GUIDANCE

Guidance on the Biocidal Products Regulation

Volume II: Efficacy
Part A: Information Requirements

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LEGAL NOTICE

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

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1 # DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	June 2013
Version 1.1	Corrigendum: - Division of the guidance in the 4 volumes of the new BPR Guidance structure - Minor editorial changes	November 2014
Version 2.0	Update to align Part A with Parts B+C: • Update to Sections 2 and 3 relating to Point 6 of the Annexes II and III Corrigendum: • 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; • In Preface: to add text and links on "Applicability of Guidance"; • To amend the formatting and numbering of all sections for clarification and to include cross reference to Annex sections	Xxxxxx 2018

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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 asses 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:

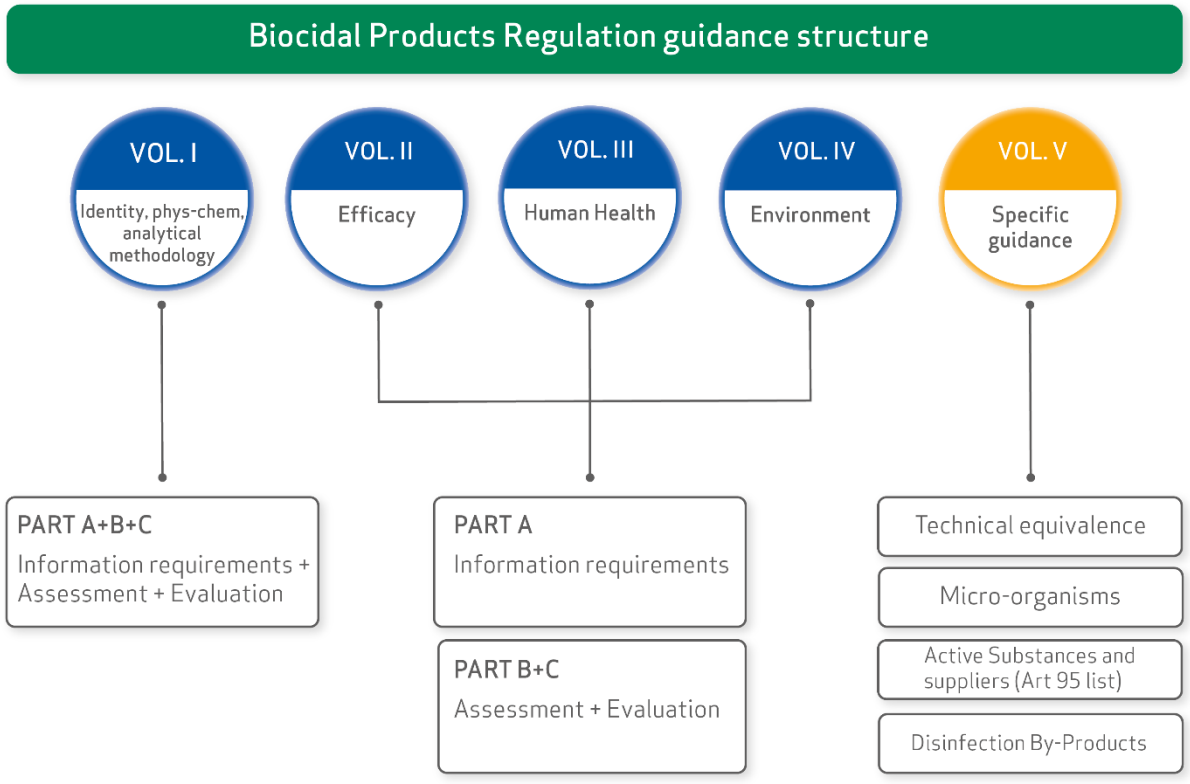

Figure 1: BPR guidance structure

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[1] [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 [https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf].

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

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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 Volume and section number

Annex II BPR section	BPR Volume + section number
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

Annex II BPR section	BPR Volume + section number
6. EFFECTIVENESS AGAINST TARGET ORGANISMS	Volume II: Section 2
7. INTENDED USES AND EXPOSURE	Volume I Section 2.7
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 Volume and section number

Annex III BPR section	BPR Volume + section number
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 I: Section 3.1
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS	Volume III: Section 3.1
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12. CLASSIFICATION, LABELLING, AND PACKAGING	Volume I: Section 3.12

1 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
EC method	Test Method 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

Standard term / Abbreviation	Explanation
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)
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 PT	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 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 ≥900 g/kg with solvent(s) removed during synthesis, with only residual amounts remaining (usually ≤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

NOTE FOR PEG CONSULTATION

Section 1 is common to all four volumes and the proposed revisions are to clarify text in relation to efficacy: this section is not specific to efficacy only and therefore includes general information that applies to all four volumes.

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[2]. 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.

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.

[2] 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.

