

# **BIOCIDAL PRODUCTS - A GUIDE FOR APPLICANTS**

- applying for authorisation/registration of biocidal products under the Biocidal Products Directive 98/8/EC and Biocides Act (RTI, 09.06.2009, 29, 174)

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## Preface

This guide deals with the European Union legislation on the authorisation and registration of biocidal products and related application procedures. It is intended to facilitate the compilation of applications, harmonise the application procedures within the EU Member States (MS), and thus promote the effective processing of applications.

- Chapter 1: The general aspects of the Biocides legislation in the European Union.
- Chapter 2: Authorisation procedure of biocidal products at the Member State level including guidance how to make an application, which application forms you will need, what your dossier shall include etc.
- Chapter 3: Other procedures for biocides set out by the Biocidal Products Directive.
- Chapter 4: Fees
- Chapter 5: Contact details of the Competent Authority (CA)

Chapters 1 to 3 have been written in co-operation with other Member States whereas Chapters 4 and 5 are Member State specific. This guide applies in Estonia.

Evaluation and approval of biocidal active substances at the EU level is described in the Biocidal Products Directive and at the web-site of the European Commission: <http://ec.europa.eu/environment/biocides/index.htm> .

Note that REACH Regulation (1907/2007/EC) applies also to the biocidal products. For further information, please consult:

- European Chemicals Agency ECHA, [http://echa.europa.eu/home\\_en.asp](http://echa.europa.eu/home_en.asp)
- National REACH Helpdesks, <http://echa.europa.eu/web/guest/support/helpdesks/>
- Estonian REACH Helpdesk, <http://reach.sm.ee/>

## Legal status

The guidance is not legally binding and you are free to take other action. However if you do follow the guidance you will normally be doing enough to comply with the law. Ultimately, only the courts can give an authoritative interpretation of the law.

This guidance is a living document. It will be amended in accordance with developments of the product authorisation system.

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## APPENDIX 1 Post-Annex I timelines

# 1 INTRODUCTION TO BIOCIDAL PRODUCTS LEGISLATION

## 1.1 General

Biocidal Products Directive (BPD) **98/8/EC**<sup>1</sup> regulates the authorisation of biocidal products for placing on the European Union market and use. After the execution of the BPD it is not allowed to place biocidal products on the market [or use them] without an authorisation or registration from a Competent Authority (CA) in a Member State (MS) of European Union (EU). MS can only authorise or register biocidal products which contain active substances included in the Annex I or IA of the BPD.

The key principle of the BPD is that if a product is authorised or registered in one MS according to the BPD, authorisation/registration shall be mutually recognised in other MS as well. However, the CA has possibility to deviate from the mutual recognition for example if the target species is not present in harmful quantities in the MS or relevant circumstances of use differ significantly from those in the MS where the biocidal product was first authorised.

Annex I is the main list of active substances permitted in biocidal products. Products containing active substances listed on Annex I require **authorisation** (Chapter 2). In certain cases simplified procedures are applied instead of full authorisation (Chapter 3).

So called low risk products containing active substances included in the Annex IA of the BPD are subject to **registration** procedure (Chapter 3) in the MS.

Basic substances included in the Annex IB have only minor use in biocides and therefore they are excluded from the authorisation/registration procedure. Basic substances i.e. substances included in Annex IB can not be marketed for biocidal use. Currently, there are no substances in Annex IB.

The BPD contains detailed rules about the data requirements, principles followed in the evaluation and decision making, confidentiality and access to data, information to be marked in labels, commitments for reporting of MS, procedures for committees and activities in transitional period. The key aims of the BPD are to establish a single European market for biocidal products while ensuring a high level of protection for human health and the environment. The BPD contains a principle of comparative assessment which enables exclusion of an active substance from the Annex I in case that there are significantly less harmful active substances available for the same use purposes.

All procedures related to authorisation and registration of biocidal products are subject to national fees. Please see chapter 4 for details.

## 1.2 Implementation of the BPD in Estonia

The BPD has been implemented in Estonia by the Biocides Act (RTI, 09.06.2009, 29, 174). The CA for authorisation and registration of biocidal products in Estonia is Health Board (see contact details in Chapter 5).

Chemicals Act, (RTI, 28.05.1998, 47, 697) provides the legal basis for organisation of the handling of chemicals and for the restriction of economic activities involving the handling of chemicals, and provides the principal safety requirements for the handling of chemicals and the procedure for notification of chemicals. (Act is available only in Estonian)

Regulation of the Minister of Social Affairs No 122 (RTL, 21.12.2004, 154, 2326) applies the specific labelling of biocidal products. (Regulation is available only in Estonian)

Fees are regulated by the State Fees Act (RT I 2010, 21, 107). (State Fees Act is available only in Estonian).

