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GUIDANCE

Guidance on the Biocidal Products Regulation

Volume IV: Environment
Part A: Information Requirements

Version 1.2
May 2018

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Guidance on the Biocidal Products Regulation: Volume IV: Environment - Part A: Information Requirements

Reference: ECHA-18-G-06-EN
Cat. Number: ED-02-18-535-EN-N
ISBN: 978-92-9020-501-2
DoI: 10.2823/49865
Publ.date: May 2018
Language: EN

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DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	June 2013
Version 1.1	Corrigendum: - Division of the guidance in the 4 volumes of the new BPR Guidance structure - Minor editorial changes	November 2014
Version 1.2	Corrigendum: • In Preface: To update the text to reflect the changes to the structure of the BPR guidance and to align the text with that in the current published Parts B+C for Volumes II, III and IV; • In Preface: to add text and links on "Applicability of Guidance"; • To amend the numbering of all sections to follow a normal sequential numbering format for the sections and to add in the heading for each section the relevant BPR Annex reference for clarification; • To relocate the "Finder" tables to follow the Table of Contents in "Notes for the Reader"; • To correct the explanation of the abbreviation ISO in the List of Abbreviations; • To delete references to the CLP transition arrangements and dates which no longer apply.	May 2018

PREFACE

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

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

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

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

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

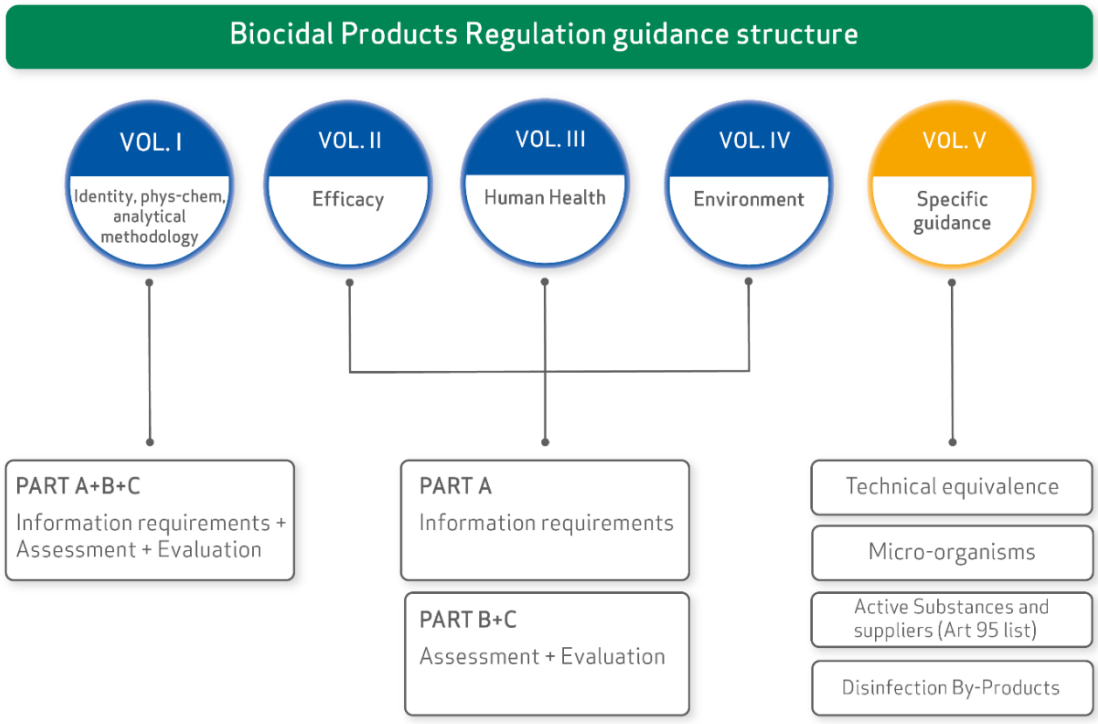

Figure 1: BPR guidance structure

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

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

Applicability of Guidance

Guidance on applicability of new guidance or guidance related documents for active substance approval is given in the published document "Applicability time of new guidance and guidance-related documents in active substance approval" available on the BPC Webpage [https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee] and for applicability of guidance for product authorisation, please see the CA-document CA-july2012-doc6.2d (final), available on the ECHA Guidance page [https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf].

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NOTES to the reader:

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

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

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

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

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

Annex II BPR section	BPR Volume + section number
1. APPLICANT	Volume I: Section 2.1
1. IDENTITY OF THE ACTIVE SUBSTANCE	Volume I Section 2.2
2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES	Volume I Section 2.3

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

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

Annex III BPR section	BPR Volume + section number
2. APPLICANT	Volume I: Section 3.1
3. IDENTITY OF THE BIOCIDAL PRODUCT	Volume I: Section 3.2
4. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES	Volume I: Section 3.3
5. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS	Volume I: Section 3.4
6. METHODS OF DETECTION AND IDENTIFICATION	Volume I: Section 3.5
7. EFFECTIVENESS AGAINST TARGET ORGANISMS	Volume II: Section 3.6
8. INTENDED USES AND EXPOSURE	Volume II: Section 3.2
9. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS	Volume III: Section 3.1
10. ECOTOXICOLOGICAL STUDIES	Volume IV: Section 3.1
11. ENVIRONMENTAL FATE AND BEHAVIOUR	Volume IV: Section 3.2
12. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT	Volume I: Section 3.11
13. CLASSIFICATION, LABELLING, AND PACKAGING	Volume I: Section 3.12

List of Abbreviations

Standard term / Abbreviation	Explanation
°C	Degree(s) Celsius (centigrade)
ADS	Additional data set
ASTM	American Society for Testing and Materials
BCF	Bioconcentration factor
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
CDS	Core data set
CEN	European Committee for Normalisation
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
DG SANCO	European Commission Directorate-General for Health and Consumers
DNA	Deoxyribonucleic acid
DoA	Date of application
$DegT_{50}$	Period required for 50% degradation (define method of estimation)
$DegT_{90}$	Period required for 90% degradation (define method of estimation)
$DisT_{50}$	Period required for 50% dissipation (define method of estimation)
$DisT_{90}$	Period required for 90% dissipation (define method of estimation)
$DegT_{50lab}$	Period required for 50% degradation under laboratory conditions (define method of estimation)
$DisT_{90field}$	Period required for 90% dissipation under field conditions (define method of estimation)
DWD	European Drinking Water Directive (Directive 98/83/EC)
EC	European Communities or European Commission
EC_{50}	Median effective concentration
EC method	Test Method as listed in the Test Methods Regulation
ECHA	European Chemicals Agency
EEA	European Economic Area. The EEA is composed of Iceland, Liechtenstein, Norway and the EU Member States.
EEC	European Economic Community

Standard term / Abbreviation	Explanation
EFSA	European Food Safety Agency
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
FELS	Fish early-life stage
FOCUS	Forum for the Coordination of Pesticide Fate Models and their Use (European pesticide project for risk assessment)
g	Gram(s)
GLP	Good laboratory practice
h	Hour(s)
ha	Hectare(s)
HPLC	High performance (or pressure) liquid chromatography
IOBC	International Organisation for Biological Control of noxious animals and plants
ISBN	International standard book number
ISO	International Organization for Standardization
ISO (TC, SC, WG)	International Organization for Standardization Technical Committee, Scientific Committee, Working Group
ISSN	International standard serial number
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union for Pure and Applied Chemistry
JRC	Joint Research Centre
Ka	Acid dissociation coefficient
Kd	Desorption coefficient
kg	Kilogram(s)
K_{oc}	Organic carbon adsorption coefficient
K_{ow}	Octanol-water partition coefficient
K_P	Solid-water partitioning coefficient of suspended matter
kPa	Kilopascal(s)
L	Litre(s)
$L(E)C_{50}$	Lethal concentration, median
LD_{50}	Lethal dose for 50% of the group of tested animals
log	Logarithm to the basis 10
m	Metre
mg	Milligram(s)
MITI	Ministry of International Trade and Industry (Japan)
MOTA	Manual of Technical Agreements of the Biocides Technical Meeting

Standard term / Abbreviation	Explanation
MSCA	Member State competent authority
MT	Material test
NMR	Nuclear magnetic resonance
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
OECD	Organisation for Economic Cooperation and Development
OH	Hydroxide
OPPTS	Office of Prevention, Pesticides, and Toxic Substances (U.S.-EPA)
PEC	Predicted environmental concentration
pH	pH-value, negative decadic logarithm of the hydrogen ion concentration
pKa	Negative decadic logarithm of the acid dissociation constant
PNEC	Predicted no effect concentration
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
(Q)SAR	(Quantitative) structure activity relationship
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	Rijksinstituut voor Volksgezondheid en Milieuhygiëne (Dutch National Institute of Public Health and Environmental Protection)
s	Second(s)
SCAS	Semi-continuous activated sludge (inherent biodegradability tests)
SETAC	Society of Environmental Toxicology and Chemistry
SMEs	Small and medium-sized enterprises
STP	Sewage Treatment Plant
TC	Technical material In accordance with FAO manual (FAO, 2010), TC is usually the final product from preparation of the active substance prior to being formulated into an end-use product. This may contain a stabiliser and/or anti-caking or anti-static agents (if required) but no other additives. TC is usually ≥900 g/kg with solvent(s) removed during synthesis, with only residual amounts remaining (usually ≤10%) and no solvent added subsequently.
Test Methods Regulation	Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation

Standard term / Abbreviation	Explanation
TK	Technical concentrate In accordance with FAO manual (FAO, 2010), TK may also be the final product from preparation of the active substance but it may contain additives (not formulants) in addition to a stabiliser, for example as safety agents. TK may also contain solvent(s) (including water), either deliberately added to a TC or not removed during preparation.
TGD	Technical Guidance Document (EU, 2003)
TNsG	Technical Notes for Guidance
UN	United Nations
UV	Ultraviolet
VDI	Verein Deutscher Ingenieure (The Association of German Engineers)
WHO	World Health Organisation
µg	Microgram(s)

1. Part A: Introduction to the Guidance on Information Requirements

Regulation (EU) No 528/2012 of the European Parliament and of the Council (Biocidal Products Regulation, the BPR) lays down rules and procedures for approval of the active substances in biocidal products at European Union (EU) level and for the authorisation of biocidal products in both Member States and at EU level[1]. The objective of the BPR is to improve the functioning of the internal market on biocidal products whilst ensuring a high level of both 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 and efficacy assessment in order to finally allow for a decision on the suitability of the substance to be approved or, the product to be authorised.

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

Due to the wide scope of the BPR and the extensive variation of efficacy, exposure and risks of biocidal products, the general rules provided in the BPR and its Annexes have to be specified in order to ensure efficient and harmonised day-to-day implementation of the regulation. The aim of the Guidance is to provide detailed and practical direction on which study data and other information should be submitted, when applying for approval and authorisation according to the BPR. The requirements outlined in Volume II Efficacy 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). 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, see 1.3 of this guidance.

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.

1.1 General structure of the guidance on information requirements

1.1.1 Information requirements in general

The information requirements are two-tiered:

[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.

I. The core data set (CDS) is mandatory for all product-types. This information always has to be submitted, unless the rules for adaptation of standard information are applicable (see below).

II. The additional data set (ADS) might be required to perform the risk assessment under the following conditions (To Note: ADS is not applicable for Efficacy data requirements):

   a. ADS information on physical chemical properties, methods of detection and identification and on the toxicological profile is required depending on the intrinsic properties of the active substance or the biocidal product.

   b. ADS information on the ecotoxicological properties and the environmental fate and behaviour of the active substance or biocidal product is required depending on the product-type, i.e. the foreseen use and route of exposure.

   c. ADS information on the ecotoxicological properties and the environmental fate and behaviour might be required to refine the initial risk assessment.

1.1.2 Comparison of BPD-BPR

Figure 2 represents a comparison of the structure of the data requirements or information requirements, respectively, under the BPD and under the BPR. In the BPD legal text as well as in the TNsG on data requirements (EU, 2008a), CDS and ADS are listed in separate Annexes but includes an additional column to indicate if the requirement is ADS (see below). 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.

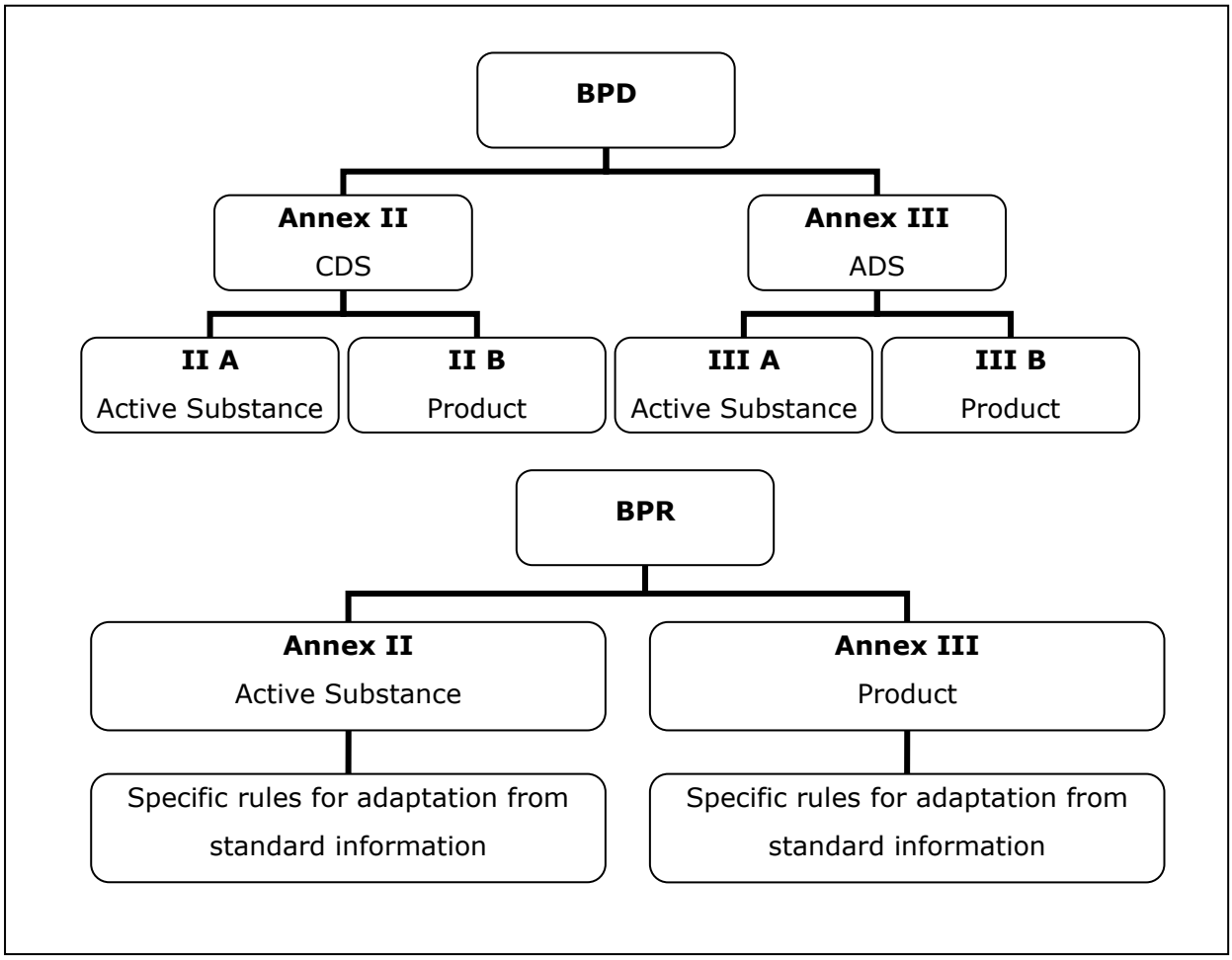


Figure 2: Structure of data/information requirements under the BPD and the BPR.

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

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

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

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

1.1.3 Document structure

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

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

Section 2 covers CDS information requirements as listed in Title 1 of Annex II, point 9 Ecotoxicological studies and point 10, Environmental fate and behaviour (of the BPR). The section explains the BPR requirements for active substances (chemical substances) and contains references to relevant test methods and further guidance. For example, it offers guidance on which test is the most suitable for specific cases. In addition, the section contains the *specific rules for adaptation from standard information*, where applicable. These *waiving* rules are generally accepted, scientifically or technically justified exemptions to the information requirements.

Section 3 provides CDS information requirements as listed in Title 1 of Annex III, point 9 Ecotoxicological studies and point 10, Environmental fate and behaviour (of the BPR). The section explains the BPR requirements for biocidal products (chemical products) and contains references to relevant test methods and further guidance. Similar to section 2, it also contains references to relevant test methods and explains the Annex III requirements. It also lists the *specific rules for adaptation from standard information*.

Section 4 provides guidance on the testing strategies for biotic and abiotic degradation.

Section 5 provides guidance on the required ADS information for each of the 22 different product-types. Reflecting the environmental exposure due to the use of the different product-types, submission of that information is mandatory.

1.2 Guiding principles with regard to information requirements in general

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

1. **The common core data set (CDS)** forms the basis of the requirements. In general, it is regarded to be a **minimum set** required for all substances and product-types.
2. **The additional data set (ADS)** includes supplementary information requirements. These are indicated in column 2 in the BPR Annexes.This information may be required depending on **the characteristics** of the active substance and/or the product-type and on the expected exposure of humans, animals and the environment. The product's use or application method needs to be taken into account under both the proposed normal use and a possible realistic worst case situation (Article 19(2) of the BPR).
3. **The adaptation of information requirements** (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; or 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 substance or the product may justify

waiving of some information requirements. The guidance on General Rules for the Adaptation of the Data Requirements is under development by the Commission and will be made available accordingly. Until then please refer to Chapter 1 Section 1.4 of the TNsG on Data Requirements (EU, 2008a) REACH, Guidance on QSARs and grouping of chemicals could also be useful *Guidance on information requirements and chemical safety assessment* Chapter R.6: QSARs and grouping of chemicals.