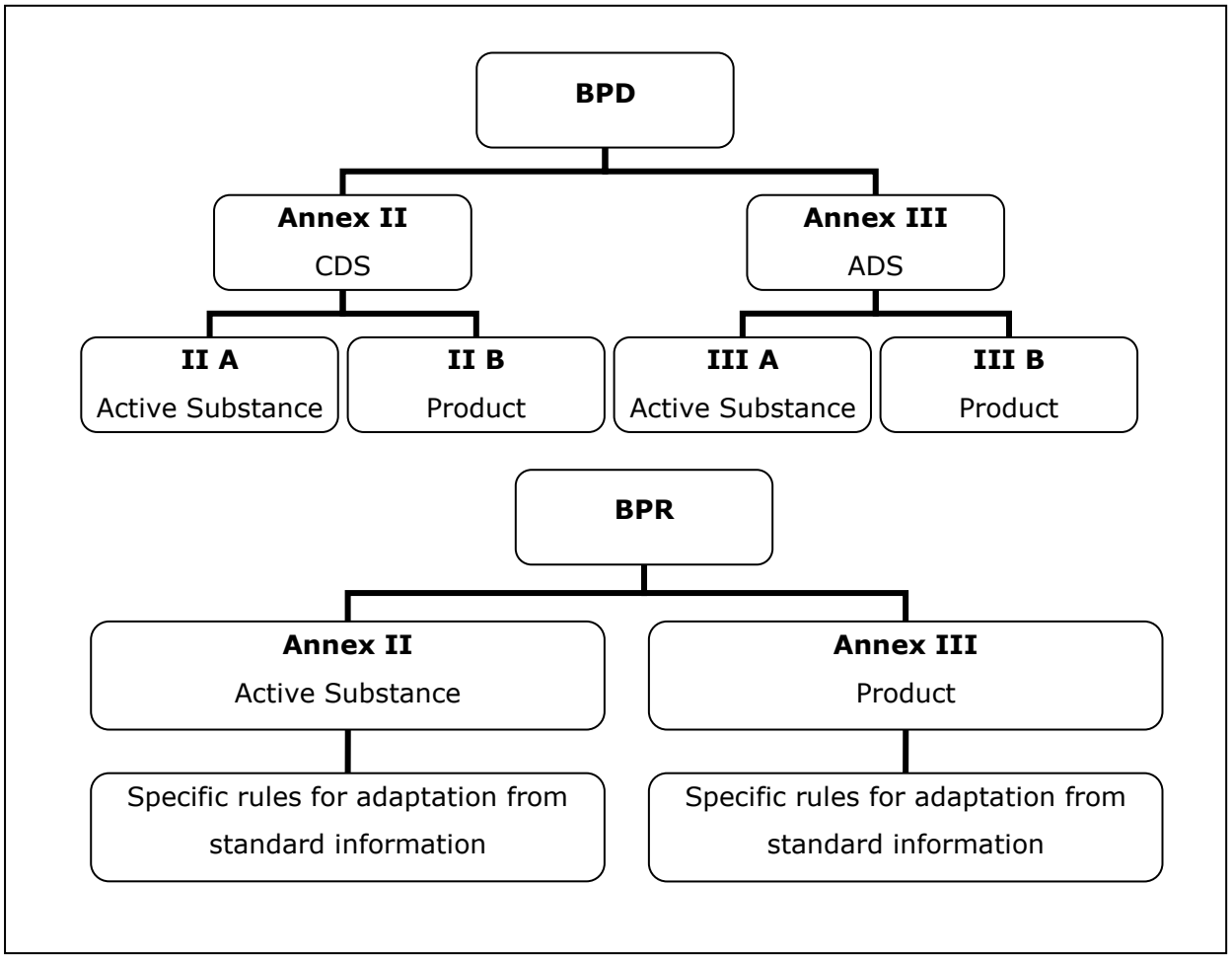

Figure 2: Structure of data/information requirements under the BPD and the BPR.

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" (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" (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 (ECHA, Guidance on information requirements and

chemical safety assessment Chapter R.6: QSARs and grouping of chemicals) could also be useful.

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 relevant data, 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 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** [3]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).

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).

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

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 document 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.
- 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.

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. ECHA Guidance on (Q)SARs and grouping of chemicals is available on the ECHA website.

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 (ECHA). 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 accordingly. Until then please refer to Chapter 1 Section 1.4 of the TNsG on Data Requirements (EU, 2008a).

NOTE TO PEG: the text above is under review and will be updated during the PEG consultation.

1.6 Testing of metabolites and transformation products

For the efficacy aspects when metabolites or transformation products are formed, 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 ≥ 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 ≥ 5%, or
  - at the end of the study the maximum of formation is not yet reached but accounts for ≥ 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

NOTE FOR PEG CONSULTATION

The list will be checked and updated and any documents not referenced in the Part A documents will be deleted: this will be done at the end of the consultation.