### ***1.3 Transitional period***

Approval of biocidal products containing existing active substances (substances on the EU market before 14th May 2000) will be fully harmonised with the EU authorisation/registration procedures after the transitional period. Transitional period is defined as a 10-year period at maximum from the date the BPD was to be implemented i.e. from 14 May 2000 to 14 May 2010. However, the transitional period has been prolonged until 14 May 2014 (Directive 2009/107/EC amending the BPD <sup>2</sup>). For some existing active substances the transitional period may be shorter than 13 years, i.e. until the decision on the inclusion of the active substance into Annex I or IA has been made in accordance with the BPD.

During the transitional period products containing existing active substances which are under evaluation at the EU level, but not yet on Annex I or IA, can continue to be placed on the market. In Estonia, however, national authorisation is required for all product types before import, marketing and use in Estonia (further information is available <http://www.terviseamet.ee/en/chemical-safety/biocides.html>).

### ***1.4 Two-stage regime of evaluation***

Under the BPD active substances and biocidal products are evaluated to ensure that they pose no unacceptable risks to humans, animals or the environment.

The two levels of evaluation relate to active substances and biocidal products:

- **For active substances**; evaluation of a dossier and agreement across all MS of the EU that an active substance can be used in biocidal products which are being supported without posing unacceptable risks to humans, animals and the environment and are shown to be sufficiently effective. When such an agreement is reached the active substance is listed on Annex I, IA or IB and can subsequently be considered for use in a biocidal product. The procedure is described in Art 11 of the BPD.
- **For biocidal products**; evaluation by a MS of a dossier submitted for authorisation/registration of a product containing specific active substance(s) listed on Annex I or IA, to determine if a product is effective in the intended uses and can be used without posing unacceptable risks. If this is the case, products can be authorised for supply, storage and use, subject to any specified conditions, in that MS. A system of mutual recognition allows for this authorisation/registration to be extended to other MS, following an application to them, unless there are deemed to be exceptional circumstances.

### ***1.5 Review programme of existing active substances***

During the transitional period existing active substances will be evaluated in a review programme laid down in the European Commission (EC) Regulation 1896/2000 <sup>3</sup>. The lists of existing active substances were first published in the EC Regulation 2032/2003 <sup>4</sup>. These lists

were updated in further EC Regulations and the different versions were consolidated in the EC Regulation **1451/2007**<sup>5</sup>. These Regulations are directly applicable legislations within the Community and binding to the MS as well as to the companies. Further information on the review programme and the Commission Regulations are available in the following Internet-sites:

- European Commission: <http://ec.europa.eu/environment/biocides/index.htm>
- Health Board, Department of Chemical Safety: [www.terviseamet.ee](http://www.terviseamet.ee)

### ***1.6 New active substances***

If a biocidal product contains a new active substance for the certain types of biocidal products, i.e. a substance that has NOT been on the market in that use in the EU before 14th May 2000, authorisation/registration is to be applied for according to the procedure of Chapter 2 of the Biocides Act (i.e. fully according to the BPD) before the product is placed on the market. In that case the decision on the inclusion of the active substance in the Annexes of the BPD is first made at the EU level (Art 11 of the BPD) and following such a decision the CA in the MS will decide on the authorisation/registration of the product nationally. The same procedure is followed if the product type of a product is not listed in the Annex I inclusion of the active substance.

### ***1.7 Active substances withdrawn from the review programme***

There may be some existing active substances which are not supported by the companies in the review programme. If they are subsequently to be used in biocidal products in those product types they will be treated in the same way as new active substances, i.e. they cannot be used in biocidal products until they have been included in the Annex I / IA for that product type.

- Consolidated list of active substances withdrawn and for which a decision of non-inclusion into Annex I or IA of Directive 98/8/EC has been adopted is available at: [http://ec.europa.eu/environment/biocides/non\\_inclusions.htm](http://ec.europa.eu/environment/biocides/non_inclusions.htm) .

### ***1.8 What is a biocide?***

A biocide is an active substance, or a preparation containing at least one active substance, intended to destroy, deter, render harmless, prevent the action of or exert some controlling effect on harmful/unwanted organisms by chemical or biological means.

An active substance is a substance or micro-organism having general or specific action on or against a harmful organism, i.e. an organism which needs to be controlled, or which has a detrimental effect for humans, their activities or the products that they use or produce, or for animals or for the environment.

Biocidal products have a very wide range of uses including disinfectants for home and industrial use; preservatives for manufactured and natural products; non-agricultural pesticides for use against insects, slugs and snails, rodents and other vertebrates. They also include a number of very specialised products such as embalming/taxidermist fluids and antifouling products.

Biocidal products are divided into four main groups: disinfectants and general biocidal products, preservatives, pest control, and other biocidal products. Altogether these main groups contain 23 product types (Table 1).

**Table 1** Biocidal product types (PT)

<b>MAIN GROUP</b>	<b>Product type</b>
I Disinfectants and general biocidal products	1. Human hygiene biocidal products
	2. Private area and public health area disinfectants and other biocidal products
	3. Veterinary hygiene biocidal products
	4. Food and feed area disinfectants
	5. Drinking water disinfectants
II Preservatives	6. In-can preservatives
	7. Film preservatives
	8. Wood preservatives
	9. Fibre, leather, rubber and polymerised materials preservatives
	10. Masonry preservatives
	11. Preservatives for liquid-cooling and processing systems
	12. Slimicides
	13. Metalworking-fluid preservatives
III Pest control	14. Rodenticides
	15. Avicides
	16. Molluscicides
	17. Piscicides
	18. Insecticides, acaricides and products to control other arthropods
	19. Repellents and attractants
IV Other biocidal products	20. Preservatives for food or feedstocks
	21. Antifouling products
	22. Embalming and taxidermist fluids
	23. Control of other vertebrates

## 2 AUTHORISATION OF A BIOCIDAL PRODUCT

### 2.1 *Who can apply for authorisation?*

Application for authorisation shall be made by, or on behalf of, the natural person or legal entity responsible for the first placing the product on the market in Estonia. The applicant may be either native or foreign but shall have a permanent office within the European Community. If the applicant is not the manufacturer of the product or its active substance, he has to present a Letter of Access providing him the right to represent his principal in Estonia in matters concerning the product or the active substance. For more details about requirements for Letter of Access see Chapter 2.5.3.

- **Applicant** may be
  - the future authorisation holder or
  - a company or person who handles practical issues of the application on behalf of future authorisation holder(s).
- **Authorisation holder** is person/entity to whom the decision on authorisation is issued to. **Responsibility for the placing the product on the market, classification and labelling etc. always lies on the authorisation holder.**

Please note that different MS may have different interpretations on the applicant, i.e. they may require that application shall always be made by the future authorisation holder.

### 2.2 *When to apply for authorisation?*

- **Products already on Estonian market:** Authorisation has to be applied for within two years after the entry into force of the Annex I inclusion directive of the active substance used in the product. If a product contains more than one active substance the deadline for the product application is the one set out in the latest of the inclusion directives relating to its active substances. Authorisation has to be applied for at the latest by the date in Annex I inclusion of the active substance used in the product. The inclusion directives can be found at:  
[http://ec.europa.eu/environment/biocides/annexi\\_and\\_ia.htm](http://ec.europa.eu/environment/biocides/annexi_and_ia.htm)

If a product belongs to several product types, authorisation for each product type shall be applied for separately. The deadlines for product applications are determined by the inclusion of the active substance to certain product type.

**Note! If no application** for the authorisation of a biocidal product is submitted by the given deadline the product shall be phased out of the market within 6 months from this deadline for the application. The 6-month deadline for the phasing out of the products not supported refers to the first placing on the market. For subsequent storage and stocks a period of grace may be granted (Art 7(3) of the BPD).

The various deadlines for applicants and authorities are presented in detail in Appendix 1.

- **Products that are not on Estonian market:** If you intend to start to place on the market a new biocidal product with active substance(s) which is already included in Annex I for the relevant product type there are no binding deadlines for submitting the application for authorisation. Placing the product on the market is not allowed before authorisation.

- **Products containing new active substances:** If you intend to start to place on the market a biocidal product with a new active substance which is not yet included in Annex I in accordance with the procedures laid down in Article 11 of the BPD. Only after Annex I inclusion the product can be authorised. Application may be submitted at any time. Placing the product on the market is not allowed before authorisation.

Uses of active substances in product types not notified and therefore not included in the review programme of existing active substances are treated the same way as products containing new active substances.

### ***2.3 Issues to consider before preparing application***

In addition to the status of the active substances in Annex I there are a few other things to consider before preparing an application for a biocidal product:

- Make sure that you consider the right product type with respect to the use purpose and pattern of your biocidal product.
  - Further information about scope of the BPD is compiled by the European Commission in the Manual of Decisions (MoD), <http://ec.europa.eu/environment/biocides/manual.htm>  
If you have any doubts, whether your products or active substances are biocides or to which product type they belong, contact the CA.
- Check that the active substance in your product is technically equivalent to the one covered by the Annex I inclusion directive. This means that the active substance has to be so similar in purity, impurities and possible isomers that the active substance evaluation for the Annex I inclusion is still applicable. In case of similarity, an access to the data package used for the inclusion of the active substance or equivalent data are needed. If the active substance is not considered equivalent corresponding data on the active substance as submitted for the Annex I active substance are needed. The CA makes the final decision on the equivalence based on the data submitted by the applicant.
  - Guidance on technical equivalence is available at: [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/guidance-documents)
- Consider carefully on the use purpose and pattern of your product. Does the risk and efficacy assessment conducted with the representative product in the active substance evaluation for the Annex I inclusion directive apply to the use of your product and there are no further elements to be taken into account in the product phase? Applicants should always consider if the efficacy data meet the requirements. If not, further data and risk assessment are necessary. The applicant is responsible for providing further data and the outstanding risk assessment for the product. See further details in Chapter 2.4.4.