4. The information requirements have been specified in as much detail as possible. However, in certain cases, **expert judgement** by the applicant and by the competent authority (CA) may be necessary in order to assess, for instance, whether an additional study is needed or on which organism or under which conditions a test should be performed. The applicant should propose the initial expert judgement, which is then examined during the evaluation. In making the decision as to whether additional testing is justified, the benefit for the risk assessment (including intended use), the compatibility with accepted risk assessment rationales, and the feasibility of the required tests may have to be considered. When providing an expert judgement one must, when relevant, take into account both the proposed normal use and a possible realistic worst case situation. Expert judgement decisions should be scientifically justified and transparent. In certain cases, the final decision on information requirements is made by the Biocidal Products Committee (BPC). Special attention is required in cases where there are endpoints of concern and clearly defined or standardised methods are lacking. Here, the applicant is obliged to investigate if relevant methods are applicable. New test methods are continuously being developed and it is the applicant's duty to be up-to-date with the state of science regarding test methods.
5. It is always the **applicant who is responsible** for the submission of the data. All data provided in the application must always be supported by study reports, other data or a letter of access. The information submitted by the applicant on both active substances and biocidal products, and also on substances of concern present in the biocidal product must be sufficient for conducting a risk assessment and an efficacy assessment, and decision-making both at EU level and on the level of the individual Member States. The applicant should consult a CA as to which data should be submitted. This will allow for proper risk mitigation measures to be decided upon if an active substance is likely to fail the criteria for entry into the *Union list of approved active substances* or if a product is likely to fail the criteria to be authorised at national or EU level.
6. The data submitted by the applicant will form the basis for classification and labelling according to the CLP Regulation (harmonised classification in case of active substances and self-classification in case of biocidal products). The active substances may be subject to harmonised classification for the first time or the data can be used to review a previous harmonised classification.
7. The data and test requirements should suit the individual circumstances and thus make it possible to assess the risks and efficacy under a range of conditions. The following parameters should be taken into account when preparing the application for authorisation:
    a. The characteristics of the application technique,
    b. The user type (e.g. professional or non-professional users), and
    c. The environment, in which the product is intended to be used or into which the product may be released.

8. Article 62 (1) of the BPR states that *In order to avoid animal testing,* ***testing on vertebrate animals*** *for the purposes of this Regulation shall be undertaken* ***only as a last resort****. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.* Concerning the latter, further detailed rules are provided in Article 62 (2) of the BPR. The data generated and collected under other legislative regimes, especially under Council Regulation (EU) No 544/2011, Council Regulation (EC) No 1907/2006 and Council Regulation (EC) No 1272/2008 should be used, taking into account the rules on data protection. Sharing of vertebrate data submitted under the BPD or BPR is mandatory.
9. With regard to **data sharing**, for guidance see the ECHA Biocides Guidance webpages and the reference to the REACH Guidance on data sharing established by ECHA (in accordance with Regulation 1907/2006 (REACH) and the Explanatory Note clarifying which chapters are of relevance to the applicants under Biocidal Products Regulation (EU) No528/2012 (BPR), [http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation].
10. For renewal of a product authorisation the applicant must submit **all relevant data required under Article 20 of the BPR, that it has generated since the initial authorisation**. This requirement corresponds to the obligation to submit any new data after the authorisation has been granted (Article 13(2) of the BPR). This only applies to data that were generated by the applicant and not any other data that may be available. For example, if several reports on similar studies are available to the applicant they should all be submitted to allow a more sound risk assessment with, among others, assessment of inter-species variability. An exception to this rule, is for resistance when all available data including a literature search, should be provided. The additional data should be of an acceptable quality (see Annex IV, point 1 of the BPR).
11. Point 8 (a) of Annex VI to the BPR states that for the evaluation of a biocidal product, the evaluating CA *shall take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues*. This means that Member States and other stakeholders should also submit relevant data to the evaluating CA relevant data, which is reasonably available to them but which has not been available to the applicant. The applicant is not responsible for this additional information. The applicant, however, is responsible to search for data from all sources which he or she may reasonably be expected to have access to.
12. Public literature data can be used in the assessment if the following conditions are fulfilled:
    a. The data comply with the BPR Annex II, III introduction points 5-9.
    b. The identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the substance addressed in the application.
    c. The reporting of the study allows evaluation of the quality of the study.

    If conditions a-c are met the applicant can claim that adequate data is publicly available. Providing that the quality of public data fulfils the criteria, it can be used as key studies.
13. There must be at least one key study or an accepted waiving justification for each CDS endpoint given in the BPR Annexes II and III (and for each PT if more than

one PT is applied for). The same applies to ADS endpoints in the BPR Annexes II and III, depending on the product-type (in the case of ecotoxicology endpoints and environmental fate and behaviour) and on intrinsic physical-chemical or toxicological properties of the substance or the product, respectively. A key study is the critical study for a certain endpoint and has to be reliable and adequate to use for the risk assessment and efficacy assessment. For criteria on the selection of key studies and further information, see 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, efficacy assessment and decision making. The need for additional studies may be justified either by the properties of the chemical (i.e. hazard) or by the predicted exposure. In Article 8(2) of the BPR it states that *where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly.* In that case, the stop-the-clock rule is applied. Data may also be required for a **substance of concern** present in the biocidal product other than the active substance. Similarly for a **co-formulant**[2] to demonstrate that it cannot be considered an active substance. . However, the detailed requirements are left mainly to be judged on a case-by-case basis and if the outcome of the applicant's assessment indicates a need for more data, the applicant should already consider further studies.

16. Point 11 of Annex VI to the BPR states that *During the process of evaluation, applicants and the evaluating bodies shall **cooperate** in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.* BPR Specifically SMEs should be allowed extensive guidance from the competent authorities in order to be able to fulfil the obligations laid down in the BPR.

17. For the approval of the active substance a specification of the active substance will need to be derived. This specification must be representative for the manufacturing process as well as for the (eco)toxicological batches tested or, in other words, the reference source would be the source for which the (eco)toxicological data submitted cover the specification. Therefore it needs to be ensured that all impurities in the proposed specification are considered in the environmental fate and (eco)toxicological studies (batches used for the

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

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).

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

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

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

1.3.2 REACH Guidance

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

1.3.3 CLP Guidance

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

1.4 General guidance on generating 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 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 CA when checking the completeness of the application and approving the justification provided for such a case. If a test has been performed, that does not comply with the Test Methods Regulation, the nature of the differences must be indicated and justified. The same applies to deviations from the test protocol used. The test protocol should be provided in full unless there is sufficient detail in the test report.

In certain cases, testing can be replaced by modelling using (Q)SAR, Quantitative Structure Activity Relation. *Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals.*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 CA on the name to be given to the active substance. This could be for example simple ions or different molecular structures, precursor/activator, or unstable/breakdown active components, or multiple component products. The specifications of the used material need to be described in detail (point 7 of Annex 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 *Guidance on intermediates*. The Guidance provided in the Technical Guidance Document concerning risk assessment of new and existing substances Part II (EU, 2003) should also be followed when designing the testing strategy for substances that are difficult to test.

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

1.5 Guidance on non-submission of information

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

1.6 Testing of metabolites and transformation products

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

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

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

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

In general, an environmental risk assessment for the relevant compartments needs to be performed for all major metabolites. However, as a first step a semi-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 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States.

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

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

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

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

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

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

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

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

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

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

Decisions

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

1.8 Sources of test methods and standards

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

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

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

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

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

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

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

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

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

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

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

2. Part A: Dossier Requirements for Active Substances

BPR Annex II, Title 1, 9 Ecotoxicological studies

NOTE to the reader:

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

2.1 Point 9 Ecotoxicological studies

The ability of the active substance to damage the function and structure of ecosystems has to be clarified with a selection of ecotoxicity tests. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported. The information provided must be sufficient to permit an assessment of the impact on non-target species likely to be exposed. The information provided must also be sufficient to permit hazard classification of the active substance (bioaccumulative, toxic) in accordance with CLP Regulation.

In the following, the words "active substance" or "substance" may also refer to metabolites, degradation or reaction products. It may be necessary to conduct separate studies for these when a potential impact cannot be sufficiently evaluated from the ecotoxicological profile of the active substance alone. Before such separate studies are performed, relevant information pertaining to metabolites, degradation or reaction products submitted in accordance with other relevant sections of Annex II to the BPR has to be taken into account. The information derived from the tests must permit a characterisation of the ecotoxicological significance of the metabolites, degradation or reaction products, and also reflect the nature and extent of the effects on non-target organisms and ecosystems.

Depending on the use and emission of the active substance, additional exposure-driven testing may be required. Tests should be performed with species representative of the environmental compartments and habitats that are exposed. Where relevant the mode of action of the substance should also be considered for selecting appropriate species. Further Guidance on exposure-driven information requirements is given in the product-type-specific guidance (section 5 of this guidance).

Testing on vertebrate animals must only be performed as a last resort, and only when the purpose and use of a product so requires. The applicant is also obliged to inquire from ECHA whether a certain vertebrate animal study is already available. Should this be the case, the test data must be shared (BPR Preamble 57 and Article 62). Absent or only low exposure to a substance may permit omitting a study if it is judged that further effect data would not help to make a better informed risk assessment. Accordingly, if a risk is found in a preliminary assessment, a refinement of the exposure assessment should be performed before further tests with vertebrate animals are carried out. Furthermore, alternative testing approaches, such as *in vitro* or *in silico* methods must be employed before a vertebrate animal test is carried out.

Further information on non-submission of data can be found in section 1.5 of this guidance. Further Guidance on alternative methods and limiting of live animal studies can be found amongst others in Annex IV of the BPR and a number of ECHA publications: *The use of Alternatives to Testing on Animals for the REACH Regulation, ECHA-11-R-004-EN; Practical guide 10: How to avoid unnecessary testing on animals. ECHA-10-B-17-EN; Guidance on the application of the CLP criteria; Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7*.

Further Guidance providing more comprehensive background information to each data requirement and its use in the risk assessment can be found in the ECHA Guidance on information requirements, Chapter R.7b-c *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7b-c.* respectively the TGD on risk assessment, Part II (EU, 2003). Other guidelines from e.g. US EPA or EFSA may also be useful for some data requirements and will be referenced specifically.

Aspects to consider for conducting and reporting ecotoxicological studies

Where relevant, tests should be designed and data analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all point estimates should be provided with confidence intervals, exact probability values should be provided rather than stating significant/insignificant).

Preference should be given to test protocols and species for which existing guidelines or published studies are available.

2.1.1 Toxicity to Aquatic Organisms

Aspects to consider for testing on aquatic organisms

When carrying out ecotoxicity tests on aquatic organisms, it is required to measure the solubility and stability of the substance in the test medium, as it may differ from the results obtained in the water solubility test (Volume I). In addition the Guidance for the environmental effects assessment for biocidal active substances that rapidly degrade in environmental compartments of concern (EU, 2009a) is relevant for testing rapidly degrading active substances.

Concentrations up to 100 mg/L should be tested. A limit test at 100 mg/L may be performed when results of a range-finding test indicate that no effects are expected.

Additional tests with aquatic organisms may be needed to refine the initial risk assessment, as they may help to reduce the uncertainty. For this purpose, further short term testing on invertebrates or fish is not useful. Likewise, short term testing may not be necessary if long term studies are available.

Additional tests may also be required if there are uncertainties that require additional environmental effects information. For example, because of the environmental fate or the mode of action of the substance, or because of exposure to different environments or habitats.

If the data from the base set (algae, daphnids and fish) shows that one trophic level is more sensitive, and this is also corroborated by the mode of action of the substance, additional ecotoxicity studies that are required because of exposure to the marine or brackish environment may only need to be supplied for the most sensitive trophic level. To contribute to reduction of the uncertainty in the PNEC derivation any such additional studies should be long term.

For the purpose of PNEC derivation or refinement, interchangeable use of marine and freshwater ecotoxicity data is possible if the difference in sensitivity between freshwater and marine organisms belonging to the same trophic level is within a factor of 10. This would indicate that no specific environmental condition is more relevant for the effect assessment.

Differences in sensitivity can be judged for acute (EC_{50}; LC_{50}) as well as chronic (NOEC; LOEC; EC_{10}) endpoints. NOEC and LOEC values should however be used with caution as they are influenced by the dosing regime and the statistical power of the test.

In comparison to the PNEC setting for the freshwater environment, an additional assessment factor of 10 always applies for the marine (including brackish) environment,

regardless of whether the data supplied is acute or chronic, or representative of marine or freshwater taxa. This additional uncertainty factor reflects the higher biodiversity in marine ecosystems compared to freshwater ecosystems, which may result in a broader distribution of species sensitivities. For brackish environments such as the Baltic Sea it represents an ecosystem with low biodiversity which is particularly sensitive to perturbations because of low ecological redundancy (TGD, (EU, 2003)). Only by conducting further studies with additional marine taxonomic groups, for example rotifers, echinoderms or molluscs, can the uncertainties with respect to the marine risk assessment be reduced and the additional assessment factor for the risk assessment be lowered.

Further considerations in the TGD (EU, 2003) on the PNEC setting for the freshwater and marine environments apply.

Further Guidance for the selection of appropriate additional aquatic tests is given in the guidance for product-type-specific testing in section 5 of this guidance, as well as in the TGD (EU, 2003), respectively in *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7b-c.*.

2.1.1.1 Short term toxicity testing on fish

Point 9.1.1 of Annex II to the BPR states that *when short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied*

One species should be tested, preferably a fresh water species or, if different aquatic environments are exposed, two species may be required. The two species selected should represent freshwater and marine (or brackish) environments. *Cyprinodon variegatus* may be used as marine species in the OECD Test Guideline 203 (Fish, Acute Toxicity Test) or the US EPA guideline OPPTS 850.1075 (Fish Acute Toxicity Test, Freshwater and Marine).

The study does not need to be conducted if a valid long-term aquatic toxicity study on fish is available.

The threshold approach (tiered strategy) according to the OECD Guidance Document must be considered: essentially the approach uses a limit test at a single threshold concentration determined by the results of *Daphnia magna* and algae tests. If no mortality is observed in the limit test, the fish acute value can be expressed as greater than the threshold value. However, if mortality is observed a full concentration-response test is triggered. So for an active substance testing would occur with alga and *Daphnia magna*, the lower of the two concentrations would then be used in a limit test for fish. See the OECD Draft guidance 'The Threshold Approach for Acute Fish Toxicity Testing' for further details.

2.1.1.2 Short term toxicity testing on aquatic invertebrates

Daphnia magna

Test according to EC method C.2 (*Daphnia sp.* Acute Immobilisation Test) or the corresponding OECD Test Guideline 202 (Daphnia sp. Acute Immobilisation Test). Testing may be omitted if results are available from any non-standard test protocols, also with a different invertebrate species. The relevance of any such data as a surrogate should be decided in a weight of evidence approach.

Other species (ADS)

In addition to *D. magna,* a broad range of other aquatic invertebrates can be tested for acute toxicity. For example, additional marine or brackish data may be necessary for the risk assessment. Alternatives to OECD test guidelines are publications from ASTM

International and ISO as well as the US EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS). Various aquatic testing methods described in the scientific literature and elsewhere are consolidated and evaluated with respect to their feasibility for routine testing and standardisation in the OECD Series on testing and Assessment No. 11 Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals (OECD, 1998). The review includes testing methods for the pelagic environment for a range of insect species such as mosquitoes, caddisflies, stoneflies and mayflies.

Most of the references cited in sections 2.1 and 3.1 of this guidance are exclusively for either freshwater or saltwater species. There are, however, some guidelines that are suitable for the testing of both freshwater and marine species.

2.1.1.3 Growth inhibition study on algae

Effects on growth rate on green algae

Test according to EC method C.3 (Algal inhibition test) or the corresponding OECD Test Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test), or for a marine species a test according to, for instance the ISO 10253 (Water quality -- Marine algal growth inhibition test with Skeletonema costatum and Phaeodactylum tricornutum). For a marine or brackish water species e.g. the US-EPA guideline OPPTS 850.5400 (Algal toxicity, Tiers I and II) may be used.

Effects on growth rate of cyanobacteria or diatoms

Required for phytotoxic and/or antimicrobial substances. Should be studied with one species, preferably a fresh water species. Tests with additional marine or brackish species such as *Skeletonema costatum* (diatom) according to the ISO 10253 (Water quality - Marine algal growth inhibition test with Skeletonema costatum and Phaeodactylum tricornutum), or *Anabaena flos-aquae* (cyanobacterium representative of both fresh and brackish environments) for OECD Test Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test) or the US EPA method OPPTS 850.5400 (Algal Toxicity, Tiers I and II) may be required if there is exposure.

2.1.1.4 Bioconcentration

This data requirement is closely related to the endpoint 9.1.7 – Bioaccumulation. The static bioconcentration factor (BCF) is the ratio of the internal concentration of a substance in an organism to the concentration in water (or other external medium) once a steady state has been achieved. Bioaccumulation refers to the net result of absorption (uptake) via different routes, distribution, metabolism and excretion of a substance in the organism.

An estimation of the intrinsic potential for bioconcentration in aquatic organisms should be submitted on the basis of physical and chemical properties (e.g. partition coefficient n-octanol/water). For surface active substances (surface tension lower than 60 mN/m) and dissociating or inorganic substances such as metals, toxicokinetic studies (including metabolism), residue studies or monitoring data on aquatic organisms (e.g. residue data in aquatic organisms and environmental concentrations) should be submitted.

Further Guidance:

- ECHA Guidance on information requirements Chapter R.7.10.1 Aquatic bioaccumulation *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.*

Estimation methods

For estimation of BCF, see TGD (EU, 2003) Chapter 3.

The evaluation of aquatic bioconcentration should include an estimate of the bio-concentration factor related to absorption of the substance via the food chain.

Experimental determination

Test according to OECD Test Guideline 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure) or the EC method C.13 (Bioconcentration: Flow-through Fish Test).

The experimental determination may not need to be carried out if it can be demonstrated on the basis of physico-chemical properties (e.g. log K_{ow} <3) or other evidence that the substance has a low potential for bioconcentration. All critical aspects of bioaccumulation such as ionic speciation, surface activity and metabolic transformation rates must be considered before experimental determination is considered unnecessary.

2.1.1.5 Inhibition of microbial activity

Test according to EC method C.11 (Biodegradation: Activated Sludge Respiration Inhibition) or the corresponding OECD Test Guideline 209 (Activated Sludge, Respiration Inhibition Test).

The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.

All available data on the toxicity to micro-organisms in the sewage treatment plant should be reviewed and evaluated. Further testing should be evaluated according to the integrated testing strategy, in the *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7b*.

2.1.1.6 Further Toxicity Studies on Aquatic Organisms (ADS)

Point 9.1.6 of Annex II to the BPR states that *if the results of the ecotoxicological studies, studies on fate and behaviour and/or the intended use(s) of the active substance indicate a risk for the aquatic environment, or if long-term exposure is expected, then one or more of the tests described in this Section shall be conducted.*

See also the product-type-specific guidance in section 5 of this guidance.

