ECHA
EUROPEAN CHEMICALS AGENCY

SUPERSEDED GUIDANCE A NEW VERSION IS AVAILABLE

GUIDANCE

Guidance on the Biocidal Products Regulation

Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C

Version 2.0
May 2018

LEGAL NOTICE

Guidance on the Biocidal Products Regulation: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology - Parts A+B+C: Information Requirements, Evaluation and Assessment

Reference: ECHA-18-G-03-EN
Cat. Number: ED-02-18-531-EN-N
ISBN: 978-92-9020-504-3
DoI: 10.2823/628864
Publ.date: May 2018
Language: EN

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

European Chemicals Agency

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

DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First edition	June 2013
Version 1.1	Corrigendum: • Division of the guidance in the 4 volumes of the new BPR Guidance structure; • Minor editorial changes.	November 2014
Version 2.0	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; • To correct the reference under Table 7; • To move the sections on "BPR Annexes II and III point 7 Intended Uses and Exposure" to Volume II, Part A. • To add a page for Section 4 for evaluation and assessment with a cross reference to currently available guidance in TNsG.	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:

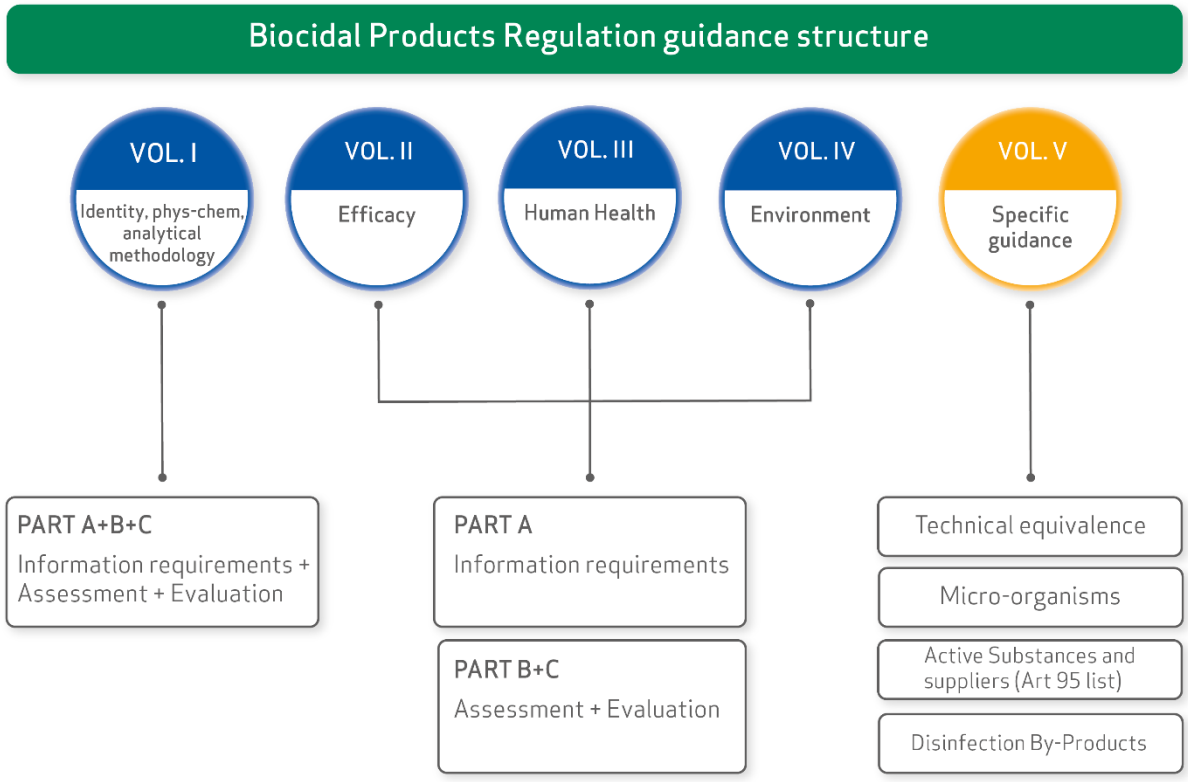

Figure 1: BPR guidance structure

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[1] [https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee] and for applicability of guidance for product authorisation, please see the CA-document CA-july2012-doc6.2d (final), available on the ECHA Guidance page [https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf].

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

Table of Contents

Figures

Tables

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
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)
AAS	Atomic absorption spectrometry
ADS	Additional data set
AEL	overall systemic limit value for the human population
ASTM	American Society for Testing and Materials
BPC	Biocidal Products Committee (ECHA body)
BPD	Biocidal Products Directive. Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products
BPR	Biocidal Products Regulation. Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
CAS	Chemical abstract (Service or System)
CAS registry number	A CAS registry number (Chemical Abstract Service index number) is a unique numerical identifier for chemical compounds, polymers, biological sequences, mixtures and alloys and does not have any chemical significance
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
Dw	Dry weight
DAD	Diode array detector
DG	European Commission Directorate General
DG SANCO	European Commission Directorate-General for Health and Consumers
DoA	Date of application
DSC	Differential Scanning Calorimetry
$DegT_{50}$	Period required for 50% degradation (define method of estimation)
$DegT_{90}$	Period required for 90% degradation (define method of estimation)
DTA	Differential Thermo-Analysis
DWD	European Drinking Water Directive (Directive 98/83/EC)
EC	European Communities or European Commission
EC method	Test Method as listed in the Test Methods Regulation
ECD	Electron Capture Detector
ECHA	European Chemicals Agency
EEA	European Economic Area. The EEA is composed of Iceland, Liechtenstein, Norway and the EU Member States.

Standard term / Abbreviation	Explanation
EEC	European Economic Community
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
EWPM	European Wood Preservation Manufacturers
FCM	Food contact material
FID	Flame ionisation detector
FPD	Flame photometric detector
g	Gram(s)
GC	Gas chromatography
GLP	Good laboratory practice
h	Hour(s)
ha	Hectare(s)
HLC	Henry's Law Constant
HPLC	High performance (or pressure) liquid chromatography
ICP	Inductively coupled plasma
ICP-MS	Inductively coupled plasma mass spectrometry
ICP-OES	Inductively coupled plasma optical emission spectrometry
ILV	Independent laboratory validation
INDEX number	The INDEX number (format XXX-XXX-XX-X) is a European number attributed to substances listed on Part 3 of Annex VI to the CLP Regulation (List of harmonised classifications and labelling).
IR	Infrared
IPCS	The WHO International Programme on Chemical Safety
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
K	Kelvin
kg	Kilogram(s)

Standard term / Abbreviation	Explanation
K_{ow}	Octanol-water partition coefficient
kPa	Kilopascal(s)
Kst	Dust explosion constant
L	Litre(s)
LEL	Lower explosion limit
LOC	Limiting oxygen concentration
LOQ	Limit of quantification
m	Metre
mg	Milligram(s)
MIE	Minimum ignition energy
MIT	Minimum ignition temperature
MMAD	Mass median aerodynamic diameter
mol	Mole(s)
MOTA	Manual of Technical Agreements of the Biocides Technical Meeting
MRL	Maximum residue limit
MS	Mass spectrometry
MSCA	Member State competent authority
MSn	A number of coupled mass spectrometers
MT	Material test
nm	Nanometre(s)
NMR	Nuclear magnetic resonance
no.	Number
NOAEC	No observed adverse effect concentration
NPD	Nitrogen phosphorus detector
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational exposure limit
OH^-	Hydroxide
OSHA	European Agency for Safety and Health at Work
Pa	Pascal(s)
pH	pH-value, negative decadic logarithm of the hydrogen ion concentration
pKa	Negative decadic logarithm of the acid dissociation constant
pKb	Negative decadic logarithm (to the basis 10) of the base 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

Standard term / Abbreviation	Explanation
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RSD	Relative standard deviation
s	Second(s)
SDS	Safety data sheet
SMEs	Small and medium-sized enterprises
SMILES	Simplified molecular-input line-entry system
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
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
UVCB	Unknown or variable composition, complex reaction products or biological material
v/v	Volume per volume ratio
VDI	Verein Deutscher Ingenieure (The Association of German Engineers)
VIS	Visible
w/w	Weight per weight ratio
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[2]. The objective of the BPR is to improve the functioning of the internal market on biocidal products whilst ensuring a high level of environmental and both human and animal health protection. In addition, the BPR removes a number of deficiencies that were identified during the implementation of Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products (BPD).

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

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

Due to the wide scope of the BPR and the extensive variation of efficacy, exposure and risks of biocidal products, the general rules provided in the BPR and its Annexes have to be specified in order to ensure efficient and harmonised day-to-day implementation of the regulation. The aim of the Guidance is to provide detailed and practical direction on which study data and other information should be submitted, when applying for approval and authorisation according to the BPR. The requirements outlined in 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 Parts B+C of Volumes III and IV.

Several documents published by the Commission and ECHA have been used as a basis for the information requirements presented; see section 1.3 of 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.

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

1.1 General structure of the guidance on information requirements

1.1.1 Information requirements in general

The information requirements are two-tiered:

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

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

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

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

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

1.1.2 Comparison of BPD-BPR

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

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

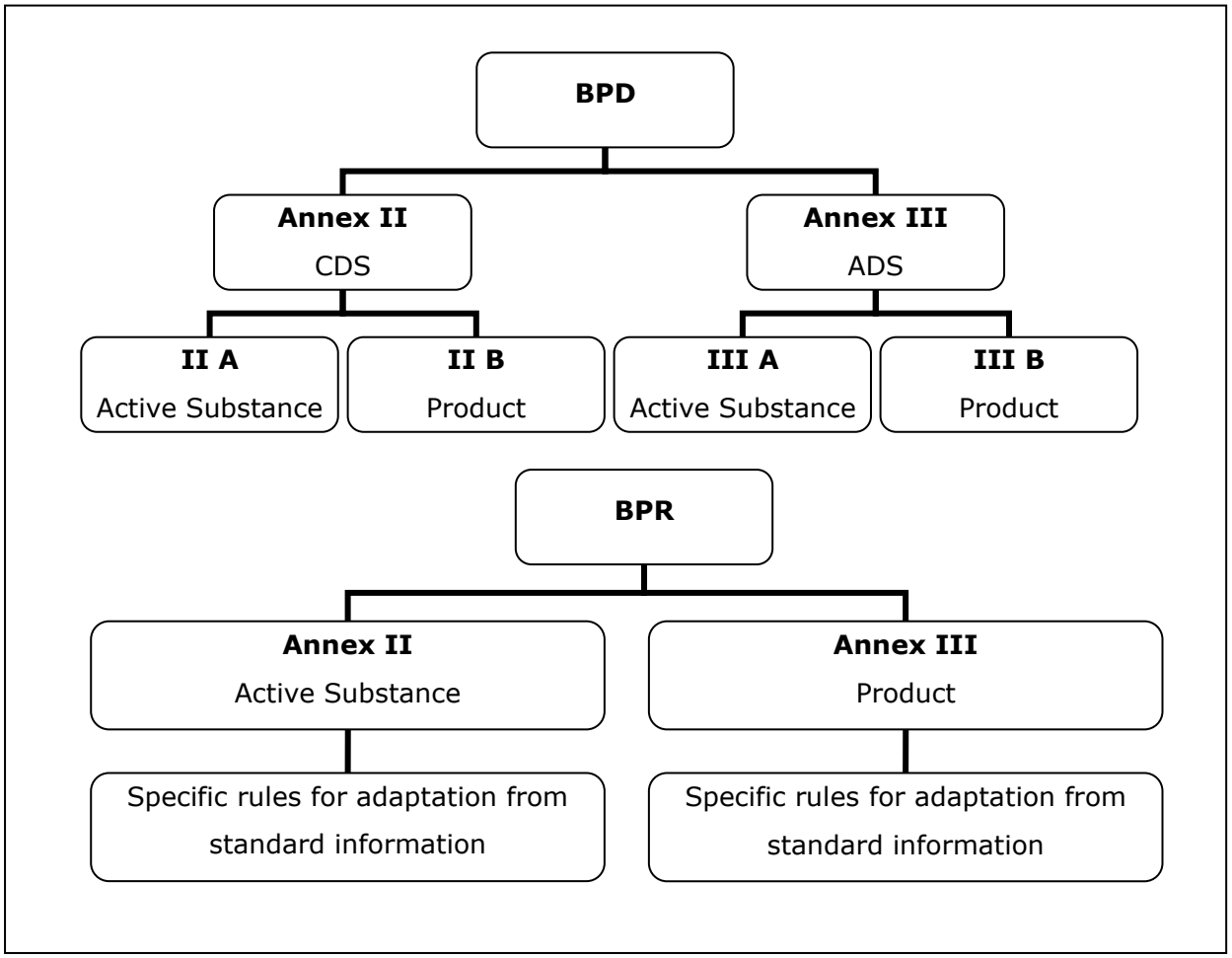

Figure 2: Structure of data/information requirements under the BPD and the BPR.

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

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

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

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

1.1.3 Volume I Parts A+B+C: Document structure

This document (Volume I, Parts A+B+C) covers the following:

- Part A: includes **general information** on information requirements (i.e. applicable to all four volumes) and the **specific information** requirements for identity/physico-chemical properties/analytics.
- Other general information relevant for the whole dossier not dealing with information requirements.
- Parts B+C: additional guidance on addressing evaluation and assessment for relevant sections of physico-chemical properties

There are 4 sections:

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

Section 2 covers CDS and ADS information requirements as listed in Title 1 of Annex II to 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 2, has been divided in two sub-sections: section 2.1 includes the general information requirements for the whole dossier (as explained above), and section 2.2 includes the specific information requirements for identity/physico-chemical properties/analytics.

Section 3 provides CDS and ADS information requirements as listed in Title 1 of Annex III 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 3, has also been divided in two sub-sections: section 3.1 includes the general information requirements for the whole dossier (as explained above) and section 3.2 the specific information requirements for identity/physico-chemical properties/analytics.

Section 4 is for evaluation and assessment with a cross reference to currently available guidance in TNsG.

1.2 Guiding principles with regard to information requirements in general

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

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

3. **The adaptation of information requirements** outlined throughout this Guidance is possible in certain cases for both CDS and ADS. For example, some of the toxicological information requirements may be adapted occasionally when the exposure is limited or when other product-type-specific factors apply; or for the efficacy 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 (ECHA, Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals) could also be useful.
4. The information requirements have been specified in as much detail as possible. However, in certain cases, **expert judgement** by the applicant and by the competent authority (CA) may be necessary in order to assess, for instance, whether an additional study is needed or on which organism or under which conditions a test should be performed. The applicant should propose the initial expert judgement, which is then examined during the evaluation. In making the decision as to whether additional testing is justified, the benefit for the risk assessment (including intended use), the compatibility with accepted risk assessment rationales, and the feasibility of the required tests may have to be considered. When providing an expert judgement one must, when relevant, take into account both the proposed normal use and a possible realistic worst case situation. Expert judgement decisions should be scientifically justified and transparent. In certain cases, the final decision on information requirements is made by the Biocidal Products Committee (BPC). Special attention is required in cases where there are endpoints of concern and clearly defined or standardised methods are lacking. Here, the applicant is obliged to investigate if relevant methods are applicable. New test methods are continuously being developed and it is the applicant's duty to be up-to-date with the state of science regarding test methods.
5. It is always the **applicant who is responsible** for the submission of the data. All data provided in the application must always be supported by study reports, other data or a letter of access. The information submitted by the applicant on both active substances and biocidal products, and also on substances of concern present in the biocidal product must be sufficient for conducting a risk assessment and an efficacy assessment, and decision-making both at EU level and on the level of the individual Member States. The applicant should consult a CA as to which data should be submitted. This will allow for proper risk mitigation measures to be decided upon if an active substance is likely to fail the criteria for entry into the *Union list of approved active substances* or if a product is likely to fail the criteria to be authorised at national or EU level.
6. The data submitted by the applicant will form the basis for classification and labelling according to the CLP Regulation (harmonised classification in case of active substances and self-classification in case of biocidal products). The active substances may be subject to harmonised classification for the first time or the data can be used to review a previous harmonised classification.

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

b. The identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the substance addressed in the application.

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

If conditions a-c are met the applicant can claim that adequate data is publicly available. Providing that the quality of public data fulfils the criteria, it can be used as key studies.

13. There must be at least one key study or an accepted waiving justification for each CDS endpoint given in the BPR Annexes II and III (and for each PT if more than one PT is applied for). The same applies to ADS endpoints in the BPR Annexes II and III, depending on the product-type (in the case of ecotoxicology endpoints and environmental fate and behaviour) and on intrinsic physical-chemical or toxicological properties of the substance or the product, respectively. A key study is the critical study for a certain endpoint and has to be reliable and adequate to use for the risk assessment and efficacy assessment. For criteria on the selection of key studies and further information, see Parts B+C of each Volume for Efficacy, Human health and Environment. A study with a reliability indicator of 3 or 4 cannot be a key study and can be used only as supportive information.