## ***2.4 Structure of application and related dossier***

### **2.4.1 General requirements for documentation**

#### **Format**

The MS and the European Commission have agreed that the information included in dossiers on biocidal products should be submitted in a standard format <sup>6</sup>. The format is the same in whichever MS the dossier is submitted. This will make it easier for the applicants to know exactly what must be done and what a dossier must contain.

The application consists of an application form and a dossier. The applicant is responsible for providing the required information and for including the study reports and other documents needed. The evaluation of the data provided by the applicant will form the basis of the evaluation by the CA.

#### **Application form**

For the present, application form consists of two parts. At a later date the whole form will be available at the European Register for Biocidal Products (R4BP).

The first part of the application form for authorisation of a biocidal product is made via the R4BP. The register is maintained by the European Commission. The application form will be available in all of the EU official languages.

In the register the applicant fills in the details of the applicant and the product. The applicant has to indicate in which MS he applies for the first product authorisation and in which EU/EEA countries for the mutual recognition. Furthermore, the applicant is requested to indicate in which MS the product is already on the market. **Note!** The product may only stay on the market of a particular MS without interruption if this MS is indicated in the application form generated via the register and submitted to all of these MS by the deadline of the application.

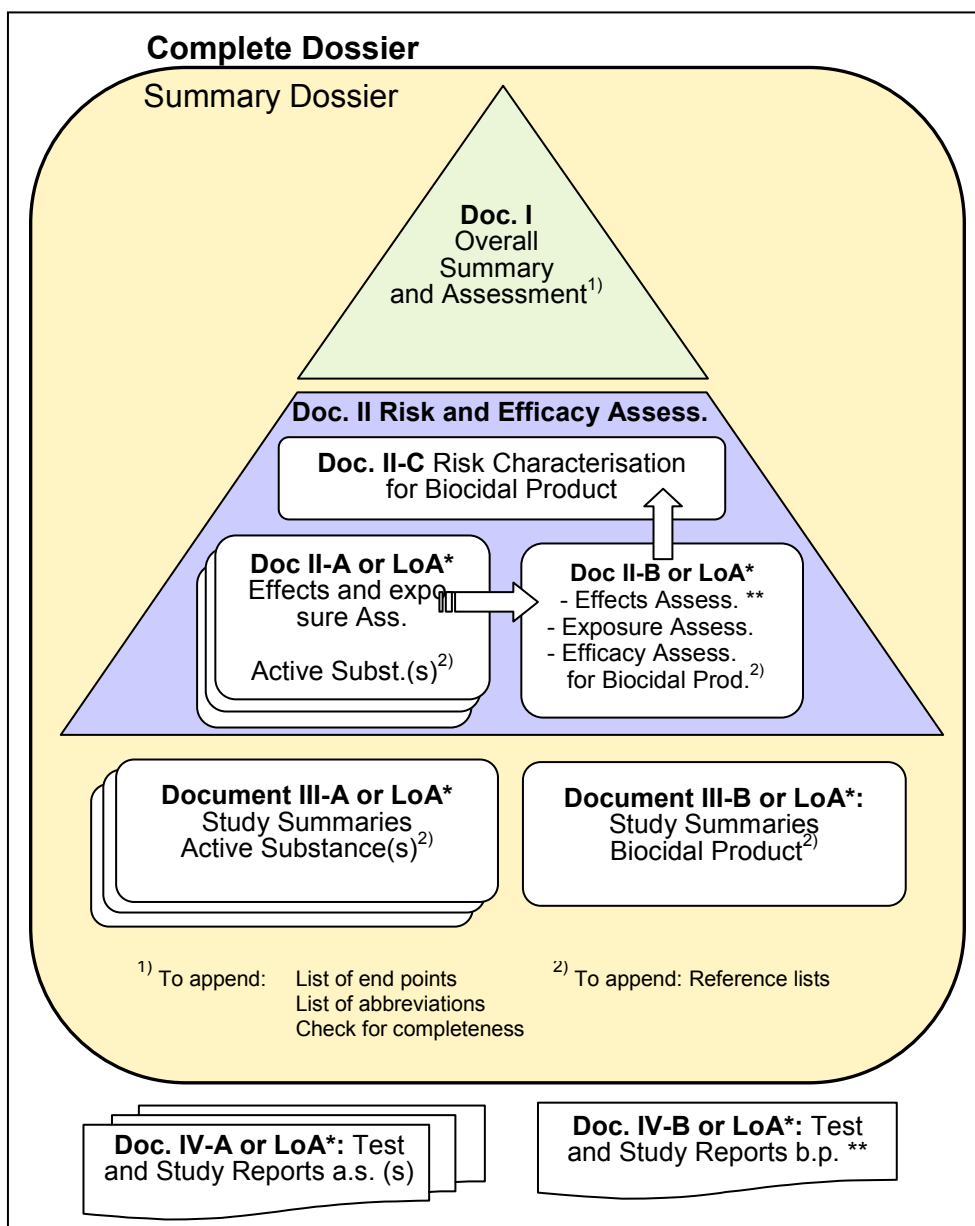
- R4BP: <https://webgate.ec.europa.eu/env/r4bp/>

The second part of the application form is a word-document which contains further details about the product and the type of application.