Further Guidance on the selection of long term aquatic toxicity tests on the basis of results from short term tests is given in TGD (EU, 2003) and *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.* Chapter R.7.8.5.3 Conclusions on Chemical Safety Assessment (PNEC Derivation).

Further ecotoxicity testing would not normally be required on aquatic species for which no short term toxicity has been demonstrated (L(E)C_{50} >100 mg/l); exemptions may be substances poorly soluble in water. For these, long term testing might be required.

Long term toxicity testing on fish (ADS)

(a) Fish Early Life Stage (FELS) Test (ADS)

Test according to OECD Test Guideline 210 (Fish, Early-Life Stage Toxicity Test). It should be performed where long term fish toxicity data is required and the substance has the potential to bioaccumulate. For marine environments, the test can be performed with *Cyprinodon variegates*.

The test is considered as the most sensitive of the fish tests, covering several life stages from the newly fertilised egg, through hatching to early stages of growth. This is believed to cover most, but not all, of the sensitive stages in the life-cycle. The FELS test

is together with the full life cycle test the only suitable approach for examining the potential toxic effects of bioaccumulation.

(b) Fish short term toxicity test on embryo and sack fry stages (ADS)

Test according to EC method C.15 (Fish, short-term toxicity test on *embryo* and *sac-fry* stages) or the corresponding OECD Test Guideline 212 (Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages). It is considered as an alternative to the FELS test for substances with log Kow < 4. For marine environments, the guideline proposes several species, e.g. *Cyprinodon variegatus*. The test covers the sensitive early life stages from the newly fertilised egg to the end of the sac-fry stage. It is considerably shorter, and hence cheaper, than the FELS test but is also considered to be less sensitive.

(c) Fish juvenile growth test (ADS)

Test according to EC method C.14 (Fish Juvenile Growth Test) or the corresponding OECD Test Guideline 215 (Fish, Juvenile Growth Test). The test provides a shorter and cheaper option to the FELS test for substances with log Kow < 5. Although it is considered to be of insufficient duration to examine all the sensitive stages in the fish life cycle, it covers the growth of juvenile fish over a fixed period and is as such considered as a sensitive indicator of fish toxicity.

(d) Fish full life cycle test (FFLCT) (ADS)

Such a test may be necessary if results from other long-term studies with fish indicate concern (see also section 2.1.1.10 of this guidance - Identification of endocrine activity).

There are currently no agreed guidelines available for a FFLCT, although two reviews of existing testing approaches and protocols under development are available, the OECD Series on Testing and Assessment No. 95 Detailed Review Paper on Fish Life-cycle tests (OECD, 2008c) and No. 171 Fish Toxicity Testing Framework (OECD, 2012a), including the Japanese medaka multi-generation test as well as one-generation FFLCT likely to be sufficient to satisfy regulatory requirements.

Although FFLCTs are generally more sensitive to endocrine disruptors than partial life cycle reproduction tests, it has not yet been demonstrated that two-generation or multi-generation tests with fish offer any further advance in sensitivity (OECD, 2012a). Nevertheless, a two-generation or multi-generation FFLCT is likely to provide an optimal response to all possible modes of chemical toxicity (endocrine and non-endocrine), and as such could be considered as providing a 'gold standard' result on developmental and reproductive endpoints. Such a test would provide definitive data on the long term fish toxicity of a substance, although these are not necessarily indicative or specific to any particular mode of action.

Long term toxicity testing on invertebrates (ADS)

a) Daphnia growth and reproduction study (ADS)

The relevant test is OECD Test Guideline 211 (D*aphnia magna* Reproduction Test).

b) Other species reproduction and growth (e.g. Mysid) (ADS)

Tests with an aquatic insect should be performed first for insecticidal substances or substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development. Tests involving sensitive life stages, special routes of uptake or other modifications, may be necessary. The rationale for the choice of test species and exposure conditions used should be provided. For the marine environment, the shrimp *Mysidopsis bahia* is the preferred test species and the relevant

test is the US EPA guideline OPPTS 850.1350 (Mysid Chronic Toxicity Test). For relevant freshwater species, see section (c) (below) of this guidance .

Test methods for other marine species and organism groups are available, e.g.:

- Polychaetous Annelids: ASTM E1562 'Standard Guide for Conducting Acute, Chronic, and Life-Cycle Aquatic Toxicity Tests with Polychaetous Annelids'.
- *Nitocra spinipes* (copepod, marine): Danish standard DS 2209:1990 (Water quality - Acute ecotoxicological test with the crustacean *Nitocra Spinipes* - Static method).

Aquatic testing methods for a variety of taxonomic groups such as marine and/or freshwater amphipods, bivalves, crustaceans and echinoderms described in the scientific literature and elsewhere are consolidated in the OECD Series on testing and Assessment No. 11 (Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals). The species tested should be representative of the exposed environment.

c) Other species development and emergence (e.g. Chironomus) (ADS)

Tests with an aquatic insect should be performed first for insecticidal substances or substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development. Tests involving sensitive life stages, special routes of uptake or other modifications, may be necessary. The rationale for the choice of test species and exposure conditions used should be provided.

The relevant test for Chironomus sp. is OECD Test Guideline 219 (Sediment-Water Chironomid Toxicity Using Spiked Water). If the substance is likely to accumulate in the sediment, the OECD Test Guideline 218 *Chironomus sp.* method for spiked sediment should be used instead to reflect the major route of exposure (see section 2.1.1.9 of this guidance - Studies on sediment dwelling organisms).

Another relevant insect species is *Chaoborus sp*. (with several species such as *Chaoborus obscuripes*, *Chaoborus flavicans*, *Chaoborus crystallinus* and *Chaoborus americanus*).

Chronic test methods with mayflies (*Cloeon sp.*, *Stenonema sp.* and *Epeorus sp.*) for the freshwater pelagic environment are described in the scientific literature and may be considered if motivated by exposure route. These tests have been given relatively high overall evaluation scores (with respect to their feasibility for routine testing) in an OECD review paper on aquatic testing methods (OECD Series on testing and Assessment No. 11, Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals (OECD, 1998).

2.1.1.7 Bioaccumulation in an appropriate aquatic species (ADS)

Bioaccumulation studies should be conducted when the substance has surface activity (i.e. surface tension < 60 mN/m at a concentration $\leq$ 1 g/l) or structural features indicating bioaccumulation (as in the case of e.g. pyridinium compounds).

There may also be other grounds for testing. A test with fish is required when there is the risk for secondary poisoning. For marine environments, *Cyprinodon variegatus* should be tested according to the EC method C.13 (Bioconcentration: Flow-Through Fish Test) or preferably the corresponding OECD Test Guidelines 305 (Bioaccumulation in Fish: Aqueous and Dietary Exposure). A range of other fish species may also be tested with this method. Testing during a juvenile life stage with rapid growth should be avoided as growth dilution might then extensively influence the outcome. In any case, the fish must be weighed to correct the results for this factor (OECD, 2012a).

Studies with invertebrates may be required for some product-types, especially if a direct release to marine or brackish environments occurs (see also the product-type-specific guidance in section 5 of this guidance). Test protocols suitable for several species are available:

- *Mytilus edulis* (mussel, marine); Pecten spp. (scallop, marine); *Crassostrea gigas* or *C. virginica* (oyster, marine) ASTM E1022 (Standard Guide for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Mollusks).
- Nereis virens or Capetella sp. (polychaetes, marine), Macoma balthica, M. nasuta or Yoldia imatula (clams, marine); Diporeia sp. (amphipod, freshwater); Chironomus tentans (midge, freshwater); Hexagenia sp. (mayfly, freshwater) ASTM E1688 (Standard Guide for Determination of the Bioaccumulation of Sediment-Associated Contaminants by Benthic Invertebrates).
- *Crassostrea virginica* (oyster, marine): US-EPA OPPTS 850.1710 (Oyster BCF)

2.1.1.8 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data may be required for non-target organisms other than fish, microalgae and invertebrates if concerns are raised from the uses and emissions of the active substance, effects detected on other aquatic species, or a preliminary risk assessment. This may involve tests on sediment dwelling organisms and aquatic macrophytes, accumulation and elimination in shellfish, or tests with additional brackish or marine organisms.

2.1.1.9 Studies on sediment dwelling organisms (ADS)

When accumulation of an active substance in an aquatic sediment is indicated or predicted by environmental fate studies, the impact on a sediment-dwelling organism should be assessed. Testing might be required for certain product-types (see product-type-specific Guidance in section 5 of this guidance) or if the risk assessment for sediment based on the equilibrium partition method indicates a possible risk to the benthic compartment.

The selection of test species should be made on the basis of mode of action information coupled to biological traits, as representatives of different taxonomic groups are available, but also habitat and feeding strategy to reflect different routes of exposure among sediment organisms. In this context, a distinction could be made between epibenthic deposit feeders (Chironomids) and endobenthic sediment ingesters (Oligochaetes). To make a distinction between sediments of different composition rather than different species, it is also recognised that the variability of sediment could be as relevant for the outcome of the test as species sensitivity. Normalisation to default organic matter is not foreseen in the TGD (EU, 2003) for sediment studies. However, it should be clearly indicated whether the organic matter content is in line with the Guidance, or strongly deviates from it, since this may influence the quality of the study.

Organisms should be exposed to spiked sediment. The presence of spiked sediment is essential because the substances for which testing is required are typically very hydrophobic substances or substances that bind covalently to sediment. Long-term tests should be performed and one long-term NOEC or EC_{10} value should be sufficient at the first stage. This value will be based on the measured bulk sediment concentration. If further refinement of the PNEC would be necessary, test species with different habitats and feeding strategies should be preferred to reflect the possible different ways of exposure.

The following recommendations can be made with respect to the test species. The recommended species are complementary to each other with respect to feeding strategy and habitat:

- Long-term Chironomid toxicity test (spiked sediment). Test according to OECD Test Guideline 218 (Sediment-Water Chironomid Toxicity Using Spiked Sediment). This test should be considered first for insecticidal substances or substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development.
- Long-term Oligochaete test (spiked sediment). If testing is needed, preference should be given to an endobenthic sediment ingester to reflect different habitat and feeding strategies. Oligochaetes such as *Tubifex sp.* or *Lumbriculus sp.* would be suitable candidates. Standardised tests for these species are OECD Test Guideline 225 (Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment) the ASTM E1367 (Standard Test Method for Measuring the Toxicity of Sediment-Associated Contaminants with Estuarine and Marine Invertebrates) and the ASTM E1706 – (Standard Test Method for Measuring the Toxicity of Sediment-Associated Contaminants with Freshwater Invertebrates).
- Long-term test (spiked sediment) with *Gammarus sp.* or *Hyalella sp.* This could be considered if a test with a third species would be necessary to reduce the uncertainty in the effect assessment. Alternatively, testing with a second sediment sample could be considered. *Gammarus sp.* and *Hyalella sp.* are epibenthic deposit feeders, but the difference with *Chironomus sp.* is apart from belonging to different taxonomic groups that they spend their whole life cycle on the sediment. Standardised tests are described in the ASTM E1367 and E1706.

2.1.1.10 Effects on aquatic macrophytes (ADS)

A test with *Lemna* sp. according to OECD Test Guideline 221 (*Lemna sp.* Growth Inhibition Test) should be performed for herbicides, plant growth regulators, and fungicides, where there is evidence that the test compound has herbicidal activity. The test should provide information on inhibition of growth and yield based on frond numbers, and on a second variable such as frond area, dry weight, or fresh weight.

If the test compound is an auxin inhibitor, or if there are clear indications from efficacy data or from testing with terrestrial non-target plants for higher toxicity to dicotyledonous plant species, then a test should be carried out using a dicotyledon species. A test protocol specifically for *Myriophyllum sibiricum* was available ASTM E1913 (Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, *Myriophyllum sibiricum* Komarov) but was withdrawn in 2012 without replacement. More general guidelines for a variety of freshwater emergent macrophytes are available in ASTM E1841 (Standard Guide for Conducting Renewal Phytotoxicity Tests With Freshwater Emergent Macrophytes). The tests should provide sufficient information to evaluate impact on aquatic plants and include details of the inhibition of shoot length, inhibition of root number and length and inhibition of fresh or dry weight.

2.1.2 Terrestrial toxicity, initial tests (ADS)

These tests are required if the risk assessment for the terrestrial compartment, based on the equilibrium partitioning method indicates a concern for the terrestrial compartment, or if there is direct or long term exposure. If there is potential continuous exposure, long-term test (see section 2.1.3 of this guidance) should be considered instead. For some product-types, these tests will be required with the core data set (see the product-type-specific guidance in section 5 of this guidance for further details). It is necessary to

submit ecotoxicity data on all three points 9.2.1 - 9.2.3 to allow a derivation of a more realistic PNEC for the terrestrial compartment than the PNEC based on the equilibrium partitioning method.

All effect concentrations from earthworms, terrestrial plants and terrestrial micro-organisms should be converted to the TGD standard soil organic matter content (3.4%) before choosing one effect value for derivation of the PNEC (EU, 2003). As stated in the TGD this is only appropriate when it can be assumed that the binding behaviour of a non-ionic organic substance in question is predominantly driven by its log K_{ow} and that organisms are exposed predominantly via pore water.

2.1.2.1 Effects on soil micro-organisms (ADS)

One or more of the following tests should be conducted:

- A test on effects on nitrogen transformation and/or carbon mineralisation in soil according to the EC method C.21 (Soil Micro-organisms: Nitrogen Transformation Test) or the corresponding OECD Test Guideline 216 (Soil Micro-Organisms, Nitrogen Transformation Test), or the EC method C.22 (Soil Micro-organisms: Carbon Transformation Test) or the corresponding OECD Test Guideline 217 (Soil Micro-Organisms, Carbon Transformation Test), respectively.
- A test on inhibition of soil non-target micro-organisms according to the ISO 14238:2012 (Soil quality - Biological methods - Determination of nitrogen mineralisation and nitrification in soils and the influence of chemicals on these processes), or the BBA guideline Part VI, 1.1 (Effects on the activity of the soil microflora), or the DIN EN ISO 23753-2 (Soil quality - Determination of dehydrogenase activity in soils - Part 2: Method using iodotetrazolium chloride).

2.1.2.2 Effects on earthworms or other soil-dwelling non-target invertebrates (ADS)

One or more of the following tests should be conducted:

- *Lumbricina* (earthworm): Test according to EC method C.8 (Toxicity to Earthworms) or the corresponding OECD Test Guideline 207 (Earthworm, Acute Toxicity Tests).
- *Caenorhabditis elegans* (nematode) according to the ASTM method E2172 (Standard Guide for Conducting Laboratory Soil Toxicity Tests with the Nematode *Caenorhabditis elegans*)

For insecticidal substances an arthropod is the preferred test species for assessing survival under short-term acute exposure. For example, *Aleochara bilineata* (rove beetle), *Poecilus cupreus* (carabid beetle), or *Pardosa sp.* (wolf spider) according to the IOBC 'Guidelines to evaluate side-effects of plant protection products to non-target arthropods' (IOBC, 2000). Tests involving sensitive life stages, special routes of uptake or other modifications, may be necessary. The rationale for the choice of test species and exposure conditions used should be provided.

2.1.2.3 Acute toxicity to plants (ADS)

Test according to OECD Test Guideline 208 (Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test), or OECD Test Guideline 227 (Terrestrial Plant Test: Vegetative Vigour Test). Where it can be clearly demonstrated by the mode of action that either seedling emergence or vegetative vigour is affected, only the relevant test

should be conducted. The exposure pathway should also govern which test to conduct. For active substances emitted to the environment through spray drift, additionally a test with plant surface treatment should be performed.

Data on species from different taxa of monocotyledons and dicotyledons must be provided, including at least one nitrogen fixating species (*e.g.,* Leguminosae). At least three species must have been tested according to these OECD Test Guidelines.

2.1.3 Terrestrial tests, long term (ADS)

These tests are required if the risk assessment for the terrestrial compartment based on the results from the acute toxicity tests indicates a concern, or if there is potential continuous exposure. For the risk assessment, the NOEC from the test on inhibition of soil micro-organisms (section 2.1.2.1 of this guidance) can be used as long-term result. The NOEC from the acute plant study (section 2.1.2.3 of this guidance) can also be used as a long-term result if, on the basis of the acute tests earthworms and micro-organisms are more sensitive. A chronic test for plants (ISO 22030 'Soil quality - Biological methods - Chronic toxicity in higher plants') is required if the acute tests show that plants are the most sensitive group.

Further Guidance:

- TGD (EU, 2003),
- *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.* Chapter R.7.11.5.3 Concluding on suitability for use in Chemical Safety Assessment

2.1.3.1 Reproduction study with earthworms or other soil-dwelling non-target invertebrates (ADS)

One or more of the following tests should be conducted:

- *Lumbricina* (earthworm) according to OECD Test Guideline 222 (Earthworm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*)), alternatively the ISO 11268-1 (Soil quality - Effects of pollutants on earthworms - Part 1: Determination of acute toxicity *to Eisenia fetida*/*Eisenia andrei*)
- *Enchytraeid* (enchytraeid worm), according to OECD Test Guideline 220 (Enchytraeid Reproduction Test) alternatively the ISO 16387 (Soil quality - Effects of pollutants on Enchytraeidae (*Enchytraeus sp.*) - Determination of effects on reproduction and survival)

For insecticidal substances or substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development, an arthropod is the preferred test species. *Hypoaspis (Geolaelaps) aculeifer* (predatory mite) according to OECD Test Guideline 226 (Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil; *Folsomia candida* (springtail) according to OECD Test Guideline 232 (Collembolan Reproduction Test in Soil) alternatively the ISO 11267 (Soil quality - Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants), *Aleochara bilineata* (rove beetle), *Poecilus cupreus* (ground beetle), or *Pardosa sp.* (wolf spider) according to the IOBC (IOBC, 2000). Tests involving sensitive life stages, special routes of uptake or other modifications, may be necessary. The rationale for the choice of test species and exposure conditions used should be provided.

2.1.4 Effects on birds (ADS)

For some product-types, where direct exposure for birds is possible tests with birds are required. This is also the case where a first risk assessment for birds, e.g. on the conclusions of mammalian toxicity data or bioaccumulation data indicates concern.

However, the bird tests are associated with high animal welfare concerns and there is a risk that results will only be of limited regulatory and scientific use. This is especially of concern for the acute oral toxicity study as indicated in section 2.1.4.1 of this guidance.