14. When more than one adequate study is available, expert judgement should be used to decide whether mean or median values should be used instead of the result of a single key study. If there is divergent data from acceptable studies, a study summary should be provided for all these studies. The study summary of each 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**[3] to demonstrate that it cannot be considered an active substance.. However, the detailed requirements are left mainly to be judged on a case-by-case basis and if the outcome of the applicant's assessment indicates a need for more data, the applicant should already consider further studies.

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

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

and the environment. BPR Specifically SMEs should be allowed extensive guidance from the competent authorities in order to be able to fulfil the obligations laid down in the BPR.

17. For the approval of the active substance a specification of the active substance will need to be derived. This specification must be representative for the manufacturing process as well as for the (eco)toxicological batches tested or, in other words, the reference source would be the source for which the (eco)toxicological data submitted cover the specification. Therefore it needs to be ensured that all impurities in the proposed specification are considered in the environmental fate and (eco)toxicological studies (batches used for the environmental fate and (eco)toxicological studies may contain impurities at levels equal or higher than the proposed specifications or it can be justified why some impurities in the proposed specification are not covered by these studies).

1.3 On the use of additional Guidance documents

1.3.1 Existing biocides Guidance and other relevant documents

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

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

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

1.7 Background documents

Legal texts

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

Regulations

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

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

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

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

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

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

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

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

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

Directives

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

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

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

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

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

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

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

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

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

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

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

Decisions

2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on

waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

1.8 Sources of test methods and standards

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Part A: Dossier Requirements for Active Substances

BPR Annex II, Title 1, points 1-13

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.

GENERAL INFORMATION

2.1 Point 1 Applicant

2.1.1 Point 1.1 Name and address

Name and address of the applicant (natural person or legal entity). If the applicant is a consortium; the composition of the consortium is required.

2.1.2 Point 1.2 Contact person

Names, address, telephone and fax numbers, email, and other contact information of the applicant. If the applicant is a consortium; the information on the contact person for each member of the consortium is required.

2.1.3 Point 1.3 Active substance manufacturer (name, address and location of manufacturing plant(s))

Name and address of the manufacturer(s).

Name, address and location of manufacturing plant(s).

2.2 Point 11 Measures necessary to protect human health, animals and the environment

2.2.1 Point 11.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

Provide technical safety precautions and where exposure cannot be prevented by other means, application of personal protective equipment (PPE) when handling the active substance, e.g. during different stages of the process, to minimise the risk of exposure to humans and the environment.

As specified in point 62 of Annex VI to the BPR, *the evaluating body shall, where appropriate, conclude the criterion (iii) under point (b) of Article 19(1) can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.*

If sufficient ventilation is required, the ventilation rate must be specified (number of air changes per hour) and it must be explained how it can be achieved (e.g. window, air conditioning).

Concerning PPE, details on the description of the equipment should be provided for example:

- for gloves: information on the material, thickness, protection level (grade);
- for respiratory protection equipment: information on the type of mask (full, half, FFP, helmet, hood, mouthpiece) and the type and class of filter or SCBA;
- for coverall: type and EN standard.

Appropriate precautions for substances which are flammable, oxidising etc. should be given. Handling, storage and transport must take into account any surface which could directly or indirectly come into contact with the product, including for example: processing equipment, piping, ventilators, transport vehicles and their washing and cleaning, as well as protective clothing and shower areas for workers. Storage precautions should include ventilation system to be used for storerooms (in general terms and other conditions for storage, e.g. temperature regime). Precautionary measures during service should especially be considered in addition to the prevention of environmental effects and measures to be taken when the substance is released to the environment due to an accident and misuse.

Materials which are incompatible with the substance, e.g. substances and products which may react with the active substance evolving toxic gases, and also other dangers such as reactions resulting in a large increase in volume, aggressive acidity, the possibility of dust explosions etc. should be indicated.

The precise type of fire-fighting equipment (i.e. both the type of extinguishing agent, including those to be avoided and any protective equipment), e.g. water or carbon dioxide, should be noted.

2.2.2 Point 11.2 In case of fire, nature of reaction products, combustion gases etc.

It should be stated what gases are evolved, either by experiment or on the basis of structure, when the substance burns or when heated in the absence of air so that it simply decomposes, e.g. nitrogen oxides, phosgene or soot.

Especially the identity of dangerous substances formed should be given (e.g. analysed according to the ISO standard 9122, Part 3).

2.2.3 Point 11.3 Emergency measures in case of accident

Specific treatment in case of an accident, for example, first aid measures following accidental eye or skin contact, ingestion or inhalation, antidotes, medical treatment if available; emergency measures to protect the environment.

Provide precise medical data regarding first aid, proven antidotes, and proven medical treatment. This should detail the effectiveness of first aid, suggested antidote doses, etc. and include full documentation of reference sources. The information here is intended for the purpose of immediate first-aid treatment. It is not intended to replace definitive diagnosis and treatment, which can only be undertaken by a qualified medical doctor.

Measures and courses of action in response to different kinds of accident scenarios (e.g. threat of release of the biocidal product, the product is actually being released and release has already occurred) should be described. In addition, actions to avert or stop release, minimise impacts of release, protect human life and property, and recover the product and by-products should be indicated.

2.2.4 Point 11.4 Possibility of destruction or decontamination following: (a) Air, (b) Water, including drinking water, and (c) Soil

This is on the prevention of health and environmental effects and measures to be taken when the product is released to the environment due to an accident or misuse.

Provide details of measures necessary to quickly limit the consequences of accidental release to the environment, and to decontaminate areas affected by the accidental release. These may include neutralisation, destruction and removal procedures.

2.2.5 Point 11.5 Procedures for waste management of the active substance for industry or professional users

Provide information necessary for safe disposal including treated material. If preliminary treatment of the waste is necessary, information about this must also be provided. If any waste generated from the substance is classified as hazardous waste (e.g. according to Commission Decision 2000/532/EC), this has to be mentioned separately and appropriate handling according to the related legislation has to be indicated.

More information is provided in Section 3.1.3.5.

2.2.6 Point 11.6 Possibility of reuse or recycling

The possibility of recovery or recycling should be given for both normal uses of the substance and quantities involved in spills.

2.2.7 Point 11.7 Possibility of neutralisation of effects

Neutralisation procedures (e.g. by reaction with an alkali to form less toxic compounds) for use, for instance, in the event of accidental spillage must be described where they are feasible. Details to be given include: proposed procedures for small and large quantities, evaluation of products of neutralisation (in small and large quantities), and procedures for disposal of neutralised waste (in small and large quantities).

2.2.8 Point 11.8 Conditions for controlled discharge including leachate qualities on disposal

For instance, controlled landfill or extensive dilution (to be specified) before discharge to surface water.

If a controlled landfill is recommended for use as a disposal site, information about the necessary preliminary treatment, the fate of the waste in the landfill, the release of active substances or breakdown products from the waste etc. must be given.

2.2.9 Point 11.9 Conditions for controlled incineration

If the suggested waste disposal method is incineration, the compounds generated by burning (e.g. whether polychlorinated dioxins and furans or other halogen compounds can be formed), recommended incineration conditions (temperature, reaction time and oxygen content) and other information needed for the safe incineration of the waste must be provided.

2.2.10 Point 11.10 Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC

Point 11.10 of Annex II to the BPR states that [….]*of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances, of Annex I and II to 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, of Annex I to 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, of Part B of Annex I to Directive 98/83/EC or Annex VIII and X to Directive 2000/60/EC*

Substances that are listed in the respective Annexes of the following legal frameworks are considered hazardous substances and therefore need to be monitored. Specify if the active substance is listed in one of the following:

- Council Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances. All biocides and their derivatives are classed in either List I or II. Direct discharge of substances in List I is prohibited. Discharge of substances in List II must be limited. In addition other substances (additives, impurities) may fall within the scope of the Lists.
- Council Directive 2006/118/EC, the Groundwater Directive, establishes a regime which sets underground water quality standards and introduces measures to prevent or limit inputs of pollutants into groundwater. Annex I lists groundwater quality standards and Annex II lists threshold values for groundwater pollutants and indicators of pollution.
- Council Directive 2008/105/EC, also known as the Priority Substances Directive, which sets environmental quality standards (EQS) for the substances in surface waters (river, lake, transitional and coastal) and confirmed their designation as priority or priority hazardous substances, the latter being a subset of particular concern. Annex I represents a list of priority substances.
- Council Directive 98/83/EC concerns the quality of water intended for human consumption. It aims at protecting human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. Chemical quality standards are specified in Annex I.
- Directive 2000/60/EC is the EU Water Framework Directive. Annex VIII lists the main pollutants. Annex X lists water policy priority substances and 'priority hazardous substances'.

2.3 Point 12 Classification, labelling and packaging

Hazard classification is a process involving identification of the physical, health and environmental hazards of a substance (or a mixture), followed by comparison of those hazards (including degree of hazard) with defined criteria in order to arrive at a classification of the substance (or mixture). The classification criteria are defined in Annex I to the CLP Regulation.

Active substances are normally subject to harmonised classification and labelling for all hazard classes (consult the Guidance documents on the application of Regulation (EC) No 1272/2008). In the sections below guidance is given on how the applicant should report existing harmonised classification and labelling or propose one. Following the assessment during the evaluation of the application, the evaluating competent authority (but not the applicant) will prepare and submit the proposal for the harmonised classification and labelling of the active substance to the Agency (Articles 36(2) and 37

of the CLP Regulation). It is advisable that the evaluating competent authority consults ECHA as early as possible to get the best support and advice in preparing the proposal.

2.3.1 Point 12.1 State any existing classification and labelling.

If available, state the existing classification and labelling as provided in Part 3 of Annex VI to the CLP Regulation, which contains lists of harmonised classifications and labelling of hazardous substances. If there is no harmonised classification for some/all endpoints or there is new information which may justify changing the existing harmonised classification, proceed to Point 12.2 below (section 2.4.2 of this guidance).

2.3.2 Point 12.2 The hazard classification of the substance resulting from the application of Regulation (EC) No 1272/2008

Point 12.2 of Annex II to the BPR states that *in addition, for each entry, the reasons why no classification is given for an endpoint should be provided.*

Propose hazard classification, labelling and packaging in line with the CLP criteria if no harmonised classification and labelling is provided in Part 3 of Annex VI to the CLP Regulation or if the new information justifies revision of the harmonised classification and labelling for a given endpoint. The need for classification should be considered based on relevant available information. The CLP Regulation does not require new testing for the purpose of classification for health or environmental hazards (Article 8(1) of the CLP Regulation); testing for the purposes of determining whether the substances entails any of the physical hazards referred to in part 2 of Annex I to the CLP Regulation, tests required in that Part are necessary unless adequate and reliable information is already available (Article 8(2) of the CLP Regulation). The background information should be clearly presented in the relevant sections of the dossier (see section 2.4 of this guidance, and also Volume III, section 2.1 and Volume IV, sections 2.1 and 2.2).

2.3.2.1 Point 12.2.1Hazard Classification

A substance (or a mixture) that fulfils the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I to the CLP Regulation is hazardous and must be classified in relation to the respective hazard classes provided for in that Annex.

For further information on the classification criteria refer to Guidance on the application of the CLP criteria (ECHA).

2.3.2.2 Point 12.2.1 Hazard pictogram

A substance (or mixture) classified as hazardous must bear a label which includes relevant hazard pictograms in accordance with Article 19 of the CLP Regulation, where applicable.

For further information on the hazard pictograms refer to **Chapter 4.3 Hazard Pictograms** in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

Pictograms can be downloaded free of charge from the web page:
http://www.unece.org/trans/danger/publi/ghs/pictograms.html.

2.3.2.3 Point 12.2.3 Signal word

A substance (or mixture) classified as hazardous must bear a label which includes a relevant signal word in accordance with Article 20 of the CLP Regulation, where applicable.

For further information on the signal word please refer to **Chapter 4.4 Signal Words** in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

2.3.2.4 Point 12.2.4 Hazard statements

A substance (or mixture) classified as hazardous must bear a label which includes the relevant hazard statements in accordance with Article 21 of the CLP Regulation, where applicable.

For further information on the hazard statements please refer to **Chapter 4.5 Hazard statement** in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

A substance (or mixture) classified as hazardous must bear a label which includes relevant supplemental hazard information in accordance with Article 25 of the CLP Regulation, where applicable.

For further information on the supplemental hazard information please refer to **Chapter 4.8 Supplemental labelling information** in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

2.3.2.5 Point 12.2.5 Precautionary statements including prevention, response, storage and disposal

A substance (or mixture) classified as hazardous must bear a label which includes relevant precautionary statements in accordance with Article 22 of the CLP Regulation, where applicable.

Annex I and Annex IV of the CLP Regulation outline the types of precautionary statements.

For further information on the precautionary statements please refer to **Chapter 4.6 Precautionary Statements** in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

2.3.3 Point 12.3 Specific concentration limits, where applicable, resulting from the application of Regulation 1272/2008

Specific concentration limits and M-factors for classification of substances and mixtures must be set, where applicable.

Article 37 of the CLP Regulation gives the procedure for submitting a proposal for harmonisation of classification and labelling of substances to ECHA together with, where appropriate, specific concentration limits or M-factors.

Section 1.1.2.3 of Annex VI to the CLP Regulation provides further information on specific concentration limits and M-factors.

2.4 Point 13 Summary and evaluation

Point 13 of Annex II to the BPR states that *the key information identified from the endpoints in each sub-section (2-12) is summarised, evaluated and a draft risk assessment is performed.*

The summary and evaluation must be provided in separate assessment documents attached to the IUCLID file (the templates will be available on the ECHA website).

SPECIFIC INFORMATION

2.5 Point 2 Identity of the active substance

The information must be sufficient to identify the substance, to define it in terms of its specification and to characterise it in terms of its nature. The information submitted should, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in BPR Article 4(1) are met. BPR Article 3(1)(c) defines 'active substance' *as a substance or a micro-organism that has an action on or against harmful organisms*.

2.5.1 Point 2.1 Common name proposed or accepted by ISO and synonyms

The name of the active substance must be provided as registered in the list in Part 3 of Annex VI to the CLP Regulation or, if the name is not included therein, as given in EINECS (the European Inventory of Existing Commercial chemical Substances) or in ELINCS (European List of New - or Notified- Chemical Substances) and the ISO common name of the substance, if available.

ECHA's classification and labelling inventory database may be used as a source for (common) names.

Generally known names, trade names, abbreviations, etc. must be included.

2.5.2 Point 2.2 Chemical name (IUPAC and CA nomenclature or other international chemical name(s))

The chemical name of the active substance must be provided according to IUPAC nomenclature and CAS nomenclature.

For substances that may exist as isomers, each isomer, if scientifically applicable, should be given correct designation.

For substances of unknown, variable composition, or biological origin (UVCB), identity and the proportion of constituents in the substance should be provided. As the chemical composition alone is insufficient for substance identification, the substance should in general be identified by its name, which will be generated by stating the origin or source of the starting materials and the most relevant steps taken during processing.

> The ECHA Guidance for identification and naming of substances under REACH and CLP, Chapter 4, (ECHA) should be applied for the purpose of identification of the active substancd

2.5.3 Point 2.3 Manufacturer's development code number(s)

Company(ies) code number(s) or internal name(s).

2.5.4 Point 2.4 CAS number plus EC, INDEX and CIPAC numbers

The CAS number, EC number, INDEX and CIPAC number must be provided, if available.

For reaction masses of isomers the CAS and/or EC numbers of the substance (comprising all isomers) and individual isomers should be provided, if available.

The CIPAC code number system is an approach for an unambiguous coding of active ingredients and variants used for pesticides.

2.5.5 Point 2.5 Molecular and structural formula (including SMILES notation, if available and appropriate)

The molecular formula should be provided according to the traditional Hill system and, where different, according to the CAS system. In addition, the SMILES notation should be provided, if available and appropriate.

An empirical formula should be determined for substances of undefined or variable composition, if possible.

For polymers the number average molecular weight (M_n) and the molecular weight distribution are required.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH and CLP, Chapter 4, (ECHA).

2.5.6 Point 2.6 Information on optical activity and full details of any isomeric composition (if applicable and appropriate)

If the active substance is optically active the value for the specific rotation (in degrees) has to be specified, indicating the temperature of measurement (in °C) and the wavelength of the incident light source (nm). The direction of rotation should also be specified as either + or -. If a sample solution is used, the concentration and solvent name should also be provided.

Typically, specific rotation is specified as follows: $[\alpha]_{\lambda}^{T}$

Where:

[α] specific rotation [°],
T temperature [°C],
λwavelength [nm]

Full details of any isomeric composition must be included, i.e. the maximum content of each (active) isomer and the ratio of the content of isomers/ diastereoisomers, where relevant. All stereoisomers have to be determined using an appropriate analytical method.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH and CLP, Appendix II (7), (ECHA).

