ECHA
EUROPEAN CHEMICALS AGENCY

SUPERSEDED GUIDANCE - NEWER VERSION AVAILABLE

# Guidance on the Biocidal Products Regulation

## Volume II: Efficacy
## Part A: Information Requirements

**Version 1.1**
**November 2014**

# LEGAL NOTICE

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

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# DOCUMENT HISTORY

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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 BPR lays down rules and procedures for the approval of biocidal active substances and the authorisation of biocidal products.

Consequently, applicants should use this document when preparing dossiers according to:

- Articles 4-9 on validation, evaluation and approval of a new active substance,
- Articles 13 and 14 on the renewal of an approval,
- Articles 12-15 on the review of an approval, or
- Articles 19-21 on the authorisation of a biocidal product.

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 it explains the guiding principles for the evaluation of the applications to be performed by the authorities. Part A of each Volume of the Guidance on BPR deals with the information requirements on active substances and on biocidal products and provides technical advice on how to fulfil the information requirements set by the BPR. There are four volumes by major areas, namely:

- I. Identity/physico-chemical properties/analytical methodology
- II. Efficacy (this document)
- III. Human health
- IV. Environment

Volume I, also includes (general) information requirements to be included in the dossier as well as the technical advice to fulfil the requirements in the area indicated above.

To make clear which sections of Annexes II and III of the BPR are covered in each of the four Volumes of Guidance Part A, a finder (see Section 1.9) has been created. The finder contains two tables relating the sections of Annexes II and III of the BPR with the Volume of the guidance where they are covered.