Further Guidance:

- *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.*
- EFSA Guidance Document on Risk Assessment for Birds and Mammals. (EFSA, 2009a)

2.1.4.1 Acute oral toxicity (ADS)

Test according to OECD Test Guideline 223 (Avian Acute Oral Toxicity Test) or SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides (SETAC, 1995). The highest dose used in tests need not exceed 2000 mg/kg body weight. The acute oral toxicity study is of only limited use for PNEC derivation. Accordingly, this study should only be performed as a last resort and be chosen with care taking into account, e.g. exposure regime, environmental fate, and mode of action of the substance, as well the relevance of the particular study for the risk assessment. Alternative non-testing approaches must be exhausted, and where relevant a food avoidance study (OECD Draft Guidance document on avoidance testing of birds, (OECD, 2011)) should be performed first to investigate whether direct oral exposure, such as ingestion of pellets, is plausible.

2.1.4.2 Short-term toxicity – eight-day dietary study in at least one species (other than chickens, ducks and geese) (ADS)

Test according to OECD Test Guideline 205 (Avian Dietary Toxicity Test). If the test for effects on reproduction (section 2.1.4.3 of this guidance) is available, this test is not necessary.

The short term dietary study is criticised (EFSA, 2009b) for being associated with substantial methodological limitations that can hamper interpretation. On the basis of recommendations from the PPR Panel (EFSA, 2009b) the short term dietary study should be conducted only for substances where the mode of action and/or results from mammalian studies indicate a potential for the dietary LD_{50} measured by the short term study to be lower than the LD_{50} based on an acute oral study. This would apply, for instance, to many of the organochlorine compounds and anticoagulants like flocoumafen. The short-term dietary test should not be conducted for any other purpose unless it can be clearly justified. When the study is justified, it should be conducted with one species only. The short-term dietary test should not be used simply to demonstrate the potential for food avoidance, as this can be achieved satisfactorily with fewer birds in a shorter (one day) study.

2.1.4.3 Effects on reproduction (ADS)

Test according to OECD Test Guideline 206 (Avian Reproduction Test).

The study does not need to be conducted if the dietary toxicity study shows that the LC_{50} is above 2 000 mg/kg food.

2.1.5 Effects on arthropods (ADS)

A test on bees and/or other beneficial arthropods may be required for insecticides, acaricides and substances in products to control other arthropods which are used outdoors, i.e. for large scale-outdoor applications like fogging (e.g. product-type 18 - products against mosquitoes for human health reasons). Additionally, for systemic insecticides exposure to bees should also be quantified. When no data is available, a qualitative assessment should be performed.

Effects on arthropods do not usually have to be assessed for uses with indoor applications only. Tests may be needed in case of drift occurring from e.g. large cooling water systems or outdoor spray uses.

2.1.5.1 Effects on honeybees (ADS)

Tests on acute oral and/or contact toxicity on bees should be done according to OECD Test Guideline 213 (Honeybees, Acute Oral Toxicity Test) and respectively OECD Test Guideline 214 (Honeybees, Acute Contact Toxicity Test). Guidelines are also available for trials for side-effects on bees as the EPPO PP 1/170/(3) (Side-Effects on Honeybees), and for brood test under semi-field conditions the OECD Series on Testing and Assessment No. 75 (Guidance Document on the Honey Bee (*Apis Mellifera L.*) Brood Test Under Semi-Field Conditions).

2.1.5.2 Other non-target terrestrial arthropods, e.g. predators (ADS)

Possible species to be tested in addition to honeybees are for instance, *Chrysoperla carnea* (common green lacewing), *Trichogramma cacoeciae* (Hymenoptera egg parasitoid), *Coccinella septempuna* (ladybird) or *Aleochara bilineata* (rove beetle) according to the IOBC 'Guidelines to evaluate side-effects of plant protection products to non-target arthropods' (IOBC, 2000). Tests involving sensitive life stages, special routes of uptake or other modifications may be necessary. The rationale for the choice of test species and exposure conditions used should be provided.

2.1.6 Bioconcentration, terrestrial (ADS)

When released into soil the intrinsic bioconcentration potential needs to be estimated based on, at least, the physical-chemical properties of the substance (e.g. the partitioning coefficient, surface-active substances and dissociating or inorganic substances).

Further Guidance:

- TGD (EU, 2003); *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.* Chapter R.7.10.8 Terrestrial Bioaccumulation

2.1.7 Bioaccumulation, terrestrial (ADS)

Bioaccumulation results from both bioconcentration and biomagnification, and is thus closely related to the assessment of bioconcentration.

For screening or first tier approaches, relevant computational methods (e.g. s or read-across) can be used to estimate the terrestrial bioaccumulation potential of a substance, if it is sufficiently justified and acceptable in each case.

Experimental studies on terrestrial bioaccumulation could be warranted if information from non-testing methods and/or bioconcentration studies indicate concern. Recommended test protocols for bioaccumulation in terrestrial oligochaetes are OECD

Test Guideline 317 (Bioaccumulation in Terrestrial Oligochaetes) and ASTM E1676 (Standard Guide for Conducting Laboratory Soil Toxicity or Bioaccumulation Tests with the Lumbricid Earthworm *Eisenia Fetida* and the Enchytraeid Potworm *Enchytraeus albidus*). Results of bioaccumulation tests with suitable sediment-dwelling invertebrates (section 2.1.1.7 of this guidance) may provide useful comparative information that can be used in a weight of evidence approach. The recommended test protocol for bioaccumulation is the US EPA OPPTS 850.4800 (Plant Uptake and Translocation Test).

Further Guidance:

- TGD (EU, 2003);
- *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7c,* R.7.10.8 Terrestrial Bioaccumulation

2.1.8 Effects on other non-target, non aquatic organisms (ADS)

Further tests (e.g. field tests) may be required if the risk assessment based on long term terrestrial tests indicates that there is still a concern for the terrestrial compartment.

2.1.9 Effects on mammals (ADS)

Point 9.9 of Annex II to the BPR states that *data are derived from the mammalian toxicological* assessment. *The most sensitive relevant mammalian long-term toxicological endpoint (*NOAEL*) expressed as mg test compound/kg bw/day shall be reported.*

Additionally, the NOEC expressed as mg test compound /kg food should be reported. Please follow the Guidance in Volume III.

2.1.9.1 Acute oral toxicity (ADS)

Please follow the Guidance in Volume III.

2.1.9.2 Short term toxicity (ADS)

Please follow the Guidance in Volume III.

2.1.9.3 Long term toxicity (ADS)

Please follow the Guidance in Volume III.

2.1.9.4 Effects on reproduction (ADS)

Please follow the Guidance in Volume III.

2.1.10 Identification of endocrine activity (ADS)

Pending the adoption of Commission's delegated acts specifying scientific criteria for determining endocrine-disrupting properties, Article 5(3) of the BPR provides the following interim criteria:

- *Active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties (note that active substances classified as carcinogen category 1 and toxic for reproduction category 1 are considered as meeting the exclusion criteria).*
- *Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for*

reproduction category 2 a and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.

Furthermore, Article 5(1)(d) states that active substances can be *identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having* endocrine-disrupting properties (scientific evidence of probable serious effects to human health or the environment).

Data on the toxicity profile and mode of action should be scrutinised as well as any other additional information. Moreover, there should be a consideration of all the existing data and Guidance as described in the OECD 'Guidance Document on the Assessment of Chemicals for Endocrine Disruption' (OECD, 2010).

If as a result of this initial consideration, the substance is identified as a potential endocrine disruptor, then agreement of the competent authorities on the need to perform additional studies and on the types of study to be performed should be sought. Fish testing should consider the need to conduct either OECD Test Guideline 229 (Fish Short Term Reproduction Assay) or OECD Test Guideline 230 (21-day Fish Assay *A Short Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition*). In the specific case that the endocrine disrupting effect is known to be based on aromatase inhibition (e.g. in certain ergosterolsynthesis-inhibiting fungicides) a fish sexual development test may be preferable (OECD Test Guideline 234 (Fish Sexual Development Test)). If the results indicate endocrine mediated effects, a full fish life cycle study should be considered (see section 2.1.1.6 of this guidance). Similarly, the need for amphibian testing should be considered (NB. such testing if conducted may also have relevance, possibly in terms of no mortality dose, for the overall assessment of risk to amphibians). Until the agreed Guidance is available, agreement of the competent authority on the specific tests required should be sought.

2.2 Environmental fate and behaviour

Information related to the fate and behaviour of the active substance and its degradation products in the environment is needed in order to be able to assess the exposure to the environment, for example, by the approximate estimation of the likely concentrations of the substance in the different compartments of the environment. The information is also relevant for the PBT assessment (P criterion) and for classification (CLP).

The data and information provided should be sufficient to:

- identify the relative importance of the types of processes involved (balance between chemical and biological degradation),
- where possible, identify the individual components present,
- establish the relative proportions of the components present and their distribution between water, including suspended particles, and sediment, and
- permit to define/determine the residue of concern and which non-target species are or may be exposed to it.

Product-type-specific Guidance on exposure-driven information requirements is given in section 5 of this guidance.

Fate and ecotoxicological studies are required for major metabolites and those ecotoxicologically relevant metabolites which give reason for concern. A risk assessment

should be performed. Please refer to section 1.6 of this guidance for a respective classification of metabolites.

Where radio-labelled test material is used, radio-labels should be positioned at sites (one or more as necessary) to facilitate the elucidation of metabolic and degradation pathways and to facilitate investigation of the distribution of the active substance and of its metabolites, reaction and degradation products in the environment.

2.2.1 Fate and behaviour in water and sediment

2.2.1.1 Degradation, initial studies

Point 10.1 of Annex II to the BPR states that *if the assessment performed indicates the need to investigate further the degradation of the substance and its degradation products or the active substance has an overall low or absent abiotic degradation, then the tests described in 10.1.3 and 10.3.2 and where appropriate - in 10.4 shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed.*

Further information is given in section 4 of this guidance Testing Strategies.

Abiotic

(a) Hydrolysis as a function of pH and identification of breakdown products

The identification of breakdown products is required when the breakdown products at any sampling time are present at ≥10% of the added parent compound.

Hydrolysis must be examined at, at least, three different pH-values. A suggested temperature range is 10-70 °C (preferably with at least one temperature below 25 °C utilised), which will encompass the reporting temperature of 25 °C and most of the temperatures encountered in the field. For substances with a low hydrolysis rate, only the preliminary test carried out at 50 °C for five days may be sufficient. A substance of which less than 10% hydrolyses in five days at 50 °C (i.e. it is considered hydrolytically stable) needs no further testing for hydrolysis.

Test according to EC method C.7 (Degradation — Abiotic Degradation: Hydrolysis as a Function of pH) or the corresponding OECD Test Guideline 111 (Hydrolysis as a Function of pH).

(b) Phototransformation in water, including identification of transformation products

The data must be submitted for a purified active substance of stated specification.

The results submitted should correspond to the light intensities and spectral distribution from northern to southern European regions, for example, in 40 and 65 degrees (proposed average 50 degrees) northern latitude during spring and autumn. This may be presented e.g. by extrapolation.

In order to assess the contribution of photochemical degradation processes in water to the fate of the active substance, both direct and indirect aqueous photolysis needs to be considered (see TGD (EU, 2003), Part II, Chapter 2 Section 2.3.6.2). A consideration of the rate of indirect aqueous photolysis should only be included in cases where the rates of other aqueous degradation processes (hydrolysis, biodegradation, direct photolysis) are slow.

Test according to OECD Test Guideline 316 (Phototransformation of Chemicals in Water – Direct Photolysis), SETAC procedures (SETAC, 1995) or US-EPA guideline OPPTS 835.2210. For indirect photolysis, no harmonised testing guideline is currently available. QSARs to estimate the indirect photolysis rate may be relevant.

Biotic

In the following, initial biodegradation studies (core data) are described. However, it is possible to directly perform simulation studies for the relevant environmental compartments and skip initial biodegradation studies e.g. for those biocides which are toxic to the inoculum (more details on the testing strategy are provided in section 4 of this guidance).

(a) Ready biodegradability

At least a screening test on ready biodegradation is always required for organic compounds, unless a simulation test for all environmental compartments considered relevant is available.

Test according to any of the EC methods C.4 (Determination of 'Ready' Biodegradability) A-F or the corresponding OECD Test Guideline 301 (Ready Biodegradability) A-F taking especially notice of the Annex to these methods concerning the evaluation of the biodegradability of chemicals suspected to be toxic to the inoculum.

(b) Inherent biodegradability (where appropriate)

May be provided if available (if the compound is not readily degradable unless a simulation test for all relevant environmental compartments is provided). Simulation tests are preferred instead of new tests on inherent biodegradability. The testing strategy to follow is described in section 4 of this guidance.

Test according to the EC method C.9 (Biodegradation — Zahn-Wellens Test) or the corresponding OECD Test Guidelines 302 B (Inherent Biodegradability: Zahn-Wellens/ EVPA Test) or according to 302 C (Inherent Biodegradability: Modified MITI Test (II)).

2.2.1.2 Adsorption/desorption

A screening test on adsorption/desorption is always required according to tier 2 of EC method C.18 (Adsorption/Desorption Using a Batch Equilibrium Method) or the corresponding OECD Test Guideline 106 (Adsorption-Desorption Using a Batch Equilibrium Method). The adsorption is studied in five different soil types for the active substance and three different soil types for major metabolites by means of adsorption kinetics at a single concentration and determination of distribution coefficients K_d and K_{OC}. Although not explicitly mentioned in the guideline the handling procedure can also be applied to sediments.

An alternative method is the estimation of adsorption with HPLC, EC method C.19 (Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC)) or the corresponding OECD Test Guideline 121 (Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge Using HPLC). This method provides an estimate of a chemical's partitioning behaviour between aqueous phases and organic surfaces of soils, sediments and sludge (K_{OC}). This estimate is normally sufficient for a preliminary exposure assessment of substances. It should be noted however, that for some substances the HPLC-technique is not yet fully validated or applicable.

The testing strategy in section 4 indicates when further tests (according to sections 2.2.1.4, 2.2.2.4 or 2.2.2.5 of this guidance) would be necessary.

If a higher tier study is provided for one of the other endpoints for the relevant compartment(s), this endpoint might be waived.

2.2.1.3 Rate and route of degradation including identification of metabolites and degradation products (ADS)

Biological sewage treatment (ADS)

(a) Aerobic biodegradation (ADS)

Please refer to 10.1.3.1 (c) STP simulation test below.

(b) Anaerobic biodegradation (ADS)

An anaerobic degradation study may be required if exposure to anaerobic conditions is likely.

Test according to OECD Test Guideline 311 (Anaerobic Biodegradability of Organic Compounds in Digested Sludge: by Measurement of Gas Production) or ISO method 11734.

(c) STP simulation test (ADS)

The only laboratory STP simulation test currently available is the EC method C.10 (Biodegradation — Activated Sludge Simulation Tests) or the corresponding OECD Test Guideline 303 A (Simulation Test - Aerobic Sewage Treatment - A: Activated Sludge Units). In its original version, this test cannot distinguish between biological degradation and other elimination processes such as adsorption and volatilisation. In the last years several modifications of the 'activated sludge units' test were developed. As a result, it is at least possible to determine the amount of active substance and metabolites in water and sludge in test systems according to the mentioned test guidelines and to calculate a limited mass balance (without volatilisation). Test designs using closed systems with radiolabelled substances to get a complete mass-balance are approved as well. Even if the modified tests are not standardised internationally, the results may be used for the refinement of the exposure assessment.

If a STP simulation test according to EC method C.10 or OECD Test Guideline 303 A is performed today, it should generally satisfy the following requirements:

- Specific analyses of active substance and metabolites in effluent and sludge to calculate a limited mass balance.
- If possible the use of closed systems and radiolabelled substances to get a mass balance.

In recent years relatively simple tests using radio-labelled material have been developed which may provide useful information on e.g. aerobic degradation in an STP. They allow for the use of low substance concentrations, give primary degradation rates, account for formation (and disappearance) of metabolites, and are relatively easy to perform. Anyhow, at present here is no harmonised way to evaluate these tests; therefore the evaluating MSCA must be contacted before conducting such tests.

Biodegradation in freshwater (ADS)

This information is relevant for substances or transformation products that are released directly or indirectly to water/sediment systems. Please refer also to section 4 of this guidance for the testing strategy on biodegradation.

(a) Aerobic aquatic degradation study (ADS)

Test according to OECD Test Guideline 309 (Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test), ISO method 14592 or US-EPA guideline OPPTS 835.3100 with non-adapted inoculum.

(b) Water/sediment degradation test (ADS)

Usually a water/sediment degradation test under aerobic conditions is required. A water/sediment degradation study under anaerobic conditions should be done if the exposure of the substance to anaerobic conditions is very likely (e.g. when a major proportion of the substance is absorbed in sediment).

Test according to EC method C.24 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) or corresponding OECD Test Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems).

Amounts of metabolites found in the water and the sediment phase shall be added up for the identification of relevant metabolites.

Biodegradation in sea water (ADS)

If a substance is to be used or released in marine environments in considerable amounts (e.g. it is known to be repeatedly used or continuously released in marine environments), then a seawater biodegradation test according to OECD Test Guideline 306 (Biodegradability in Seawater) will be required.

A modified version of ISO 14592 (shake flask batch test) with seawater at environmentally relevant concentrations may be performed (radio-labelled).

Alternatively, a water/sediment degradation study in seawater according to modified guidelines may be done.

Biodegradation during manure storage (ADS)

A study on biodegradation in manure is needed for substances which are applied in animal housings and go to manure storage before release to the environment. This is probably the case with veterinary hygiene biocidal products and biocidal pest control products. Please refer also to section 4 of this guidance Testing Strategy and section 5 Product Type-specific data set of this guidance.

For the time being, there is no harmonised guideline for testing biodegradation in manure storage systems. Meanwhile zero degradation in manure may be taken into account in a first tier assessment.

Please contact ECHA or the evaluating Member State competent authority to discuss concretely how to perform a respective study. An OECD test guideline is under development.

2.2.1.4 Adsorption and desorption in water/aquatic sediment systems and, where relevant, adsorption and desorption of metabolites and degradation products (ADS)

This information is relevant for substances or transformation products that are released directly or indirectly to water/sediment systems. Please refer also to section 2.2.1.2 of this guidance.

In addition to the tests described there, a specific study with sediments or sewage sludge may be provided to refine the initial risk assessment, if adsorption to it is of concern.

