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Guidance on the Biocidal Products Regulation

Volume II: Efficacy

Part A: Information Requirements

Version 2.1, March 2022

LEGAL NOTICE

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

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NOTES to the reader:

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

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

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

List of Abbreviations

Standard term / Abbreviation	Explanation
(Q)SAR	(Quantitative) structure activity relationship
ASTM	American Society for Testing and Materials
BPC	Biocidal Products Committee (ECHA body)
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)
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytic Council Ltd.
CLP (Regulation)	Classification, Labelling and Packaging Regulation. Regulation (EC) No 1272/2008 of the European Parliament and of the Council on Classification, Labelling and Packaging of substances and mixtures
DG	European Commission Directorate General
DWD	European Drinking Water Directive (Directive 98/83/EC)
EC	European Communities or European Commission
eCA	Evaluating Competent Authority
EC methods	Test Methods as listed in the Test Methods Regulation
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of (new or notified) Chemical Substances
EN	European norm
EPA (DK, USA)	Environmental Protection Agency (of Denmark, or the United States of America)
EPPO/OEPP	European and Mediterranean Plant Protection Organization
EU	European Union
FPD	Flame photometric detector
g	Gram(s)
GC	Gas chromatography
GLP	Good laboratory practice
ha	Hectare(s)
ISBN	International standard book number
ISO	International Organization for Standardization
ISO (TC, SC, WG)	International Organization for Standardization Technical Committee, Scientific Committee, Working Group
ISSN	International standard serial number
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union for Pure and Applied Chemistry
JRC	Joint Research Centre
kg	Kilogram(s)
mg	Milligram(s)
MOTA	Manual of Technical Agreements of the Biocides Technical Meeting

Standard term / Abbreviation	Explanation
OECD	Organisation for Economic Cooperation and Development
Pa	Pascal(s)
PPPR	Plant Protection Products Regulation. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of concerning the placing of plant protection products on the market
PT	Product-type
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RSD	Relative standard deviation
s	Second(s)
SMEs	Small and medium-sized enterprises
TC	Technical material In accordance with FAO manual (FAO, 2010), TC is usually the final product from preparation of the active substance prior to being formulated into an end-use product. This may contain a stabiliser and/or anti-caking or anti-static agents (if required) but no other additives. TC is usually ≥900 g/kg with solvent(s) removed during synthesis, with only residual amounts remaining (usually ≤10%) and no solvent added subsequently.
Test Methods Regulation	Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation
TGD	Technical Guidance Document (EU, 2003)
TNsG	Technical Notes for Guidance
UN	United Nations
VDI	Verein Deutscher Ingenieure (The Association of German Engineers)
WHO	World Health Organisation

1 Part A: Dossier Requirements for Active Substances

BPR Annex II, Title 1, 6 Effectiveness against target organisms

NOTE to the reader:

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

1.1 Point 6 Effectiveness against target organisms

Efficacy data are a fundamental component in the regulatory management and decision making process for active substances. Efficacy data are required to establish the benefit arising from the use of the active substance in biocidal products and must be balanced against the risks their use poses to man and the environment.

Approval of an active substance will only be granted according to Art. 4 (1) of the BPR if a representative biocidal product containing the active substance fulfils the minimum requirements in the active substance part of Volume II Parts B+C. Thus, the data provided must show the efficacy of an active substance used in biocidal products or, where such claims are made, in treated articles. The information given according to BPR Annex II point 6 on the effectiveness and intended uses of the active substance must be sufficient to permit an evaluation of the representative biocidal product. It is particularly important that efficacy tests on a representative product reflect the use conditions given for the active substance. When active substances are used in treated articles, use conditions often differ widely. In this case it can be meaningful to reflect different use-conditions by submitting different efficacy tests with the example product. Furthermore, efficacy studies must establish that the concentration of the active substance used for the risk assessment is a relevant and efficacious concentration for the use(s) intended.

The efficacy studies with the representative biocidal product should generally be carried out in accordance with section 2.1 (of this guidance). If the information requirements differ for active substance approval, this is indicated below.

The information must include, for every product type separately.

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

Please follow guidance in Section 2.1.1.

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

Please follow guidance in Section 2.1.2.

1.1.3 Point 6.3 Effects on representative target organism(s)

Please follow guidance in Section 2.1.3

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

Please follow guidance in Section 2.1.4.

1.1.5 Point 6.5 Mode of action (including time delay)

Please follow guidance in Section 2.1.5.

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

Point 6.6 of Annex II to the BPR refers to *"(…) any available standard protocols, laboratory tests or field trials used including performance standards where appropriate".*

During the review of an active substance at the active substance approval stage, both the efficacy of the active substance itself and of a representative biocidal product containing that active substance are assessed.

Information, in the form of studies or justifications, must be provided to support the requirements set out in sections 2.1.1 to 2.1.5 of this guidance.

The information for the submission of efficacy data given in sections 2.1.6 and 2.1.7 of this guidance is also relevant for active substance approval. Please note: the SPC mentioned in section 2.1.6 is not relevant for active substance approval. Please provide the information in IUCLID instead.

1.1.6.1 Efficacy of the active substance

During the active substance approval stage, the efficacy of the active substance itself must be demonstrated.

This is normally done by carrying out testing using the technical active substance, or a simple dilution of the active substance in water or an appropriate matrix. The testing is carried out without other substances present which may affect the efficacy.