2.5.7 Point 2.7 Molar mass

The molar mass (g/mol) must be provided.

For polymers the number average molar mass and the molar mass distribution are required.

2.5.8 Point 2.8 Method of manufacture (synthesis pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability

A description of the synthesis pathway in brief terms; the chemical reactions taking place, starting materials, intermediate steps, solvents and constiuents/intermediates generated in the synthesis etc. must be presented.

The methods of extraction and purification should be provided, where relevant.

When relevant, where the data refers to a pilot plant production system, the information required must be resubmitted once the industrial scale production plant enters into operation and production has stabilised. This will be covered by an application for the assessment of technical equivalence.

Chemical engineering data is not required as a rule, but submission may be required, where necessary (e.g. information on the temperatures and pressure at which synthesis takes place if not ambient and atmospheric while at such conditions dioxins could be formed).

2.5.9 Point 2.9 Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit

Give typical concentration and upper and lower limits for typical commercial batches of the active substance in g/kg or %w/w.

For substances of unknown or variable composition the purity is 100% minus unreacted starting materials.

The specification should be for the active as manufactured. Where the active is delivered in a solvent and/or stabilisers are present then an explanation should be provided e.g. the active is not stable in isolation as a dry technical material (TC), the active is delivered in a solvent for ease of manufacture (including manufacture of the biocidal product), transportation, or for classification purposes etc.

An explanation as to how the specification has been set or derived must be provided e.g. based on a 5-batch analysis with the mean ± 3 standard deviation.

Where the active substance is manufactured as a technical concentrate (TK) then as well as a specification for the active as manufactured, a dry weight specification must be provided. The dry weight specification can be calculated.

If the specification relates to the 5-batch analysis data from a pilot plant then an updated specification based on the batch analysis data from full scale industrial production must be provided when this is available (see section 2.6.11 of this guidance).

2.5.10 Point 2.10 The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances

The following information on impurities[4] and additives, that includs by-products of synthesis, optical isomers, degradation products (if the substance is unstable),

[4] An impurity is an unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added. An impurity is regarded as significant if it occurs or potentially occurs in a quantity ≥ 1 g/kg in the substance as manufactured. A significant impurity may be considered relevant or non-relevant depending, in particular, on its known toxicological and ecotoxicological properties. An impurity can be considered of toxicological and/or ecotoxicological relevance. An impurity may be relevant even if it occurs in a quantity < 1 g/kg (e.g. very toxic substances like dioxin). Relevant impurities can be defined as substances, including but not limited to, that meet the criteria to be classified as hazardous in accordance with CLP Regulation, or the available information (e.g. from (Q)SARs)

unreacted and end-groups etc. of polymers and unreacted starting materials of UVCB substances must be provided, where possible:

- Common name and chemical name in conformity with sections 2.6.1 and 2.6.2 of this guidance
- CAS and EC numbers, if available,
- Molecular and structural formula, conform with section 2.6.5 of this guidance,
- Molar mass, conform with section 2.6.7 of this guidance,
- The typical concentration and the range of concentrations expressed as g/kg or percentage w/w. Details of how the specification has been derived (e.g. based on the 5-batch analysis mean ± 3 standard deviations) must be provided. This should be for the active substance as manufactured. Where the active substance is manufactured as a technical concentrate (TK) then a dry weight specification must be provided as well as a specification for the active as manufactured. The dry weight specification can be calculated.
- The maximum content of the active isomer(s) and the ratio of the content of isomers/ diastereoisomers, where relevant.
- An indication of the functions of the components added to the active substance prior to the formulation of the biocidal product (e.g. stabiliser, antifreeze, antifoaming agent, dispersing agent, and inhibitors) must be provided.
- If the specification relates to the 5-batch analysis data from a pilot plant then an updated specification based on the batch analysis data from full scale industrial production must be provided when this is available (see section 2.6.11 of this guidance).
- Constituents present in quantities ≥1 g/kg must be identified.
- Constituents that are regarded as (eco)toxicologically relevant even at levels below 1 g/kg must be determined and identified.
- The limit of 1 g/kg applies to a dry technical material (TC) and therefore for technical concentrates (TK) the limit will apply to theoretical dry material. Hence impurities, even if below this limit for the TK, must be determined if they are ≥ 1 g/kg on a dry weight basis.

2.5.11 Point 2.11 Analytical profile of at least five representative batches including information on content of the impurities referred to in point 2.10.

For all active substances as manufactured, an analysis of at least five representative production batches is required. The analysis is one of the tools used to estimate whether the proposed specification of the active substance can be accepted as well as characterising the active substance in detail, in order to facilitate the risk assessment.

Where the active substance is not isolated but manufactured as a technical concentrate (TK), the batch data on the technical concentrate should be provided (i.e. on the active

---

indicates that the impurity has an (eco)toxicological hazard. Relevant impurities have the inherent capacity to cause unacceptable effects within the meaning of Article 19(1)(b) of the BPR. Compared to the active substance, relevant impurities show additional (or more severe) toxic properties (in the sense of the definition above).

as manufactured). For TK a specification for the active as manufactured (TK) and a theoretical dry weight specification must be provided.

Where the active substance is generated *in situ* then data on the precursors used to generate the active substance may be required.

2.5.11.1 General requirements

- The report must be GLP compliant.
- Data on the production date and size of the batches must be reported.
- It must be reported if the data come from pilot plant production or full scale industrial product.
- Batch analysis must be performed on batches representative of the manufacturing process for each source (manufacturing plant) being specified.
- The purity and impurity contents must be expressed in g/kg or percentage w/w.
- The analytical closure of the individual batches should be at least 98%; meaning, at least 98% of the manufactured substance should be accounted for. Only fully identified impurities may be counted towards this total (excluding e.g. sulfated ash, volatiles, insolubles etc).
- All impurities present ≥1 g/kg must be fully identified and quantified using a validated method of analysis. The limit of 1 g/kg applies to a dry technical material (TC) and therefore for technical concentrates (TK) the limit will apply to theoretical dry material. Hence impurities, even if below this limit for the TK, must be determined if they are ≥ 1 g/kg on a dry weight basis.
- Analytical methods used must be reported in detail and should be highly specific or specific[5]. Details of the validation data requirements are outlined in section 2.9 of this guidance.
- Isomeric ratios of constituents with chiral atoms must be investigated.
- If the possibility exists that exceptionally dangerous constituents (e.g., dioxins, nitrosamines or other dangerous substances) can be formed during manufacture, these must be investigated independent of their content (even below 1 g/kg) and categorised as relevant impurities or substances of concern.
- If the presence of heavy metals is expected (e.g. for inorganic compounds), data on the content of lead, arsenic, cadmium and, if relevant, of other heavy metals is required.
- In general, batches tested should be no older than five years from the date of dossier submission. Deviation is possible if the applicant can ensure the manufacturing process has not changed. Quality control data should be provide if the age of the batch analysis is >5 years but <10 years. The batch analysis should not be older than 10 years.

[5] Non-specific method: Any analytical method in which quantification is based on a functional group (moiety) within the analyte rather than for the specific analyte.

Specific method: HPLC or GC method with a retention match with a reference standard of the analyte.

Highly specific method: LC-MS/MS with two ion transitions validated or GC-MS or LC-MS with three ion transitions validated and a retention time match with a reference standard of the analyte.

- Where the data have been provided for pilot plant material then batch analysis data for at least five representative batches must be provided once full scale production commences.

2.5.11.2 Exceptions

If a specific or highly specific analytical method is not feasible, the applicant may use a suitable non-specific method, e.g. for the determination of peroxide contents. Confirmation of identity may be required (e.g. using mass spectral data, NMR, analysis using a different technique).

If a CIPAC method is used for quantification then, provided it has been established that the method is suitable for the substance and matrix, validation data and confirmation of identity do not need to be addressed. Example chromatograms to demonstrate the specificity of the method, where relevant, should be provided.

For active substances and precursors that cannot be defined in detail (e.g. paraffin oils, plant extracts and other complex mixtures), other means of characterisation may be used if appropriate. Marker compounds may be chosen and/or relevant physical properties may be used (e.g. diffraction index, density).

2.5.12 Point 2.12 The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower

The scientific names of species, common names and strains, and polymer starting materials should be provided, if relevant.

Further Guidance:

- Guidance to Member States and industry on the data requirements for naturally occurring substances used as attractants / repellents (EU, 2005a);
- Addendum to TNsG on Data Requirements for oils and extracts (PT 19) (EU, 2011b).
- ECHA Guidance for identification and naming of substances under REACH and CLP, Appendix II (7), (ECHA).

2.6 Point 3 Physical and chemical properties of the active substance

When assessing physico-chemical properties, priority is given to first hand experimental results (primary references) provided that the methods are suitable for the substance under investigation and that they operate within their validity range. In exceptional cases, it is acceptable to use reference book data for physico-chemical properties of organic or inorganic substances. However, data on physico-chemical properties should be of sufficient quality i.e. they must be reliable.

Instead of verbal descriptions, an actual numeric value or a range should be used in the report, avoiding verbal terms such as “high” or “low” as far as possible. Note that some of the data generated in this section affect the classification and labelling.

For UVCB substances, some tests are scientifically not reasonable. Therefore either a justification for not providing an experimental result should be given instead. Further, a range of values, a representative value or values of the individual constituents should be given instead of a single value depending on the substance. For some of the endpoints, more specific Guidance regarding UVCB substances is given in the ECHA Guidance on information requirements and chemical safety assessment (ECHA)).

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1 Physicochemical properties (ECHA).

2.6.1 Point 3.1 Appearance

NOTE to the reader:

In contrast to what is stated in Annex II to the BPR for points 3.1.1 and 3.1.2, the information on the physical state should be submitted first and the information on aggregate state second. Please take note that the sections below are presented in this order .

2.6.1.1 Point 3.1.1 Physical state (at 20 °C and 101.3 kPa)

In contrast to what is stated in Annex II to the BPR, the information on the physical state (at 20 °C and 101.3 kPa) should be provided under **point 3.1.1**.

Footnote 4 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of a stated specification or for the active substance as manufactured, if different.*

The physical state should be stated for an ambient temperature of 20 °C and an ambient atmospheric pressure of 101.3 kPa . The physical state may be solid, liquid, or gaseous.

In addition, a substance may be a colloid, i.e. it is microscopically dispersed evenly throughout another substance in a system consisting of two separate phases. Colloids or colloidal systems may also be solid, liquid, or gaseous.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Chapter 2.1.4 Physical state, (ECHA).

2.6.1.2 Point 3.1.2 Aggregate state (at 20 °C and 101.3 kPa)

In contrast to what is stated in Annex II to the BPR, the information on the aggregate state (at 20 °C and 101.3 kPa) should be provided in the item 3.1.2.

Footnote 4 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of a stated specification or for the active substance as manufactured, if different.*

A description of the form or structure must be reported, at an ambient temperature of 20 °C and an ambient atmospheric pressure of 101.3 kPa .

This can be aerosol, compact, crystalline, dispersion, fibre, filament, flakes, particulates, paste, pellets, powder, suspension, viscous, or other.

2.6.1.3 Point 3.1.3 Colour (at 20 °C and 101.3 kPa)

Footnote 4 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of a stated specification or for the active substance as manufactured, if different.*

The colour must be reported, at an ambient temperature of 20 °C and an ambient atmospheric pressure of 101.3 kPa .

2.6.1.4 Point 3.1.4 Odour (at 20 °C and 101.3 kPa)

Footnote 4 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of a stated specification or for the active substance as manufactured, if different.*

A description of the odour associated with the active substance as manufactured and of a purified active substance as noted during the handling of the materials in laboratories or production plants, must be reported, at an ambient temperature of 20 °C and an ambient atmospheric pressure of 101.3 kPa .

This can be e.g. ammonia-like, biting, characteristic of sulphur-containing compounds, characteristic of aromatic compounds, faint, garlic-like, odourless, pungent, slight, sweetish or other.

Odour should not be investigated for substances that are hazardous by inhalation.

2.6.2 Point 3.2 Melting/freezing point

Footnote 5 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

The measurement of the melting/freezing point should be taken up to 360 °C.

Usually the freezing point of liquid substances should be determined if above –20 °C. An indication that no freezing has occurred during preliminary tests is also acceptable. For viscous liquids the pour point is an acceptable alternative.

Test according to EC method A.1 (Melting/Freezing Temperature). It is advisable to use the Differential Scanning Calorimetry (DSC) or Differential Thermo-Analysis (DTA) (discussed in EC method A.1) since they give additional information about the thermal stability of the substance such as decomposition onset and energy.

If the melting/freezing point cannot be determined, the sublimation or decomposition temperature should be provided.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.2 Melting point/freezing point, (ECHA).

2.6.3 Point 3.3 Acidity, alkalinity

For active substances containing water, the pH-value of the active substance itself should be determined. If the solid and non-aqueous liquid active substances are to be used in biocidal products applied as aqueous dilutions, pH-value of a 1% aqueous dilution, emulsion or dispersion of the active substance should be determined. Test according to CIPAC method MT 75.3.

In cases where substances are acidic (pH<4) or alkaline (pH>10), test the acidity/alkalinity according to CIPAC method MT 31. Alternatively, test according to CIPAC method MT 191.

Test according to the OECD Test Guideline 'Determination of pH, Acidity and Alkalinity' which is currently being developed.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.17 Dissociation Constant, (ECHA).

2.6.4 Point 3.4 Boiling point

Footnote 5 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

The measurement of the boiling point should be taken up to 360 °C.

The boiling point should be measured at the normal atmospheric pressure of 101.3 kPa unless decomposition occurs, in which case reduced pressure can be used.

If the boiling point cannot be determined, the sublimation or decomposition temperature should be provided.

Test according to EC method A.2 (Boiling Temperature). DSC (discussed in EC method A.2) allows the determination of the melting and boiling point in a single test.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.3 Boiling point, (ECHA).

2.6.5 Point 3.5 Relative Density

Footnote 7 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

The relative density of gas substances can be calculated from their molecular weight and the Ideal Gas Law. Polymer density should be determined by buoyancy methods, where appropriate.

For liquids and solids, test according to EC method A.3 (Relative Density), based on OECD Test Guideline 109 (Density of Liquids and Solids), which was revised in October 2012.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.4 Relative Density, (ECHA).

2.6.6 Point 3.6 Absorption spectra data (UV/Vis, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths, where relevant

Footnote 8 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

Absorption spectra and mass spectrum must be determined and reported for the identification of impurities of concern, too.

For the UV/Vis (ultraviolet-visible spectral region), the spectra in neutral (pH = 7), acid (pH < 2) and alkaline (pH > 10) environments are required. The spectrum should be recorded in the range 200 – 400 nm for UV active substances and from 200 – 800 nm for substances which absorb in the Vis range. In addition, the molar absorption coefficient (ε) needs to be determined.

The relevant OECD Test Guideline is guideline 101 (UV-VIS Absorption Spectra).

Full interpretation of the data to support the structure is required.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH and CLP, 4.2.1.3 Analytical Information, (ECHA)

- Manual of decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC), 9.6 Guidance on spectral analysis (EU, 2006)

2.6.7 Point 3.7 Vapour pressure

Footnote 9 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

Vapour pressure at two temperatures (at 20 °C and 25 °C) or as a vapour pressure curve should be recorded. The unit is the Pascal (Pa).

Where the vapour pressure is less than 10^{-5} Pa at 20 °C, the vapour pressure at 20 °C and 25 °C may be estimated by a vapour pressure curve.

The vapour pressure does not need to be measured, if calculations indicate that the value is less than 10^{-5} Pa at 20 °C.

The study does not need to be conducted if the melting point is above 300 °C. A limit value based on measurement or a recognised calculation method is sufficient where the melting point is between 200 °C and 300 °C.

Test according to EC method A.4 (Vapour Pressure), based on OECD Test Guideline 104 (Vapour Pressure).

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.5 Vapour pressure, (ECHA)

2.6.7.1 Point 3.7.1 Henry's law constant

Point 3.7.1 of Annex II to the BPR states that the *Henry's law constant must always be stated for solids and liquids if it can be calculated.*

The Henry's law constant (HLC) depends on the water solubility, vapour pressure and molecular weight of a substance, and expresses the tendency of a substance to evaporate from aqueous solutions. The unit should be stated as Pa x m^3 x mol^{-1}. The water solubility and the vapour pressure used for a calculation of the HLC need to be given at the same temperature.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, Appendix R.7.1-1 Henry's law constant and evaporation rate, (ECHA).

2.6.8 Point 3.8 Surface tension

Footnote 10 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of a stated specification.*

The surface tension should be measured using an aqueous solution of sufficient concentration such that any surface activity potential is expressed; i.e. at 90% of saturation (the concentration must be quoted) to maximum concentration of 1g/l (where viscosity permits).

