>2</sup>	+ or -	-
Is the test protocol depicting a relevant end point? <sup>3</sup>	+ or -	-
Have untreated controls been tested? <sup>4</sup>	+ or -	-
Have the controls (i.e. growth) been validated according to a relevant guidance or standard document?	Quantification	Expert judgement
Has the intended inhibition/killing/controlling effect of the harmful organisms occurred and does it fulfil the requirements set by a relevant guidance or standard document?	+ or -	-
Has statistical significance of the results been calculated? <sup>5</sup>	+ or -	-

<sup>1</sup>i.e. the material becomes deteriorated by microbial growth under the given use conditions

<sup>2</sup>i.e. in which way do they deteriorate the matrix?

<sup>3</sup>i.e. in preventive use: inhibition of deterioration by harmful organisms; in curative use: killing/controlling effect of harmful organisms

<sup>4</sup>Untreated controls including: the same material, the same product formulation without the active substance

<sup>5</sup> Where statistical analysis is possible, as a minimum, a mean and standard deviation should be given. If applicable, statistical calculations can be done according to Annex V of IBRG ([www.ibrg.org](http://www.ibrg.org)) PDG16-007.2 Tier 1 Basic efficacy for biocidal Active Substances used to preserve Aqueous based products.

ANNANKATU 18, P.O. BOX 400,  
FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU