ECHA
EUROPEAN CHEMICALS AGENCY

Introduction to guidance on the Biocidal Products Regulation

Part A: Information requirements
Volumes I – IV
Version 1, March 2022

Version	Changes	Date
1.0	This document replaces the Introduction chapters that were previously included separately in the Part A guidance of each of the four Volumes (I-IV). This file now provides the introduction to each of these Volumes. The introduction has been updated overall to better reflect the current situation, and reflections on the now obsolete guidance under the preceding Biocidal Products Directive have been removed.	March 2022

Introduction to guidance on the Biocidal Products Regulation Part A: Information requirements Volumes I-IV

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

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List of abbreviations

Standard term / Abbreviation	Explanation
ADS	Additional data set
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
CA	Competent authority (MSCA)
CDS	Core data set
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
DoA	Date of Application
ECHA	European Chemicals Agency
ESD	Emission scenario document
EU	European Union
GLP	Good laboratory practice
HEAdhoc	Human Exposure ad hoc working group
HEEG	Human Exposure Expert Group
IUCLID	International Uniform Chemical Information Database
MSCA	Member State competent authority

OECD	Organisation for Economic Cooperation and Development
PT	Product-type
(Q)SAR	(Quantitative) structure activity relationship
RAAF	Read-Across Assessment Framework
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SME	Small and medium-sized companies
TAB	Technical Agreements for Biocides
TNsG	Technical Notes for Guidance

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 and renewal of active substances in biocidal products at European Union (EU) level and for the authorisation and renewal 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 both human and animal health protection. The information requirements were amended by Regulation (EU) 2021/525.

Study data and other information must fulfil the minimum requirements whilst being sufficient for classification and labelling according to the CLP Regulation[2], and to conduct a proper risk and efficacy assessment in order to allow a decision on the suitability of the substance to be approved or the product to be authorised.

The BPR sets out rules on information requirements (see e.g. Articles 6-8, 13, 20-21, 31 and 45) that are specified for active substances in Annex II, and for the respective biocidal products in Annex III (in Title 1 of Annex II/III for chemicals and Title 2 of Annex II/III for micro-organisms).

Due to the wide scope of the BPR and the extensive variation of efficacy, exposure and risks of biocidal products and their use in treated articles, 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 Volume II of the Guidance 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 is available separately in Guidance on micro-organisms (Volume V).

Several documents published by the Commission and ECHA have been used as a basis for the information requirements presented, see section 1.2 of this guidance.

This Guidance is primarily addressed to applicants seeking approval or renewal 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, including the adequacy and relevance of the submitted information.

This Introduction includes general information that is applicable to the Part A of volumes I-IV and contains general guiding principles relevant for all four Volumes.

1. Guiding principles on information requirements in general

The following guiding principles reflect the general guidance on information requirements which

[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.
[2] Note that according to the BPR Annex II, a carcinogenicity study does not need to be conducted if the substance is classified as mutagen category 1A or 1B. Therefore, in such cases information that would be sufficient for classification and labelling cannot be required for carcinogenicity.

apply to all four volumes.

1. **The common core data set (CDS)** forms the basis of the requirements. In general, it is regarded as a minimum set required for all substances and product-types. This information has to be submitted always, unless the rules for adaptation of standard information are applicable (see below).

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). This information 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.

3. **The adaptation of information requirements** ('data waiving'), set out in BPR Annex IV and 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; for the efficacy of 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 active substance or the product, or testing not being technically possible or scientifically necessary may justify waiving of some information requirements. The Guidance under REACH should also be noted, especially the Read-Across Assessment Framework (RAAF) and *Guidance on information requirements and chemical safety assessment* Chapter R.6: QSARs and grouping of chemicals. A template[3] is also available for providing a weight of evidence assessment.

4. In certain cases, **expert judgement** may be necessary from the applicant and/or from the competent authority (CA) 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 prepare 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 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. Special attention is required in cases that concern critical endpoints and clearly defined or standardised methods are lacking. Here, the applicant is obliged to investigate if relevant methods are applicable. The lists of test methods outlined for each data requirement in this guidance may not be exhaustive, particularly as new methods are continuously being

[3] Available at https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

developed. It is the applicant's duty to be up to date on the state of the science and to use the most relevant, robust methods and reducing and replacing the use of animals as far as possible.

5. It is always the **responsibility of the applicant** to submit the data. All data provided in the application must be supported by study reports, other data or a letter of access. The information submitted by the applicant on active substances, biocidal products and 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. For questions on which data should be submitted, the applicant should make proposals and consult the evaluating CA.

6. The data submitted by the applicant will form the basis for classification and labelling according to the CLP Regulation. The active substances may be subject to harmonised classification for the first time, or the data can be used to review the existing harmonised classification.

7. The data and test requirements should suit the individual circumstances and 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), and

    c. The environment where the product is intended to be used or into which the product may be released.

    d. The way in which treated articles may be used

8. Sharing of vertebrate data submitted under the BPD or BPR is mandatory. 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.* Further detailed rules are provided in Article 62(2) of the BPR. The data generated and collected under other legislative regimes, especially under plant protection products (Council Regulation (EU) No 544/2011), REACH (Council Regulation (EC) No 1907/2006) and CLP (Council Regulation (EC) No 1272/2008) should be used, taking into account the rules on data protection.

9. For guidance on data sharing, see the ECHA Biocides Guidance webpages[4], the practical guide on data sharing[5] 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).

10. For the renewal of active substance approval, please refer to the specific guidance available on the ECHA website[6].

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[4] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation
[5] Available at https://echa.europa.eu/practical-guides/bpr-practical-guides
[6] https://echa.europa.eu/documents/10162/2324906/data_req_assessment_applications_renewal_of_approval_as_en.pdf

11. 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, these should all be submitted to allow a more sound risk assessment with, among others, assessment of inter-species variability. As an exception to this rule, all available data on resistance should be provided, including a literature search. The additional data should be of acceptable quality; see Annex IV, point 1 of the BPR.

12. 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 to the evaluating CA any relevant data that 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.

13. Public literature data can be used in the assessment if all 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 are defined in the publication and are comparable with the substance addressed in the application.

    c. The reporting of the study allows evaluation of the quality of the study.

    If the above conditions are met, the applicant can use such information as key studies, providing that the quality of the information is sufficient, and the data is public literature and not subject to any legal restrictions, such as copyright. Publicly available information that do not meet these conditions may be considered on a case-by-case basis.

14. 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. Although key studies are not a requirement in the BPR and the concept is not fully defined, the term is in general used to indicate the most relevant and critical studies for each endpoint. A key study has to be reliable and adequate to use for the risk assessment and efficacy assessment. In principle, a study with a reliability indicator[7] of 3 or 4 cannot be a key study and can be used only as supportive information.

15. When more than one adequate study is available, expert judgement should be used to decide whether e.g. mean or median values should be used instead of the result of a single key study. Elaboration on this is available for many endpoints in Parts B+C of this guidance (ECHA Guidance on BPR, Parts B+C to Volumes I, II, III, IV). 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 IUCLID.

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[7] Klimisch, H. et al. *A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data.* Regulatory toxicology and pharmacology: RTP 25 1 (1997): 1-5

16. It is always possible to require additional information or studies if this is considered necessary for risk assessment, efficacy assessment, and decision making. The need for additional studies may be justified by the properties of the substance (i.e. hazard) or by the predicted exposure. Article 8(2) of the BPR 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, and for a **co-formulant** 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. See also BPR Article 30(2) for national authorisation and 44(2) for Union authorisation.

17. 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.* Especially SMEs should be allowed extensive guidance from the competent authorities to be able to fulfil the obligations laid down in the BPR.

18. 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. In other words, the reference source would be the source for which the (eco)toxicological data submitted cover the specification. 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, otherwise the applicant must justify why some impurities in the proposed specification are not covered by these studies. For sources not included in the first approval, technical equivalence needs to be established according to ECHA Guidance Volume V, Guidance on applications for technical equivalence.

2. On the use of additional Guidance documents

2.1 Other Guidance under BPR

In addition to this guidance document, other guidance may clarify some information requirements and/or the context and the scientific background. Please consult the following information where the obligations, context or scientific background may have been clarified:

- Guidance on BPR, Parts B+C to Volumes I, II, III, IV
- Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (available in the ECHA website[8])
- Each Working Group of the Biocidal Product Committee has a living document Technical

[8] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

Agreements on Biocides (TAB) containing Working Group agreements. These documents are available on the ECHA webpage[9].

- Recommendations of the Ad hoc Working Group on Human Exposure (HEAdhoc), Opinions of the Human Exposure Expert Group (HEEG) and the Biocides Human Health Exposure Methodology provide guidance with regard to the information to be used for assessing human exposure. These documents are available at the ECHA HEAdhoc webpage[10]

- Recommendations provided by BPC Working Groups for substances generated in situ[11]

- Documents agreed at BPC Working Group meetings, available in S-CIRCABC[12]

- Emission Scenario Documents (ESD) which represent the main guidance to estimate the amount of substances released into the environment[13].

- The Commission may have addressed some of the obligations in further detail in the Biocides competent authorities meeting documents available via a "related links" on the ECHA BPR webpage[14].

The Coordination Group may have addressed some obligations especially with respect to product authorisation. These documents are available in S-CIRCABC[15].

2.2 Biocides Guidance before BPR

Part A in each of the Volumes I-IV of the BPR Guidance replaced the TNsG on Data Requirements in support of the BPD (EU, 2008a). This BPD Guidance is in general not considered relevant anymore but could be applicable in some individual cases depending on the specific circumstances.

2.3 REACH Guidance

REACH Guidance represents a major guidance source that should be taken into account in 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 on REACH can be obtained from the ECHA website: https://echa.europa.eu/guidance-documents/guidance-on-reach.

2.4 CLP Guidance

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

[9] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups
[10] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure
[11] https://echa.europa.eu/regulations/biocidal-products-regulation/in-situ-generated-active-substances
[12] https://webgate.ec.europa.eu/s-circabc/w/browse/d02f78aa-983c-4187-9776-c8b5f706511b
[13] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents
[14] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation
[15] https://webgate.ec.europa.eu/s-circabc/w/browse/2f03ff78-2c6a-412d-9db0-78e40e79d3e2

3. General Guidance on generating the information

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

According to point 5 of Annex II and Annex III of the BPR, *tests submitted for the purpose of the approval of an active substance shall be conducted* ***in accordance with the methods described in Commission Regulation (EC) No 440/2008****, or any revised version of these methods not yet included in that Regulation. However, if a method is inappropriate or not described in Commission Regulation (EC) No 440/2008, other methods shall be used which are scientifically appropriate and their appropriateness shall be justified in the application.* **When test methods are applied to nanomaterials**, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations or adjustments that have been made to account for the specific characteristics of these materials. Recommended test methods are listed in the endpoint sections. Some of the BPR data requirements refer to OECD test guidelines as the corresponding EC methods are not available or may be outdated.

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'.* This Directive establishes **rules and principles for the replacement and reduction of the use of animals** and the refinement of the breeding, accommodation, care and use of animals.

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 no "other international standards" are considered equivalent to GLP.

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).

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. Among other factors, the need to minimise testing on vertebrate animals needs to be taken into account, making every effort to minimise testing on vertebrate animals (Article 90(2) of the BPR). Covering a data requirement with studies that are not performed according to the Test Methods Regulation or recommended in the ECHA guidance on BPR should first be proposed by the applicant when collecting data for the application, consulting the evaluating CA already during data collection, before deciding whether further testing is necessary. 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. See *Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs 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**, as defined in Article 3(2)(a) of the BPR. For some of the physical and chemical properties' tests, the purified substance should be tested, which is indicated in footnote 2 in BPR Annex II, 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 of the BPR. The "Active substance as manufactured" is the active substance in its natural state or as obtained by any manufacturing process, including any additive necessary to preserve it and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the active substance or changing its composition. Furthermore, the identification of the active substance includes its purity and the identities and content of impurities and additives which have to be defined, and the composition of the test substance has to be comparable with them.

Sharing of vertebrate data submitted under the BPD or BPR is mandatory. Please refer to BPR Article 62 and also the information provided in chapter 1.1 above.

In order to implement **the three R's**, **R**eplacement, **R**eduction and **R**efinement of animal testing 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. Alternative tests either not using test animals or reducing the number of test animals are under development and when endorsed, these tests are preferred in performing new tests.

A chemical substance approved as an active substance (included in the *Union list of approved active substances)* is defined according to Article 3(2)(a) and its naming must follow the guidance for identification and naming of substances under REACH and CLP. **The composition of the substance used for testing** needs to be described in detail i. e. a complete description of the composition for all batches used in tests is needed. Where testing is done using an active substance, the same specification as the manufactured substance must be used, except where radiolabelled 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 or authorisation is applied 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. For sources different from the approved sources, technical equivalence needs to be established according to ECHA Guidance Volume V, Guidance on applications for technical equivalence. When the long-term stability is in doubt, the composition of the active substance and the biocidal product should be determined before testing. Where appropriate, details of the stability of the active substance in any vehicle used during testing should also be specified. For certain tests (e.g. some physico-chemical tests) there are specific requirements on purity of the active substance.

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. Any deviations from the test guidelines must be fully justified.

Some active substances may need special attention (OECD, 2000a) due to having characteristics that impede testing or limit the methods that can be used. 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.

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 submitted 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.

4. Testing of metabolites and transformation products

In this context, the term *metabolites and transformation products* are used to cover metabolites, transformation products, degradation products and breakdown products.

For efficacy, when metabolites or transformation products are formed during use, 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 toxicology, the possibility of the formation of metabolites and transformation products not investigated by the usual testing must be taken into account. See section 1.8 on metabolism studies in mammals.

For the environmental risk assessment, metabolites (including transformation products) 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 needs to be performed also for those

ecotoxicologically relevant metabolites that are minor metabolites.

5. Background documents

Legal texts

For the detailed legal texts (plus amendments and annexes, when applicable) cited in this guidance document and listed below, 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.

Commission Implementing Regulation (EU) No. 88/2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012.

Commission delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.

Directives

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

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

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

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

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

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

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

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

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

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

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

Decisions

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

6. 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.

DIN Standards can be purchased from the website of DIN, the German Institute for Standardisation: http://www.din.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: https://www.cencenelec.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: https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm.

TCIPAC methods may be purchased from the Collaborative International Pesticides Analytical Council: http://www.cipac.org.

UN manual for tests and criteria: https://unece.org/about-ghs.

US EPA Office of Chemical Safety and Pollution Prevention Test Guidelines can be obtained from the EPA website: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances.

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