These tests should be conducted as a full test (tier 3) according to EC method C.18 (Adsorption/Desorption Using a Batch Equilibrium Method) or the corresponding OECD Test Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) with sediments, or with sludge, for example according to US-EPA guideline OPPTS 835.1110 (Activated sludge sorption isotherm); or according to EC method C.24 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) or the corresponding OECD Test Guideline 308 (Aerobic or Anaerobic Transformation in Aquatic Systems).

Please also refer to the testing strategy in section 4 of this guidance.

2.2.1.5 Field study on accumulation in the sediment (ADS)

Field studies on accumulation in the sediment would be required in two sediment types if the $DT_{90field}$ > one year and the $DT_{50field}$ > three months, or if during laboratory tests non-extractable residues are formed in amounts > 70% of the initial dose after 100 days with a mineralisation rate of < 5% in 100 days. As it is not expected that these triggers will be met, it is assumed that such studies would not be provided. Furthermore the results could not be used to refine the risk assessment. Anyhow, no standardised test guideline is currently available. Some general guidance is available from SETAC (SETAC, 1995).

2.2.1.6 Inorganic substances: information on fate and behaviour in water (ADS)

For the moment there is no harmonised guideline addressing this endpoint.

2.2.2 Fate and behaviour in soil (ADS)

Tests on fate and behaviour in soil only become necessary if there is exposure to soil.

If the results from tests specified under section 2.2.1.1 Biotic (a) or (b) of this guidance of the data set for the active substance indicate the need to do so or the active substance has an overall low or absent abiotic degradation, then the tests described under this Section in the following paragraphs are required.

The data submitted under this paragraph should clarify, in addition to the degradation of the substance, other relevant routes of dissipation in soil, such as volatilisation, leaching and transformation into bound residues. The testing strategy on biodegradation of biocidal active substances (see Figure 3 and text in section 4 of this guidance) provides more specific information.

2.2.2.1 Laboratory study on rate and route of degradation (ADS)

Point 10.2.1 of Annex II to the BPR states that [….] *including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types.*

The rate and route of aerobic degradation should be studied in one soil type for ≥ 100 days including identification of the processes involved and identification of major metabolites, degradation products and bound residues under appropriate conditions. The criteria for selection of suitable soil types should address the physico-chemical properties of the substance itself (e.g. pK_a). If there is reason to believe that the route of degradation is pH dependent, the route of degradation should be reported for at least one additional soil with a different pH value. The study can be of shorter duration if the required results are already available.

The rate of aerobic degradation should be investigated in three additional soil types for the active substance and for major metabolites. If the degradation rate for the metabolite(s) can be determined from the study on the active substance, there is no need to perform separate studies for the metabolite(s). The study should provide the best possible estimates of the time taken for degradations of 50% ($DegT_{50lab}$) of a substance under more relevant environmental conditions than those of a test on ready or inherent biodegradation.

These tests should be conducted according to EC method C.23 (Aerobic and Anaerobic Transformation in Soil) or the corresponding OECD Test Guideline 307 (Aerobic and Anaerobic Transformation in Soil) or OECD Test Guideline 304A (Inherent Biodegradability Test in Soil). If the results show that bound residues may amount to > 10%, they should be characterised (see section 2.2.2.7 of this guidance).

2.2.2.2 Field studies, two soil types (ADS)

Soil dissipation studies have to be conducted for the active substance, major metabolites, degradation and reaction products in those conditions where $PEC/PNEC_{soils}$ > 1 **and**

the $DegT_{50lab}$ > 60 days in one or more soils, determined at 20 °C at a moisture content of the soil related to a pF value of 2 (suction pressure) **or**

the $DegT_{90lab}$ > 200 days in one or more soils, determined at 20 °C at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 200 days.

If there is danger for the groundwater, the result of this study can be used to refine the preliminary risk assessment.

Further guidance on the degradation and transformation parameters of the active substance/metabolite is provided in FOCUS Groundwater (EU, 2002a)and FOCUS Degradation Kinetics (EU, 2011d).

The soil dissipation studies should provide estimates of the time taken for dissipation of 50% and 90% (DT_{50} and DT_{90}) and if possible the time taken for degradation of 50% and 90% ($DegT_{50}$ and $DegT_{90}$) of the active substance under field conditions. Where relevant, information on metabolites, degradation and reaction products must be reported.

Individual studies on a range of representative soils (in contrast to what is stated in Annex II of the BPR, the information should normally be provided for four different types) must be continued until > 90% of the amount applied has dissipated. The maximum duration of the studies is normally 24 months.

Field studies must cover representative test conditions for the respective emission in use as a biocide (e.g. injection of contaminated STP sludge, contaminated manure, leaching from artificial matrix like paint or spray application, where relevant).

Test according to NAFTA Regulatory Directive - DIR2006-01 Guidance Document for Conducting Terrestrial Field Dissipation Studies (NAFTA, 2006).

2.2.2.3 Soil accumulation studies (ADS)

Field soil accumulation tests are required in two soil types if the $DisT_{90field}$ > one year and the $DisT_{50field}$ > three months, or if during laboratory tests non-extractable residues are formed in amounts > 70% of the initial dose after 100 days with a mineralisation rate of < 5% in 100 days.

The tests should provide sufficient data to evaluate the possibility of the accumulation of the active substance and of its transformation products in soil.

No standardised test guideline is currently available. Some general guidance is available from (Boethling, et al., 2009).

2.2.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products (ADS)

This information is relevant for substances or transformation products that are released directly or indirectly to soil.

Please refer also to section 2.2.1.2 of this guidance. In addition to the tests described there, a full scale study (isotherms, mass balance, desorption) with soil needs to be provided in case of direct exposure to soil of a substance unless it is shown to be readily biodegradable.

A full scale adsorption test may also be appropriate to refine the PEC value in those cases where:

- PEC/PNEC > 1 as a result from indirect exposure (e.g. spreading of contaminated sewage sludge on land) and the substance is not readily biodegradable,
- modelling results indicate that relevant concentrations of the substance may reach groundwater (Council Directive 98/83/EC).

Full test (tier 3) according to EC method C.18 (Adsorption/Desorption Using a Batch Equilibrium Method) or the corresponding OECD Test Guideline 106 (Adsorption/desorption Using a Batch Equilibrium Method) with soils. The criteria for the selection of suitable soil types should address the physico-chemical properties of the substance itself (e.g. pK_a).

The testing strategy in section 4 of this guidance indicates when which sorption test is necessary to be provided.

2.2.2.5 Further studies on sorption (ADS)

Please refer to section 2.2.1.2 of this guidance . The testing strategy in section 4 of this guidance indicates when which sorption tests would be necessary.

2.2.2.6 Mobility in at least three soil types and, where relevant, mobility of metabolites and degradation products (ADS)

In most cases, the mobility of a substance in soil can be estimated by means of running mathematical model calculations, processing adsorption coefficient and degradation rates of the substance (and its transformation products) but also pedological and climatic parameters.

Column leaching studies (ADS)

Column leaching studies must be carried out where in the adsorption/desorption studies provided under the endpoint 10.2.4 it is not possible to obtain reliable adsorption coefficient values. Soil column leaching studies can provide reliable and useful lower limits of the K_{OC} if the expected K_{OC} value is less than about 25 L/kg.

The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance.

Studies must be carried out in three to four soils (in accordance with the test guideline) with varying pH, organic carbon content and texture. At least three soils should have a pH at which the test substance is in its mobile form. During the test period, the soil leaching columns should be kept in the dark at an ambient temperature (18 and 25 °C) within a range of ±2 °C.

Test according to OECD Guidance Document 312 (Leaching in Soil Columns).

Lysimeter studies (ADS)

Where it is indicated from data on adsorption and degradation in soil that relevant amounts of a substance may reach groundwater it may become necessary to carry out an outdoor confirmatory study. For guidance on how to perform a long term study on mobility of a substance in undisturbed soil under outdoor conditions refer to OECD Guidance Document 22 (Performance of Outdoor Monolith Lysimeter Studies).

Field leaching studies (ADS)

Similarly to section 2.2.2.6 of this guidance, follow OECD Test Guideline 22 (Performance of Outdoor Monolith Lysimeter Studies).

2.2.2.7 Extent and nature of bound residues (ADS)

The determination and characteristics of bound residues is recommended to be combined with a soil simulation study.

Required if the results of soil simulation studies (section 2.2.2.1 of this guidance) indicate that bound residues may be formed which account for more than 10% of the active substance added. Testing should be done according to SETAC procedures (SETAC, 1995) with a radio-labelled active substance and the nature of the bound residues should be characterised as far as possible according to, for example, (Schnitzer, 1982) or after an acetone/methanol-ultrasonic treatment according to OECD Test Guideline 304A (Inherent Biodegradability in Soil).

The unavailability of bound residues should be thoroughly investigated using different solvents.

Further Guidance:

- DG-AGRI Guidance Document on Persistence in Soil (EU, 2000c)
- Environmental Persistence of Organic Pollutants: Guidance for Development and Review of POP Risk Profiles (Boethling, et al., 2009)

2.2.2.8 Other soil degradation studies (ADS)

Such further studies should identify rates of degradation in different release conditions and main routes of degradation in soil in detail. Any major metabolites (or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added) should be identified and their degradation rates should be studied. For example, a soil photolysis study is required where the deposition of the active substance at the soil surface is significant (e.g. is over 10% of the substance applied) on the basis of results under endpoint 10.1.1.1b, the data set for the active substance and photolysis is considered to be a major way of degradation.

An anaerobic soil degradation study according to e.g. EC method C.23 (Aerobic and Anaerobic Transformation in Soil) or the corresponding OECD Test Guideline 307 (Aerobic and Anaerobic Transformation in Soil) is required for one soil if exposure to anaerobic conditions is likely where the active substance or material treated with it is used. The general guidance for the corresponding data requirement for an aerobic degradation study (section 2.2.2.1 of this guidance) applies here also.

2.2.2.9 Inorganic substances: information on fate and behaviour in soil (ADS)

Main issues for the fate of inorganics are the adsorption and desorption and aging of these substances in the soil matrix. This information is relevant for substances or transformation products that are released directly or indirectly to soil (or to surface

water). Bioavailability of metals is highly influenced by soil pH, the content of Fe and Al oxyhydroxydes, soil organic matter, and least importantly by the soil clay mineral content. Background metals are generally reduced in bioavailability as a result of aging in soils (or sediments), or transformation to less bioavailable salts. It seems that aging reactions are almost over after about one year and are reversible. At present, information regarding the aging reactions of different metals and metalloids, and sorbing solids, is very limited, so it is not possible to generalise which metals age at the fastest rate or with greater/less reversibility.

To derive adsorption coefficients for e.g. metals the total soil metal content and total metal pore water concentration of a wide geographical variety of *in situ* contaminated soils should be tested.

The principles in EC method C.18 (Adsorption/Desorption Using a Batch Equilibrium Method) or the corresponding OECD Test Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) also apply for inorganics.

Further Guidance:

- Evaluation and revision of Csoil parameter set RIVM report 711701021. (Otte, et al., 2001)
- Framework for Inorganic Metals Risk Assessment (External Review Draft) Section 4: Metal-Specific
- Topics and Methods (US EPA, 2004)

2.2.3 Fate and behaviour in air

2.2.3.1 Phototransformation in air (estimation method). Identification of transformation products

An estimation of the phototransformation of a substance is necessary to complete the risk assessment for any compound that is subject to ambient or artificial light. Although for some chemicals direct photolysis may be an important breakdown process, the most effective elimination process in the troposphere for most substances results from reactions with photochemical generated species like OH radicals, ozone and nitrate radicals. In a first approach, the specific first order degradation rate constant of a substance with OH-radicals can be estimated by (Q)SAR methods. Further details can be found in TGD (EU, 2003).

A qualitative discussion of the potential formation of breakdown products should be included.

Furthermore, an assessment of the global warming potential, the stratospheric ozone depletion potential, the potential for tropospheric ozone formation as well as the acidification potential should be submitted (part B of the BPR technical Guidance (guidance under development)).

Further Guidance:

The software AOPWIN™ estimates the gas-phase reaction rate for the reaction between the most prevalent atmospheric oxidant, hydroxyl radicals, and a chemical. In addition, AOPWIN™ informs if nitrate radical reaction will be important. Atmospheric half-lives for each chemical are automatically calculated using assumed average hydroxyl radical and ozone concentrations (http://www.epa.gov/opptintr/exposure/pubs/episuite.htm). It is integrated into the Estimation Programs Interface Suite (EPI Suite™) developed by the EPA's Office of Pollution Prevention Toxics and Syracuse Research Corporation (SRC).

2.2.3.2 Fate and behaviour in air, further studies (ADS)

If the active substance is to be used in preparations for fumigants or it has a hazard potential to the atmospheric environment, its degradation behaviour has to be determined experimentally (e.g. according to the methods described in (OECD, 1992). For the most important processes, the rate constants should first be estimated theoretically and then, after considering the relative importance of the various processes, confirmed experimentally.

For experimental estimation the data must be submitted for a purified active substance of stated specification.

The identification of transformation products which at any sampling time account for more than 10% of the active substance added is required unless the half-life of the transformation product is less than three hours.

The data submitted should be applicable to atmospheric conditions (light intensities, spectral distribution, etc.).

Further Guidance:

- Procedure for Assessing the Environmental Fate and Ecotoxicity of Pesticides (SETAC, 1995)

2.2.4 Additional studies on fate and behaviour in the environment (ADS)

No additional studies proposed.

2.2.5 Definition of the residue (ADS)

2.2.5.1 Definition of the residue for risk assessment (ADS)

Relevant components for the risk assessment are considered the parent substance and:

- all major metabolites in the relevant receiving compartments fresh- and marine water, sediment, STP influent/effluent, active sludge, soil, groundwater and air, or
- all metabolites that pose a comparable or higher hazard than the active substance.
-

Further Guidance:

- OECD Guidance Document on the Definition of Residue (OECD, 2006)

2.2.5.2 Definition of the residue for monitoring (ADS)

The worst case principle is that the parent and metabolites considered relevant for risk assessment (see section 2.2.5.1 of this guidance) are also relevant for monitoring. Waiving of this requirement is possible:

- by identifying those components in the residue that are most representative for all other components
- on basis of the (non-)concern of a metabolite identified in the risk assessment.

This may differ between the receiving compartments freshwater and marine, sediment, STP influent/effluent, active sludge, soil, groundwater, and air.

2.2.6 Monitoring data (ADS)

The worst case principle is that the parent and metabolites considered relevant for risk assessment (see section 2.2.5.1 of this guidance) are also relevant for monitoring. Waiving of this requirement is possible:

- by identifying those components in the residue that are most representative for all other components
- on basis of the (non-)concern of a metabolite identified in the risk assessment.

This may differ between the receiving compartments freshwater and marine, sediment, STP influent/effluent, active sludge, soil, groundwater, and air.

2.2.6.1 Identification of all degradation products (>10%) must be included in the studies on degradation in soil, water and sediments (ADS)

In contrast to what is stated in Annex II of the BPR, metabolites according to the definition given in section 1.6 of this guidance, need to be identified.

Further Guidance:

- *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.*
    - Chapter R.7b: Endpoint specific guidance R.7.9.5 Conclusions for degradation/biodegradation;
    - Chapter R.7c: Endpoint specific guidance R.7.10.3.3 Field data on aquatic bioaccumulation;
- Important information on the use of monitoring data in the environmental exposure assessment is given in Chapter 2.2 of Part II of the TGD (EU, 2003).

3 Part A: Dossier Requirements for Biocidal Products BPR Annex III, Title 1, 9 Ecotoxicological studies

NOTE to the reader:

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

3.1 Ecotoxicological studies

3.1.1 Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required.

Point 9.1 of Annex III to the BPR states that:

- *Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP).*
- *Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary.*

Synergistic effects are defined as an interaction between two or more components of the product leading to an effect of the mixture which is greater than that expected by concentration addition by a factor of 5.

3.1.2 Further Ecotoxicological studies

Point 9.2 of Annex III to the BPR states that *further studies chosen from among the endpoints referred to in section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product*.

For the determination of the relevant components, see Guidance for mixture toxicity assessment (under development).

3.1.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Such testing may be required if tests on other non-target organisms are needed on the basis of intended uses and results from the other tests in section 2 of this guidance (data set for the active substance) or a preliminary risk assessment. For instance, tests on sediment dwelling organisms, aquatic plant growth (including macro-algae), accumulation and elimination in shellfish or tests on marine macro-algae or other additional tests on estuarine and marine organisms may be needed.

The decision on the need of such further studies should be decided on a case-by-case basis after consulting with the competent authority.

Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment.

3.1.4 If the biocidal product is in the form of bait or granules the following studies may be required:

3.1.4.1 Supervised trials to assess risks to non-target organisms under field conditions

This endpoint concerns non-target organisms for which the use pattern of the biocidal product may lead to direct or indirect exposure, which, in combination with the mode of action and critical effects of the substance, raise concern. Examples are honey bees or other arthropods which may be exposed to insecticides under field conditions, or birds and mammals which may be exposed to rodenticides either by direct consumption of the product or through their diet via preying or scavenging on exposed animals. For honeybees, Guidance is currently being drafted. See also section 2 of this guidance and the product-type-specific guidance in section 5 of this guidance.

Further Guidance:

Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7b, R.7.11 Effects on terrestrial organisms;

Guidance on risk assessment for birds and mammals (EFSA, 2009a).

3.1.4.2 Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

In order to assess risks to predators or scavengers, residue data in target organisms concerning the active substance and including toxicologically relevant metabolites would be needed. For birds a study on avoidance should be made according to the OECD draft Guidance document on avoidance of testing on birds (OECD, 2011).

3.1.5 Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

As a refinement higher tier field studies (soil and/or water-sediment compartment) may be required to identify secondary ecological effects when a habitat such as a water body, wetland, forest or field is treated. A habitat may vary significantly in size as well as biological complexity, and the requirement for a field study, as well as its scope, must therefore be tailored to the type of habitat to be treated, and how it is treated. The judgement of whether a large proportion is treated should concern not only the whole habitat area but importantly potential exposure to important physical and ecological components or zones of the habitat/ecosystem such as keystone species, food components or zones for spawning, nesting or foraging. The assessment may concern a range of different trophic levels and species from micro-organisms to top predators.

Ecological effects of biocides are varied and are often inter-related with other effects. Major types of effects are listed below and will vary depending on the organism, community or habitat under investigation and the type of biocide. Different biocides have markedly different effects on aquatic/soil life which makes generalisation very difficult. Effects expressed on the level of individuals may ultimately compromise the long-term viability and performance of species populations and also affect community or ecosystem structure and function.