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

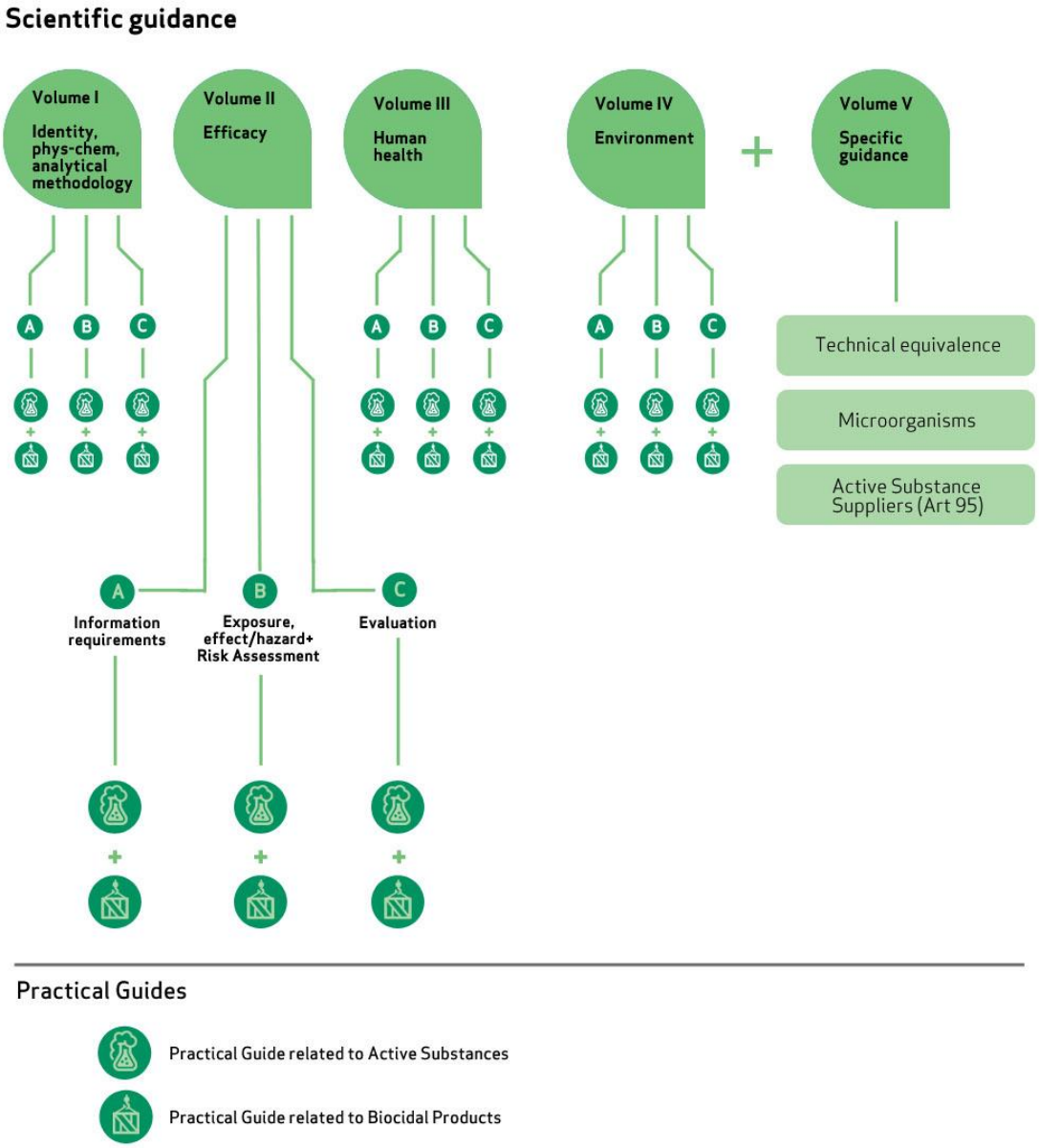


**Figure 1: BPR guidance structure**

The four volumes of the new BPR guidance structure are 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. 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.

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.

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# 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 |
| 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 |

| Standard term / Abbreviation | Explanation |
|---|---|
| GLP | Good laboratory practice |
| ha | Hectare(s) |
| ISBN | International standard book number |
| ISO | International Standards Organisation |
| ISO<br>(TC, SC, WG) | International Standards Organisation<br>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 | 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<br>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.<br>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 |

# I. 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[1]. 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 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 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 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 Part B of Volumes III and IV.

Several documents published by the Commission and ECHA have been used as a basis for the information requirements presented. The most important documents are listed in the 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.

[1] 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 Structure of the Guidance on information requirements

### 1.1.1 Information requirements

The information requirements 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:

   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.

In each of the volumes, the information requirements are divided into two parts:

1) The CDS and ADS for active substances in Chapter II,

2) the CDS and ADS for biocidal products in Chapter III.

The CDS together with the ADS comprise the complete set of information on the basis of which an overall and adequate risk assessment can be carried out.

### 1.1.2 Comparison BPD-BPR

**Error! Reference source not found.** represents a comparison of the structure of the ata 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. 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.

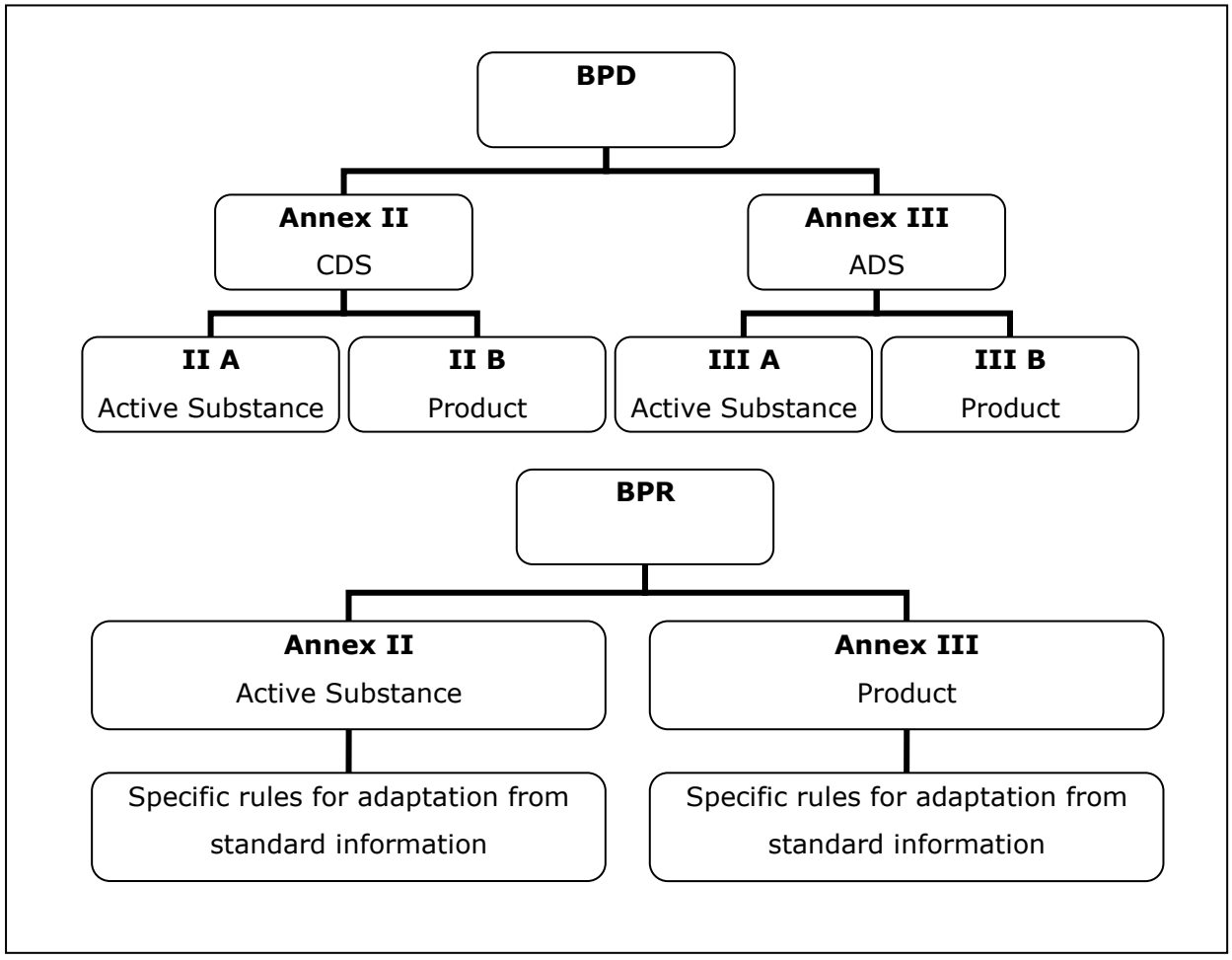


**Figure 2: Structure of data/information requirements under the BPD and the BPR.**

Unlike under 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 1 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 Document structure

As detailed in the preface, the guidance on BPR consists of four volumes and each volume has three Parts. Part A deals with Information Requirements.

This document (Volume II, Part A) covers the specific information requirements for efficacy.

**Chapter I** contains general guiding principles for information submission.

**Chapter II** covers CDS and ADS information requirements as listed in Title 1 of Annex II to the BPR. The chapter 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 chapter 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.

**Chapter III** provides CDS and ADS information requirements as listed in Title 1 of Annex III of the BPR. The chapter explains the BPR requirements for biocidal products (chemical products) and contains references to relevant test methods and further guidance. Similar to Chapter II, 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*.

The endpoint-specific sections Chapters II and III are numbered in the same way as the BPR text.

## 1.2 Guiding principles with regard to information requirements

The following guiding principles reflect the general guidance on information requirements 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. 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** (i.e. 'data waiving') outlined throughout this Guidance is possible in certain cases for both CDS and ADS. As an example, some of the toxicological information requirements may be adapted occasionally when the exposure is limited or when other product-type-specific factors apply. 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 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, 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 decision-making both at EU level and on the level of the individual Member States. The applicant should consult a competent authority 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 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. 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 competent authority *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 competent authority 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. 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. For criteria on the selection of key studies and further information, see TNsG on Preparation of Dossiers and Study Evaluation (EU, 2008b). 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 key 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 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. General rules and information requirements for substances of concern are is under development by the Commission and will be made available accordingly. . However, the detailed requirements are left mainly to be judged on a case-by-case basis. If the outcome of the applicant's assessment indicates a need for more data, the applicant should already consider further requirements.

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 in each of the four Volumes of the BPR Guidance replaces the TNsG on Data Requirements in support of the BPD (EU, 2008a). The remaining Guidance and other relevant documents that have been drafted to be used under the BPD, should also still be followed after 1 September 2013 until such a time that all the new Guidance under the BPR is completed and published. Completion of all the new BPR guidance will be published on ECHA's website.

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).

The BPD Guidance and MOTA are accessible either from the ECHA website:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation.

The Evaluation Manual is available at the Biocides Circa website maintained by DG ENV:

https://circabc.europa.eu/w/browse/92668ddd-fd3e-4b7e-9232-b80686747060.[2]

### 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: http://echa.europa.eu/support.

### 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: http://echa.europa.eu/support.

## 1.4 General guidance on generating the information

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

According to point 5 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 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*

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*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. The TGD on risk assessment for new notified substances and existing substances (EU, 2003) contains further information.

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, **R**eplacement, **R**efinement and **R**eduction 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 competent authority 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 IIto 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 this 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 competent authority. 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).

## 1.6 Testing of metabolites and transformation products

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-quantative 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 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

The 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. More information on the Test Methods Regulation and alternative methods is available at the website of the DG-JRC Institute for Health and Consumer Protection (http://ihcp.jrc.ec.europa.eu/our_activities/alt-animal-testing/test_method_reg).

The 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).

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

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

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).

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

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

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

Orders for ISO International Standards 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).

The 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).

## 1.9 Finder

Please note that the numbering of the sections and sub-sections in this guidance corresponds to the numbering of the BPR Annexes. This means that the numbering of the sections is not always consecutive and that in some Volumes the numbering does not start at 1.

For reference the following table has been added to relate the Annexes sections with the sections in this document or to provide information on the location of the information (i.e the BPR Guidance Volume).

Table 2 lists the sections of Annexes II and III of the BPR and provides either:

- a link to the section of this document giving the technical advice to fulfil the requirements, or
- indicates where the information can be found; i.e which Volume/Part of the Guidance on BPR where the information can be found.

**Table 2: Section of Annex II BPR *vs* Section of this document /Volume of the BPR guidance**

| Annex II BPR section | Section of this document /Volume of the BPR guidance |
|---|---|
| 1. APPLICANT | Volume I Identity/physico-chemical properties/analytical methodology |
| 2. IDENTITY OF THE ACTIVE SUBSTANCE | Volume I Identity/physico-chemical properties/analytical methodology |
| 3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES | Volume I Identity/physico-chemical properties/analytical methodology |
| 4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS | Volume I Identity/physico-chemical properties/analytical methodology |
| 5. METHODS OF DETECTION AND IDENTIFICATION | Volume I Identity/physico-chemical properties/analytical methodology |
| 6. EFFECTIVENESS AGAINST TARGET ORGANISMS | Chapter II Section 6 |
| 7. INTENDED USES AND EXPOSURE | Volume I Identity/physico-chemical properties/analytical methodology |
| 8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS | Volume III Human Health |
| 9. ECOTOXICOLOGICAL STUDIES | Volume IV Environment |
| 10. ENVIRONMENTAL FATE AND BEHAVIOUR | Volume IV Environment |
| 11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT | Volume I Identity/physico-chemical properties/analytical methodology |
| 12. CLASSIFICATION, LABELLING, AND PACKAGING | Volume I Identity/physico-chemical properties/analytical methodology |

**Table 3: Section of Annex III BPR *vs* Section of this document / Volume of the BPR guidance**

| Annex III BPR section | Section of this document /Volume of the BPR guidance |
|---|---|
| 1. APPLICANT | Volume I Identity/physico-chemical properties/analytical methodology |
| 2. IDENTITY OF THE BIOCIDAL PRODUCT | Volume I Identity/physico-chemical properties/analytical methodology |
| 3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES | Volume I Identity/physico-chemical properties/analytical methodology |
| 4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS | Volume I Identity/physico-chemical properties/analytical methodology |
| 5. METHODS OF DETECTION AND IDENTIFICATION | Volume I Identity/physico-chemical properties/analytical methodology |
| 6. EFFECTIVENESS AGAINST TARGET ORGANISMS | Chapter III Section 6 |
| 7. INTENDED USES AND EXPOSURE | Volume I Identity/physico-chemical properties/analytical methodology |
| 8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS | Volume III Human Health |
| 9. ECOTOXICOLOGICAL STUDIES | Volume IV Environment |
| 10. ENVIRONMENTAL FATE AND BEHAVIOUR | Volume IV Environment |
| 11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT | Volume I Identity/physico-chemical properties/analytical methodology |
| 12. CLASSIFICATION, LABELLING, AND PACKAGING | Volume I Identity/physico-chemical properties/analytical methodology |

# II. DOSSIER REQUIREMENTS FOR ACTIVE SUBSTANCES

## 6. Effectiveness against target organisms

Active substance approval requires only a minimal efficacy assessment, sufficient to show an innate level of activity for the active substance. At the same time, information on the effectiveness and intended uses of the active substance must be sufficient to permit an evaluation of the representative biocidal product and to define its conditions of use. Actual efficacy studies are required for the representative biocidal product in accordance with Chapter III Section 6. However, as these studies serve the purpose of the active substance approval, the conditions under which they may be conducted are given below.

A detailed description of the test method should be available, and all information needed for the validation of the results should be provided. A GLP certificate is not mandatory.

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

Provide information on the function of the active substance..

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

Please follow guidance in Chapter III Section 6.2.