#### **Dossier**

Product dossier consists of data and documents as presented in Figure 1 <sup>6</sup>. In addition, proposal for Safety Data Sheet (SDS) and proposal for labelling in the official language i.e. in Estonian shall be prepared by the applicant.

**Figure 1** The structure of the dossier documentation required for the application for authorisation of a biocidal product, provided that the active substance is listed in Annex I.



\* LoA = Letter of access

\*\* In the case of applications for registration of low-risk products, the effects assessment is confined to data on the active substance(s) only. In general, the data to be provided in Doc. IV-B and III-B are limited.

## **Practical details on submission of the application**

The application shall be sent to Health Board.

Technical requirements:

- one paper copy of the whole application (application form, Doc I – IV, Safety Data Sheet (SDS), draft labels, use instructions). Docs I-II must be MS Word-documents or MS Word-compatible. Doc III i.e. study summaries must be either in IUCLID 5 or Word-documents
- one electronic copy of the whole application on CD-rom
- language:
  - draft SDS, draft label and use instructions must be available in Estonian
  - other documents are accepted in Estonian or English. If the application is for an authorisation, which is to be used later for the purpose of mutual recognition, it is recommended that the dossier is submitted in English.

### **2.4.2 General principles on the submission of experimental studies**

The applicant shall submit to the CA all data on physical-chemical properties, toxicological, environmental fate and ecotoxicological effects, efficacy and other properties of the chemical that is necessary for the assessment of the conditions for issuing an authorisation. The Technical Notes for Guidance (TNsG) on Data Requirements <sup>7</sup> describes the data needed which was originally set by Annexes II and III of the BPD. MS specific data may be required in some cases (e.g. country specific exposure data).

The original study reports shall be attached to the application. However, the original study reports (Doc IV) and the study summaries (Doc III) are not required if the applicant has a written proof of his right to refer to them in his application (Letter of Access, LoA) and these documents have already been submitted either for the evaluation of the active substance for Annex I or in another application for product authorisation. The appendices of the application shall be numbered using the codes in the TNsG on Data Requirements <sup>7</sup>. If several studies are related to one item, they should be distinguished by lower case letters following the appendix number (e.g. 6.1.1a, 6.1.1b).

Studies must be conducted and reported either according to the methods mentioned in the Council Regulation 440/2008 on test methods or according to the OECD (Organisation for Economic Co-operation and Development) guidelines for testing of chemicals. The main rule is that studies must also comply with the principles of Good Laboratory Practice (GLP) and the study report shall contain a certificate of this. Further guidance on GLP is given in the TNsG on Data Requirements, Chapter 6 <sup>7</sup>.

If it is not technically possible or scientifically justifiable to submit the required information or carry out the required studies, or if the studies are not conducted according to the guidelines referred above, then the reasoning must be given in the application. If such justifications are not given, or if the application is otherwise insufficient, the CA will ask the applicant to submit the missing information and studies. The processing of the application will continue after the supplementary data has been presented.

The BPD encourages limiting the duplication of testing on vertebrate animals, whenever possible. According to this principle, before starting a new test, literature searches should be conducted and the other owners of the required documentation should be consulted in order to

find out, whether the available information is sufficient for the reliable evaluation of the possible hazards of the chemical. In order to receive the contact details of other data owners the applicants are invited to contact the CA. If information is available, but it is inadequate, the scope of the additional studies required will be considered on a case-by-case basis.

### 2.4.3 Data requirements

Data requirements for the biocidal active substances and products are listed in Annexes II-IV of the BPD (see table 2).

Table 2 Data requirements for active substances and biocidal products.

	<b>BPD Annex number</b>
Core data for a.s.	II A
Core data for b.p.	II B
Additional data for a.s.	III A
Additional data for b.p.	III B
Data for a.s.	IV A
Data for b.p.	IV B

Further advice is available in the TNsG for Data Requirements <sup>7</sup>.

### 2.4.4 Risk assessment to be prepared by the applicant

The applicant has to carry out a preliminary risk assessment for the product if the risk assessment conducted with the representative product in the active substance evaluation does not cover the applied uses. If risk assessment of active substance covers the intended uses of the product and the applicant has letter of access to the data, no extra assessment is needed.