- Death of the organism
- Cancers, tumours and lesions on fish and animals
- Reproductive inhibition or failure
- Suppression of immune system
- Disruption of endocrine (hormonal) system
- Cellular and DNA damage
- Teratogenic effects (physical deformities such as hooked beaks on birds)

- Poor fish health marked by low red to white blood cell ratio, excessive slime on fish scales and gills, etc.
- Other physiological effects such as egg shell thinning
- Intergenerational effects (effects are not apparent until subsequent generations of the organism). Can include for example changes in growth and development or impairment of reproductive capacity in individuals, or genetic drift or change in sex ratio in the population
- Altered species succession
- Altered community or ecosystem structure
- Altered energy transfer and trophic state
- Tolerance development on a species or community level
- Decline in biodiversity, impaired ecological functions and services

These effects are not necessarily caused solely by exposure to biocides, pesticides or other organic contaminants, but may be associated with a combination of environmental stressors such as eutrophication, alien species and pathogens.

Aim of the test

The test should provide sufficient data to evaluate possible effects at species, population or community and ecosystem level.

Test conditions

Studies must be carried out in systems representative to habitats to which the product is applied. Important aspects to consider are e.g. the use of reference areas, replicates history of the (treated and non-treated) areas, climatic conditions, timing, duration of exposure, frequency, dosage and concentration distribution in time and location.

Test guideline

There are no internationally agreed standard protocols for field studies, only recommendations mainly developed within the Plant Protection framework, which may be helpful. In contrast to laboratory tests rigid protocols are not desirable for field studies. The trial should rather be designed individually addressing the problems that have been identified. Consult the list below for recommendations regarding field studies:

- Ecological effects of pesticide use in the Netherlands. Modelled and observed effects in the field ditch; RIVM report 500002003 (de Zwart, 2003)
- Guidelines for ecological impact assessment in the United Kingdom (IEEM, 2006)Exposure and ecological effects of toxic mixtures at field-relevant concentrations. Model validation and integration of the SSEO programme; RIVM Report 860706002/2007 (Eijsackers, et al., 2007)
- Guidance for summarizing and evaluating aquatic micro- and mesocosm studies; RIVM Report 601506009/2008 (de Jong, Brock, Foekema, & Leeuwangh, 2008).
- Ecological effects of pesticides (FAO, 1996)
- Ecological Monitoring Methods. (Grant & Tingle, 2002)

3.2 Environmental fate and behaviour

The test requirements below are applicable only to the relevant components of the biocidal product.

Product-type-specific guidance on this issue is given in section 5 of this guidance.

3.2.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

Information on how the active substance or a substance of concern due to handling it or from a waste water treatment plant etc. to which compartment of the environment (soil, sediment, water, air) can be released into the environment, and an estimation on how large the amounts released are.

Sources of environmental exposure: for example production, distribution, storage, mixing and loading, uses and disposal or recovery should be described. The measured or estimated extent of release: frequency and intensity (e.g. dose and duration) should be indicated. The descriptions should cover the most significant routes of exposure.

Define aquatic recipients in detail: for instance surface water, groundwater, estuaries or marine environment. Assess possible ways of transformation and distribution.

Information on representative measured concentrations or monitoring data, for example, in wastewater or in the environment or on concentrations based on model calculations, and which can be used as predicted environmental concentrations in the relevant environmental compartments.

3.2.2 Further studies on fate and behaviour in the environment (ADS)

Point 10.2 of Annex III to the BPR states that *further studies chosen from among the endpoints referred to in Section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required.*

For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern.

3.2.3 Leaching behaviour (ADS)

For treated articles, please refer to Volume I section 2.7.6.4 of this guidance.

The type of leaching test to be provided is highly depending on the product type and the specific use of the biocidal product, respectively. For many product types, no harmonised leaching test guidelines are available yet. However, for product type 8 the following guidelines were agreed upon during the discussion under the review programme. Therefore they may be a starting point for other product types as well.

Use class 3, laboratory tests:

- Series on Testing and Assessment Number 107 – Preservative-treated wood to the environment: For wood held in storage after treatment and for wooden commodities that are not in contact with ground; ENV/JM/MONO 2009(12) (OECD, 2009b).
- CEN/TS 15119-1: Durability of wood and wood-based products — Determination of emissions from preservative treated wood to the environment — Part 1: Wood held in the storage yard after treatment and wooden commodities exposed in use Class 3 (not covered, not in contact with the ground) — Laboratory method.

Use class 3, semi-field test:

- Nordtest method NT Build 509 Leaching of active ingredients from preservative-treated timber – semi-field testing.

Use classes 4 & 5, laboratory tests:

- OECD Test Guideline 313 'Estimation of Emissions from Preservatives – Treated Wood to the Environment: Laboratory Method for Wooden Commodities that are not covered and are in Contact with Freshwater or Seawater'.
- CEN/TS 15119-2: Durability of wood and wood-based products — Determination of emissions from preservative treated wood to the environment — Part 2: Wooden commodities exposed in use class 4 or 5 (in contact with the ground, fresh water or sea water) — Laboratory method.

Please contact the evaluating MSCA before conducting new leaching tests to clarify the conditions under which a test should be conducted.

3.2.4 Testing for distribution and dissipation in the following: (ADS)

In principle, no further distribution and dissipation studies with the product in soil are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient. However, if there are indications that other components in the product influence distribution and degradation characteristics, this may trigger additional studies. The same test guidelines described for the active substance tested with the product should be used.

3.2.4.1 Soil (ADS)

See guidance in section 2.2.2 of this guidance.

3.2.4.2 Water and sediment (ADS)

See guidance in section 2.2.1 of this guidance.

3.2.4.3 Air (ADS)

See guidance in section 2.2.3 of this guidance.

3.2.5 If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

The aquatic risk from overspray exposure needs to be assessed with either field studies or mathematical models. So far, there is no harmonised approach available for the risk assessment of biocides. FOCUS 'Surface Water' is the recommended model application for the assessment of plant protection products (EU, 2012c); however, to suit for biocidal uses, e.g. the input parameters would need to be adapted. Furthermore, it would be necessary to clarify which scenarios are representative for the emission of biocidal products and whether to use the outcome of FOCUS models for surface water and/or sediment assessment.

Further Guidance:

- DG SANCO Guidance Document on Aquatic Ecotoxicology, a detailed working document, (EU, 2002b)

3.2.6 If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Currently, Guidance is under development.

4 Testing Strategies

4.1. Testing strategy for abiotic degradation

Information on abiotic degradation in water and air is part of the core data set as they are valuable parameters to be considered, e.g. for further laboratory studies and identification of metabolite formation.

For the aquatic compartment, the results from the initial abiotic degradation tests on hydrolysis (section 2.2.1.1 Abiotic (a) of this guidance) might be taken into account in the exposure assessment if not already covered by results on biodegradation. Degradation via phototransformation (section 2.2.1.1 Abiotic (b) of this guidance) is in most cases not to be taken into account in the exposure assessment due to the high turbidity of most water bodies. Only in case of very clear water (e.g. in open sea), phototransformation might be considered in the exposure assessment.

Metabolites formed in the aquatic compartment as major metabolites (see definition in section 1.6 of this guidance) should be included in a conservative first tier exposure assessment. Where metabolites are formed in significant levels they should also be included for consideration in the environmental risk assessment to address the risk in those water bodies where photolysis may be an important fate pathway.

For the atmosphere, estimation of the phototransformation in air (section 2.2.3.1 of this guidance) is required for active substances of all product-types as a part of their preliminary risk assessment. Additional data on abiotic degradation in the atmosphere (section 2.2.3.2 of this guidance Fate and behaviour in air, further studies) are initially required only for active substances which are to be used as fumigants. This study may also be necessary for any other active substance if the preliminary risk assessment shows risk for the atmosphere.

4.2. Testing strategy on biodegradation of biocidal active substances

4.2.1. Aim

A strategy on biodegradation and application in risk assessment for organic compounds has been developed which:

- delivers degradation rate constants for use in the risk assessment,
- provides information on (relevant) metabolites formed,
- makes use of all available data,
- avoids unnecessary (and expensive) testing as much as possible and
- is based on accepted guidance as much as possible.
-

The resulting biodegradation testing strategy is represented in Figure 3 .

4.2.2. (Eco)Toxicity

Many biocides have an anti-bacterial activity. This may pose a problem for biodegradability testing of biocides. Biocides which are toxic to the inoculum may give false negative test results, which may lead to requirements for further tests and/or will influence the outcome of risk assessments. Therefore it is recommended to test the toxicity to bacteria before commencing with biodegradation studies, and to relate the outcome of the toxicity test to the circumstances (e.g. substance concentration) prescribed for the biodegradation studies foreseen. Thus the most appropriate biodegradation test can be selected. The inhibition of the respiration of activated sludge can be tested using EC method C.11 (Biodegradation: Activated Sludge Respiration

Inhibition)or the corresponding OECD Test Guideline 209 (Activated Sludge, Respiration Inhibition Test). It must be noted however, that this test is rather insensitive due to the high biomass content used. Notes on the evaluation of chemicals which may be toxic in ready biodegradability tests are provided in Annex IV to EC method C.4. A-F (Determination of 'Ready' Biodegradability) or the corresponding OECD Test Guideline 301 (Ready Biodegradability) A-F. That annex suggests testing substance concentrations at less than 1/10 of the EC_{50}. The 'closed bottle' test method EC C.4 E (corresponding to OECD Test Guideline 301 E) is normally performed with substance concentrations down to 2 mg/l. For lower concentrations, the use of ^{14}C-labelled material will generally be required. Especially for biocides which may be toxic for bacteria at concentrations used in the standard ready or inherent biodegradability tests, it is advised to enter directly into simulation tests for the relevant compartment, using environmentally relevant concentrations of radiolabelled material.

4.2.3. Temperature

The results of (laboratory) biodegradation studies should be calculated to reflect an average EU ambient temperature of 12 °C:

$$DegT_{50}\ (12\ ^{\circ}C) = DegT_{50}\ (t)\ x\ e^{(0.08x(T-12))}$$

Note: Please make sure the right input parameter is used in any model calculations (e.g. EUSES, MAMPEC, PEARL, PELMO) as the Q10 factor is currently not harmonised in all regulatory contexts.

4.2.4. Screening tests

The screening tests have a long history, are standardised and therefore have been incorporated in many chemical substance legislations. There are, however, a number of drawbacks attached to the current EC methods and the corresponding OECD ready and inherent biodegradability tests. In general the current tests have been designed to categorise substances in readily vs. not-readily or inherently vs. not-inherently biodegradable. They do not deliver rate constants for primary degradation of parent compounds. Default rate-constants have been attached to these tests in order to be able to use them for risk assessment. For biocides an important drawback may be that they require rather high substance concentrations (2-400 mg/l), which may give toxicity problems. Furthermore, such high substrate concentrations are generally not in line with the circumstances in which biodegradation takes place in reality. Degradation kinetics at high substrate concentrations may differ from those at lower concentrations.

The screening tests do not provide information on the formation of metabolites (other than mineralisation products). Substances which are either readily biodegradable or inherently biodegradable (according to the above criteria) can be considered to have such a high mineralisation rate that formation of relevant metabolites is highly unlikely. Notwithstanding this consideration, it is recognised that even substances which are readily or inherently biodegradable may form metabolites which are (transiently) available and may lead to exposure under continuous releases. In such cases further (simulation) tests may be required if the PEC/PNEC is more than one and the risk assessment needs refinement in relation to metabolites.

4.2.4.1. Ready biodegradation (CDS)

Ready biodegradability tests are stringent tests which provide limited opportunity for biodegradation and acclimatisation to occur. It may be assumed that a chemical giving a positive result in a test of this type will rapidly biodegrade in the environment and therefore be classified as 'readily biodegradable' in Annex VI of CLP. Tests on ready biodegradability are required for the core data set of active substances and are described in EC method C.4 A-F (Determination of

'Ready' Biodegradability) or the corresponding OECD Test Guideline 301 (Ready Biodegradability) A-F (see section 2.2.1.2 of this guidance).

Information on ready biodegradability tests and the interpretation of their results is summarised in chapters 2.3.6.4 and 2.3.6.5 of the TGD for new and existing substances (EU, 2003). Ready biodegradability tests provide information on ultimate degradation (mineralisation), which can be used to determine whether the parent compound is readily biodegradable or not. To make the results of ready tests useful for risk assessment, rate constants have been assigned to the results of the test. It is considered to be helpful to distinguish why a ready test has not been passed. It may be that the pass level (certain level of mineralisation within 28 days) is not reached and/or that the additional kinetic criterion of the 10-days window is failed. Different rate constants are assigned in these situations. The proposed rate constant for readily biodegradable substances can be found in the TGD for new and existing substances in tables 6 (STP, chapter 2.3.6.4), 7 (surface water, chapter 2.3.6.5) and 8 (soil, chapter 2.3.6.5) (EU, 2003).

4.2.4.2. Inherent biodegradability (CDS)

Inherent biodegradability tests are tests which allow prolonged exposure of the test compound to micro-organisms, a more favourable test compound/biomass ratio as well as chemical or other conditions, that favour biodegradation. A compound giving a positive result in a test of this type may be classified as "inherently biodegradable", but, because of the favourable conditions employed, its rapid and reliable biodegradation in the environment may not be assumed. Tests on inherent biodegradability are required for the core data set of active substances 'where appropriate', meaning if available. They are described in EC method C.9 (Biodegradation — Zahn-Wellens Test) or the corresponding OECD Test Guidelines 302 B (Inherent Biodegradability: Zahn-Wellens/ EVPA Test) or OECD 302 C (Inherent Biodegradability: Modified MITI Test (II)).

Core-data testing for inherent biodegradability may in general not be appropriate, since these tests do not provide adequate information for risk assessment purposes. Therefore, simulation tests are preferred instead of new tests on inherent biodegradability. Nevertheless, if inherent biodegradation data are available (which may well be the case for biocides which are already on the market), the output of the test can be used if the tests fulfil specific criteria:

Zahn-Wellens test:	Pass level must be reached within 7 days, log-phase should be no longer than 3 days, and percentage removal in the test before biodegradation occurs should be below 15 %.
MITI-II test:	Pass level must be reached within 14 days, log-phase should be no longer than 3 days.
SCAS test:	Even if a substance is biodegradable according to the SCAS test, the degradation rate is set to zero and further tests are generally required.

Information on inherent biodegradability tests and the interpretation of the results of the tests is summarised in in chapters 2.3.6.4 and 2.3.6.5 of the TGD for new and existing substances (EU, 2003). The proposed rate constant for inherently degradable substances can be found in TGD in tables 6 (STP, chapter 2.3.6.4), 7 (surface water, chapter 2.3.6.5) and 8 (soil, chapter 2.3.6.5).

4.2.5. Simulation tests

Simulation tests are tests which provide evidence of the rate of biodegradation under some environmentally relevant conditions. Tests of this type may be subdivided according to the environment they are designed to simulate a) biological treatment (aerobic); b) biological treatment (anaerobic); c) river; d) lake; e) estuary; f) sea; and g) soil.

Simulation tests may be performed directly, thus skipping the screening stage biodegradation tests. This may be required for biocides which are toxic to the inoculum (section 4.2.2 of this guidance). If a substance is not readily or inherently biodegradable, further refinement of the degradation rate and route is needed:

- For all environmental compartments which are directly exposed, a respective simulation test needs to be conducted. This is to ensure that a full environmental risk assessment can be performed for these directly exposed compartments (this full environmental risk assessment also needs to consider the environmental risks posed by any major metabolites or any ecotoxicologically relevant metabolites).
- Potential atmospheric deposition should also be taken into account.

Thus further conditions given in the following sections refer only to substances which are not readily or inherently biodegradable. If a substance is not readily biodegradable and either not vB or not classified as B or T, it may not be necessary to conduct simulation studies for the indirectly exposed environmental compartments. For the PBT assessment, the substance would thus be considered vP, but it would not have any regulatory consequences (as the substance is not in addition vB nor fulfils two (or even three) of the three PBT criteria). As soon as there is new information and this results in the substance being considered as B or T in addition to its classification as vP, it may become necessary to perform a P assessment. For the environmental risk assessment in the indirectly exposed compartments, the first tier assessment can be performed without the need for simulation studies (i.e. the risk assessment can focus on the active substance only, utilising information from the available core data, e.g. hydrolysis, photolysis etc.). A robust argument about the formation of potential metabolites of concern is required. Additional simulation studies in indirectly exposed compartments may be useful to refine the first tier risk assessment.

Any simulation test should at least fulfil the following criteria:

- give measured rates for primary degradation and an indication of the mineralisation potential;
- allow for quantification and identification of metabolites formed during the test;
- provide an indication of the degradation rates or persistence of the metabolites.

At this stage in the scheme, it becomes important to which compartment(s) the emission takes place. Simulation tests after indirect release are relevant for substances which do not degrade or dissipate in the first receiving compartment and thus are transported to consecutive compartments.

4.2.5.1. Sewage Treatment Plant (STP)

If the substance first enters an STP before release to the environment, an STP simulation test can be used to refine the initial risk assessment for STP or subsequently exposed compartments. The provided information on the degradation and the distribution of the substance in the respective compartments can be used as direct input parameters in calculation models.

For the relevant test methods, please follow guidance in section 2.2.1.3 Biological sewage treatment (c) of this guidance.

4.2.5.2. Water/sediment

If the biocide is directly emitted to water, a water simulation test is required.

A water/sediment simulation test shall be performed for substances with K_p (sediment) > 2000 (with quantification of bound residues) for direct or indirect emission to water/sediment systems.

If the substance has a water solubility well below 1 µg/L, depending on the physico-chemical properties, it may not be warranted to conduct a water simulation study. As substances with such low water solubility may often be adsorptive, rather a water/sediment simulation study than a water simulation study may be required.

There might also be a need to perform a water/sediment simulation study when the surface water is directly exposed in case no adsorption/desorption test with sediment is available (please refer to section 4.3 of this guidance).

For the relevant test methods for water simulation studies, please follow guidance in section 2.2.1.3 Biodegradation in freshwater (a) of this guidance.

The water/sediment simulation tests should be performed according to test methods given in section 2.2.1.3 Biodegradation in freshwater (b) of this guidance.