The efficacy studies submitted on the active substance should be capable of demonstrating the innate activity of the active substance against representatives of the proposed target organisms at the concentration relevant for the risk assessment.

For that purpose, innate activity of an active substance could be defined as the capacity of an active substance to provide an effect on one or more target organisms relevant to the use being considered.

Generally, efficacy data are generated from laboratory tests, are performed by the applicant. Nevertheless, efficacy data from literature could also be acceptable if the application rate, target organisms, area of use and the identity of the active substance is described and are relevant (for general requirements to be fulfilled by literature see point 13 in section 1of the Introduction to guidance on the BPR Volume I-IV, Part A: Information Requirements). For example, if cited literature is used to support a preserving effect it must also show that untreated test specimens supported growth. When curative effects are claimed the cited literature must demonstrate the efficacy of the active substance according to the requirements per PT. The use of cited literature should be agreed between the applicant and the evaluating CA (eCA) on a case by case basis.

If no efficacy tests with the active substance itself are available, tests carried out with a formulated product may be acceptable where a suitable justification is provided by the applicant addressing the possible influence of co-formulants on the efficacy. If the co-formulants used potentially have biocidal activity, it is essential to demonstrate that the efficacy is due to the active substance and not to the co-formulants, e.g. a test should be performed with all co-formulants but without the active substance.

1.1.6.2 Efficacy of the representative biocidal product at the active substance approval stage

Although approval for the Union list is primarily concerned with the active substance, efficacy data is also required for a representative product to demonstrate that the active substance is capable of producing an effect on the target organism when included in a formulated product.

Ideally efficacy data on an existing biocidal product should be submitted. If this is not possible, data on a "dummy product[1]" could be acceptable to demonstrate that the active substance is capable of producing an effect on the target organism in a relevant formulation.

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

Efficacy data packages for formulations containing two or more active substances are not fully suitable for determining the activity contribution from the active substance under evaluation. For that reason great attention should be paid to justify the contribution of the active substance under evaluation to the total efficacy of the product. Information about the mode of action/function of the other active substances present in the product is also requested. For more details please refer to Volume II parts B+C, section 4.3.

The evaluation of the effectiveness of the representative product at the stage of active substance approval is not as detailed as that carried out for product authorisation.

Nevertheless, the level of efficacy (e.g. the kind of activity "curative" or "preventive") have to be consistent with the uses claimed and fulfil the minimum requirements mentioned in the active substance part (Guidance on the BPR: Volume II, Parts B+C).

1.1.6.3 Approval of the active substance

Where the innate activity of both the active substance and representative biocidal product against the target organisms has been demonstrated, a recommendation can be made for approval of the active substance.

Where the level of activity demonstrated for the representative biocidal product would not normally be considered high enough for a product authorisation, the applicant should justify why the levels of activity noted should be considered acceptable (e.g. where there only is a dummy product containing only the active substance under consideration, or where the active substance will always be used in combination with one or more other active substances).

Where the applicant provides an acceptable justification, approval of the active substance should still be recommended and the efficacy more fully addressed at the product authorisation stage.

It is not necessary to demonstrate efficacy against all of the claimed target organisms at the active substance approval stage. However, approval will only be granted for use against those organisms for which efficacy has been demonstrated. Additional target organisms may be added at product authorisation, but must be supported by suitable efficacy data.

[1] A "dummy product" is a product that is not fully formulated. It is not intended to be placed on the market. For more information please consult section 4.4 of the *Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C)*

1.1.7 Point 6.7 Any known limitations on efficacy

Please follow guidance in section 2.1.8.

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

Please follow guidance in section 2.1.8.1.

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

Please follow guidance in section 2.1.8.2.

1.2 Point 7 Intended uses and exposure

1.2.1 Point 7.1 Field of uses envisaged for biocidal products and, where appropriate, treated articles

The intended and potential use should be indicated together with the fields of use. For active substance evaluation at least one realistic use per PT should be given. Additional uses may be identified and supported at product authorisation stage.

The information on the intended use should be in accordance with the uses presented in section 1.1.1 of this guidance (BPR Point 6.1) and should be sufficient to allow an approximate and realistic estimation of human and environmental exposure to the product or treated article, respectively under conditions reflecting a representative use. Additionally, it should be sufficient to allow an approximate and realistic estimation of the efficacy of the active substance/biocidal product.

The uses intended should be relevant to the product type(s) under consideration.

Uses taking place outside the EU should be disregarded. Any operation carried out with a view to exporting the biocidal product or the treated article outside the EU should also be disregarded.

1.2.2 Point 7.2 Product-type(s)

The intended product-type(s) as listed in Annex V to the BPR should be indicated.

1.2.3 Point 7.3 Detailed description of the intended use pattern(s) including in treated articles

Provide a detailed description of the overall use patterns linked to the fields of use intended. Use means all operations carried out with a biocidal product, including storage, handling, mixing and application.

The information on the intended use in accordance with BPR Point 6.1 (see section 1.1.1 of this guidance) should be sufficient to allow efficacy evaluation and an approximate but realistic estimation of human and environmental exposure to the active substance under realistic worst case conditions and for an evaluation of the use-conditions under which the biocidal product is intended to be used.

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

- For disinfectants state the area of use e.g. ‘surface disinfection in hospitals and other health care institutions’, instead of only ‘surface disinfection’.