The preliminary risk assessment for a product is to be based on:

- the effects assessment for all active substances in a product
- the effects assessment for the biocidal product including substances of concern
- assessment of physical-chemical properties of the product
- the exposure assessment for the biocidal product including substances of concern: Where appropriate, the applicant can adopt or adapt parts from the Doc. II-B submitted with the application(s) for Annex I inclusion of the active substance(s).
- the assessment of unacceptable effects of the product
- the risk characterisation for the biocidal product: Where appropriate, the applicant can adopt or adapt parts from the Doc. II-C submitted with the application(s) for Annex I inclusion of the active substance(s). In any case, the risk characterisation must address all uses for which the product in question is intended to be used.
- the assessment of efficacy of the product.

As outlined above no reassessment of the human health, environmental effects and physical-chemical properties should be carried out for active substances already included in Annex I or IA. Hence, the documents (Doc. II-A) provided with such applications should be used as basis for the effects assessment for the product. Product-specific data as required by Annex IIB and IIIB of the BPD have to be provided, summarised and evaluated by the applicant.

More guidance is available on TNsG for Preparation of Dossiers and Study Evaluation<sup>6</sup> and TNsG on Product Evaluation<sup>8</sup>. Detailed advice on risk assessment is given in Technical Guidance Document on Risk Assessment (TGD)<sup>9</sup> and Emission/Exposure Scenario Documents available at JRC web-site [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides)

## **2.5 Confidentiality, data protection**

### **2.5.1 Confidentiality**

Article 19 of the BPD (Biocides Act §27) establishes conditions for the confidentiality of information which an applicant considers to be commercially sensitive (i.e. disclosure of which might harm the applicant industrially or commercially). This information should only be made known to the competent authorities and the European Commission. A system of confidentiality is necessary to protect the results of the research and development of individual companies by not allowing third parties to use the information for their own commercial benefit. The Article lists items which can not be claimed to be confidential.

The applicant must indicate, with full justification, which information is considered to be confidential. The CA will then decide whether the justification is sufficient. The identity of non-active substances not contributing to the classification of the product will always be confidential if requested by the applicant. Other information which may be considered as confidential includes the following:

- technical details of the manufacturing process
- names and addresses of test laboratories, sites and personnel
- individual medical details.

Such confidentiality is normally for an indefinite period, and is independent of data protection. Therefore, even after a period of data protection expires, confidential information will continue to be confidential.

Confidentiality operates independently of the patent protection requirements, and without prejudice to Council Directive 90/313/EEC on the freedom of access to information on the environment, or to the provisions of Directives 67/548/EEC, 1999/45/EC and 95/46/EC.

### **2.5.2 Data protection**

Data submitted to the CA in connection to application can not be used for the benefit of second or subsequent applicant with out letter of access (LoA) from the owner of the data unless the data protection period has expired. Rules for data protection are listed in Article 12 of the BPD.

- Further guidance is given at the General Note on Data Protection which is available at the Commission web-site: <http://ec.europa.eu/environment/biocides/borderline.htm> .

### **2.5.3 Letter of access**

According to Article 12 of the BPD a letter of access (LoA) is required if the applicant is to make use of proprietary data from the original applicant or from someone whose right to grant such permission can be attributed to the original applicant.

To simplify and to make the application process more efficient, the following will be required of letters of access:

- the letter of access shall be marked with a date
- the letter of access shall be signed by person/persons authorised to sign for the principal
- a specified list of the proprietary studies to which the applicant has a right to make reference shall be enclosed
- if the letter of access is to be limited in time, it must be stated clearly (in such cases authorisation will be approved for the specific period of time).

Withdrawal of the LoA prior to its expiry date does not affect the validity of authorisation issued on the basis of the LoA in question.

Please notice that an incomplete letter of access may result in a dismissal of the application.

## ***2.6 Handling of application***

### **2.6.1 Check for completeness**

After receiving the application the CA confirms receipt of it via the R4BP. Processing of the application starts after the State fee has been paid.

The CA starts the handling of the application by checking that all the required documents have been submitted and the technical quality (number of copies, order of files, etc.) is acceptable. This is called completeness check. When necessary, the applicant will be asked to complete his application. When new appendices are submitted, updated reference lists shall also be attached. If the application is not completed before a set deadline, the CA can reject an insufficient application.

The MS have agreed on the harmonised timelines for handling of applications for authorisation. The CA carries out the completeness check within 3 months after the reception of an application. MS confirms acceptance or rejection of the application via the R4BP.

**Note!** If application is rejected as non complete the product shall be phased out of the market in 6 months from this rejection. The 6-month deadline for the phasing out of products not supported refers to the first placing on the market. For subsequent storage and stocks a period of grace may be granted (Art 7(3) of the BPD). The various deadlines for applicants and authorities are presented in detail in Appendix 1.

### **2.6.2 Evaluation of the dossier**

When the application and its appendices have been found to be sufficient the CA starts the evaluation of the dossier. CAs' evaluation is based on the risk assessment made by the applicant as much as possible. In the evaluation the properties of the product and the relevant aspects of use are assessed, i.e. physical-chemical properties, analytical methods, efficacy and possible resistance, human health effects and exposure and environmental effects and exposure. Principles and guidance for the evaluation of a product dossier are given in TNsG on Product Evaluation<sup>8</sup>.