### 6.3 Effects on representative target organism(s)

Please follow guidance in Chapter III Section 6.3.

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

Please follow guidance in Chapter III Section 6.4.

### 6.5 Mode of action (including time delay)

Please follow guidance in Chapter III Section 6.5.

### 6.6 Efficacy data to support these claims on biocidal products

*and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate.*

Include studies to support the claims made throughout Chapter II Section 6. If more information is needed to explain the label claim (e.g. method of application) please provide this information here. Follow guidance in Chapter III Sections 6.6 and 6.7 taking into account the following remarks:

- Efficacy data are required on the active substance at the active substance approval stage. These data should be able to demonstrate that the active substance has innate activity against a representative target species. When the active substance is in general combined with other active substances in a biocidal product, the innate activity of the active substance under approval should also be addressed on its own. The data generated in connection with the efficacy testing of the representative biocidal product may be utilised in addition to the data obtained from the testing of the active substance.
- Efficacy data are also required on the representative biocidal product (accompanying the application for the approval of an active substance). These should be able to demonstrate that the active substance has the ability to produce an effect on a representative target organism when it is included in a formulated product.
- It is not necessary to demonstrate efficacy against all of the target organisms at the active substance approval stage, as additional target organisms may be added at product authorisation.
- Where the innate activity of both the active substance and representative biocidal product against the target organisms has been demonstrated, a recommendation should be made for the active substance approval. Where activity has been demonstrated for the representative biocidal product, and where those activity levels would not be high enough for a product authorisation, the applicant should be asked to defend why the levels of activity noted should be considered acceptable. 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.
- As only a minimal evaluation of efficacy takes place at the stage of active substance approval, a comprehensive efficacy evaluation should be carried out at product authorisation.
- The term "label claims" should be interpreted to include all claims made for the efficacy of the product, not just those on the product label itself.

## 6.7 Any known limitations on efficacy

Please follow guidance in Chapter III Section 6.8.

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

Please follow guidance in Chapter III Section 6.8.1.

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

Please follow guidance in Chapter III Section 6.8.2.

# III. DOSSIER REQUIREMENTS FOR BIOCIDAL PRODUCTS

## 6. Effectiveness against target organisms

Please read the introduction in Chapter II Section 6.

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 normal conditions of use.

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

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

Provide information on the function of the biocidal product.

### 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. Where complexes of organisms are involved, generic names that are representative of the diversity of the complex must be indicated. Where human and/or animal pathogens are involved, the specific names must be provided.

Indicate in which parts of EU the organisms to be controlled exist.

### 6.3 Effects on representative target organisms.

The effects on the target organisms required for the claimed efficacy should be described and specified if possible for each use and method of application if these have different effects.

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

The possible existence of a threshold concentration for the desired effect should be stated. This is the case if the dependence between the desired effect and the concentration of the active substance is not found (or is much weaker) below a certain concentration (the threshold concentration).

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

The likely use concentrations in the target should be stated for each use and method of application. Indicate if the use concentrations should be different in different parts of EU.

Justification for the selection of the use concentrations should be provided. The likely use concentration should ideally be the minimum effective concentration under real conditions for the respective service life, taking into account all relevant parameters that impact on efficacy.

## 6.5 Mode of action (including time delay)

The mode of action in terms, where relevant, of the biological, biochemical and physiological mechanisms and biochemical pathways involved should be stated. Information on time delay should be included, where applicable. The information on time does not need to be provided e.g. for products that take some time to manifest their effect such as insect growth regulators. 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).

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

The term "label claims" should include all claims made for the efficacy of the product, such as those on advertising material or accompanying leaflets, as well as those on the product label. A detailed evaluation of the efficacy data against the label claims should be carried out. The evaluation should include all relevant target species (or representative species), the effects of product usage, the duration and speed of effect, any claims for residual action, together with any other specific claims.

## 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.*

The TNsG on product evaluation (EU, 2008c) provides further amplification in this area. Although at the time of writing, detailed product-type-specific guidance is not yet available for all product-types and use patterns, details for those product-types currently outstanding are now in preparation. This product-type-specific guidance intended to replace the appendices of the TNsG may be published as separate documents to the TNsG or its revision, and therefore applicants are advised to check for the availability of the revised TNsG or its individual appendices to come. At the time of writing, Sweden was also investigating the issues around testing of the efficacy of treated articles for different product-types which may affect this Guidance with regard to the label claims for treated articles.

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 are comparable with the purpose applied for and with the environmental characteristics relevant for the intended use.

