Guidance on the Biocidal Products Regulation

Volume II: Efficacy
Part A: Information Requirements

DRAFT ADDENDUM to Version 2.0: New sections 2.2 & 2.3: "Point 7 Intended uses and Exposure “ ONLY

xxxxxxxx 2018
LEGAL NOTICE

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation (BPR). However, users are reminded that the text of the BPR is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.
1 DOCUMENT HISTORY

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NOTE FOR PEG CONSULTATION

New sections 2.2 & 2.3: “Point 7 Intended uses and Exposure “ ONLY.

To be included in Vol II A consultation. (N/B. the removal of Point 7 from Vol I A is under update to Volume A under current consultation)

Section headings left in to maintain section numbering

1 Part A: Introduction to the Guidance on Information Requirements

2 Part A: Dossier Requirements for Active Substances

2.1 Point 6 Effectiveness against target organisms

2.2 Point 7 Intended uses and exposure

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

The intended and possibly 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 envisaged use should be in accordance with the uses presented in section 2.1.1 of this guidance (BPR Point 6.1) and should be sufficient to allow an approximate and realistic estimation of the efficacy of the active substance and of human and environmental exposure to the product or treated article, respectively under realistic and representative use worst case conditions.

The uses envisaged should be relevant to the product type(s) under consideration. If the applicant wishes to exclude specific uses such as for reasons of protection of human health or the environment these should also be specified here.

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.

2.2.2 Point 7.2 Product-type(s)

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

2.2.3 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 envisaged. Use means all operations carried out with a biocidal product, including storage, handling, mixing and application.

The information on the envisaged use in accordance with BPR Point 6.1 (see section 2.1.1 of this guidance) and 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 efficacious.
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.

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

Indicate users with the help of the user categories:

- 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.

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1 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
2.2.4 Point 7.5 Likely tonnage to be placed on the market per year and, where relevant, for the envisaged 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), and where relevant for the envisaged 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.

2.2.5 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 II, III and IV of the BPR Guidance structure.

2.2.6.1 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.

2.2.6.2 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.

2.2.6.3 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).

2.2.6.4 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 envisaged 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.

2.2.6.4.1 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 envisaged 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.

Further Guidance:

• 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 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.

### 2.2.6.4.2 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 of this guidance. 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).
Part A: Dossier Requirements for Biocidal Products

3.1 Point 6 Effectiveness against target organisms

3.2 Point 7 Intended uses and exposure

The SPC 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.\(^2\)\(^3\) The information indicated on the label, instructions for use\(^4\) and other information sources (e.g. web pages) should be consistent with the information in the Summary of the Biocidal Product Characteristics (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) 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, first aid instructions and emergency measures to protect environment, also instructions for safe disposal of the product and 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.

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

Please follow guidance in section 2.2.1 of this guidance.

3.2.2 Point 7.2 Product-type

Please follow guidance in section 2.2.2 of this guidance.

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

Please follow guidance in section 2.2.3 of this guidance.

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

Please follow guidance in section 2.2.4 of this guidance.

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\(^2\) 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.

\(^3\) 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

\(^4\) Article 69(2) of BPR.
3.2.5 **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 envisaged 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.

3.2.6 **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, 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. A description of the application technique (e.g. dipping, spreading, spraying, automatic/manual dosing etc.) should be included. The substances that may have to be added to the solution and 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.

3.2.7 **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 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.
3.2.8  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.

3.2.9  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 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.

3.2.10 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.

Further guidance on exposure assessment of biocidal products see Parts B+C Evaluation and Assessment of Volumes II, III and IV of the BPR Guidance structure.

3.2.10.1 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 1.2 point 4 of this guidance). 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 2.2.6.1 of this guidance.

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

Please follow guidance in section 2.2.6.2 of this guidance.

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

Please follow guidance in section 2.2.6.4 of this guidance.

3.2.10.4 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.