- For material preservatives information on the type of matrices should be given. Furthermore information on ageing, weathering etc. which could limit efficacy should be given.
- For material preservatives of product-types 6, 7, 9, and 10, the different environments in which the material treated with the product is intended to be used should be indicated (e.g. indoors or outdoors, in cattle sheds, preserved material used in contact with drinking water or food storage).
- For product-type 8, the use classes, (as defined in the standard EN 335-1 Durability of wood and wood-based products. Definition of use classes - Part 1: General), in which wood treated with the product is intended to be used should be indicated for wood preservatives. For uses not described in this standard, such as curative or antisapstain products, see also Volume II, Parts B+C: PT 8.
- For product-type 21, in addition to the fields of use, specify also if the product or treated article, respectively, is intended to be used in marine environments, in brackish water and/or in fresh waters. The uses should also distinguish between for example, aqua-culture, buoys and other small static objects, sluice doors, harbour constructions, oil rigs, inlet pipes of cooling water systems, marine sensors, ships' hulls (e.g. deep sea, coastal, inland waterway vessels), etc.
- For treated articles, intended and/or potential uses which show a specific exposure pattern or specific use-conditions should be listed, even if they belong to the same product-type (e.g. use for antimicrobial treatment of underwear, use for treatment of food containers, etc.). If necessary, the applicant should suggest use-categories which include similar exposure patterns, and/or similar use-conditions relevant for efficacy.

1.2.4 Point 7.4 Users, e.g. industrial, trained professional, professional or general public (non-professional)

Indicate users with the help of the user categories[2] :

- Industrial user: user involved in manufacturing, handling and/or packaging of actives or products at industrial sites (e.g. handling of in-can preservatives);
- Trained professional: professional user using end-products outside industry in the course of their professional activities and have extra-training or certification process (e.g. handling of avicides and piscicides);
- Professional user: professional user using end-products outside industry, but in the course of their professional activities (e.g. handling of preservatives in liquid-cooling and processing systems);
- General public (non-professional user): member of the population or citizen that make a private use of a biocidal product at a workplace or at home (consumer) (e.g. handling of disinfectants for water beds or mosquito repellents).

Users outside the EU should be disregarded.

[2] See also for additional information the Note for guidance (CA-May16-Doc.5.4.a- Final) User categories of anticoagulant rodenticides: common understanding and adaptation to national situations in case of mutual recognition - /CircaBC/SANTE/BPR - Public/Library/documents finalised

1.2.5 Point 7.5 Likely tonnage to be placed on the market per year and, where relevant, for the intended major use categories

An estimate of the quantity of the active substance placed, or to be placed, on the EU market by the applicant (i.e. imported or produced) per year. The quantities for biocidal use and in which product-type(s) should be given, and where relevant for the intended major use categories, within each product-type. The quantities for use other than as a biocide should be indicated, if available. In case of the renewal of approved active substances, tonnage data should cover the last three years. For new substances not previously marketed, production plans covering three years after authorisation should be provided.

1.2.6 Point 7.6 Exposure data in conformity with Annex VI to this Regulation

The principles of the exposure assessment, as outlined in Annex VI to the BPR on the common principles for the evaluation of dossiers for biocidal products points 32-34, and 45 should be taken into account when assessing the exposure associated with the uses and disposal of an active substance. According to Annex VI, an exposure assessment needs to be carried out for human and environmental populations for which exposure to a biocidal product occurs or can reasonably be foreseen.

For further guidance on exposure assessment on active substances, see Parts B+C - Evaluation and Assessment of Volumes III and IV of the BPR Guidance.

1.2.6.1 Point 7.6.1 Information on human exposure associated with the intended uses and disposal of the active substance

The provided information should be sufficient to allow an approximate but realistic estimation of human (occupational and consumer) exposure associated with the proposed/expected uses and disposal of an active substance. The prediction of the exposure levels should also describe a realistic worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modelling.

1.2.6.2 Point 7.6.2 Information on environmental exposure associated with the intended uses and disposal of the active substance

The provided information should be sufficient to allow an approximate but realistic estimation of environmental exposure associated with the proposed/expected uses and disposal of an active substance. The prediction of the exposure levels in all relevant environmental compartments and respective biota should also describe a realistic worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modelling.

1.2.6.3 Point 7.6.3 Information on exposure of food producing animals and food and feeding stuffs associated with the intended uses of the active substance

To estimate exposure of food producing animals follow the Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (see Volume III Parts B+C Section 6).

1.2.6.4 Point 7.6.4 Information on exposure from treated articles including leaching data (either laboratory studies or model data)

Articles treated with or incorporating biocidal products can lead to consumer and environmental exposure if chemical constituents of the biocidal product are released in any way from these types of articles. Exposure from treated articles during service life may in some situations be the most significant exposure to the active substance (and to substance(s) of concern in the case of product authorisation applications). Specifically, articles consisting of different types of polymers can be used in a large range of consumer applications, which makes the exposure situation very complex. The diversity of applications has consequences both for the exposure of consumers and the environment. For consumers, possible worst case exposure scenarios have to be defined. Then, applications leading to simultaneous consumer exposure within a certain timeframe have to be modelled. For the environment, emissions from uses with similar exposure patterns (e.g. down the drain, direct exposure to soil, etc.) should be summed up for the respective compartment. When treated articles are imported into the EU, the only possible way to carry out a risk assessment is by active substance evaluation. It is therefore important that the applicant for an active substance approval describes the intended or potential uses in a way as detailed as possible so that the appropriate exposure scenarios can be applied. Here it is noted that the applicant may not always have this detailed knowledge, in particular with regards to treated articles imported into the EU.

The applicant submitting an application for approval of an active substance (or for authorisation of a biocidal product to treat an article) which is intended to be used in biocidal products to treat an article must submit an exposure assessment. The assessment can be based on model calculations with well supported default values and/or measured laboratory leaching values, or based on the results of an exposure study. For several product-types, information on leaching will be required as listed in Volume IV Parts B+C (section 2) on product-type-specific data requirements on the foreseeable route of entry into the environment based on the intended use.

It has to be decided on a case-by-case basis how detailed the exposure assessment has to be: i.e. whether all intended uses in treated articles need to be covered or not. Here a balance has to be found between the ability of the applicant to obtain all the relevant information to carry out a detailed exposure assessment, the requirements for the approval process and the relevance of each use in relation to the foreseen exposure.

The need for additional data needs to be judged on a case-by-case basis. The REACH Guidance on exposure assessment on treated articles (ECHA) is very comprehensive and can be applied in many cases. The OECD Guideline document on how to write emission scenarios for the life-cycle step service life (OECD, 2008a) can also be useful.

1.2.6.4.1 Environment

Depending on the use, either the tonnage approach or an approach in which leaching rates are determined from the treated article is required for the calculations. If the tonnage approach is not used, information on the likely application rate must be stated for the most relevant uses and modes of application. Generally, a detailed quantitative description of the fields of use intended should be given to allow for a realistic worst-case estimation of environmental exposure of the active substance (or any substances of concern for applications for product authorisation). When using the tonnage approach, it may be necessary to allocate a certain percentage of the overall tonnage to certain uses if such uses have a different exposure profile. Information on the estimated service life time of the treated article and possible reapplications, if relevant, is required.

In general, a tiered approach should be followed for leaching rate determination:

- Tier 1: worst-case assumption where 100% of the active substance (and for product authorisation applications – if present in the biocidal product – the substance(s) of concern). The life time can be different and depends on the product-type and use of the treated article.
- Tier 2: validated laboratory leaching test. The uncertainty of using a laboratory test to predict environmental concentrations should be addressed by using an assessment factor.
- Tier 3: semi-field tests or field studies. The duration of the field- or semi-field study should reflect the exposure situation and enable an extrapolation to the service life of the treated article.

The service life time of an article can be different and depends on the product-type and use of the treated article. For polymers, default values for the life times of different consumer articles are given in the OECD Emission scenario document on plastic additives (OECD, 2009a). For wood preservatives, the service life time of treated timber is defined by the mode of application and the use classes (OECD, 2009b). Guidance on extrapolation of leaching rates for life time calculations can be found in the Emission Scenario Document for product-type 8 (OECD, 2000b).

For polymers, it has to be taken into account that leaching rates can vary quite significantly depending on the type of polymer (polyethylene leaches less than polyamide), the type of application (incorporation or coating) and of the use (a regularly washed textiles leaches much more than a kitchen worktop). This observation will apply for many other types of treated articles. For wood preservatives, no reliable method exists to predict the leaching rate based on physico-chemical properties and therefore leaching studies are normally required.

For some product-types like e.g. PT 1, 2, 4, 7, 9, and 10, the biocidal product is often added as a premix concentrate to a surface treatment system or a polymer. The surface treatment system or the polymer may subsequently be applied to a surface and/or incorporated into the matrix from which leaching of the active substance(s) (and possibly substances of concern) will take place. As these surfaces/matrices may have many different characteristics, it is important that the applicant submits data for the leaching behaviour of different types of surfaces/matrices which are likely to cover the worst-case leaching behaviour. The emissions during service life are considered to be diffuse emissions that usually cause exposure on a wider scale compared to local emissions. Possible environmental emissions from articles treated with the same active substance and similar exposure patterns should be summed up. Uses within the same exposure pattern can be summarised to simplify the aggregated exposure assessment.

<u>Further Guidance:</u>

- ECHA REACH Guidance on information requirements and chemical safety assessment. Chapter R.17: Estimation of exposure from articles (ECHA);
- Guidance note on leaching rate estimations for substances used in biocidal products in PT 07, 09 and 10 (EU, 2010b);
- Workshop on determination of the leaching rate from treated wood to the environment (EU, 2005b);
- OECD Test Guideline 313 Estimation of Emissions from Preservative - Treated Wood to the Environment;
- OECD Series on Testing and Assessment Number 107 Preservative- treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground; ENV/JM/MONO(2009)12 (OECD, 2009b);

- CEN/TS 15119-2 (2012): Durability of wood and wood-based products - Determination of emissions from preservative treated wood to the environment - Part 2: Wooden commodities exposed in Use Class 4 or 5 (in contact with the ground, fresh water or sea water) - Laboratory method;
- CEN/TS 15119-1 (2008): Durability of wood and wood-based products - Determination of emissions from preservative treated wood to the environment - Part 1: Wood held in the storage yard after treatment and wooden commodities exposed in Use Class 3 (not covered, not in contact with the ground) - Laboratory method.
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1.2.6.4.2 Human Health

In a tier 1 exposure estimation, the chemical composition of the article is used to assess whether the total amount of the active substance (or substances of concern in case of product authorisation applications) present in the article may exceed the AEL or reference value. In a tier 2 assessment, exposure estimations may be refined by data obtained in e.g. leaching tests. Such tests must be conducted in appropriate media (for example, artificial sweat, saliva, etc.). They should also be specific for the intended material (for example type of polymer), use situation (for example mouthing, wearing on the skin), consistency of the article (for example, hard, smooth or porous) and duration of exposure. It is also important to obtain leaching rates during the service life of an article because in many cases articles give a high level of exposure during the first period of use and a lower level of exposure after repeated uses.

A special case of treated articles are food contact materials, which must also undergo a dietary risk assessment (see data requirements in Annex II 8.16 and Annex III 8.8, 8.9 and 8.10). For this, the Guidance listed below is available.

In a real life situation, daily exposure to different articles treated with the same active substance may occur. Consequently, an aggregated exposure assessment may be necessary. Uses with the same exposure pattern can be summarised to simplify the aggregated exposure assessment. If an active substance is used in a large number of different consumer articles, it is likely that a consumer is exposed from multiple uses. To reflect this in an exposure assessment, it may be considered as a first step to compare the acute exposure of single characteristic uses to a chronic AEL value.

Further Guidance:

- TNsG on Human Exposure to Biocidal Products (EU, 2007). This document contains some models for exposure scenarios from treated articles in section 2.6.9. For scenarios not covered by the available models, the general principles for secondary exposure assessment in the document should be followed in order to build scenario-specific models;
- Guidance for Food Contact Materials (Commission Regulation (EU) No 10/2011). This regulation defines test conditions for migration studies. The migration studies give amounts of substances in food or per surface area. Consumer exposure is then calculated using the migration results and assuming a 60kg person consuming 1kg of food in contact with 6.0dm^2 FCM in a day. The EFSA 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 (EFSA, 2008) is currently under revision and should be consulted when finished for current body weight and food intake default values. It should be noted that only plastic materials are covered by the regulation. Other materials should be assessed in line with the principles for plastic materials;

Suitable exposure assessment models for specific scenarios available from other sources may be used for the assessment of treated articles, e.g. a generic risk assessment model for insecticide treatment of mosquito nets and their subsequent use (WHO, 2004).

2 Part A: Dossier Requirements for Biocidal Products

BPR Annex III, Title 1, 6 Effectiveness against target organisms

NOTE to the reader:

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

2.1 Point 6 Effectiveness against target organisms

Authorisation will only be granted according to Art. 19 (1) b of the BPR if a biocidal product is sufficiently effective. Thus, the data provided must show the efficacy of a biocidal product or, where such claims are made in treated articles. The intended function and the given use conditions must be reflected in the efficacy tests.

The efficacy assessment of a biocidal product is based on substantiating the efficacy claims made for a product. The assessment is made on the product and its instructions and conditions of use.

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

For each product type and use area separately, the following information (sections 2.1.1 to 2.1.9) must be included.

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

It is often necessary to describe the function of the biocidal product in more detail, particularly if use in treated articles is intended. In many cases it is not sufficient to refer only to terms (e.g. bacteriostatic, fungicidal, attracting) although they provide useful clarification within the overall description. The function should be described in terms of a problem formulation: which problem is caused by the unwanted organism? How does the biocidal treatment prevent or solve the problem? It is hereby often essential to describe the conditions of use and the type of material which is to be protected. Use conditions and materials can often vary greatly and in this case it is necessary to define the use conditions and materials for which the biocidal product is supposed to be effective.

In case of articles where the protection of humans or animals is intended, it is even more crucial to describe the problem and the protection goal to describe the function. This is a necessary precondition to evaluate the efficacy of such treatment.

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

For an organism to be controlled provide both the common name and the scientific name when possible and also the sex, strain and stadia where relevant and appropriate. In cases where groups of organisms are to be controlled, generic names that are representative of the group must be indicated (e.g. bacteria, flying insects, animal fouling).

For groups that are not specifically addressed in BPR Guidance: Volume II (Parts B+C), it may be useful to provide examples of relevant species within the stated group.

If relevant, indicate in which parts of EU the organisms to be controlled exist.

List the products, organisms or objects which are to be protected and against which organisms or group(s) of organisms. Make it clear whether humans or animals must be protected.

2.1.3 Point 6.3 Effects on representative target organisms.

The effects on the target organisms required for the claimed efficacy should be described and specified for each use and method of application if these have different effects. For microorganisms, it needs to be indicated whether the intended effect is biostatic or biocidal for each use.

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

2.1.4 Point 6.4 Likely concentration at which the active substance will be used

The likely use concentrations of active substance(s) and applied dose rate of product should be stated for each use and method of application. When a dose range is suggested an explanation should be given when to use the lower or upper limit. It should be indicated and justified if the use concentrations are different in different parts of EU and whether they should be different in different materials, for different use-conditions, etc.

The dose rate used in the efficacy assessment and risk assessment should be consistent. When a dose range is suggested efficacy should be demonstrated at the lower limit.

2.1.5 Point 6.5 Mode of action (including time delay)

The mode of action in terms of the biological, biochemical and physiological mechanisms and biochemical pathways involved should be stated.

Information on time delay should be included, where applicable.