For field studies conducted outside the territory of the Member State in which the authorisation is being sought, a justification of the relevance of such data must be made. The extent of the information required will vary depending on the product-type and proposed use pattern and upon the similarity of the conditions in the two countries. Justification may include, as relevant and appropriate, information on the harmful organism (e.g. comparison of genera/species and its 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 of these trials for testing the efficacy of preservatives (Main Group II: product-types 6-13) are described in the Guidance on the General principles and practical considerations for testing the efficacy of preservatives (EU, xxx, under consultation).

The test method should measure a response and, as appropriate, an endpoint relevant to the label claims. The method should employ an untreated control and, if possible, a reference product for comparison. 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.

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.

The tests (and data generated) should be based on sound scientific principles and practices. Compliance with quality standards such as ISO 9000 is highly recommended. More detailed guidance on appropriate test methods is provided in paragraph 52 of Annex VI in the BPR and in the TNsG on Product Evaluation (EU, 2008c). An OECD Guidance Document on use of efficacy methods for treated articles and materials is available (OECD, 2007b). A Guidance document on use of efficacy methods is being developed by the OECD (Overview of Efficacy testing methods for biocides. Draft 1999).

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

- For product-types 1 and 2, the European standard efficacy method tests of the CEN for disinfectants and antiseptics (e.g. EN13727 and 13624; several others are in preparation) are highly recommended. An overview of all EN tests for disinfectants can be found in EN14885. Relevant OECD Test Guidelines and guidance are available (e.g. OECD Guidance Document for establishing the efficacy of biocides used in swimming pools and spas (OECD, 2012b), several others are being developed.

- For product-types 3, 4 and 5 the European standard efficacy testing methods of the CEN are highly recommended; several of these are in preparation. An overview of all EN tests for disinfectants can be found in EN14885. Relevant OECD tests are being developed. For product-type 5, standard efficacy testing method is in preparation by COM working group. The scope of the test is the application of biocides during the drinking water production and distribution for public supply.

- A product specific Guidance Document on product-types encompassed within Main Group I (product-types 1-5, Disinfectants) can be found in the TNsG on product evaluation (EU, 2008c), the specific appendix is under revision.
- For product-type 8, the European standard efficacy tests of CEN are highly recommended for wood preservatives. These standards are not suitable to all wood preservatives. Modifications to them or development of new ones may be necessary. See specific guidance in the TNsG on product evaluation (EU, 2008c), the specific appendix is under revision.
- For product-type 10, see specific guidance in the TNsG on product evaluation (EU, 2008c) .
- For product-type 14, EPPO guidelines for efficacy testing are highly recommended (e.g. EPPO guidelines 97, 113, 114, 169 and 198 for rodenticides). Further product specific Guidance document on product-type 14 can be found in the TNsG on product evaluation (EU, 2008c) and a revised appendix to chapter 7 on efficacy of rodenticides (EU, 2009b).
- For product-type 16, EPPO guidelines for efficacy testing are highly recommended (e.g. EPPO guidelines 95 for molluscicides in terrestrial environment).
- For product-type 18, see specific guidance in the TNsG on product evaluation (EU, 2008c) and the revised appendix to chapter 7 on efficacy to insecticides and other arthropods (EU, 2012b).
- For product-type 19, EPPO guidelines 199 and 200 are available for efficacy testing of rodent repellents intended for plant protection. These might be modified for biocidal use. For insect repellents see product specific guidance in the TNsG on product evaluation (EU, 2008c) and the revised appendix to chapter 7 on efficacy to insecticides and other arthropods (EU, 2012b).
- For product-type 21, the standard test protocols of CEPE (1993) and ASTM (1987) for conducting efficacy tests are recommended for antifouling products. The latter is an internationally recognised draft test method. Further product specific Guidance document on product-type 21 can be found in the TNsG on product evaluation (EU, 2008c), the specific appendix is under revision.
- For product-type 22, the specific guidance is under development.
- For treated articles of product-type 1, 2, 4, 7, 9 (10) there is an OECD Guidance Document available (OECD, 2008d).

## 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.

### 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. This is addressed in the TNsG on product evaluation (EU, 2008c).

### 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 Chapters II and III Section 9.

Provide information on unnecessary suffering and pain for target vertebrates, where relevant.

## 6.9 Summary and evaluation

The findings on the effectiveness against target organisms (6.1-6.8.2) are summarised and evaluated.

# REFERENCES AND BACKGROUND DOCUMENTS

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