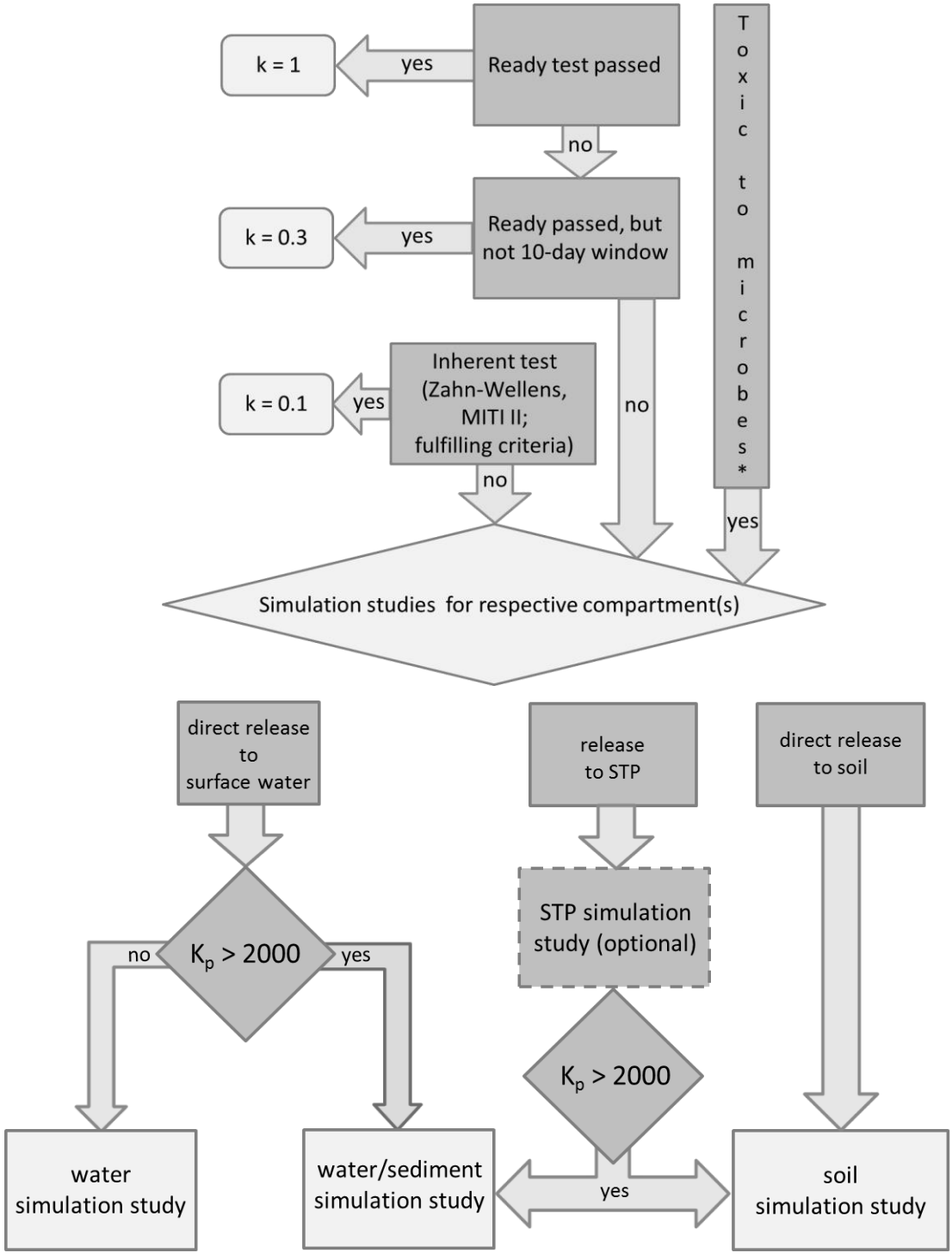
For the assessment of substances released to marine environments, the test system has to be adapted accordingly. Section 5 of this guidance_provides more guidance on the product-types for which this is the case, and section 2.2.1.3 Biodegradation in seawater of this guidance describes the relevant seawater biodegradation test methods.

4.2.5.3. Soil

If the biocide is directly applied or emitted to soil, a soil simulation test is required. The route(s) of degradation should be studied in one of the soils tested. Such a test should be done in three different additional soil types which, depending on the characteristics of the substance, should cover a wide range of relevant soil characteristics.

If the soil compartment is indirectly exposed, but the substance has a K_p > 2000, it partitions to STP sludge which is spread on soil. Therefore soil simulation degradation testing is warranted in these cases. For the relevant test methods, please refer to section 2.2.2.1 of this guidance.

An outdoor soil lysimeter study/field study may be relevant to complete the soil testing strategy, e. g. according to OECD Guidance Document 22 for the performance of outdoor monolith lysimeter studies. See section 2.2.2.6 and section 4.3 of this guidance for further guidance.



* please refer to section 4.2.2 of this section

Figure 3 Biocides biodegradation test strategy

4.3. Testing strategy for adsorption/desorption

To perform the environmental risk assessment, an adsorption coefficient is necessary. Depending on the environmental pathways, it needs to be decided which test(s) may be adequate:

In general, a screening test on adsorption/desorption is required according to the test methods referred to in section 2.2.1.2 of this guidance. Although not explicitly mentioned in the guideline the handling procedure can also be applied to sediments or activated sludge.

A specific study with sediments or sewage sludge, if adsorption to these is of concern, may be provided in case of direct exposure to sediment for a refinement of the initial risk assessment or if no water/sediment study is available (see also section 4.2.5.2 of this guidance). Please refer to section 2.2.1.4 of this guidance for the relevant test methods.

In case of direct exposure to soil a full scale study (isotherms, mass balance, desorption) with soil needs to be provided unless it is shown to be readily biodegradable. In case of indirect exposure (e.g. spreading of contaminated sewage sludge on land) to soil this study may be conducted to refine the initial risk assessment.

A full scale adsorption test with soils may also be appropriate to refine the PEC value in those cases where modelling results indicate that relevant concentrations of the substance may reach groundwater. Please refer to section 2.2.2.4 of this guidance for the relevant test methods and the selection of suitable soils.

To further refine the risk assessment for soil or subsequently groundwater, soil column leaching studies can provide reliable and useful lower limits of the K_{OC} if the expected K_{OC} value is less than 25 L/kg. The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance. Please refer to section 2.2.2.6 Column leaching studies of this guidance for the relevant test methods.

Where it is indicated from data on adsorption and degradation in soil that relevant amounts of a substance may reach groundwater it may become necessary to carry out an outdoor confirmatory study. For guidance on how to perform a long term study on mobility of a substance in undisturbed soil under outdoor conditions refer to sections 2.2.2.6 Lysimeter studies and Field leaching studies of this guidance.

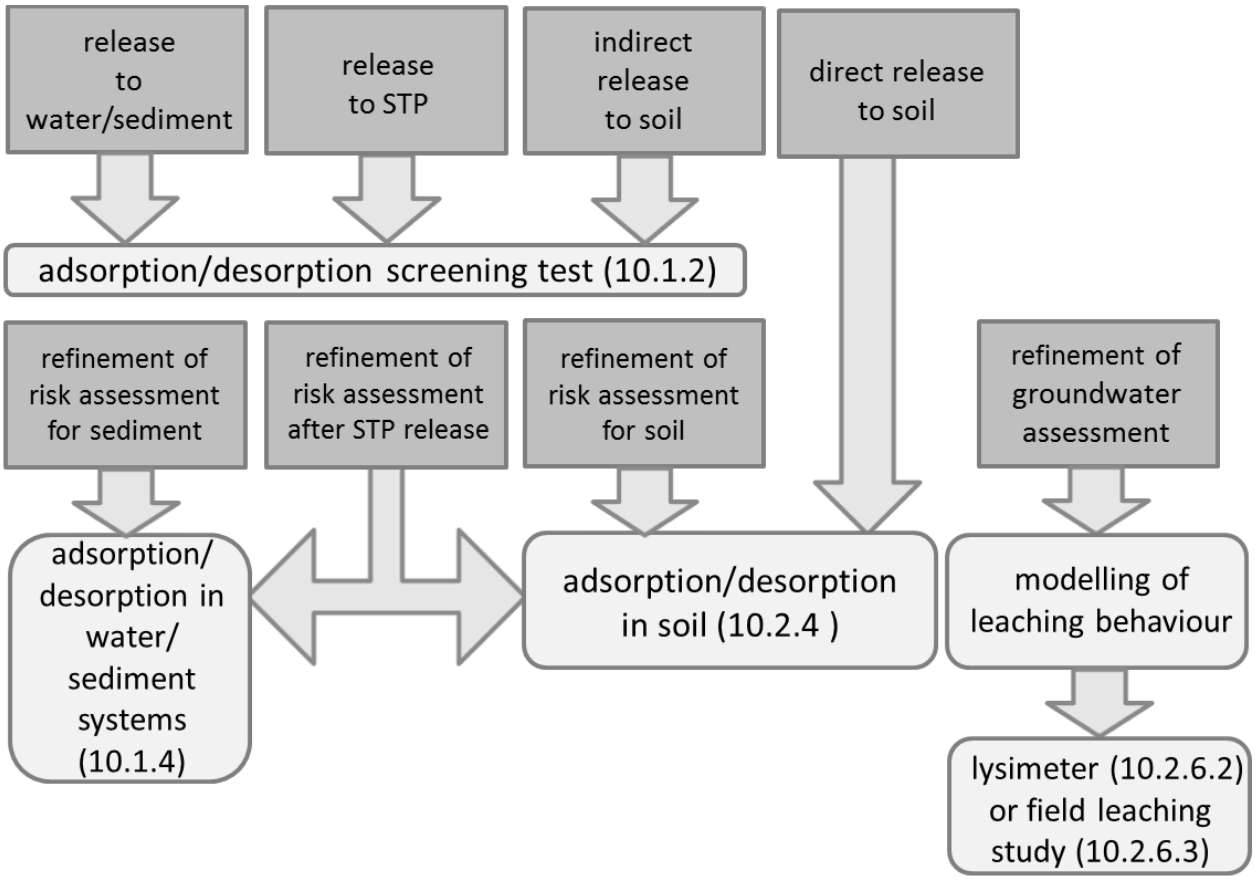


Figure 4: Testing strategy for adsorption/desorption and mobility

5 Product Type Specific Additional Data Set (ADS) for active substances and biocidal products regarding ecotoxicological profile, including environmental fate and behaviour

A risk assessment is performed on the basis of the data requested in Annexes II and III (information requirements for the active substance and the biocidal product, respectively). Based on the product-type, for which an active substance will be used, and thus the emission pathways, additional information to those required for the core data set (CDS) might be necessary to be able to perform an initial risk assessment.

These data are usually required to be delivered together with the CDS. If the initial risk assessment shows an indication of risk for man or the environment, the applicant should conduct further studies according to the guidance in sections 2, 3 and 4 of this guidance (as applicable) in order to refine the risk assessment and reach a conclusion.

Detailed exposure scenarios have not yet been developed for all 22 product-types or all uses within a product-type. Thus, other uses might exist that give rise to direct exposure, for which additional tests might also be necessary. Therefore, section 5 of this guidance would need refinement when exposure scenarios are available for all product-types.

If brackish or marine environments are exposed, in addition to the freshwater ecotoxicological tests which are CDS, additional tests should be performed with species representative of brackish or marine environments and habitats. It should be considered to conduct long term tests as this may reduce the uncertainty of the effect assessment.

Long term ecotoxicity data is required if there is potential continuous emission to the terrestrial or the aquatic environment, e.g. because of leaching from a biocidal product or a treated article. If the release is intermittent[3] or the intended use is limited to small or closed spaces with insignificant release, initial short-term tests providing acute ecotoxicity data may be sufficient to meet the additional testing requirements, unless there are concerns that chronic effects may arise when taking into account, for example the mode of action or the expected environmental fate of the substance. For this situation consultations with the evaluation competent authority or ECHA should be sought before further testing is conducted.

In the following sections, for each product-type, those tests are listed which are required in addition to the CDS. For further instructions which test is to be preferred in the case of a number of possible tests, please consult the respective sections in sections 2 and 3 of this guidance.

Here only the typical uses as depicted in the available emission scenario documents are taken into account. If there are emission pathways for the biocidal products which differ from these emission pathways; different, additional or less information may be necessary. In case of any confusion concerning the information requirements for any specific active substance or biocidal product, please contact ECHA or the evaluating competent authority.

An overview of the data requirements for the active substance can be found in Table 4 below.

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[3] Intermittent release: intermittent but only recurring infrequently i.e. less than once per month and for no more than 24 hours (e.g. batch processes only required for a short period of the year)

5.1. Guidance on product-type specific additional data set for (chemical) active substances

Product-type 1: Human hygiene

The release to the environment is usually diffuse via STP. No supplementary test data regarding the ecotoxicological and fate profile beyond those listed in the core data set need to be generated in order to perform a preliminary risk assessment for this emission pathway.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Due to the potential continuous release to surface water, chronic aquatic toxicity data is normally required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For substances to be used as soil or solid waste disinfectants, direct release to soil is to be taken into account. In such case it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Toxicity to plants

Furthermore, it is necessary to conduct studies on fate and behaviour (if not readily biodegradable) in case of direct emission to soil:

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 3: Veterinary hygiene

Due to potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Releases into manure storage facilities are possible. In such case it is necessary to perform a test for estimation of fate in the manure storage facility:

10.1.3.4 Biodegradation during manure storage

It is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests for the soil compartment after manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil after manure application (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types.

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

For use in poultry farms, where wild birds are attracted, a risk assessment for birds is necessary:

9.4 Effects on birds

If the substance is to be used in freshwater or marine fish nurseries, additional aquatic ecotoxicity tests need to be performed where relevant with marine/brackish species and biodegradation tests are required. If there is potential continuous release, long term ecotoxicity tests are normally required:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.2 Biodegradation in freshwater

10.1.3.3 Biodegradation in sea water

Product-type 4: Food and feed area

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Product-type 5: Drinking water

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Releases into manure storage facilities are possible if the active substance is used in disinfectants for animal drinking water. In such case it is necessary to perform a test for the estimation of fate in the manure storage facility:

10.1.3.4 Biodegradation during manure storage

It is also necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests in soil after manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil after manure application (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 6: Preservatives for products during storage

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Where direct releases to the terrestrial compartment occur (e.g. via leaching), it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 7: Film preservatives

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Where direct releases to the terrestrial compartment occur (e.g. via leaching), it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 8: Wood preservatives

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

In case of direct releases to a freshwater compartment (e.g. in use classes (UC) 3 and 4b), an aquatic degradation test is required:

10.1.3.2 Biodegradation in freshwater

Direct releases to the terrestrial compartment are possible (e.g. in UC 3 and 4a). It is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless

pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If the substance is to be used for wood in UC 5 (salt water) defined in the standard CEN 335-1 (CEN 1992), the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Where direct releases to the terrestrial compartment occur (e.g. via leaching) it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 10: Construction material preservatives

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For remedial treatment as well as spray application in general, high releases to the terrestrial compartment are possible. It is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 11: Preservatives for liquid-cooling and processing systems

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For substances to be used in cooling systems with open cooling towers, a high water discharge to air and subsequent deposition onto soil is possible. In these cases, it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

For substances to be used in the cooling systems releasing their cooling water directly to a freshwater compartment (e.g a river or a lake), a degradation test in freshwater is required:

10.1.3.2 Biodegradation in freshwater

For substances to be used on sites situated near the coast and using marine/brackish water in their cooling systems, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 12: Slimicides

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For inland use of drilling and oil recovery preservatives, it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

For offshore uses, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 13: Working or cutting fluid preservatives

Due to the potential continuous release to surface water, chronic aquatic toxicity data would be necessary for this product-type, unless the release is intermittent or the intended use is limited to closed spaces with insignificant aquatic release:

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

9.1.3 Growth inhibition test on algae (if no NOEC is available from the core data set)

Product-type 14: Rodenticides

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

It is also necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests in soil after manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

For substances to be used in direct contact to soil or in case of manure application from treated animal housings it is necessary to conduct studies on fate and behaviour (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If used outdoors in the form of baits, granulates or powder, a risk assessment for birds is necessary.

9.4 Effects on birds

Product-type 15: Avicides

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

It is also necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests in soil after manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil after manure application (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type, unless the release is intermittent or the intended use is limited to closed spaces with insignificant aquatic release:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

For substances to be used in direct contact to soil or in case of manure application from treated animal housings it is necessary to conduct studies on fate and behaviour (if not readily biodegradable):

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If used outside of buildings in the form of baits, granulates or powder, a risk assessment for birds is necessary

9.4 Effects on birds

For molluscicides used in marine waters, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 17: Piscicides

Chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

As well as aquatic degradation tests in case that direct releases to the freshwater compartment are possible:

10.1.3.2 Biodegradation in freshwater

If the substance is to be used in a marine environment, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 18: Insecticides, acaricides and products to control other arthropods

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

For products used outdoors as well as products to be used by gassing, fogging or fumigation, release to soil is possible. It is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests, also in case of manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If used outdoors in the form of baits, granulates or powder, a risk assessment for birds is necessary:

9.4 Effects on birds

Furthermore, tests with bees are required and tests with additional insects or other arthropods may also be requested depending *e.g.* on the exposure route:

9.5 Tests with arthropods

9.5.1 Tests with honeybees

9.5.2 Tests with other non-target terrestrial arthropods, e.g. predators

Product-type 19: Repellents and attractants

Due to the potential continuous release to surface water, chronic aquatic toxicity data would normally be required for this product-type:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

Aquatic degradation tests are necessary, if direct releases to the freshwater compartment are possible:

10.1.3.2 Biodegradation in freshwater (a. Aerobic aquatic degradation study or b. Water/sediment degradation test).

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

It is also necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests in soil after manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil after manure application (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If the substance is to be used as a shark repellent, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Product-type 20: Control of other vertebrates

For products to be used in animal housing, releases to manure storage facilities are possible. A study on biodegradation during manure storage is necessary:

10.1.3.4 Biodegradation during manure storage

For products used outdoors in contact with soil, direct release to soil is possible. It is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests, also in case of manure application:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil after manure application (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

If used outside of buildings in the form of baits, granulates or powder, a risk assessment for birds is necessary

9.4 Effects on birds

Product-type 21: Antifouling products

Aquatic degradation tests for freshwater are necessary, if direct releases to the freshwater compartment are possible:

10.1.3.2 Biodegradation in freshwater

Chronic aquatic toxicity data would be necessary for this product-type, if continuous direct releases to the freshwater compartment are possible during use:

9.1.3 Growth inhibition test on algae (if no chronic data (NOEC or EC_{10}) is available from the core data set)

9.1.6.1 Long term toxicity testing on fish

9.1.6.2 Long term toxicity testing on invertebrates

If the substance is to be used in a marine environment, the aquatic toxicity tests need to be performed additionally with marine/brackish species and a saltwater biodegradation test is required as well:

9.1.1/9.1.6.1 Tests with fish (marine/brackish species)

9.1.2/9.1.6.2 Tests with invertebrates (marine/brackish species)

9.1.3 Growth inhibition test on algae (marine/brackish species)

9.1.8 Tests with any other specific, non-target organisms (flora and fauna) believed to be at risk

10.1.3.3 Biodegradation in sea water

Several additional tests with marine/brackish species are required to accurately assess the risks for these substances:

9.1.7 Bioaccumulation tests in an appropriate aquatic species (fish as well as invertebrate species)

9.1.9 Tests on sediment dwelling organisms

9.1.10 Tests on aquatic macrophytes

For substances, which can have direct emission to soil, it is necessary to perform initial or, if there is potential continuous exposure, long term terrestrial effects tests:

9.2.1 Tests with soil micro-organisms

9.2.2/9.3.1 Tests with earthworms or other soil-dwelling non-target invertebrates

9.2.3/9.3 Tests with plants

Furthermore, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products

Product-type 22: Embalming and taxidermist fluids

For substances to be used in direct contact to soil, it is necessary to conduct studies on fate and behaviour in soil (if not readily biodegradable; initial tests on soil organisms are not required since the release occurs in deeper soil layers and not on the soil surface):

10.2.1 Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types

10.2.4 Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation product.