Where it is expected that there is a time delay before the effects start, information should be provided to address this, for example insect growth regulators (e.g. larvicides) that take some time to manifest their effect (e.g. on adult population of flies and mosquitoes). Also conditions that influence on efficacy (of disinfectants or preservatives), like temperature, humidity and other should be added. Where available, the results of experimental studies must be reported.

Where it is known that in order to exert its intended effect the active substance must be converted into a metabolite or degradation product following application or use of a preparation containing it, justification should be submitted for why this metabolite or degradation product is not considered to be the active substance. In addition, available information relating to the formation of reactive metabolites or reaction products must be provided. This information must include:

- The chemical name, empirical and structural formula, molecular mass, and CAS and EC (EINECS, ELINCS or No Longer Polymers list) numbers if available;
- The processes, mechanisms and reactions involved;
- Kinetic and other data concerning the rate of conversion and if known the rate limiting step; and
- Environmental and other factors effecting the rate and extent of conversion.

Indicate also if the actual active substance is the result of a combined action of different products, when such a combination is necessary to achieve the intended effect (i.e. *in situ* generated active substance).

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

The directions for use and the claims made for the biocidal product are included in a summary of the biocidal product characteristics (SPC) in accordance with Article 22(2) (BPR).

A label claim is information which is provided to the user which describes the biocidal effects that will result from using a biocidal product under its normal conditions of use (i.e. when it is used at the recommended dose/application rate, by the recommended application method(s) and in the appropriate areas, etc.). The product label can only include claims that are in line with the authorised uses, as given in the SPC[3].

Label claims should be as specific as possible, or if more general claims (such as "fast acting") are made, then they should be further clarified in the PAR where possible (e.g. "fast acting – acts within 5 minutes"). If no clarification is provided, the evaluating Competent Authority should ask the applicant to specify the claim. A judgement as to what a normal user would reasonably expect from the claim should be made. The evaluation should be made according to this claim and the directions for use should be taken into account.

Please also refer to the specific section for the different PTs in Vol II, parts B+C of the efficacy guidance (e.g. Appendix 1 and 4 for disinfectants, chapter 5.5.6.1 for wood preservatives, chapter 5.7.1.1.7 for antifoulings, chapter 5.6.2.4.1 "Norms and criteria" for rodenticides) to understand which requirements and pass criteria apply for certain claims. For preservatives, it needs to be made clear whether the claims refer to curative or preservative effects. Marketing statements that are not related to the biocidal function (e.g. new fragrance, better formula) are not subject to the efficacy evaluation and should not be stated in the product application. The claims demonstrated become part of the products authorisation.

2.1.7 Point 6.7 Efficacy data to support these claims,

Point 6.7 of Annex III to the BPR states that [….] *including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant.*

Volume II, Parts B+C provide further elaboration in this area, including treated articles. Product-type-specific guidance where available can be found in Parts B+C. Applicants are advised to check for the future availability of new guidance.

The applicant must demonstrate that the biocidal product or treated article is effective and suitable for its intended use when applied according to its instructions for use. This can be confirmed by provision of data that may include laboratory studies, simulated-use or semi-field test data or other relevant study data, provided that the test conditions reflect instructed conditions of use.

For field studies the extent of the information required will vary depending on the product-type and proposed use pattern. The data provided should include all appropriate information that is necessary for an evaluation of the reported results. This generally includes information on the harmful organism (e.g. relevance to the Member State in

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

which authorisation is sought) and relevant case-dependent information which can include meteorological parameters (e.g. mean temperatures and rainfall), location details or physico-chemical parameters of the system in which the biocidal product is used.

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

The test method should measure a response and, as appropriate, an endpoint relevant to the label claims. The method should employ an untreated control. However, this may not be always possible for field studies.

Appendix 1 of this guidance provides a check-list for preservatives for the suitability of the planned or submitted test.

Where earlier formulations of the product/treated article or other products/treated articles containing the same active substances are cited as supporting evidence, all relevant formulation details must be provided and the relevance of this evidence to the current formulation must be fully justified, preferably through bridging efficacy studies.

The tests (and data generated) should be based on sound scientific principles and practices. Although GLP is not required for efficacy studies, testing should be carried out in accordance with a relevant quality standard, e.g. ISO 17025[4], ISO 9001[5] or GLP . More detailed guidance on appropriate test methods is provided in Volume II Parts B+C .

2.1.8 Point 6.8 Any known limitations on efficacy

Provide possible restrictions or recommendations concerning the use of the product in specific environmental or other conditions. State possible factors that can reduce the efficacy, for instance hot, cold or humid environments or the presence of other substances, in addition to the reasons for these. State if the product cannot be mixed or used consecutively with, for example, other biocidal products or detergents, or if the use of the product with other biocidal products is recommended.

2.1.8.1 Point 6.8.1 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

Provide information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies, including also cross-resistance. This information must be submitted even where it is not directly relevant to the uses for which authorisation is sought or to be renewed (e.g. different species of harmful organism), as it may provide an indication of the likelihood of resistance development in the target population.