The CA writes the assessment report in Estonian or in English. If the application is for an authorisation, which is to be used later for the mutual recognition, English should be used. The CA sends the assessment report to the applicant.

If new data is submitted for the evaluation of the product in addition to those evaluated for the Annex I inclusion of the active substance the CA will evaluate this. If necessary this evaluation may be discussed with other member state's CAs. If it comes up in the evaluation that further data are needed this data can be required in a reasonable time frame and the deadline for the decision by the CA will be postponed ("stopping the clock").

### **2.6.3 Decision on authorisation**

The CA normally makes the decision whether to authorise or not the product within 12 months after approval of the application as complete. See the corresponding timelines for mutual recognition in Chapter 2.9. The ultimate deadline for decision for products already on the market is given in the Annex I inclusion directive of the active substance.

The CA will give a written authentication of the authorisation (i.e. decision). Authorisation can be granted for a maximum period of ten years. In practice this means until the expiry date of the Annex I inclusion of the active substance. It is stated in the decision when re-authorisation shall be applied for. The application for re-authorisation has to be made in the same way as the first application for authorisation. Any new studies required by the CA and any other possible new studies and updated reference lists must be submitted in this connection. Any new information has to be indicated in the application.

The CA issues the authorisation with a national number and updates the R4BP accordingly.

The decision on authorisation will be in Estonian or in English.

Assessment report is transmitted to the applicant together with the decision.

## ***2.7 Prerequisites for authorisation of biocidal product***

The CA will evaluate the product dossier according to the common principles laid down in Annex VI of the BPD. As the result of this evaluation MS shall authorise a biocidal product only if:

(a) The active substance(s) is listed in Annex I or IA and requirements laid down in these Annexes (i.e. specific provisions) are fulfilled. The applicant must have access on the data used for the Annex I inclusion or corresponding own data. Technical equivalence of the active substances from different sources shall be proven.

(b) Certain conditions are fulfilled when the biocidal product is used as authorised (i.e. according to the instructions for use):

- The biocidal product is sufficiently effective and has no unacceptable effects on target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates.
- The biocidal product has no unacceptable effects itself or as a result of its residues on human or animal health, directly or indirectly.
- The biocidal product has no unacceptable effects itself or as a result of its residues on the environment.

- The nature and quantity of its active substances and any toxicologically or ecotoxicologically significant impurities and co-formulants, and its toxicologically/environmentally significant residues can be determined.
- The physical and chemical properties of the biocidal product have been determined and deemed acceptable for purposes of the appropriate use, storage and transport.
- A biocidal product classified as toxic, very toxic or as a category 1 or 2 carcinogen, as a category 1 or 2 mutagen or as toxic for reproduction category 1 or 2 shall NOT be authorised for marketing or use by general public.

Authorisation decision may include conditions for use in order to meet the above mentioned requirements for authorisation of a biocidal product. These conditions may deal with for example user type (i.e. industrial, professional, non-professional), use conditions (e.g. Hazard Class of treated wood), application rates or other details of dosage.

## ***2.8 Modification and cancellation of authorisation***

Any change in the applicant, i.e. if the identity of the company responsible for placing the biocidal product on the Estonian market changes, have to be notified to the CA without in advance. When necessary, a new letter of access from the owner of the documentation shall be submitted to make it possible to refer to the documentation submitted earlier. Also, changes in the product name shall be notified in advance to the CA. In this case renewed labels, safety data sheets and instructions for use must also be submitted to the CA. The CA will confirm or refuse these changes in writing.

If the composition of the product changes, a written request to the CA must be made 6 months in advance. The request shall include detailed information on the new composition and any possible changes in classification, labelling etc. The planned timetable for the change shall also be presented as well as a clearly reasoned account of the feasibility of using the risk assessment for the previous formulation in the evaluation of health and environmental effects, physical-chemical properties and efficacy for the new formulation. The *CA will make a decision on the composition change*. However, if the suggested change is fundamental, i.e. the risks to health or the environment or the efficacy can not reliably be assessed on the basis of the data for the approved product, the product is considered to be a new one. In such a case new authorisation must be applied.

The CA can cancel an authorisation or alter its conditions, if it becomes evident after the authorisation that the product no longer fulfils the prerequisites for authorisation or the conditions attached to the decision. Also the authorisation holder may propose the cancellation of authorisation to the CA. In such cases proposals concerning the necessary transitional periods for finishing the manufacturing, importing, placing on the market and use shall also be presented.

Guidance for situations where modification or cancellation has to be taken into account in the mutual recognition is given in Chapter 2.9.

## ***2.9 Mutual recognition of authorisation***

A biocidal product already authorised or registered by one MS ("reference MS") can be authorised or registered in another MS ("concerned MS") via mutual recognition procedure

(Art 4 of the BPD.). Concerned MS can request to change conditions of authorisation in following cases:

- the target species is not present in harmful quantities
- unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated
- the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those in the MS where the biocidal product was first authorised, and an unchanged authorisation may therefore present unacceptable risks to humans or the environment.