Inconsistencies between the water solubility result and the solubility reported should be fully addressed.

If the data demonstrate that the active substance is surface active the critical micelle concentration (CMC) needs to be determined.

Test according to EC method A.5 (Surface Tension), based on OECD Test Guideline 115 (Surface Tension of Aqueous Solutions).

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.6 Surface tension, (ECHA).

2.6.9 Point 3.9 Water solubility

Footnote 11 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified active substance of stated specification.*

The studies must include the effect of pH (5 to 9) and temperature on solubility.

The water solubility should be determined at 20 °C.

The temperature dependent solubility at 10 °C and 30 °C should be reported.

The water solubility should be determined unless the substance is hydrolytically unstable. Phrases such as "insoluble in water" are insufficient; instead a limit test should be performed so that a positive statement can be made (e.g. down to the analytical limit). For complex mixtures, a mass balance may be the only practical method. However, the extract should be compared (e.g. HPLC) with the mixture to check for differential solubility values of the components.

Where the stability of the active substance in aqueous media is such that the water solubility cannot be determined, a justification based on test data must be submitted.

Colloid and micelle formation and other possible observations must be reported.

No single method is available to cover the whole range of solubility values in water, from "relatively soluble" to "very low soluble" substances. General test guidelines (OECD Test Guideline 105 (Water Solubility); EC method A.6 (Water Solubility)) include two test methods which cover the whole range of solubility values but are not applicable to volatile substances. For metals and sparingly soluble inorganic metal compounds a specific water solubility approach (OECD Guidance Document 29 on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media) was designed to measure transformation to the dissolved fraction under standard conditions.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.7 Water Solubility, (ECHA).

2.6.10 Point 3.10 Partition coefficient (n-octanol/water) and its pH dependency

Footnote 12 of Point 3.1 of Annex II to the BPR states that *the information provided should be for the purified substance of stated specification.*

For substances which dissociate within an environmentally relevant pH range (pK_a 5-9), values for K_{ow} must be derived for the neutral form and also for the dissociated form.

Where the stability of the active substances in aqueous media is such that the partition coefficient cannot be determined, a justification based on test data must be submitted.

For those substances, which are extremely soluble in one of the phases, a limit value should be provided. If necessary, it can be based on the individual solubility values in n-octanol and water.

If the test cannot be performed a calculated value along with calculation details should be provided, if relevant.

Test according to EC method A.8 (Partition Coefficient), corresponding partly to OECD Test Guideline 107 (Partition Coefficient (n-octanol/water): Shake Flask Method) and partly similar to OECD Test Guideline 117 (Partition Coefficient (n-octanol/water), HPLC Method). In addition, the OECD Test Guideline 123, Slow-stirring method, can be used to generate data for this endpoint.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.8 Partition coefficient, (ECHA).

2.6.11 Point 3.11 Thermal stability, identity of breakdown products

In contrast to what is stated in Annex II to the BPR, footnote 13 of Point 3.1 of Annex II to the BPR states that *the information should be provided for the active substance as manufactured.*

Data on thermal stability, namely the melting point, sublimation or decomposition is to be identified.

If possible, thermal breakdown compounds are to be evaluated and the possibility of formation of dangerous degradation products is to be considered.

There is no relevant EC method. Test according to OECD Test Guideline 113 (Screening Test for Thermal Stability and Stability in Air).

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, 2.9.3.3.1 Thermal stability tests and temperature control, (ECHA).

2.6.12 Point 3.12 Reactivity towards container material

Suitable container materials which are resistant against corrosion and do no react with the substance in question, and/or container materials that cannot be used with the substance, must be specified taking into consideration the properties of the chemicals (e.g. pH and impurities) and storage conditions (e.g. pressure and temperature).

The information can be obtained from experience in use and the chemical structure of the substance. A comprehensive explanation should be provided.

2.6.13 Point 3.13 Dissociation constant (ADS)

The information provided should be for the purified active substance of stated specification unlike implied by the BPR.

The acid-base constant (pKa, pKb) should always be provided if it can be determined.

Test according to OECD Test Guideline 112 (Dissociation Constants in Water).

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.17 Dissociation Constant, (ECHA).

2.6.14 Point 3.14 Granulometry

Must be determined and reported for active substances such as powders or granules etc..

Granulometry determines the particle size distribution. A presentation of the particle size distribution is necessary to interpret the data (e.g. in the form of a histogram of the particle size vs. mass, particles size vs. number of particles, etc).

The percentage of particles in mass with aerodynamic diameter <50 µm must be determined (see also Volume III, section 2.1.7.2 on acute toxicity by inhalation).

Many methods are available for particle size measurements, but none of them are applicable to the entire size range. For further information on granulometry testing, please consult the REACH guidance on information requirements and chemical safety assessment Chapter R.7 (ECHA). The guidance provides more detailed information on the available international methods for measuring particle size distribution. The applicant should select the most appropriate method for their substance.

Please follow more specific Guidance in section 3.7.5.6 of this guidance

2.6.15 Point 3.15 Viscosity (ADS)

This data is always required for liquid substances.

The viscosity should be determined at 20 °C and 40 ºC.

There is no relevant EC method. Test according to OECD Test Guideline 114 (Viscosity of Liquids) where the following determination methods are recommended:

- Capillary viscometer;
- Flowcup;
- Rotational viscometer;
- Rolling ball viscometer;
- Drawing ball viscometer.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.18 Viscosity, (ECHA).

2.6.16 Point 3.16 Solubility in organic solvents, including effect of temperature on solubility (ADS)

Footnote 14 of Point 3.1 of Annex II to the BPR states that *The information provided should be for the purified active substance of a stated specification.*

Must be examined using at least two common solvents with different polarities.

Results should be provided as mg/l of solvent.

Test according to CIPAC method MT 181 (Solubility in Organic Solvents). The method is not suitable for substances with solubility under 10 mg/l.

2.6.17 Point 3.17 Stability in organic solvents used in biocidal products and identity of relevant breakdown products (ADS)

Footnote 15 of Point 3.1 of Annex II to the BPR states that *The information provided should be for the purified active substance of a stated specification or the active substance as manufactured, if different.*

The information is only required if the active substance as manufactured is delivered in an organic solvent.

Information on the stability of a test substance in a solvent is relevant, particularly when samples are to be stored. Factors affecting the rate of degradation include rates of

hydrolysis, of photolysis and of oxidation. Identification of the degradation products will allow an assessment of whether they are likely to be more toxic than the parent material in subsequent ecotoxicity studies.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.16 Stability in organic solvent and degradation products, (ECHA).

2.7 Point 4 Physical hazards and respective characteristics

The physical hazards of the active substance (endpoints 4.1 to 4.16, Annex II to the BPR) correspond to the physical hazard classes included in the CLP Regulation. The criteria and testing methods or standards for each of these physical hazards required in the BPR are described in the corresponding section of Part 2 of Annex I to the CLP Regulation.

For the purposes of determining whether a substance entails any of the physical hazards referred to in Part 2 of Annex I to the CLP Regulation: the manufacturer, importer or downstream user must perform the tests required by the above mentioned Part 2, unless there is adequate and reliable information available (see Article 8(2) of the CLP Regulation). Further to this for each relevant physical hazard a reference to the corresponding test according to UN Recommendations on the Transport and Dangerous Goods, Manual of Test and Criteria, UN-MTC (UN, 2009), starting with a UN test method name is provided.

Further information can be found in the Guidance on the Application of the CLP Criteria (ECHA).

2.7.1 Point 4.1 Explosives

Criteria for explosives are described in the section 2.1 of Annex I to the CLP Regulation.

Test according to UN Test series 1 to 3 (further test series 4 to 6 are necessary for classification) described in Part I of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.2 Explosives (ECHA).

2.7.2 Point 4.2 Flammable gases

Criteria for flammable gases are described in the section 2.2 of Annex I to the CLP Regulation,

Test according to ISO 10156 and EN 1839.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.3 Flammable gases (ECHA).

2.7.3 Point 4.3 Flammable aerosols

Criteria for flammable aerosols are described in the section 2.3[6] of Annex I to the CLP Regulation.

Test according to 75/324/EC amended by 2008/47/EC which are harmonised with UN-MTC Section 31.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.4 Flammable aerosols (ECHA).

2.7.4 Point 4.4 Oxidising gases

Criteria for oxidising gases are described in the section 2.4 of Annex I to the CLP Regulation.

Tests or calculation methods as described in ISO 10156 (Gases and gas mixtures. Determination of fire potential and oxidising ability for the selection of cylinder valve outlets) as amended should be performed.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.5 Oxidising gases (ECHA).

2.7.5 Point 4.5 Gases under pressure

Criteria for gases under pressure are described in the section 2.5 of Annex I to the CLP Regulation.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.6 Gases under pressure (ECHA).

2.7.6 Point 4.6 Flammable liquids

Criteria for flammable liquids are described in the section 2.6 of Annex I to the CLP Regulation.

Possible test methods for determining the flash point of flammable liquids are listed in Table 2.6.3, Section 2.6.4.4. of Annex I to CLP.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.7 Flammable liquids (ECHA).

2.7.7 Point 4.7 Flammable solids

Criteria for flammable solids are described in the section 2.7 of Annex I to the CLP Regulation.

Test according to UN Test N.1 as described in Section 33.2.1 of the UN-MTC.

[6] Please note that the 4th Adaptation to Technical Progress (ATP) will amend the criteria in Section 2.3, Annex I, the CLP Regulation.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, 2.8 Flammable solids (ECHA).

2.7.8 Point 4.8 Self-reactive substances and mixtures

Criteria for self-reactive substances and mixtures are described in the section 2.8 of Annex I to the CLP Regulation.

Test according to the tests series A to H, as described in the Part II of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.9 Self-reactive substances and mixtures (ECHA).

2.7.9 Point 4.9 Pyrophoric liquids

Criteria for pyrophoric liquids are described in the section 2.9 of Annex I to the CLP Regulation.

Test according to UN Test N.3 as described in Section 33.3.1.5 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.10 Pyrophoric liquids and solids (ECHA).

2.7.10 Point 4.10 Pyrophoric solids

Criteria for pyrophoric solids are described in the section 2.10 of Annex I to the CLP Regulation.

Test according to UN Test N.2 as described in Section 33.3.1.4 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.10 Pyrophoric liquids and solids (ECHA).

2.7.11 Point 4.11 Self-heating substances and mixtures

Criteria for self-heating substances and mixtures are described in the section 2.11 of Annex I to the CLP Regulation.

Test according to UN Test N.4 as described in Section 33.3.1.6 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.11 Self-heating substances and mixtures (ECHA).

2.7.12 Point 4.12 Substances and mixtures which in contact with water emit flammable gases

Criteria for substances and mixtures which in contact with water emit flammable gases are described in section 2.12 of Annex I to the CLP Regulation.

Test according to UN Test N.5 as described in Section 33.4.1.4 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.12 Substances and mixtures which in contact with water emit flammable gases (ECHA).

2.7.13 Point 4.13 Oxidising liquids

Criteria for oxidising liquids are described in the section 2.13 of Annex I to the CLP Regulation.

Test according to UN Test O.2 as described in Section 34.4.2 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.13 Oxidising liquids and Oxidising solids (ECHA).

2.7.14 Point 4.14 Oxidising solids

Criteria for oxidising solids are described in the section 2.14 of Annex I to the CLP Regulation.

Test according to UN Test O.1[7] as described in Section 34.4.1 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.4 Oxidising gases (ECHA).

2.7.15 Point 4.15 Organic peroxides

Criteria for organic gases are described in the section 2.15 of Annex I to the CLP Regulation.

Test according to UN Test series A to H as described in Section 28 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.14 Organic peroxides (ECHA).

2.7.16 Point 4.16 Corrosive to metals

Criteria for corrosive to metals are described in the section 2.16 of Annex I to the CLP Regulation.

Test according to UN Test C.1 as described in Section 37.4 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.15 Corrosive to metals (ECHA).

[7] At the time of writing, work is in progress at the UN-level to modify Test O.1: Test for oxidising solids. This includes changing the reference substance and introducing a gravimetric method for the measurement. For further information, see document UN/SCEGHS/23/INF.17 available at the following link: http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c4/ST-SG-AC10-C4-2012-11e-ST-SG-AC.10-C3-2012-75e.pdf

2.7.17 Point 4.17 Additional physical indicators for hazards

2.7.17.1 Point 4.17.1 Auto-ignition temperature (liquids and gases)

For liquids and gases, the term '**auto-ignition**' instead of 'self-ignition' is generally used. Auto-ignitability is of high importance for the assignment of temperature classes in explosion protection (i.e. ATEX in Europe) of plants and equipment.

Test according to EC method A.15, which references several national and international standards (e.g. EN 14522, etc.). The test procedure is applicable to gases, liquids and vapours which, in the presence of air, can be ignited by a hot surface.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.12.1 Auto-ignition, (ECHA).

2.7.17.2 Point 4.17.2 Relative self ignition temperature for solids

Criteria for self-heating substances are described in Section 2.11 of Annex I to the CLP Regulation.

Test according to UN Test N.4 as described in Section 33.3.1.6 of the UN-MTC.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria, Section 2.11 Self-heating substances and mixtures (ECHA).

2.7.17.3 Point 4.17.3 Dust explosion hazard

A dust explosion hazard is applicable to all powders and products containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air (relevant for particulates up to 1 mm in diameter).

Materials that cannot be oxidised are exempt from testing (e.g. most inorganic salts). If active substances are prone to dust explosions, describe measures to reduce the chance of dust explosions. Next to investigation of the relevant variables, which will indicate the chance and force of dust explosions in certain situations, it is also possible to dissolve an active substance in a carrier (e.g. water or oil), to form a technical concentrate (TK), to reduce the chance of dust formation.

Perform a screening method based on an open Hartman Tube according to VDI 2263 Part 1: VDI manual Chemical and process engineering – Volume 4: Occupational safety Part 1. IT-security for industrial automation – General mode) to determine whether a dust should be considered:

- Group A: Combustible dusts which ignite and propagate flame (explosive);
- Group B: Non-combustible dusts which do not ignite (non-explosive).

Category A substances should then be further tested. The following variables should be determined for explosive dusts:

Lower explosion limit

The lower explosion limit (LEL, expressed in $g.m^{-3}$) is defined as the minimum concentration of dust in air which can explode when exposed to an ignition source. A standardised test method is available, i.e. EN 14034 (part 3).

Explosion constant, maximum explosion pressure and minimum ignition energy

If a dust explosion hazard is expected, the dust explosion constant (K_{st}) should be determined by means of the explosion indices test (EN 14034, part 2), expressed in

bar.m.s^{-1}, and the minimum ignition energy (MIE) by means of the method EN 13821. When determining the K_{st}, the p_{max} (maximum explosion pressure) is also determined.

Minimum ignition temperature and smouldering temperature

Explosions may also be induced by hot surfaces. Therefore, the minimum ignition temperature (MIT) and smouldering temperature should be investigated according to EN 50281.

If the applicant can motivate that no dust layers will be formed on top of electrical equipment, the MIT may be waved.

Silos and limiting oxygen concentrations

In case of storage in silos, it is advisable to investigate the Limiting Oxygen Concentration (LOC). Tests are not described in this Guidance Document, considering storage of dusty substances in silos is thought to be rare for biocides.

2.8 Point 5 Methods of detection and identification

The applicant has to supply validated analytical methods required for the determination of the active substances (and where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives), and for relevant residues thereof in/on soil, in air, in drinking and surface water, in body fluids and tissues, and in treated food or feeding stuffs.

For substances, which are difficult to analyse, a description of the problems should be provided.

The objective of validating analytical methods is to demonstrate that they are suitable for their intended uses. The methods should allow the user to determine all of the analytes to fully characterise the active as manufactured and all the analytes included in the residues definitions established during evaluation. The methods should use commonly available techniques/equipment and avoid hazardous substances (e.g. carcinogenic substances like diazomethane, benzene or chloroform). Enforcement methods are required to demonstrate appropriate limits of quantification (LOQ), to be sufficiently selective, so that the interfering substances never exceed a percentage of the LOQ (see specific information outlined below under section 2.9.1 and 2.9.2 of this guidance), and demonstrate acceptable recovery and repeatability.

Description of an analytical method

Full descriptions of validated methods must be provided. The submitted method description must include the following points:

- Definition of the analyte;
- Apparatus;
- Reagents (including purity as well as full details of standard compounds purity and associated method of determination or clear reference of origin, if commercially available);
- Analytical procedure including sample processing, extraction, clean up, derivatisation, determination (if appropriate);
- Description of calibration including the use of matrix matched standards (if appropriate);
- Procedure for the calculation of results from raw data;
- Result tables (if results are not presented in separate studies).

The following information should be offered if appropriate:

- Schematic diagram of the analytical procedure;

- Stages where an interruption of the procedure is possible;
- Hazards or precautions required;
- A statement about extraction efficiency of solvents used.

Analytical methods should use instrumentation regarded as "commonly available":

- GC detectors: FPD, NPD, ECD, FID, MS, MSn (incl. ion trap and MS/MS),
- GC columns: capillary columns;
- HPLC detectors: MS, MS/MS, FLD, UV, DAD;
- HPLC columns: reversed phase, ion-exchange, normal phase;
- AAS, ICP-MS, ICP-OES;
- further analytical techniques in certain cases.

Stability

If reference is sought with regard to the stability of the samples, the OECD Guidance document on pesticide residue analytical methods (OECD, 2007a) should be consulted.

Further Guidance:

- OECD Guidance Document on pesticide residue analytical methods, (OECD, 2007a);
- DG SANCO Guidance document on pesticide residue analytical methods, (EU, 2010a).

2.8.1 Point 5.1 Analytical methods including validation parameters for the determination of active substance as manufactured and where appropriate, for relevant residues, isomers and impurities of the active substance and additives (e.g. stabilisers).

Point 5.1 of Annex II to the BPR states that *for impurities other than relevant impurities this only applies if they are present at ≥ 1g/kg.*

Information on analytical methods is required concerning the determination of the active substance, isomers, impurities and residues of the starting materials and additives (e.g. stabilisers), which are of toxicological or ecotoxicological concern (i.e. which are relevant for risk assessment) or which are present in quantities ≥ 1 g/kg in the active substance as manufactured.

The following validation parameters must be addressed for the active substance, impurities and additives:

Recovery (Accuracy)

The determination of recovery for the active substance in the technical material (TC) is not required. However, for technical concentrates (TK) an assessment of accuracy in terms of recovery is required.

For impurities and additives, recovery rates should be determined at the level of the measurements i.e. for the determination of the active substance in a formulation or an impurity at a constant level, one recovery rate (measured at the stated composition) is sufficient.

For the determination of residues or impurities of varying levels the recovery rates should be determined for at least two concentration levels: one near the LOQ and one at two to three orders of magnitude higher and within the range of the calibration curve.

The following recoveries would be regarded as acceptable:

Table 4: Acceptable recovery values for residues or impurities

% active (nominal)	Mean % recovery	% impurities (nominal)	Mean % recovery
>10	98-102	>1	90-110
1-10	97-103	0.1-1	80-120
<1	95-105	<0.1	75-125
0.01-0.1	90-110		
<0.01	80-120		

Source: SANCO 3030/99 (EU, 2000a)

Repeatability

Repeatability of the determination of the active substance and impurities and additives should be addressed by the analysis of at least five independent sample solutions of the same batch of TC or TK. The repeatability for the active and the repeatability for impurities for the technical grade active substance should be compared, if available, to the modified Horwitz ratio, an inter-laboratory precision index.

Calibration

Analytical calibration should extend over a range appropriate for the lowest and highest (±20%) nominal concentration of the analyte in relevant analytical solutions. Duplicate determinations at three or more concentrations or single determinations at five or more concentrations should be performed.

Raw data of calibration have to be provided with the studies. The equation and plot of the calibration and the correlation coefficient (R^2) must be provided.

Specificity

Fully labelled chromatograms from the analysis of the active and all impurities and additives must be provided. These should include chromatograms from the analysis of the reference standards and the technical material. An explanation must be provided for any interference which contributes more than ± 3% to the total quantity determined.

Derivatisation

For the technical grade active substance the mean yield and precision of any derivatisation step does not need to be addressed.

Confirmation of identity

Provided the analytical method used to quantify the active, impurity or additive is specific or highly specific (see Section 2.2.1.11 for method definitions) then analysis using a confirmatory method is not required. Where a non-specific method (e.g. a titration) is used then confirmation of identity will be required. This requirement does not need to be addressed where a CIPAC method has been used. Information on the approaches to assess confirmation of identity is outlined in Section 2.2.4.2.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH and CLP; Chapters 4.2.1.3. / 4.2.2.3. / 4.2.3.2. (ECHA).

2.8.2 Point 5.2 Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in/on the following where relevant

Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in soil, air, water and sediment as well as animal and human fluids and tissues need to be provided, where relevant.

Analytical methods normally have to be validated to ascertain whether the method is suitable for the purpose. It is nevertheless possible that a specific method is not fully validated but can still be concluded as acceptable for the purpose if it is a specific method with official status (e.g. published by ISO, CEN, OSHA). Some flexibility should be allowed for such situations.

The following Guidance applies to the information requirements 5.2.1 to 5.2.4:

- Methods for the analysis of parent compounds and/or metabolites of concern must be submitted.
- For each method and for each relevant representative matrix, the specificity, precision, recovery, and LOQ must be experimentally determined and reported. Information on calibration is a key validation parameter.
- In principle, the residue methods proposed should be multi-residue methods; a standard multi-residue method must be assessed and reported in terms of its suitability for residue determination. Where the residue methods proposed are not multi-residue methods, or are incompatible with such methods, an alternative method must be proposed. Where this requirement results in an excessive number of methods for individual compounds, a "common moiety method" may be acceptable.

The following validation data are required for residue monitoring methods:

Calibration

Analytical calibration should extend over a range appropriate for the lowest and highest (±20%) nominal concentration of the analyte in relevant analytical solutions. Duplicate determinations at three or more concentrations or single determinations at five or more concentrations should be performed. Raw data of calibration have to be provided with the studies. The equation and plot of the calibration and the correlation coefficient (R^2) should be provided.

Selectivity/Specificity (matrix interference)

Uncorrected recoveries and blank (control) values should be reported. Blank values in the area of analytical interest (untreated samples and procedural blanks) have to be determined from the matrices used in fortification experiments and should not be higher than 30% of the LOQ. If this is exceeded, detailed justification should be provided. Matrix effects such as peak suppression and enhancement can also occur with some techniques such as HPLC/MS-MS and GC. To check for these effects, the calibration curve generated using standards prepared in matrix extracts of an untreated sample (matrix matched standards) should be compared with the calibration curve generated with standards in solvents.

Fully labelled chromatograms should be provided. These should cover the analysis of a standard, a fortified sample at the lowest fortification level and an unfortified (blank) sample. Two blank control samples should be analysed per matrix.

Range of acceptable recoveries

In general, the mean recovery at each fortification level and for each commodity should be in the range of 70-110%.

Precision - Repeatability (expressed as relative standard deviation)

The precision of the method in a validation study should be reported as the relative standard deviation (RSD) at each fortification level. Five determinations should be made at each fortification level. In general, the RSD should be ≤ 20% per commodity and level. Where outliers have been identified (e.g. via Dixon's or Grubb's test) and discarded, this fact, the data of the outlier and the statistical significance must be clearly indicated. A maximum of one outlier may be disregarded at each fortification level.

Where an MRL is required then fortification at this level will also be required.

Confirmatory techniques

Confirmatory methods are required to demonstrate the selectivity of the primary method for all representative sample matrices. It has to be confirmed that the primary method detects the right analyte (analyte identity) and that the analyte signal of the primary method is quantitatively correct and not affected by any other compound.

Confirmation simultaneous to primary detection

A confirmation simultaneous to the primary detection using one fragment ion in GC-MS and HPLC-MS or one transition in HPLC-MS/MS may be accomplished by one of the following approaches:

- In GC-MS, HPLC-MS, by monitoring at least two additional fragment ions (preferably m/z > 100) for low resolution system and at least one additional fragment ion for high resolution/accurate mass system;
- In GC-MSn (incl. Ion Traps and MS/MS), HPLC-MS/MS, by monitoring at least one additional SRM transition.

For all mass spectrometric techniques, a mass spectrum (for a single MS) or a product ion spectrum (in case of MSn) should be provided to justify the selection of the additional ions.

Confirmation by an independent analytical technique

Confirmation can also be achieved by an independent analytical method. The following are considered sufficiently independent confirmatory techniques:

- chromatographic principle different from the original method
    - e.g. HPLC instead of GC;
- different stationary phase and/or mobile phase with significantly different selectivity:
    - the following are not considered significantly different:
        - in GC: stationary phases of 100% dimethylsiloxane and of 95% dimethylsiloxane + 5% phenylpolysiloxane;
        - in HPLC: C18- and C8-phases.
- alternative detector:
    - e.g. GC-MS vs. GC-ECD, HPLC-MS vs. HPLC-UV/DAD.
- derivatisation, if it was not the first choice method;
- high resolution/accurate mass MS;
- in mass spectrometry an ionisation technique that leads to primary ions with a different m/z ratio than the primary method (e.g. ESI negative ions vs. positive ions).

It is preferred that confirmation data are generated with the same samples and extracts used for validation of the primary method.

For the CIPAC titration method, no confirmatory method is needed.

Derivatisation

For analysis of some compounds, such as those with high polarity or with poor chromatographic properties, derivatisation may be necessary. Derivatives may be prepared prior to chromatographic analysis or as part of the chromatographic procedure (pre- or post-column). The use of derivatisation methods should be fully reported and justified. The derivative should be stable and its formation reproducible. The calibration is preferably conducted using standard solutions of that derivative, unless the derivatisation step is an integral part of the detection system. If the derivative is unavailable as a reference standard it should be generated with the sample derivatisation procedure and a full justification should be submitted. The method is considered to be specific to the analyte of interest if the derivatised species is specific to that analyte.

If the standard solution of the analyte is also derivatised then for complex matrices, the mean yield and precision of the derivatisation step must be addressed by using matrix matched standards.

Independent laboratory validation studies

Independent laboratory validation (ILV) studies are necessary to perform when compliance with an MRL is required in order to demonstrate the reproducibility of the analytical method. ILV studies are generally needed for the determination of residues in plant materials and additionally for methods for the determination of residues in food of animal origin, if such methods are required.

An ILV is not required for confirmatory methods. Usually, an independent laboratory validation should be conducted with samples of the representative commodities and tissues. The sample set (number of samples and fortification levels) of the primary validation has to be applied for the ILV also.

The laboratory chosen to conduct the ILV trials must not have been involved in the method development and in its subsequent use. Provided this criterion is met, the laboratory chosen to conduct the ILV trials may be in the applicant's organisation, but must not be at the same location. If the chosen laboratory requires communication with the developers of the method to carry out the analysis, this should be reported. Any subsequent additions or modifications to the original method should also be reported.

An ILV may not be necessary if available published multi-residue methods have been validated for the representative commodities.

2.8.2.1 Point 5.2.1 Soil

Generally, it is confirmed during evaluation, where relevant, which compounds (parent and/or metabolites) should be monitored based on the evaluation of fate and behaviour of the active substance in the environment.

The proposed LOQ must not exceed the PNEC soil, if technically possible without exceeding the general limit of 0.05 mg/kg dw.

If the active substance degrades very quickly, i.e. $DegT_{50}$ and $DegT_{90}$ values of the active substance and the relevant metabolites are lower than two and three days; respectively, analytical methods for residues in soil are not required except in the case of continuous exposure.

2.8.2.2 Point 5.2.2 Air

If the substance is volatile (i.e. if the vapour pressure >0.01 Pa) or sprayed, or occurrence in air is otherwise probable, the respective analytical methods need to be submitted.

Relevant health based limit values or relevant exposure levels need to be taken into account when judging the suitability of the proposed LOQ.

No confirmatory methods are required for the determination of residues in air if sufficient confirmatory methods are available (sufficient validation data are available) for the determination in soil or water (EU, 2010a).

Generally, the active substance or a relevant volatile degradation product are considered to be the relevant residues in air for monitoring purposes.

Limit of quantification

In the case of analytical methods for air regarding the general population, the LOQ must be equal or lower than the concentration C which is defined as:

$$C = \frac{AEL \times 0.1 \times 60}{20} \text{ [mg/m}^3 \text{ air]}$$

Where:

0.1 safety factor

60 body weight [kg]

20 air intake [volume per day in m³]

AEL overall systemic limit value for the human population as a whole – resembling the AOEL. The lowest AEL value available should be used.

The approach using AEL is preferred to that using the occupational exposure limit (OEL) also in the case of analytical methods for air concerning professional users.

The methods must be suitable for detecting both particle associated and gaseous residues.

2.8.2.3 Point 5.2.3 Water (surface, drinking, etc.) and sediment

If the substance itself and any of its degradation products fall within the definition of pesticides given in Annex I to Council Directive 98/83/EC (European Drinking Water Directive, DWD); analytical methods must be submitted that allow determination of the relevant parametric values specified in the DWD with adequate reliability.

Analytical methods must be submitted, which allow monitoring of the quality of surface water and groundwater which meet the criteria stipulated by the Directive 2000/60/EC (EU Water Framework Directive).

Detection and analytical methods for surface water obtained from ponds, rivers, streams, etc. and sediment, analytical methods for marine surface water as well as marine sediment should be provided if relevant exposure can be expected.

Residue definition

Generally, it has to be confirmed during evaluation, where relevant, which compounds (parent and/or relevant metabolites) should be monitored based on the evaluation of fate and behaviour of the active substance in the environment and the toxicological and ecotoxicological potential.

Limit of quantification for drinking water

The LOQ in drinking water must be ≤0.1 µg/L (EU drinking water limit based on DWD) or the toxicologically derived standard for drinking water where this is lower than the general limit of 0.1 µg/L.

Limit of quantification for surface water

The LOQ must be below the PNEC water if technically possible.

2.8.2.4 Point 5.2.4 Animal and human body fluids and tissues

Where an active substance is classified as toxic or very toxic, validated analytical methods must be submitted which allow determination of the active substance at the NOAEC.

Residue definition

Active substances classified as toxic or very toxic are considered to be the relevant residues in human body fluids and tissues. They must be analysed for monitoring purposes. The inclusion of metabolites may be confirmed during evaluation.

Limit of quantification

The LOQ should be set at 0.05 mg/L for body fluids and 0.1 mg/kg for tissues.

2.8.3 Point 5.3 Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (ADS)

Point 5.3 of Annex II to the BPR states that [….] *(not necessary if neither the active substance nor articles treated with it come into contact with food producing animals, food of plant or animal origin, or feeding stuffs).*

Analytical methods for the residues of the active substance may be required for monitoring purposes in various matrices, for control of MRL compliance, for the identification of misuse and for the estimation of human and animal exposure.

These methods should be specific for the purpose, use commonly available equipment and non-hazardous chemicals. Furthermore, a confirmatory method needs to be submitted. Residue analytical methods (primary methods, confirmatory methods and ILV) must be validated according to the latest versions of Guidance for biocides or plant protection products.

Analytical methods for residues are required, presuming that the biocidal product may come into contact with food, foodstuffs and feeding stuffs. This is always the situation for product-types 3, 4, 5 and also for certain uses of other product-types. For biocides of product-type 21 residue analytical methods must be submitted for fish and shellfish. The need for residue analytical methods for other product-types depends on the assessment of the transfer of the active substance into food and feeding stuffs.

Analytical methods in food, foodstuffs and feeding stuffs are not required for naturally occurring non-toxic active substances.

The residue analytical methods must be able to determine the relevant residue of the active substance with an LOQ below the relevant action levels or MRLs. The definition of the relevant residue is based on the physical and chemical properties of the active substance, the toxicological properties as well as the metabolism in plants and livestock. Separate residue definitions for risk assessment and for monitoring purposes must be set. Therefore, the active substance and/or relevant metabolites and degradation products could be included in the residue definition. If the active substance undergoes a complex metabolism it is highly recommended to define a marker compound.

Generally, an LOQ of 0.01 mg/kg should be met. In special cases, the LOQ may need to be lower than 0.01 mg/kg (e.g. in infant formulae and follow-on formulae).

Further Guidance:

- Guidance on pre-registration of Plant Protection Products, (EU, 2000b). This Guidance is applicable for generating residue data for the estimation of consumer exposure and supporting studies on the fate and behaviour of the active substance in foodstuffs, the environment, ecotoxicology and toxicology.
- Guidance on post-registration monitoring of pesticide residues, (EU, 2010a). This Guidance explains the requirements and the assessment on residue analytical methods for monitoring of pesticides.

The following Guidance documents are intended for the use in official laboratories involved in pesticide control in food and feed:

- Guidance Document on Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed, (EU, 2011c).
- OECD Guidance Document on pesticide residue analytical methods, (OECD, 2007a).
- OECD series on emission scenario documents number 19. Complementing guideline for writing emission scenario documents: the life-cycle step "service-life" (OECD, 2008a). While the OECD document talks about emission mechanisms of substances from (solid) articles, it is highly relevant for the evaluation of biocides uses in (solid) articles.
- Guidance on information requirements and chemical safety assessment Chapter R.17: Estimation of exposure from articles (ECHA). The Guidance is relevant for the calculation/modelling of exposure from articles during service life. It also gives valuable guidance on how to summarise release from articles accumulated in society, emitting the same substance.