Where there is evidence or information to suggest that in commercial or experimental use the development of resistance is likely, evidence must be generated and submitted as to the sensitivity to the substance on the part of the populations of the harmful organism concerned. In such cases a management strategy designed to minimise the likelihood of resistance or cross-resistance developing in target species must be provided. This should include possible recommendations concerning the avoidance of the continuous use of the product to prevent the development of resistant strains in addition to the reasons for these. It may be acceptable to make a reference to the CAR, however if more recent or relevant information on the product is available this should be

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

[5] Quality management systems – requirements.

provided. This is addressed in the TNsG on product evaluation (EU, 2008c) Appendix 6.2[6].

2.1.8.2 Point 6.8.2 Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms

Provide observations on undesirable or unintended side effects. Provide observations such as on adverse reaction to fastenings and fittings used in wood following the application of a wood preservative, corrosion risk on sanitary fittings following application of disinfectants, etc. Provide information on effects on beneficial and other non-target organisms, only as far as this is not covered under Volume IV Sections 1 and 2.

Provide information on unnecessary suffering and pain for target vertebrates, where relevant (PT14, 15, 17, 19, 20).

2.1.9 Point 6.9 Summary and evaluation

The findings on the effectiveness against target organisms (BPR Annex III, Title 1, 6.1-6.8.2) are summarised and evaluated. Describe how the provided tests demonstrate the efficacy against all the target organisms at the use concentration and use conditions instructed (e.g. application method, contact time).

When authorisation is sought for a product family the evaluation should be done per *meta* SPC, not per product.

2.2 Point 7 Intended uses and exposure

The SPC (Summary of the Biocidal Product Characteristics) is the summary document for the biocidal product which contains administrative information, information of product classification and labelling, authorised uses and direction for use. An example of the label and instruction for use must be provided for each application for product authorisation[7,8]. The information indicated on the label, instructions for use[9] and other information sources (e.g. web pages) should be consistent with the information in the SPC.

Based on the conclusions of the efficacy assessment the following information should be included in the Section 4 Authorised uses of the draft SPC: any uses of a biocidal product, which clearly describe the target organism(s), field(s) of use, application method(s), application rate(s), application conditions where relevant (e.g. use under high soiling, at 4°C) and frequency and category(ies) of users. Instructions for use should be given which can be use specific, meta- SPC specific, or general for the whole SPC.

Considering the exposure and risk assessment the draft SPC also includes all risk mitigation measures which should be considered for relevant use of product, particularly of likely direct or indirect effects, resistance, first aid instructions and emergency measures to protect environment, also instructions for safe disposal of the product and

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

[7] Label(s) must be provided in accordance with Annex III, Section 12 of BPR. Please note that at the same time the biocidal product labels are not part of the product authorisation.

[8] See also Note for guidance (CA-Nov15-Doc.4.2- Final) Submission of example labels, instructions for use, safety data sheets and models or drafts of the packaging, labelling and leaflets within an application for product authorisation - /CircaBC/SANTE/BPR - Public/Library/documents_finalised

[9] Article 69(2) of BPR.

its packaging and conditions of storage of the product. These instructions should be given which can be use specific, meta- SPC specific, or general for the whole SPC.

2.2.1 Point 7.1 Field(s) of use envisaged for biocidal products and, where appropriate, treated articles

Please follow guidance in section 1.2.1 of this guidance.

2.2.2 Point 7.2 Product-type

Please follow guidance in section 1.2.2 of this guidance.

2.2.3 Point 7.3 Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles

Please follow guidance in section 1.2.3 of this guidance.

2.2.4 Point 7.4 User e.g. industrial, trained professional, professional or general public (non-professional)

Please follow guidance in section 1.2.4 of this guidance.

The description of the user on the authorised label might be different from the user categories described under BPR Point 7.4, due to the national policy and laws.

2.2.5 Point 7.5 Likely tonnage to be placed on the market per year and where relevant, for different use categories

An estimate of the quantity of the product or treated article, respectively, placed or to be placed on the EU market by the applicant (i.e. imported or produced) per year. The quantities for biocidal use and in which product-types, and where relevant, for the intended major use categories within each of the product-types. The quantities for use other than as a biocide should be indicated, if available. In case of the renewal of authorisation, tonnage data should cover the last three years. For new products, not previously marketed, production plans covering the next three years after authorisation should be provided.

Where relevant, this information can be added to the confidential annex of the application.

2.2.6 Point 7.6 Method of application and a description of this method

The method of application of product in different uses should be explained. If the product is to be diluted, this should be stated and recommendations on how to do this should be given (e.g. 3 gram product per 5 litre water). A description of the application technique (e.g. dipping, spreading, spraying, automatic/manual dosing etc.) should be included. If additional substances have to be added to the solution, their dosages must also be given.

If specific technical device will be used together with the product, a description of this device should be provided.

If a device is used to produce the active substance *in situ* and dose it directly, information should be provided on control and safety measures to avoid over and under dosing.

The devices used to generate the active substance *in situ* themselves are not covered by the provision of BPR and consequently are not subject to the authorisation.

2.2.7 Point 7.7 Application rate and if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes.

The recommended dose of the product and the active substance per object should be stated (e.g. per surface area of the material to be protected or as a concentration in a water system).

For disinfectants applied in order to disinfect surfaces, information on the amount of product applied per m2 should be provided. If the product is to be diluted, the substance used for dilution and the final concentration of the product as well as the active substance in the solution - as a percentage - must be stated.

For product-type 21, the final concentrations of each biocidal component in the antifouling coating layer of the antifouling product and in addition the thickness of the film should also be given.