Table 4 An overview of product-type specific additional information requirements for active substances

(BPR Annex II)

\+ = required for **specific uses** within the respective PT (triggered by emission pathways).

(+) = required for **specific uses** within the respective PT (triggered by emission pathways), if not readily biodegradable

Please refer also to the text for the respective PT in relation to the specific uses and their emission pathways triggering the information requirements.

Please refer also to section 4 of this guidance Testing Strategies.

Product-type:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
9. ECOTOXICOLOGICAL STUDIES																						
9.1. Toxicity to Aquatic Organisms																						
9.1.1. Short-term toxicity testing on fish			+					+			+	+				+	+		+			
9.1.2. Short-term toxicity testing on aquatic invertebrates			+					+			+	+				+	+		+			
9.1.3. Growth inhibition study on algae [4]		+	+	+	+	+	+	+	+	+	+	+	+			+	+	+	+		+	
9.1.6.1. Long term toxicity testing on fish		+	+	+	+	+	+	+	+	+	+	+	+			+	Ap	+	+		+	
9.1.6.2 Long term toxicity testing on invertebrates		+	+	+	+	+	+	+	+	+	+	+	+			+	+	+	+		+	

[4] This study is a core data requirement but is noted here again since it is required if no NOEC is available from the core data set

Product-type:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
9.1.7. Bioaccumulation in an appropriate aquatic species[5]																					+	
9.1.8. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk[6]			+					+			+	+				+	+		+		+	
9.1.9. Studies on sediment dwelling organisms																					+	
9.1.10. Effects on aquatic macrophytes																					+	
9.2. Terrestrial toxicity, initial tests																						
9.2.1. Effects on soil micro-organisms		+	+		+	+	+	+	+	+	+	+		+	+	+		+	+	+	+	
9.2.2. Effects on earthworms or other soil-dwelling non-target invertebrates		+	+		+	+	+	+	+	+	+	+		+	+	+		+	+	+	+	
9.2.3. Acute toxicity to plants		+	+		+	+	+	+	+	+	+	+		+	+	+		+	+	+	+	
9.3. Terrestrial tests, long term		+	+		+	+	+	+	+	+	+	+			+	+		+	+	+	+	
9.3.1. Reproduction study with earthworms or other soil-dwelling non-target invertebrates		+	+		+	+	+	+	+	+	+	+			+	+		+	+	+	+	

[5] Two studies are required (e.g. for PT21): Bioaccumulation in an appropriate species of fish and in an appropriate invertebrate species

[6] Three studies with marine/brackish species are required for specific uses in those PTs which are marked with "+": acute toxicity to fish, to invertebrates and a growth inhibition test on algae

Product-type:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
9.4. Effects on birds			+											+		+		+		+		
9.5. Effects on arthropods																		+				
9.5.1. Effects on honeybees																		+				
9.5.2. Other non-target terrestrial arthropods, e.g. predators																		+				
10. ENVIRONMENTAL FATE AND BEHAVIOUR																						
10.1. Fate and behaviour in water and sediment																						
10.1.3.2. Biodegradation in freshwater			+					+			+						+		+		+	
10.1.3.3. Biodegradation in sea water			+					+			+	+				+	+		+		+	
10.1.3.4. Biodegradation during manure storage			+		+									+	+	+		+	+	+		
10.2. Fate and behaviour in soil																						

Product-type:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
10.2.1. Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions. Laboratory studies on rate of degradation in three additional soil types		(+)	(+)		(+)	(+)	(+)	(+)	(+)	(+)	(+)	(+)		(+)	(+)	(+)		(+)	(+)	(+)	(+)	(+)
10.2.4. Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products		(+)	(+)		(+)	(+)	(+)	(+)	(+)	(+)	(+)	(+)		(+)	(+)	(+)		(+)	(+)	(+)	(+)	(+)

According to the outcome of the risk assessment, further data might be required for the active substance. Thus, not all endpoints of the ADS are assigned to specific PTs/emission pathways.

5.2. Guidance on product-type specific additional data set for biocidal products

Information on the releases following the use of the product is always required and it is a part of the core data set (section 3.2.1 of this guidance). However, for some PTs additional information on the release after use of the product is needed and therefore further detailed below, depending on the PT.

If a product contains two or more active substances or a substance(s) of concern, or if other ingredients of the product might enhance the bioavailabilty of the active substance, the effects of the product on non-target organisms might be significantly different to those of the active substances alone. In those cases, where a direct release of a product to a given compartment is possible, so that the composition of the product is maintained, additional tests regarding the effects towards non-target organisms performed with the product might be necessary. For the compartments directly exposed, the risk assessment can be performed based on the results of the tests performed with the product.

Please note in addition:

- Other uses might exist which give rise to direct exposure, for which additional tests might also be necessary;
- According to the outcome of the risk assessment further data might be required for the product. Thus, not all endpoints of the ADS are assigned to specific PTs;
- Data on the average amount of the product which may be left in the package to be disposed of should be submitted.

Product-type 1: Human hygiene

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes for human hygiene biocidal products information should be supplied (as far as not covered in BPR Annex III Section 7) on the maximum and average amounts of the product that are applied on one person at a time. For disinfectants in general, information should be supplied on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the point treated during use and during washing, etc. (e.g. per unit of surface area per unit of time) by evaporation, dissolving in water or another way. Release rates to be given can be either default estimates or measured.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

For substances to be used as soil or solid waste disinfectants, direct release to soil is possible. Furthermore, for substances to be used by gassing, fogging, fumigation or aerosol sprays high releases to the atmosphere and subsequent deposition is possible. It is necessary to perform initial terrestrial tests (as referred to in section 3.1.2 of this guidance) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, information should be supplied for disinfectants in general, on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the point treated during use and during washing, etc. (e.g. per unit of surface area per unit of time) by evaporation, dissolving in water or another way. Release rates to be given can be either default estimates or measured.

Product-type 3: Veterinary hygiene

For substances to be used as soil or solid waste disinfectants, direct release to soil is possible. Furthermore, for substances to be used by gassing, fogging, fumigation or aerosol sprays high releases to the atmosphere and subsequent deposition is possible. It is necessary to perform initial terrestrial tests (as referred to in section 3.1.2 of this guidance) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

For use in poultry farms, where wild birds are attracted, a test with the product with birds is necessary if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Study on 'Effects on birds' according to section 3.1.4 of this guidance.

If the substance is to be used in marine fish nurseries, the aquatic toxicity tests with marine/brackish species also need to be performed with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance, respectively;
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively;
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, information should be supplied for disinfectants in general, on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the point treated during use and during washing, etc. (e.g. per unit of surface area per unit of time) by evaporation, dissolving in water or another way. Release rates to be given can be either default estimates or measured.

Product-type 4: Food and feed area

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes for food and feed area disinfectants information should be supplied on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the point treated during use and during subsequent washing, etc. (e.g. per unit of surface area per unit of time) by evaporation, their dissolving in water or another way. The release rates given can be either default estimates or measured.

Product-type 5: Drinking water

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes for drinking water disinfectants information should be supplied on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the drinking water treatment during or after use (e.g. per volume of treated water per unit of time) by evaporation or are dissolved in water or are released in some other way. Release rates to be given can be either default estimates or measured.

Product-type 6: Preservatives for products during storage

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes, for preservatives for products during storage information should be supplied on:

- the binding of the active substance to the material treated,
- on factors influencing binding properties, and
- on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the treated material (e.g. per unit of surface area per unit of time) by evaporation, dissolving or any other way.

Release rates to be given can be either default estimates or measured leaching rates.

In case measured leaching rates are provided, please provide them under

10.3 Leaching behaviour

Different leaching rates may be required, for example in relation to leaching from preserved paints or coatings to be used outdoors with a risk of wetting, leaching from preserved paints or coatings when washed indoors or otherwise in contact with water during its service life and volatilisation from preserved paints or coatings in contact with indoor or outdoor air.

Product-type 7: Film preservatives

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes, for film preservatives information should be supplied on:

- the binding of the active substance to the material treated,
- on factors influencing binding properties
- on how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the treated material (e.g. per unit of surface area per unit of time) by evaporation, dissolving or any other way.

Release rates to be given can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour

Different leaching rates may be required, for example in relation to leaching during the washing of freshly preserved film (e.g. a textile or a film), leaching from a treated film to be placed outdoors with a risk of wetting, leaching from the treated film when washed indoors or otherwise in contact with water during its service life, and volatilisation from the treated film in contact with indoor or outdoor air.

Product-type 8: Wood preservatives

High releases to the terrestrial compartment are possible during storage of freshly treated wood. It is necessary to perform initial terrestrial tests (as referred to in section 3.1.2 of this guidance) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

If the substance is to be used for wood in hazard class 5 (salt water) defined in the standard EN 335-1 (CEN 1992), the aquatic toxicity tests with marine/brackish species are required with the product as well if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance , respectively;
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance , respectively;
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

Alternatively to testing the product, it would be possible to test the leachate. No harmonised methods are currently available though, and further discussion regarding the scope of these tests would be necessary.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes, for wood preservatives information should be supplied on:

- the binding of the active substance to the material treated,
- factors influencing binding properties
- how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the treated material (e.g. per unit of surface area per unit of time) by evaporation, dissolving or any other way.

Release rates to be given can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour

Different leaching rates may be required in relation to leaching during storage of freshly preserved wood, leaching from wood above ground with risk of wetting, leaching from wood in contact with water, leaching from wood in contact with soil and volatilisation from wood in contact with air.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes, for material preservatives information should be supplied on:

- the binding of the active substance to the material treated,
- factors influencing binding properties
- how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the treated material (e.g. per unit of surface area per unit of time) by evaporation, dissolving or any other way.

Release rates to be given can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour

Different leaching rates may be required, for example in relation to leaching during the washing of freshly preserved material (e.g. a textile), leaching from a treated textile or plastic in or above ground outdoors with a risk of wetting, leaching from the treated material when washed or otherwise in contact with water during its service life, and volatilisation from the treated material in contact with indoor or outdoor air.

Product-type 10: Construction material preservatives

For spray application, high releases to the terrestrial compartment are possible. It is necessary to perform initial terrestrial tests (as referred to in section 2.1.2 of this guidance - CDS) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, for the quantification of emission fluxes, for material preservatives information should be supplied on:

- the binding of the active substance to the material treated,
- factors influencing binding properties,
- how and in what percentage the active substance, its transformation products or the other ingredients in the product are released from the treated material (e.g. per unit of surface area per unit of time) by evaporation, dissolving or any other way.

Release rates to be given can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour

Different leaching rates may be required, for example in relation to leaching from a treated construction material in or above ground outdoors with a risk of wetting, leaching from the treated material placed indoors and washed or otherwise in contact with water during its service life, and volatilisation from the treated material in contact with indoor or outdoor air.

Product-type 11: Preservatives for liquid-cooling and processing systems

For substances to be used in the cooling systems with an open cooling tower, a high water discharge to air and subsequent deposition onto soil is possible. In these cases, it is necessary to perform initial terrestrial tests (as referred to in section 3.1.2 of this guidance – CDS) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration).

Product-type 12: Slimicides

For inland use of drilling and oil recovery preservatives, it is necessary to perform initial terrestrial tests (as referred to in BPR Annex III, point 9.2) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

For offshore use, the aquatic toxicity tests with marine/brackish species need to be performed additionally with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance, respectively
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

Alternatively to testing the product, it would be possible to test the leachate. No harmonised methods are currently available though, and further discussion regarding the scope of these tests would be necessary.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

> In addition to the data to be submitted as core data, give information for example on the percentage of the active substance or a substance of concern adsorbed to pulp or paper in the manufacturing process. Indicate measured or estimated extent of release: frequency and intensity (e.g. dose and duration).

Product-type 13: Working or cutting fluid preservatives

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

> In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration).

Product-type 14: Rodenticides

If used outside of buildings in the form of baits, granulates or powder, an avian toxicity test (as referred to in section 2.1.4 of this guidance (Effects on birds) and as referred to in section 3.1.4 of this guidance) is necessary with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

Furthermore, in order to assess risks to predators residue data in target organisms concerning the active substance and including toxicologically relevant metabolites would be needed if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

> In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration). Information should be supplied on the leaching rate of active substances due to weathering of e.g. baits, granules or contact pastes. This can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour.

Product-type 15: Avicides

In order to assess risks to predators residue data in target organisms concerning the active substance and including toxicologically relevant metabolites would be needed if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

> In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration). Information should be supplied on the leaching rate of active substances due to weathering of e.g. baits, granules or contact pastes. This can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour.

Product-type 16: Molluscicides

For products used outside buildings in contact with soil, release to soil is possible. It is necessary to perform initial terrestrial tests (as referred to in section 3.1.2 of this guidance) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

If used outside of buildings in the form of baits, granulates or powder, an avian toxicity test (as referred to in section 2.1.4 of this guidance (Effects on birds) and as referred to insection 3.1.4 of this guidance) is necessary with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

For molluscicides used in marine waters, the aquatic toxicity tests with marine/brackish species need to be performed with the product as well if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance, respectively
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

For molluscicides to be used in water, residue studies with the product are necessary if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests on bioconcentration in aquatic organisms according to section 2.1.1.4 of this guidance.

Furthermore, possible monitoring data or results of residues studies including toxicologically relevant metabolites, if these cause harmful effects on human health.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration). Information should be supplied on the leaching rate of active substances due to weathering of e.g. baits, granules or contact pastes. This can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour.

Product-type 17: Piscicides

For piscicides, the freshwater aquatic toxicity tests (as referred to in section 2.1.1 of this guidance) need to be performed with the product as well if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

If the substance is to be used in a marine environment, the marine/brackish aquatic toxicity tests need to be performed with the product as well if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively;
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

Residue studies with the product are also necessary if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests on bioconcentration in aquatic organisms according to section 2.1.1.4 of this guidance.

Furthermore, possible monitoring data or results of residues studies including toxicologically relevant metabolites, if these cause harmful effects on human health.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration).

Product-type 18 and 19: Insecticides, acaricides and products to control other arthropods and Repellents and attractants

For products used outside buildings as well as products to be used by gassing, fogging or fumigation, release to soil is possible. It is necessary to perform initial terrestrial tests (as referred to in section 2.1.2 of this guidance) with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

If used outside of buildings in the form of baits, granulates or powder, an acute avian toxicity test (as provided to in section 2.1.4.2 of this guidance) is necessary with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

Furthermore, a test with bees (as referred to in section 2.1.5 of this guidance) is necessary if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

For products to be used by gassing, fogging or fumigation of a large proportion of a specific habitat type, an assessment of the secondary ecological effect might be necessary:

9.5 Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration). Information should be supplied on the leaching rate of active substances due to weathering of e.g. baits, granules or contact pastes. This can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour.

If the substance is to be used as a shark repellent, the aquatic toxicity tests with marine/brackish species need to be performed additionally with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance, respectively;
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively;
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

Product-type 20: Control of other vertebrates

If used outside of buildings in the form of baits, granulates or powder, an avian toxicity test (as provided in section 3.1.4 of this guidance) is necessary with the product as well if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration). Information should be supplied on the leaching rate of active substances due to weathering of e.g. baits, granules or contact pastes. This can be either default estimates or measured leaching rates.

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour.

Product-type 21: Antifouling products

The aquatic toxicity tests with marine/brackish species need to be performed additionally with the product if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests with fish according to section 2.1.1 or 2.1.1.6 Long term toxicity testing on fish of this guidance, respectively;
- Tests with earthworms or other soil-dwelling non-target invertebrates according to sections 2.1.2.2 or 2.1.3.1 of this guidance, respectively;
- Growth inhibition tests on algae according to section 2.1.1.3 of this guidance.

Alternatively to testing the product, it would be possible to test the leachate. No harmonised methods are currently available though, and further discussion regarding the scope of these tests would be necessary.

Residue studies are also necessary:

9.3 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

- Tests on bioconcentration in aquatic organisms according to section 2.1.1.4 of this guidance.

Furthermore, possible monitoring data or results of residues studies including toxicologically relevant metabolites, if these cause harmful effects on human health.

In addition, further information on the release due to the use of the product is needed:

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, indicate for example the measured or estimated extent of release: frequency and intensity (e.g. dose and duration).

If measured leaching rates are provided, please provide them under:

10.3 Leaching behaviour

Especially for antifouling products in order to quantify emission fluxes, information should be supplied on the average and maximum leaching of the active substance from the film (e.g. per unit of surface area per unit of time). Factors influencing the leaching properties (e.g. time passed after application, temperature, pH, salinity, vessel speed, erosion rate of coating, film thickness)

should be named. Release rates to be given can be either default estimates or measured leaching rates.

Product-type 22: Embalming and taxidermist fluids

10.1 Foreseeable routes of entry into the environment on the basis of the use envisaged

In addition to the data to be submitted as core data, information should be supplied for embalming and taxidermist fluids on how and in what percentage the active substance, its transformation products or other ingredients in the product are released from the point during use and during storage of treated material, etc. (e.g. per unit of surface area per unit of time) by evaporation, dissolving in water or another way. Release rates to be given can either default estimates or measured.

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