3 Part A: Dossier Requirements for Biocidal Products

BPR Annex III, Title 1, points 1-13

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.

GENERAL INFORMATION

3.1 Point 1 Applicant

Applications for authorisation of a biocidal product may be made by, or on behalf of, prospective authorisation holders.

3.1.1 Point 1.1 Name and address

Name and address of the applicant and prospective authorisation holder (natural person or legal entity) if different.

3.1.2 Point 1.2 Contact person

Names, address, telephone and fax numbers, email, and other contact information of the applicant and prospective authorisation holder, if different.

The authorisation holder must be established in the EU.

3.1.3 Point 1.3 Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

Name, address and location of manufacturing plant(s).

3.2 Point 11 Measures to be adopted to protect humans, animals and the environment

3.2.1 Point 11.1 Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire

See guidance in section 2.2.1 of this guidance .

3.2.2 Point 11.2 Identity of relevant combustion products in cases of fire

See guidance in section 2.2.2 of this guidance .

3.2.3 Point 11.3 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment

See guidance in section 2.2.3 of this guidance .

3.2.4 Point 11.4 Possibility of destruction or decontamination following release in or on the following:

3.2.4.1 Point 11.4.1 Air

See guidance in section 2.2.4 of this guidance .

3.2.4.2 Point 11.4.2 Water, including drinking water

See guidance in section 2.2.4 of this guidance .

3.2.4.3 Point 11.4.3 Soil

See guidance in section 2.2.4 of this guidance .

3.2.5 Point 11.5 Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)

Provide information necessary for safe disposal. If preliminary treatment of the waste is necessary, information about this must also be provided. If any waste generated is classified as hazardous waste (e.g. according to Commission Decision 2000/532/EC), this has to be mentioned separately and appropriate handling according to the related legislation has to be indicated.

The possibility of recovery or recycling should be indicated for both normal uses of the substance and quantities involved in spills.

A chemical or other disposal method for the product should be indicated. Furthermore, information on disposal methods for the waste generated when using the product should also be provided (e.g. precipitates generated, instruments for spreading, residues treated with the product).

Information must be provided on how the package is to be emptied and cleaned and on the recycling or disposal method for empty packages.

Recycling or disposal methods for the waste generated from a treated product, and in the processing of the treated product (e.g. shavings, cuttings or other waste from the treated product) and for treated products no longer in use (e.g. impregnated wood) should be described, if applicable.

Recycling or disposal methods for the waste generated from a treated material (e.g. for chips from metal-cutting where the product is used), and in the processing of the possible treated material (e.g. waste from treated paper pulp or porous sand strata for product-type 12) and for treated material or treated process water or metal working fluid no longer used should be provided, if applicable.

The Guidance provided for the corresponding data requirement for the active substance applies also here.

When the product is applied to a system with water which is to be released into surface water with or without pre-treatment, as may be for product-type 11 and 12, information on the necessary waste water treatment methods and times and/or the on minimum dilution for the active substance in waste water should be provided (in order to assure a sufficient degree of degradation or dilution before being released into a water course to protect aquatic organisms from harmful effects).

3.2.6 Point 11.6 Procedures for cleaning application equipment where relevant

The procedures should be such that the likelihood of accidental contamination of water or its sediments is minimised.

3.2.7 Point 11.7 Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms

If mitigation measures are proposed to prevent action against non-target organisms then accuracy of these mitigation measures must be proved resulting in a safe use.

3.3 Point 12 Classification, labelling and packaging

Point 12 of Annex III of the BPR states that *As established in point (b) of Article 20(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted.*

Example labels, instructions for use and safety data sheets shall be provided.

An applicant for authorisation of a biocidal product must propose classification, labelling and packaging which complies with the CLP Regulation.

Directive 67/548/EEC (Dangerous Substances Directive, DSD) and Directive 1999/45/EC (Dangerous Preparations Directive, DPD) were repealed from 1 June 2015 and classification according to these directives is no longer allowed. The CLP criteria must be applied for classification, labelling and packaging of both substances and mixtures.

In accordance with Article 15 of the CLP Regulation, when manufacturers, importers or downstream users placing a substance or mixture on the market may have to re-classify it at any time in light of new scientific or technical information, or following a change in composition.

In accordance with Article 4 of the CLP Regulation, the responsibility for classification lies with the manufacturer, importer or downstream user who places a (substance or) mixture, such as biocidal products, on the market. The CLP Regulation requires self-classification[8] by industry of the (substances or) mixtures they supply. Mixtures must always be self-classified according to the criteria and rules provided in the CLP Regulation text. All biocidal active substances are normally subject to harmonised C&L for all endpoints, however this is not the case for non-active ingredients (please consult Annex VI and (Article 36(2) of the CLP Regulation)).

Hazard classification is a process involving identification of the physical, health and environmental hazards of a substance or a mixture, followed by comparison of those hazards (including degree of hazard) with defined criteria in order to arrive at a classification of the (substance or) mixture.

The need for classification of biocidal products must be considered based on relevant available information. According to the CLP Regulation, for mixtures (such as biocidal products), classification for physical hazards should normally be based on the results of tests carried out on the mixtures themselves. When considering health and

[8] For the purposes of this Guidance self-classification is defined as the decision on a particular hazard C&L of a (substance or) mixture is taken by the manufacturer, importer or downstream user of that (substance or) mixture, or, where applicable, by those producers of articles who have the obligation to classify.

environmental hazards, the classification should preferably be based on available information (including test data) on the mixture itself, except when classifying for e.g. CMR effects or for the evaluation in relation to the bioaccumulation and degradation properties within the 'hazardous to the aquatic environment' hazard class referred to in Sections 4.1.2.8 and 4.1.2.9 of Annex I to the CLP Regulation. In these cases classification of the mixtures should be based on the information on the substances. If no *in vivo* test data are available on a mixture, such data should normally not be generated; rather, all available information on the ingredients of the mixture should be used to derive a classification. Only when the manufacturer, importer or downstream user has exhausted all other means of generating information, new tests may be performed. The background information should be clearly presented in the relevant sections of the dossier (see section 3.6 and 3.7 of this guidance, and also in Volume III, section 2.1 and Volume IV, sections 3.1 and 3.2).

The Guidance documents on the application of Regulation (EC) No 1272/2008 (ECHA) provide a detailed guide on the application of the CLP criteria. These documents should be used in the light of BPR requirements.

3.3.1 Point 12.1 Hazard classification

A (substance or a) mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I to the CLP Regulation is hazardous and must be classified in relation to the respective hazard classes provided for in that Annex.

For further information on the classification criteria refer to Guidance on the application of the CLP criteria, Part 1 (ECHA).

3.3.2 Point 12.2 Hazard pictogram

A (substance or) mixture classified as hazardous must bear a label which includes relevant hazard pictograms in accordance with Article 19 of the CLP Regulation, where applicable.

For further information on the hazard pictograms refer to Chapter 4.3 Hazard Pictograms in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

Pictograms can be downloaded free of charge from the webpage:

http://www.unece.org/trans/danger/publi/ghs/pictograms.html

3.3.3 Point 12.3 Signal word

A (substance or) mixture classified as hazardous must bear a label which includes a relevant signal word in accordance with Article 20 of the CLP Regulation, where applicable.

For further information on the signal word please refer to Chapter 4.4 Signal Words in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

3.3.4 Point 12.4 Hazard statements

A (substance or) mixture classified as hazardous must bear a label which includes the relevant hazard statements in accordance with Article 21 of the CLP Regulation, where applicable.

For further information on the hazard statements please refer to Chapter 4.5 Hazard statement in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

A (substance or) mixture classified as hazardous must bear a label which includes relevant supplemental hazard information in accordance with Article 25 of the CLP Regulation, where applicable.

For further information on the supplemental hazard information please refer to Chapter 4.8 Supplemental labelling information in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

3.3.5 Point 12.5 Precautionary statements including prevention, response, storage and disposal

A mixture classified as hazardous must bear a label which includes relevant precautionary statements in accordance with Article 22 of the CLP Regulation, where applicable.

Annex I and Annex IV of the CLP Regulation outline the types of precautionary statements.

For further information on the precautionary statements please refer to Chapter 4.6 Precautionary Statements in the Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (ECHA).

3.3.6 Point 12.6 Proposals for safety data sheets should be provided, where appropriate

Safety data sheets for active substances and biocidal products should be prepared and made available in accordance with Article 31 of Regulation (EC) No 1907/2006, where applicable. They must be included in the application for product authorisation, where appropriate.

Further Guidance:

- ECHA Guidance on the compilation of safety data sheets (ECHA), under revision.

3.3.7 Point 12.7 Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included

A justification for the packaging (type, materials, size etc.) and the compatibility of the product with proposed packaging materials must be provided. Packaging must be in compliance with Article 35 of the CLP Regulation.

Further Guidance:

- ECHA Guidance on the Application of the CLP Criteria (ECHA).

3.4 Point 13 Evaluation and Summary

Point 13 of Annex III to the BPR states that *the key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed.*

The summary and evaluation must be provided in separate assessment documents attached to the IUCLID file (the templates will be available on the ECHA website).

The Decision on technical equivalence if relevant should be also provided.

SPECIFIC INFORMATION

3.5 Point 2 Identity of the biocidal product

The information must be sufficient to identify the biocidal product, to define it in terms of its specification and to characterise it in terms of its nature. The information submitted should, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in BPR Article 19 are met. Article 3(1)(a) of the BPR defines 'biocidal product' as:

- *any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,*
- *any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.*

3.5.1 Point 2.1Trade name or proposed trade name

If different trade names are used in different Member States, all of those have to be cited.

3.5.2 Point 2.2 Manufacturer's development code and number of the product, if appropriate

Company(ies) code number(s) or internal name(s).

3.5.3 Point 2.3 Complete quantitative (g/kg, g/l or % w/w (v/v) composition of the biocidal product

Point 2.3 of Annex III of the BPR states that *i.e. declaration of all active substances and non-active substances (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained. For non-active substances, a safety data sheet in compliance with Article 31 of regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in case of a reaction mixture, the final composition of the biocidal product shall be given.*

It is recognised that the content of the active substance will vary from batch to batch on manufacture and as a result of sampling and analytical errors. To account for these variations the following general limits should be applied to the active substance content at the point of manufacture:

Table 5: Tolerance limits of the active substance content at the point of manufacture

Declared nominal content of active [g/kg or g/L]	Tolerance limit
Up to 25	±15% of the declared nominal content for homogenous formulations (e.g. emulsifiable concentrates, soluble concentrates, aqueous suspension concentrates) ±25% of the declared content for non-homogenous preparations (e.g. granules, water dispersible granules)
Above 25 up to 100	±10% of the declared nominal content
Above 100 up to 250	±6% of the declared nominal content
Above 250 up to 500	±5% of the declared nominal content
Above 500	±25 g/kg or g/L of the declared nominal content

For dilute products or heterogeneous products then alternative limits can be specified but must be justified.

The following information must be provided:

- Information on individual ingredients (active substance(s) and co-formulants) before mixing and the final composition of the product;
- The chemical name of each ingredient according to IUPAC or CA and their content in the product (g/kg) as well as trade names:
- CAS number and EC number (EINECS, ELINCS or No Longer Polymer List number);
- Structure or structural formula;
- Functions of the ingredients (e.g. solvent);
- Classification of components or mixtures according to 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), as appropriate;
- Indication of any substances of concern.

If a non-active ingredient is a preparation, full quantitative and qualitative specification of this preparation must be provided.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH and CLP, (ECHA).

3.5.4 Point 2.4 Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

Further Guidance:

- Manual on development and use of FAO and WHO specifications for pesticides, second revision, (FAO, 2010).
- ECHA Guidance for identification and naming of substances under REACH and CLP, Chapter 4.3.1.1 Information on chemical composition, (ECHA).

3.6 Point 3 Physical, chemical and technical properties

Data must be provided to demonstrate that the physical, chemical and technical properties of the formulation will be acceptable and that in use the biocidal product under practical conditions will result in an acceptable performance.

For further Guidance, see the Evaluation manual (EU, 2012a) and the FAO manual (FAO, 2010).

3.6.1 Point 3.1 Appearance (at 20 °C and 101.3 kPa)

Please follow guidance in section 2.6.1 of this guidance.

3.6.1.1 Point 3.1.1 Physical state (at 20 °C and 101.3 kPa)

Please follow guidance in section 2.6.1.1 of this guidance.

3.6.1.2 Point 3.1.2 Colour (at 20 °C and 101.3 kPa)

Please follow guidance section 2.6.1.3 of this guidance in.

3.6.1.3 Point 3.1.3 Odour (at 20 °C and 101.3 kPa)

Please follow guidance section 2.6.1.4 of this guidance in.

3.6.2 Point 3.2 Acidity/alkalinity

Point 3.2 of Annex III of the BPR states that *The test is applicable when the pH of the biocidal product or its dispersion in water (1%) is outside the pH range 4-10.*

In the case of aqueous biocidal products, the pH value of the biocidal product as formulated should be determined and reported. In the case of solid and non-aqueous liquid biocidal products which are to be applied as aqueous dilutions or dispersions the pH of a 1 % dilution or dispersion of the biocidal product should be determined and reported. Test according to CIPAC method MT 75.3.

The acidity/alkalinity must be determined when the pH of the biocidal product as formulated or its 1% dilution or dispersion is < 4 or >10. The acidity/alkalinity should be determined using CIPAC method MT 31. Alternatively, test according to CIPAC method MT 191.

Test according to the OECD Test Guideline 'Determination of pH, Acidity and Alkalinity' which is currently being developed.

3.6.3 Point 3.3 Relative density (liquids) and bulk, tap density (solids)

In contrast to what is stated in Annex II to the BPR, the relative density should be determined in gases, liquids and solids. Please follow the guidance in section 2.6.5 of this guidance . The bulk and tap density can only be determined in solids. The recommended method is OECD Test Guideline 109 (Density of Liquids and Solids), updated in October 2012. This update includes bulk and tap density for solids, based on the CIPAC method MT 186 (Bulk density). Please note that OECD Test Guideline 109 (Density of Liquids and Solids) can also be used for testing the relative density (as already stated in section 2.6.5 of this guidance).

3.6.4 Point 3.4 Storage stability, stability and shelf-life

Data are required to demonstrate that the biocidal product is stable on storage under the conditions and for the shelf life claimed for the product.

3.6.4.1 Point 3.4.1 Storage stability tests

3.6.4.1.1 Point 3.4.1.1 Accelerated storage test

The relevant test method is CIPAC method MT 46.3 (storage at 54 °C for two weeks).

Accelerated storage data generated can be used to give an indication that the biocidal product will be stable for two years at ambient temperature. These data can be used to demonstrate that the product is likely to be stable for two years at ambient storage to support an authorisation. Yet, this does not negate the need to generate ambient storage data, which must be generated to confirm the ambient storage of the biocidal product.

The accelerated storage stability test does not necessarily have to be conducted in the sales packaging. As outlined in CIPAC method MT 46.3, the accelerated storage study could be conducted in a glass jar.

The data also give an indication of the stability of the biocidal product if for intermittent periods it was subject to higher than normal temperatures. If it can be clearly demonstrated that the biocidal product will not be subjected to temperatures above 30^0C during storage then accelerated storage data will not be required provided that a full ambient storage study has been provided. Appropriate label phrases will be required to indicate that the biocidal product must not be stored at higher temperatures.

If the active is heat sensitive then the following conditions can be used to generate accelerated storage data:

Table 6: Conditions for accelerated storage testing for heat sensitive active substances

Temperature (±2°C)	Time (weeks)
54	2
50	4
45	6
40	8
35	12
30	18

3.6.4.1.2 Point 3.4.1.2 Long term storage test at ambient temperature

Data must be generated in the worst case commercial packaging to support the ambient storage of the product for the claimed shelf life.

It is recognised that generating ambient storage data to support a shelf life of greater than two years may be problematic. To support these longer shelf life claims then, in general, an ambient storage study for two years should be provided along with relevant quality control data that assesses key parameters prior to and after storage for the required shelf life. The following information/data must be provided with the quality control data:

- Details of the storage conditions (length of storage, temperature and details of packaging the product has been stored in);
- Details and supporting validation data used to determine the active content (to be reported under section 3.8.1 of this guidance); and

- Justification of the physical chemical and technical properties determined in the QC data and how this supports the stability of the product.

For formulations that can be categorised according to the formulation types as included in revision 2 of the FAO manual (Manual on development and use of FAO and WHO specification for pesticides – November 2010 (FAO, 2010)), primarily, GIFAP (Croplife International) monograph no. 17 (Croplife, 2009) is the leading Guidance. Information on the relevant physical, chemical and technical properties for different formulation types is outlined in the Evaluation manual (EU, 2012a) and the FAO manual (FAO, 2010).

For all proposed packaging types, packaging suitability should be addressed.