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 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; (DSD, Dangerous Substances Directive).

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 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; (DPD, Dangerous Preparations Directive).

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).

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 purchases 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 is sufficiently effective. Thus, the data provided shall 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 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.x (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

Provide follow guidance in Section 3.x.

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.x.

2.1.3 Point 6.3 Effects on representative target organism(s)

Please follow guidance in Section 3.x

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.x.

2.1.5 Point 6.5 Mode of action (including time delay)

Please follow guidance in Section 3.x.

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

Point 6.6 of Annex II to the BPR states that [….] ……. *including 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 6.1 to 6.5.

The guidance given in Chapter III Sections 6.6 and 6.7 for the submission of efficacy data is also relevant to this chapter. Please note: the SPC mentioned in Chapter III Section 6.6 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. This is so that 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 a sufficient effect on one or more target organisms relevant to the use being considered.

Generally, efficacy data are generated from laboratory tests, 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. 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 evaluation 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 in order to demonstrate that the active substance is capable of producing an effect on the target 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 could be acceptable to demonstrate that the active substance is capable of producing an effect on the target organism in a relevant matrix.

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

Where studies are submitted on formulations containing multiple active substances, *these will not be considered suitable to demonstrate the efficacy of the active substance under consideration*, as it is not possible to determine the contribution of that substance alone to the overall efficacy.

This principle also applies to cases where it is intended that the active substance will always be used in combination with one or more additional substances. 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 "biocidal" or "biostatic") have to be consistent with the uses claimed and fulfil the minimum requirements mentioned in the active substance part (parts II 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 is a dummy product containing only the active substance under consideration, but 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, where they are supported by suitable efficacy data.

2.1.7 Point 6.7 Any known limitations on efficacy

Please follow guidance in Section 3.x.

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.x.

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.x.

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 in its realistic worst case conditions of its instructed use.

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

The information must include, for every product type separately.

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 this case it is not sufficient to refer to terms as bacteriostatic, attracting, etc. The function should be described in terms of a problem formulation: in which way is the article damaged or deteriorated? How does the biocidal treatment protect it from such damage? 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).

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 shall be protected. For material protection, describe the character of the damage caused by the organisms.

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 static or cidal for each use.

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

For vertebrate target organisms information on humaneness of the treatment should be provided in this section.

3.1.4 Point 6.14 Likely concentration at which the active substance will be used

The likely use concentrations of active(s) 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 available, the results of experimental studies must be reported.

Where it is expected there is a time delay before the start of the effects, information should be provided on 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 (i.e. when such a combination is necessary to achieve the intended effect).

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 (e.g. 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[4].

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 on the label 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. 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, pilot plant or field test data or other relevant study data, provided that the test conditions reflect relevant and realistic (worst case) conditions within the intended 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, as relevant and appropriate, information on the harmful organism (e.g. relevance to the Member State in which authorisation is sought), meteorological parameters (e.g. mean temperatures and rainfall) and location details.

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

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[4] See also: European Commission Note for Guidance Linking biocidal label claims and the product authorisation CA-March17-Doc.4.3 – Final

The test method should measure a response and, as appropriate, an endpoint relevant to the label claims. The method should employ an untreated control The efficacy test reports should contain dose response data for dose rates lower than the recommended rate. However, this may not be always possible for field studies.

In Appendix 1 , check-lists are provided 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[5], ISO 9001[6] 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 grounds for these. State if the product cannot be mixed with, for example, other biocidal products 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 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 in order to prevent the development of resistant strains and the grounds for these. It may be acceptable to reference the CAR, however if more recent or relevant information on the product is available this should be provided. This is addressed in the TNsG on product evaluation (EU, 2008c) Appendix 6.2[7].

[5] General requirements for the competence of testing and calibration laboratories

[6] Quality management systems – requirements.

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

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, 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 (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.

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 Evalation. (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 demostrating 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

NOTE FOR PEG CONSULTATION

TO BE DISCUSSED/DECIDED: proposal to include this Appendix or to add as a reference with a link to a document published separately on ECHA BPR Efficacy WG website

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?[1]	Verbal explanation	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?	Verbal explanation	Expert judgement
Are the tested organisms relevant for the intended use? [2]	+ or -	
Is the test protocol depicting a relevant end point?[3]	+ or -	-
Have untreated controls been tested?[4]	+ 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[5]	+ or -	-

[1]i.e. the material becomes deteriorated by microbial growth under the given use conditions

[2]i.e. in which way do they deteriorate the matrix?

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

[4]Untreated controls including: the same material, the same product formulation without the active substance

[5] as a minimum, as mean and standard deviation. If applicable, statistical calculations can be done according to Annex V of IBRG (www.ibrg.org) PDG16-007.2 Tier 1 Basic efficacy for biocidal Active Substances used to preserve Aqueous based products

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