2.2.8 Point 7.8 Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human and animal health and the environment

Indicate the recommended duration of application and possible re-applications including estimated life-time of the treated article if relevant.

Describe, where relevant, how the applications should differ in different parts of the EU or under otherwise differing use-conditions.

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

- For disinfectants of Main Group 1, potential information on effects of temperature and humidity on the frequency of application must be supplied where relevant. The contact time needed to provide sufficient efficacy should be stated. The waiting period and, if applicable, the necessity of rinsing or wiping to avoid the presence of unacceptable residues from treated equipment in food or feed products should be given.
- For material preservatives of product-types 6, and 7 to 10, instructions on the minimum drying time or time to reach resistance to leaching (fixation) of the product in the material treated has to be described. Information on the effects of e.g. temperature and humidity on drying or fixation has to be given, i.e. when the treated material is dry enough for safe exposure of humans and the environment. Furthermore, when possible, a qualitative or quantitative method should be stated for determining that the proper drying or resistance to leaching has been achieved.
- For product-types 11 and 12, when used in an open system with process water, information on the minimum dilution or treatment time for the active substance in waste water should be given in order to assure a sufficient degree of degradation

or dilution before it is released to a water course to protect aquatic organisms from harmful effects.

- For pest control products of Main Group 3, for products used in e.g. fumigation, clearance times sufficient to protect bystanders etc. should be given.
- For molluscicides (product-type 16) and piscicides (product-type 17), necessary waiting periods should be given to prevent harm or dislodging of unacceptable residues from treated tanks or basins for e.g. the subsequent batch of aquaculture.
- For product-type 21, instructions on the minimum drying time of the coating and information on the effects of for instance, temperature and humidity on drying have to be given, i.e. it should be indicated when the coating is dry enough to be ready for launching and whether the coating should be washed before launching in order to reduce the primary release into the aquatic environment. Furthermore, a method for ensuring that a proper coating has been achieved should be given.

2.2.9 Point 7.9 Proposed instructions for use

Any instructions for the end user for proper use of the product should be given here.

The applicant should consider and define the parameters necessary for the effective use of the biocidal product, for example where this is relevant for the respective product:

- The methods by which the biocidal product is employed (for example: spray, wipe, disperse);
- The areas where the product should be applied (e.g. insecticide under refrigerator, in the cracks and crevice, with a bandwidth of 20 cm);
- The necessary preparatory measures, e.g. clean surfaces;
- The time that the biocidal product should be allowed to be in contact with the target (for example: minutes, hours, days);
- The frequency of application or re-application;
- The temperature range within which the biocidal product should be used;
- The dose rate;
- The necessary precautionary measures.

2.2.10 Point 7.10 Exposure data in conformity with Annex VI of this Regulation

According to Annex VI on the common principles for the evaluation of dossiers for biocidal products, an exposure assessment needs to be carried out for human and environmental populations for which exposure to a biocidal product occurs or can reasonably be foreseen.

For further guidance on exposure assessment of biocidal products see Parts B+C Evaluation and Assessment of Volumes III and IV of the BPR Guidance.

2.2.10.1 Point 7.10.1 Information on human exposure associated with production and formulation, proposed/expected uses and disposal

Sufficient information on exposure to the biocidal product likely to occur during the proposed conditions of use must be submitted. The information should include all relevant stages of production and formulation and of use and all possible exposure routes. Actual exposure data and/or calculations using recommended models are

acceptable. Test reports of any studies conducted because an exposure of the biocidal product on humans through the particular route is possible must be submitted. An expert judgment is needed to decide if any other studies are required (see section 1, point 4 of the Introduction toguidance on the BPR, Volumes I-IV, Part A: Information Requirements). A starting point is assessment of human exposures to biocides, see BPR Guidance, Volume III Human Health Parts B+C.

Please also follow guidance in section 1.2.6.1 of this guidance.

2.2.10.2 Point 7.10.2 Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal

Please follow guidance in section 1.2.6.2 of this guidance.

2.2.10.3 Point 7.10.3 Information on exposure from treated articles including leaching data (either laboratory studies or model data)

Please follow guidance in section 1.2.6.4 of this guidance.

2.2.10.4 Point 7.10.4 Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions

Possible incompatibility with any products or active substances should be mentioned.

REFERENCES AND BACKGROUND DOCUMENTS

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Appendix 1 Check list for efficacy tests preservatives

Question	Possible answers	Test not acceptable if
Is the identity of the tested BP clear?	+ or -	-
Is the tested product the reference BP/the BP applied for?	+ or -	Usually not if -
Is the tested material relevant for the intended PT and use?[1]	Written justification	Expert judgement
Is the loading/ concentration of the active substance in its matrix ≤ what is stated in the use descriptions?	+ or -	-
Is the test-protocol used relevant for the function of the representative BP/the BP applied for?	Written justification	Expert judgement
Are the tested organisms relevant for the intended use? [2]	+ or -	-
Is the test protocol depicting a relevant end point?[3]	+ or -	-
Have untreated controls been tested?[4]	+ or -	-
Have the controls (i.e. growth) been validated according to a relevant guidance or standard document?	Quantification	Expert judgement
Has the intended inhibition/killing/controlling effect of the harmful organisms occurred and does it fulfil the requirements set by a relevant guidance or standard document?	+ or -	-
Has statistical significance of the results been calculated?[5]	+ or -	-

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

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

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

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

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