Guidance is not yet available for all types of biocides e.g. for product-type 21 and product-type 6.

3.6.4.1.3 Point 3.4.1.3 Low temperature stability test (liquids)

The relevant test method is CIPAC method MT 39.3.

The stability of the product on storage at 0°C for seven days should be addressed.

If the label gives clear instructions that the product must not be stored under conditions of ≤ 0°C (e.g. a phrase like 'protect from frost' on the label) then the low temperature storage does not need to be addressed.

For some formulation types the stability on freeze/thaw cycles may have to be investigated.

3.6.4.2 Point 3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product

In the storage stability studies the active substance content, relevant physical and chemical properties (e.g. pH) and relevant technical properties must be determined prior to and after storage.

Where relevant the effects of light, temperature and humidity must be investigated as part of the storage stability studies.

For the ambient storage studies, the biocidal product must be stored in the worst case commercial packaging and the stability of the packaging must be assessed. This should include observations on the appearance of the packaging and an assessment of the weight change on storage.

In these studies a storage in the worst case packaging is representative for the other commercial packaging. An assessment of all packaging types must be made. In general, the product should be stored in the worst case packaging and the relevance of these data to the other packaging types specified must be clearly outlined. Acceptable extrapolations for different packaging types are outlined below:

Table 7: Acceptable extrapolations for different packaging types for storage stability studies

Packaging used in shelf life study	Acceptable extrapolations
Water based formulations e.g aqueous suspension concentrates, soluble concentrates	
Any, except metal	All packaging types, apart from metal are supported with no further data
Solvent based formulations e.g. emulsifiable concentrates	
HDPE	HDPE/EVOH, HDPE/F, HDPE/PA packs would all be supported without further data
HDPE/EVOH or HDPE/F or HDPE/PA	Data generated in one of these three packaging will support authorisation in the other two packagings with acceptable seepage data in the required packaging HDPE packs would be supported with acceptable seepage data

Seepage data

Data are only required to demonstrate that the required packaging is stable for the required shelf life (e.g. no leakage, no ballooning, no panelling of the packaging, no deformations) rather than a new shelf life study in which all chemical and physical properties are investigated prior to and after storage. The weight change on storage should also be determined.

Where seepage is observed then the new packaging cannot be authorised. Any panelling and/or ballooning in the new packaging is an indication that the new packaging is not fully resistant to the formulation and/or air entrainment. In such cases, to ensure no adverse effects on the physical and chemical properties of the biocidal product then a complete shelf life study conducted in the new packaging will be required.

Solid preparations

Extrapolation to all types of packaging is acceptable except to more flexible packs. For solid formulations sold in flexible packs the effects of stacking on the packaging and the physical and chemical properties must be investigated. The stacking undertaken must reflect those encountered in commercial practice.

Trigger sprayers

For ready for use biocidal products applied via a trigger sprayer then the satisfactory operation of the trigger sprayer prior to and after storage should be addressed. This should include the spray pattern, the amount of spray delivered with each operation and observations on the nozzle for blockages. Where the product is stored with the trigger sprayer then the satisfactory operation should be addressed after storage. Where the biocidal product is not applied in one single operation then the intermittent use of the sprayer during the storage internal should also be addressed: the satisfactory operation of the sprayer following successive uses followed by storage of the biocidal product must reflect commercial practice and cover the stated shelf life.

The satisfactory operation of aerosols prior to and after storage should also be addressed.

The active substance content should be determined using a validated method of analysis. It is generally recognised that a decrease in the active content of ≤10 % should not adversely affect the efficacy and risk assessment of the product. Where the degradation of the active content is >10%, or in cases where a decrease of <10% may impact on the efficacy and/or the risk assessment, then a justification for the acceptability of the decrease should be provided. This may require an assessment of the degradation on the efficacy and risk assessment. The fate (degradation products) of the active substance may have to be assessed. Alternatively, a more appropriate shelf life, in which the degradation of the active content is considered acceptable, should be proposed. For this reason, particularly when the active is known to degrade, it is advantageous to perform ambient storage studies in which the active content is assessed at interim time periods.

Substances of concern and relevant impurities should be considered for inclusion in the storage stability/shelf life studies. The level of the substance of concern or relevant impurity prior to storage and after storage should be determined using a fully validated method of analysis.

In cases where the substance of concern or relevant impurity cannot possibly increase on manufacture or storage of the biocidal product then they do not need to be included in the storage stability/shelf life study. A justification outlining clearly why the substance of concern or relevant impurity has not been included in the storage stability/shelf life study should be provided.

The relevance of the levels of the substance of concern or relevant impurity, including where relevant changes observed on storage, in the biocidal product should be addressed.

Where a substance of concern or relevant impurity is determined on storage then it should be determined using a validated method of analysis.

Where relevant the retention of palatability should be addressed. Reference to the efficacy assessment is acceptable to address this requirement.

Where an aversive agent[9] is present in the product and the presence of the aversive agent has been referenced in the risk assessment then its stability on storage, using a validated method of analysis, must be assessed.

3.6.4.2.1 Point 3.4.2.1 Light

This endpoint is addressed in this section 3.6.4.2 (above).

3.6.4.2.2 Point 3.4.2.2 Temperature and humidity

This endpoint is addressed in this section 3.6.4.2 (above).

3.6.4.2.3 Point 3.4.2.3 Reactivity towards container material

Please follow guidance in sections 3.6.4.1 and 3.6.4.2 (above) of this guidance.

3.6.5 Point 3.5 Technical characteristics of the biocidal product

Technical characteristics applicable to the formulation type must be addressed. Where relevant these must be generated to cover the maximum and minimum in use concentrations specified for the biocidal product.

[9] An aversive agent is a substance which is added to a biocidal product with the intent of deterring or limiting its ingestion.

Information on the relevant physical, chemical and technical properties for different formulation types is outlined in the Evaluation manual (EU, 2012a) and the FAO manual (FAO, 2010).

3.6.5.1 Point 3.5.1 Wettability

The relevant test method is CIPAC method MT 53.3.1.

Wettability is determined to ensure the preparation is readily wetted in use. The data are required for solid preparations which are to be dispersed in water.

The method as written describes the wetting of wettable powder preparations but it also applicable to water soluble powders, water soluble granules and water dispersible granules.

A preparation is considered acceptable if there is complete wetting in one minute without swirling. Where a preparation is outside this limit then evidence must be submitted demonstrating acceptable wetting on use of the biocidal product e.g. in the application equipment.

3.6.5.2 Point 3.5.2 Suspensibility, spontaneity and dispersion stability

Applicability depends on the formulation type (nature) of the biocidal product.

Suspensibility

Test according to CIPAC method MT 15.1 for wettable powders, CIPAC method MT 161 for aqueous suspension concentrates, CIPAC method MT 168 for water dispersible granules, CIPAC method MT 177 for water dispersible powders (simplified method) and CIPAC method MT 184 for suspensibility of formulations forming suspensions on dilutions with water.

Suspensibility is determined to demonstrate that a sufficient amount of the active substance is suspended to give a homogeneous mixture during application. For the determination of suspensibility, chemical assay ('active' suspensibility) is the only fully reliable method to measure the mass of an active substance still in suspension.

However, gravimetric determination (total suspensibility) or solvent extraction determination may be used providing that these methods have been shown to give equivalent results to those of the chemical assay.

Where there is more than one insoluble active substance present in the preparation, chemical assay ('active' suspensibility) is the only acceptable method.

The test should be performed at the highest and lowest dilutions recommended for use of the preparation.

The mean measured active suspensibility must not be less than 60% or greater than 110%. Where a preparation is outside these limits then evidence must be submitted demonstrating that the preparation is homogeneous on application through appropriate application equipment e.g. determination of the active substance content in the spray at the beginning, middle and end of a spraying operation at the highest and lowest use rates on the label.

Spontaneity of dispersion and dispersion stability

Test according to CIPAC method MT 160 regarding suspension concentrates and CIPAC method MT 174 on the degree of dispersion of water dispersible granules.

The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water.

As for the determination of suspensibility, chemical assay is the only reliable means to measure the mass of an active substance in suspension.

However, gravimetric determination or solvent extraction determination may be used on a routine basis providing that these methods have been shown to give equivalent results to those of the chemical assay.

Where there is more than one insoluble active substance present in the preparation, chemical assay is the only acceptable method.

The mean measured minimum active suspensibility or dispersibility must not be less than 60% or greater than 105%. Where a preparation is outside these limits then evidence must be submitted demonstrating that the preparation is homogeneous on application.

3.6.5.3 Point 3.5.3 Wet sieve analysis and dry sieve test

Applicability depends on the formulation type (nature) of the biocidal product.

Wet sieve test

Test according to CIPAC method MT 59.3 Wettable powders, suspension concentrates, capsule suspensions and CIPAC method MT 167 Wet sieving after dispersion of water dispersible granules, CIPAC method MT 179 Degree of dissolution and solution stability, CIPAC method MT 182 Wet sieve test with re-cycled water and CIPAC method MT 185 Wet sieve test.

The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which cause the blockage of nozzles or filters on application equipment.

The test is applicable to wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders.

A maximum of 2% may be retained on a 75 mm sieve. Where a preparation is outside this limit then evidence must be submitted showing the preparation may be satisfactorily applied through appropriate application equipment with no blockages.

Dry sieve

Test according to CIPAC method MT 59.1 for dusts and CIPAC method MT 59.2 (MT 58) for granular formulations (GR).

The test is designed to determine the size distribution of dustable powders and granules for direct application to allow acceptable application.

For dustable powders, the active substance content of material remaining on the sieve must be determined to demonstrate there was no separation of the active substance from the carrier if > 5% of the preparation is retained on a 75 µm sieve. Not more than (0.005 x AI content in g/kg) % should be present as the AI in the residue on the sieve.

3.6.5.4 Point 3.5.4 Emulsifiability, re-emulsifiability and emulsion stability

Applicability depends on the formulation type (nature) of the biocidal product.

The relevant test methods are CIPAC method MT 36.3 for 0.1 – 5% dilutions, CIPAC method MT 173 for 0.1% - 2% dilution, and CIPAC method MT 180 on Dispersion stability of suspo-emulsions.

The data are required to determine whether a preparation forms and maintains a stable emulsion.

Tests should be performed in CIPAC water A and D and at the highest and lowest concentrations recommended for use.

The emulsion generated under the conditions of MT 36.3 may be at maximum 2ml cream after 30 minutes, trace of oil. If any separation is observed re-emulsification should be complete after 24 hours.

The emulsion generated under the conditions of MT 180 may be at maximum 2ml cream after 30 minutes, trace of oil. If any separation is observed, re-emulsification should be complete after 24 hours.

The absorbance measured for the formulation under the conditions of MT 173 must between 95-105% after four hours.

Where a preparation is outside these limits then evidence must be submitted showing the preparation remains homogeneous when applied.

If more than a trace of oil separates consideration should be given to reformulation.

3.6.5.5 Point 3.5.5 Disintegration time

The disintegration time is applicable to all products that are tablets and depend on disintegration of the tablet in a solvent (water) for optimal efficacy. Applicable to ST (water soluble tablets) and WT (water dispersible tablets) formulations.

There is no relevant standard method available.

The data should demonstrate the tablet disintegrates rapidly on addition to water and that the formulation is readily dispersed and no blockages occur in the application equipment on use. A maximum disintegration time is to be specified.

The specified disintegration time should be supported by a study showing the disintegration is achieved within the specified maximum time, and that the product is sufficiently dispersed. If continuous agitation is required, this should be specified on the instructions for use/label.

3.6.5.6 Point 3.5.6 Particle size distribution, content of dust/fines attrition, friability

Particle size distribution

The particle size distribution of powder biocidal products and granules must be addressed. The data generated must be sufficient to categorise the formulation type and is required to demonstrate that the biocidal product can be successfully applied using the appropriate application equipment. The relevant test methods are as follows:

Size distribution (powders):

- CIPAC Method MT 187: Particle size analysis by laser diffraction

Nominal size range (granules):

- CIPAC Method MT 170: Dry sieve analysis of water dispersible granules
- CIPAC Method MT 187: Particle size analysis by laser diffraction

For all powder biocidal products and biocidal products that are applied in a manner that generates exposure to aerosols, particles or droplets then the MMAD (mass medium aerodynamic diameter) must be determined. The percentage of particles in mass with aerodynamic diameter <50 µm must be established. Information regarding suitable test methods is outlined in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, R.7.1.14 Granulometry, (ECHA).

Dust

The dust content of solid preparations (granules and powders) must be determined to ensure there is no unacceptable risk to operators or bystanders or potential for blockage of application equipment.

The dust content should be generated using the following test method:

- CIPAC Method MT 171: Dustiness of granular products

Where the apparent dust content is >1% (by weight), the particle size and nature of the dust must be investigated in order to evaluate the potential risk to operators and bystanders. Methods applicable for determining the particle size of the dust are outlined in the ECHA Guidance on information requirements and chemical safety assessment (ECHA).

Where a granular material is described as 'dusty' then evidence is required that the material may be satisfactorily applied through application equipment.

Attrition, friability

Attrition is defined as the wearing away of the surface of a granule by friction or impact, particularly by granule-to-granule interaction.

Friability is defined as the tendency of a granule to crumble, breaking down into smaller particles.

These data are required to determine whether a granular material is robust under normal conditions of use and transport.

The relevant test methods (applicable for granules or tablets) are:

- CIPAC Method MT 178: Attrition resistance of granules
- CIPAC Method MT 178.2: Attrition resistance of dispersible granules

Where the material has an attrition resistance of <98% then the particle size of the dust must be determined and the risk to operators and bystanders must be addressed. Information on assessing the particle size of the dust is outlined above.

Where the material has an attrition resistance of <98% then evidence is required that the material may be satisfactorily applied through the application equipment.

3.6.5.7 Point 3.5.7 Persistent foaming

Applicability depends on the formulation type (nature) of the biocidal product. The data are required when the product is applied in water for use. The data are not required when the product is intended to be for foam application.

Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation.

Although CIPAC method MT 47.2 was standardised for the determination of persistent foam in suspension concentrates it is also applicable to other preparations which are dispersed in water.

The test must be performed at the highest and lowest in use concentrations recommended for use.

The level of foam generated under the conditions of CIPAC method MT47.2 should not exceed 60ml after 1 minute. Where a preparation is outside these limits then evidence must be submitted showing that there is no unacceptable risk to operators following use of the preparation through the appropriate application equipment.

3.6.5.8 Point 3.5.8 Flowability / Pourability / Dustability

Applicability depends on the formulation type (nature) of the biocidal product.

Flowability

The relevant test method is CIPAC method MT 172.

The data are required to demonstrate that granular materials remain free flowing after storage under pressure.

Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat.

The method is not appropriate to those granules where water has been added as a formulant. For such granules alternative data to demonstrate that application through the equipment would be satisfactory must be provided.

The sample should flow through the sieve after a maximum of five liftings.

Pourability (rinsability)

The relevant test method is CIPAC method MT 148.

The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. The method is appropriate to suspension concentrates, capsule suspensions and suspoemulsions.

The residue observed with MT 148 should not exceed 5% residue and the rinsed residue should not be more than 0.25%.

The test can be performed in the commercial packaging using the recommended rinsing instructions if the standard lab test is failed.

Higher residues may cause hazardous situations during waste disposal. A justification is required on why high residues would not pose an issue or instructions should be provided on safe waste disposal.

Higher residues may also affect the ability to prepare the biocidal product at the maximum in use rate and hence adversely affect the efficacy. Appropriate evidence that the efficacy will not be adversely affected maybe required.

Dustability

The relevant test method is CIPAC method MT 34. However, the equipment used in this method is not readily available. Therefore, data are required showing the preparation may be satisfactorily applied as a dust through the proposed application equipment and that there is no unacceptable compaction or caking following a heat test under pressure.

3.6.5.9 Point 3.5.9 Burning rate - smoke generators

Evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness (see also sections 3.7.5.10 and 3.7.5.11 of this guidance) support the proposed use. Where relevant the data must support intermittent use of the product.

The duration and burning rate of a smoke generator should be specified to establish how long it takes before the preparation stops generating smoke. A test is required, based on a representative in-use situation, to show the burning rate and duration comply with the specified rates.

The burning rate should correspond with the proposed use.

There is no relevant standard method available.

3.6.5.10 Point 3.5.10 Burning completeness - smoke generators

Burning completeness must be determined by weighing the preparation before and after use. It should be demonstrated that by far the largest part of the active substance went up in smoke. This also requires determination of the concentration active substance in the residue.

There is no relevant standard method available.

3.6.5.11 Point 3.5.11 Composition of smoke - smoke generators

The smoke composition must be analysed for the concentration of the active substance and decomposition products, if any, to guarantee that the produced smoke does indeed contain the active substance and no decomposition products.

There is no relevant standard method available.

The smoke should deliver the required active concentration and any decomposition products to be efficacious and the amount of active and any decomposition products should be supported by the toxicological and environmental risk assessments.

If, based on theoretical considerations, e.g. based on the endpoints provided for the active substance (degradation/combustion products after decomposition), or the heat generated during the generation of smoke is well below the decomposition temperature of the active substance and/or the absence of halogens or other compounds which may generate toxic fumes, a test may be waived.

3.6.5.12 Point 3.5.12 Spraying pattern - aerosols

Homogeneity must be determined according to FEA method 644 (Filled Aerosols Packs – Evaluation of Aerosol Spray Patterns).

Spray diameter must be determined at 30 cm distance.

3.6.5.13 Point 3.5.13 Other technical characteristics

Any other relevant technical characteristics that are not covered by this Guidance should be reported here.

3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

Data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes).

If all properties of each component are known and it can be clearly demonstrated that a chemical reaction can be excluded then data to demonstrate the chemical compatibility will not be required.

Any known incompatibilities (physical and chemical) should be mentioned.

3.6.6.1 Point 3.6.1 Possible physical incompatibility with any products should be mentioned.

Method ASTM E1518 (Standard Practice for Evaluation of Physical Compatibility of Pesticides in Aqueous Tank Mixtures by the Dynamic Shaker Method) can be used to investigate the physical compatibility.

3.6.6.2 Point 3.6.2 Possible chemical incompatibility with any products should be mentioned.

3.6.7 Point 3.7 Degree of dissolution and dilution stability

Applicability depends on the formulation type (nature) of the biocidal product.

Degree of dissolution

The information is required for products used in a water soluble bag and for all tablets.

The dissolution rate should be demonstrated regarding tablets and products used in water soluble bags in water and that the formulation dissolves or disperses rapidly. The test should be performed at the highest concentration. As the greater the amount of solid to water the more difficult it will be to disperse.

The relevant test method is CIPAC method MT176 (water soluble bag). There is no specific method for tablets.

Dilution stability

The relevant test methods are CIPAC method MT 179 and MT41.

The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc. The results submitted should fully describe the appearance and amount of any separation or sediment.

The test should be conducted at the maximum in use concentration specified on the label.

For method MT 41, the acceptable limit would be a 'trace' of sediment after 30 minutes. For method MT 179, the amount of residue obtained on a 75 µm sieve should not exceed 2%. Where a preparation is outside this limit then evidence must be submitted showing the material separated will not block application equipment or present an unacceptable risk to the operator or affect the efficacy.

3.6.8 Point 3.8 Surface tension

Test according to EC method A.5 (Surface Tension) and OECD Test Guideline 115 (Surface Tension of Aqueous Solutions).

For all liquid biocidal products the surface tension at the highest in use concentration recommended for use should be determined.

For liquid biocidal products containing ≥10% hydrocarbons and for which the kinematic viscosity is less than 7 x 10^{-6} m^2/sec at 40 °C the surface tension of the biocidal product as formulated should be determined at 25 °C.

For further Guidance see section 2.6.8 of this guidance.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R7a: Endpoint specific guidance, R.7.1.6 Surface Tension, (ECHA).

3.6.9 Point 3.9 Viscosity

This data is always required for liquid formulations.

The viscosity should be determined at 20 °C and 40 ºC.

There is no relevant EC method. Test according to OECD Test Guideline 114 (Viscosity of Liquids), where the following determination methods are recommended:

- Capillary viscometer;
- Flowcup;
- Rotational viscometer;
- Rolling ball viscometer
- Drawing Ball Viscometer.

For liquid biocidal products containing ≥10% hydrocarbons and for which the kinematic viscosity is less than 7 x 10^{-6} m^2/sec at 40 °C the surface tension of the biocidal product as formulated should be determined at 25 °C.

Further Guidance:

- ECHA Guidance on information requirements and chemical safety assessment Chapter R7a: Endpoint specific guidance, R.7.1.18 Viscosity, (ECHA)

3.7 Point 4 Physical hazards and respective characteristics

The physical hazards of the biocidal products (endpoints 4.1 to 4.16, Annex III of the BPR), correspond to the physical hazards classes for mixtures included in the CLP Regulation. The criteria and testing methods or standards for each of these physical hazards required in the BPR are described in the corresponding section of Part 2 of Annex I to the CLP Regulation.

For the purposes of determining whether a product entails any of the physical hazards referred to in Part 2 of Annex I to the CLP Regulation: the manufacturer, importer or downstream user must perform the tests required by the above mentioned Part 2, unless there is adequate and reliable information available (Article 8(2), of the CLP Regulation). Furthermore, in this guidance for each relevant physical hazard a reference to the corresponding test according to UN Recommendations on the Transport and Dangerous Goods, Manual of Test and Criteria ,UN-MTC (UN, 2009), starting with an UN test method name is provided.

Further information can be found in the Guidance on the Application of the CLP Criteria (ECHA).

3.7.1 Point 4.1 Explosives

Please follow the guidance in section 2.7.1 of this guidance.

3.7.2 Point 4.2 Flammable gases

Please follow the guidance in section 2.7.2 of this guidance.

3.7.3 Point 4.3 Flammable aerosols

Please follow the guidance in section 2.7.3 of this guidance.

3.7.4 Point 4.4 Oxidising gases

Please follow the guidance in section 2.7.4 of this guidance.

3.7.5 Point 4.5 Gases under pressure

Please follow the guidance in section 2.7.5 of this guidance.

3.7.6 Point 4.6 Flammable liquids

Please follow the guidance in section 2.7.6 of this guidance.

3.7.7 Point 4.7 Flammable solids

Please follow the guidance in section 2.8.7 of this guidance.

3.7.8 Point 4.8 Self-reactive substances and mixtures

Please follow the guidance in section 2.7.8 of this guidance.

3.7.9 Point 4.9 Pyrophoric liquids

Please follow the guidance in section 2.7.9 of this guidance.

3.7.10 Point 4.10 Pyrophoric solids

Please follow the guidance in section 2.7.10 of this guidance.

3.7.11 Point 4.11 Self heating substances and mixtures

Please follow the guidance in section 2.7.11 of this guidance.

3.7.12 Point 4.12 Substances and mixtures which in contact with water emit flammable gases

Please follow the guidance in section 2.7.12 of this guidance.

3.7.13 Point 4.13 Oxidising liquids

Please follow the guidance in section 2.7.13 of this guidance.

3.7.14 Point 4.14 Oxidising solids

Please follow the guidance in section 2.7.14 of this guidance.

3.7.15 Point 4.15 Organic peroxides

Please follow the guidance in section 2.7.15 of this guidance.

3.7.16 Point 4.16 Corrosive to metals

Please follow the guidance in section 2.7.16 of this guidance.

3.7.17 Point 4.17 Additional physical indications of hazard

3.7.17.1 Point 4.17.1 Auto-ignition temperatures of products (liquids and gases)

Please follow the guidance in section 2.7.17.1 of this guidance .

3.7.17.2 Point 4.17.2 Relative self-ignition temperature for solids

Please follow the guidance in section 2.7.14.2 of this guidance

3.7.17.3 Point 4.17.3 Dust explosion hazard

Please follow the guidance in section 2.7.17.3 of this guidance.

3.8 Point 5 Methods of detection and identification

Information on analytical methods is required for assessing compliance with conditions for issuing authorisation for a biocidal product. This information is also required for the post-authorisation control and monitoring purposes, and for the assessment of justifications which should be provided for the methods used for the generation of data as required in accordance with the BPR. If there are multiple active substances, an analytical method should be able to distinguish and individually quantify them. Validation of analytical methods does not have to be performed and reported to GLP. In particular cases where a specific analytical method cannot be developed, a common moiety approach or titration method may be acceptable.

Please also follow guidance in section 2.8 of this guidance.

Further Guidance:

- ECHA Guidance for identification and naming of substances under REACH; chapters 4.2.1.3. / 4.2.2.3. / 4.2.3.2., (ECHA).

3.8.1 Point 5.1 Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product

The analytical method must be suitable to accurately determine the active substance content. In the case of a preparation containing more than one active substance, a method capable of determining each, in the presence of the other, should be provided. If a combined method is not submitted, the technical reasons must be stated.

Generally, linearity, specificity, recovery and repeatability should be addressed.

Linearity

See information for the technical material in section 2.8 of this guidance.

Specificity (Selectivity)

Example chromatograms from the analysis of a standard, sample and a blank formulation are required. The blank formulation should contain all the formulants and no active substance. Where the formulation contains two or more active substances and each has been determined using a separate method then adequate data must be provided to demonstrate that each active substance does not interfere with the determination of the others.

Repeatability

See information for the technical material in section 2.8 of this guidance.

Recovery (Accuracy)

The accuracy of the method should be reported as mean recovery for the pure active substance in the biocidal product. At least two recovery determinations should be made on representative samples containing a known quantity of the analyte. Samples should ideally be laboratory-prepared co-formulant mixes to which a known quantity of analyte is added and the whole sample analysed to reduce sampling error. However, where it is not possible to prepare a sample matrix without the presence of the analyte or there are difficulties in replicating the sample to be analysed (for example with pellet formulations), the standard addition method may be used.

The recovery data should meet the following requirements:

Table 7 Acceptable recovery values for residues or impurities

% active (nominal)	Mean % recovery
A>10	98-102
1-10	97-103
<1	95-105
0.01-0.1	90-110
<0.01	80-120

Source: SANCO 3030/99 (EU, 2000a)

Where available the active content can be determined in the formulation using a CIPAC method. When a CIPAC method has been validated for the active substance in the same

formulation type then full validation data are not required. In such cases only specificity data are required.

For substances of concern and relevant impurities, the same requirements are applicable as for the active substance with additional requirements to confirm the identity of the impurity. If the method used to determine the substance of concern or relevant impurity is not regarded as highly specific then confirmation of the result using a fully validated confirmatory method of analysis is required. See footnote 5 in section 2.6.11 of this guidance

For further information on procedures for confirmation of identity see section 2.8.2 of this guidance .

3.8.2 Point 5.2 In so far as not covered by Annex II 5.2 and 5.3, analytical methods for monitoring purposes (ADS)

Point 5.2 of Annex III to the BPR states that [….]*including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant in or on the following*:

Residue definition

Generally, it has to be confirmed during evaluation, where relevant, which relevant components of the biocidal products should be monitored in addition based on its evaluation of fate and behaviour of the components and the toxicological and ecotoxicological potential.

Components of the biocidal product classified as toxic or very toxic are considered to be the toxicologically relevant components (see section 2.6.11 of this guidance). They must be analysed for monitoring purposes if human exposure cannot be excluded. Validation of the analytical methods employed must be performed.

Limit of quantification

The LOQ should correspond to the limits for the active substance in section 2.8.2.4 of this guidance

Components of the biocidal product classified as dangerous for the environment are considered to be the ecotoxicologically relevant components (see section 2.6.11 of this guidance). They must be analysed for monitoring purposes if environmental exposure cannot be excluded. Validation of the analytical methods employed must be performed.

Limit of quantification

The LOQ should correspond to the limits for the active substance in section 2.8.2 of this guidance.

3.8.2.1 Point 5.2.1 Soil (ADS)

Please follow guidance in section 2.8.2.1 of this guidance

3.8.2.2 Point 5.2.2 Air (ADS)

Please follow guidance in section 2.8.2.2 of this guidance

3.8.2.3 Point 5.2.3 Water (including drinking water) and sediment (ADS)

Please follow guidance in section 2.8.2.3 of this guidance

3.8.2.4 Point 5.2.4 Animal and human body fluids and tissues (ADS)

Please follow guidance in section 2.8.2.4 of this guidance

3.8.3 Point 5.3 Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (ADS)

Point 5.3 of Annex III to the BPR states that [….] *(not necessary if neither the active substance or the material treated with it come into contact with food producing animals, food of plant and animal origin or feeding stuffs*

The requirements for the active substance itself are given in section 2.8.3 of this guidance. Analytical methods are required for all active substances in a biocidal product.

The quantification of residues of non-active ingredients is required for substances with toxicological concern and for residue levels exceeding 0.01 mg/kg.

Please follow guidance in section 2.8.3 of this guidance.

4. Parts B+C: Evaluation and Assessment

Guidance on evaluation and assessment of physico-chemical properties is given in the TNsG on Product Evaluation (Chapter 3) [TNsG Chapter 3][10].

There is no ECHA BPR guidance developed for this section, however with experience of evaluation of dossiers under the BPR, the BPC Working Group on Analytical Methods and Physico-chemical Properties may in the future consider that this section needs to be developed. In the meantime the evaluation and assessment should be carried out using the principles described in the TNsG on Product Evaluation (Chapter 3).

[10] Link to ECHA BPD guidance page: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/biocidal-products-directive

References and Background Documents

Croplife. (2009). *Croplife 2009, Technical Monograph n°17, 2nd Edition Guidelines for Specifying the Shelf Life of Plant Protection Products.*

ECHA. (n.d.). *Guidance document on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008.*

ECHA. (n.d.). *Guidance for identification and naming of substances under REACH and CLP.*

ECHA. (n.d.). *Guidance on exposure assessment on treated articles.*

ECHA. (n.d.). *Guidance on information requirements and chemical safety assessment Appendix to Part F CSR Template with explanation.*

ECHA. (n.d.). *Guidance on information requirements and chemical safety assessment Chapter R.17: Estimation of exposure from articles.*

ECHA. (n.d.). *Guidance on information requirements and chemical safety assessment: Endpoint specific guidance. R7.*

ECHA. (n.d.). *Guidance on intermediates.*

ECHA. (n.d.). *Guidance on the application of the CLP criteria.*

ECHA. (n.d.). *Guidance on the compilation of safety data sheets.*

EFSA. (2008). *Note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation. Short title: Note for Guidance for Food Contact Materials.*

EU. (2000a). *Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.SANCO/3030/99.* SANCO/3030/99 rev.4 11/07/00.

EU. (2000b). *Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, Section 5) of directive 91/414. SANCO/3029/99 rev.4 11/07/00.*

EU. (2003). *Technical Guidance Document (TGD) on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the.*

EU. (2005a). *Guidance to Member States and industry on the data requirements for naturally occurring substances used as attractants/repellents.*

EU. (2005b). *A workshop for technical experts evaluating wood preservatives for the Competent Authorities implementing the Biocidal Products Directive, Directive 98/8/EC, assessing the leaching from treated wood to the environment.*

EU. (2006). *Manual of decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC).*

EU. (2007). *Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal Products.*

EU. (2008a). *Technical Guidance Document in support of the of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on Data Requirements for active substances and biocidal products. Short title: TNsG Data Requirements.*

EU. (2008b). *The Technical Notes for Guidance on Dossier preparation including preparation and evaluation of study summaries under Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market. Short title: TNsG on Dossier Preparation of Dossiers and St.*

EU. (2010a). *DG SANCO Guidance document on pesticide residue analytical methods.*

EU. (2010b). *Guidance note on leaching rate estimations for substances used in biocidal products in Product Types 07, 09 and 10.*

EU. (2011a). *Manual of Technical Agreements of the Biocides Technical Meeting (MOTA). Version 4.*

EU. (2011b). *Addendum-TNsG-Data_Requirements_PT18_PT19_Oils_and_extracts.*

EU. (2011c). *Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed. Document No SANCO 12495/2011.*

EU. (2012a). *Technical Notes Guidance EU Evaluation Manual for the Authorisation of Biocidal Products. Short title: Evaluation manual.*

EWPM. (1996). *guidance document of the European Wood Preservation Manufacturers Group.*

FAO. (2010). *Manual on the Development and Use of FAO and WHO Specifications for Pesticides, second revision.*

OECD. (2000a). *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. Series on Testing and Assessment, No 23.*

OECD. (2000b). *OECD Series on Emission Scenario Document No 2: Emission Scenario Document for Wood Preservatives.*

OECD. (2007a). *Guidance Document on Pesticide Residue Analytical Methods. OECD Environment, Health and Safety Publications, Series on Testing and Assessment No. 72 and Series on Pesticides. ENV/JM/MONO(2007)17.*

OECD. (2008a). *OECD Series on Emission Scenario Documents number 19. Complementing guideline for writing emission scenario documents: the life-cycle step "service-life" .ENV/JM/MONO(2008)41/REV1.*

OECD. (2009a). *OECD Series on Emission Scenario Documents No 3: Emission Scenario Document on Plastic Additives; ENV/JM/MONO(2004)8/REV1 revised 2009.*

OECD. (2009b). *OECD Series on Testing and Assessment, No 107. Preservative- treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground. ENV/JM/MONO(2009)12.*

UN. (2009). *Recommendations on the Transport of Dangerous Goods. Manual of Tests and Criteria. ST/SG/AC.10/11/Rev.5. (UN-MTC).* New York and Geneva.

WHO. (2004). *A generic risk assessment model for insecticide treatment of mosquito nets and their subsequent use.*

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