Conditions that may be changed are (Art 20(3) (e), (f), (h), (j), and (l)):

- directions for use and the dose rate
- particulars of likely direct or indirect adverse side effects and any directions for first aid
- directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;
- the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, measures for protection and feedingstuff and directions to prevent animals from being exposed)
- information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water.

### **When to apply**

For products already on the MS market mutual recognition shall be applied at the same time as the first application is made for (see Chapter 2.2). If application is not made in due time product must be removed from the market within 6 months as explained in Chapter 2.2.

For products that are not on MS market, mutual recognition can be applied for at any time after the first authorisation has been granted.

### **How to apply**

Application for mutual recognition takes place in two phases. In a first step the following is submitted **by the deadline mentioned above**:

- A filled in and signed paper copy of the application form generated via the R4BP in Estonian or English (see Chapter 2.4.1).

In a second step following is submitted within two months of the having obtained the first authorisation:

- a certified copy of the first authorisation granted including translation into Estonian or English,
- product assessment report by the reference MS
- one electronic copy of the summary dossier, where the first member state has filled in the evaluation boxes
- draft label, use instructions and SDS in Estonian.

- Fee for handling the application has to be paid (see Chapter 4).

### **Practical details on submission of the application**

- see Chapter 2.4.1/ Practical details on submission of the application.

The CA confirms the receipt of the application via the R4BP. Within 120 days the CA issues decision with a national number and updates the R4BP accordingly.

### **2.10 Provisional authorisation**

Provisional authorisation (Art 15(2) of the BPD) may be granted for a product containing at least one new active substance *i.e.* active substance that was not used in biocidal products before 14 May 2000. Also MS other than the one in charge of evaluating the new active substance dossier ('rapporteur') may grant a provisional authorisation to a biocidal product containing this active substance once the rapporteur has submitted the CA report with a recommendation to include it in Annex I to the BPD.

Provisional authorisation may be granted for three years at maximum. It may be extended by one more year if the handling of the active substance has not been completed at the EU level. After the inclusion of the new active substance in Annex I, an application for a regular authorisation is to be submitted.

Provisional authorisation is not subject to mutual recognition.

#### **How to apply**

The dossier required for provisional authorisation consists of an application form and a dossier. Filling the application form is explained in Chapter 2.4.1. In case the product and/or its intended use is the same as used in the active substance risk assessment as a representative product the data requirements are as follows:

- details of the applicant, manufacturer of the active substance(s) and the product
- LoA to data used for risk assessment of the new active substance(s)
- identity of the biocidal product:
- intended uses
- classification, packaging and labelling, including a draft label and use instructions
- Safety Data Sheet

If the product and/or its intended use are not the same as used in the active substance risk assessment a full dossier in accordance with Chapter 2.4 has to be submitted. In case the product contains also existing active substances dossier or LoA to those dossiers are required.

### **Practical details on submission of the application**

- see Chapter 2.4.1/ Practical details on submission of the application

The CA confirms the receipt of the application via the R4BP. If the product or its intended use differs from that under evaluation by the rapporteur, the MS must evaluate the data before granting authorisation. After evaluation of the dossier the CA issues decision with a national number and updates the R4BP accordingly. The fee (see Chapter 4) has to be paid.

## **3 OTHER PROCEDURES FOR BIOCIDES**

### ***3.1 Registration of low-risk biocidal product***

A low-risk biocidal product contains only active substances included in the Annex IA. It may not contain any other substance classified as hazardous being in the product in such a concentration that leads to the classification of the product as hazardous or a substance causing other ground for concern. In order to meet the criteria for "low risk" the biocidal product may only pose a low risk to humans, animals and the environment under the conditions of use. The active substances on Annex IA cannot be classified as carcinogenic, mutagenic, toxic for reproduction or sensitising and cannot be bioaccumulative or not readily biodegradable.

Low risk products are subject to registration procedure in the MS (Art 3(2) (i) of the BPD). With respect to data requirements the product registration procedure is lighter than authorisation. The time frame given for the CA to handle the application for registration is shorter than for authorisation i.e. 60 days.

#### **When to apply**

Timelines for application are as described in Chapter 2.2.

#### **How to apply**

Principles in Chapters 2.1-2.3 apply for the registration also. The dossier required for a low-risk biocidal product consists of an application form and a dossier. Application form is explained in Chapter 2.4.1. The data requirements are as follows:

- details of the applicant, manufacturer of the active substance(s) and the product
- letter of access to any relevant data needed
- identity of the biocidal product:
- intended uses
- efficacy data
- analytical methods
- classification, packaging and labelling, including a draft label and use instructions in Estonian
- Safety Data Sheet in Estonian

#### **Practical details on submission of the application**

- see Chapter 2.4.1/ Practical details on submission of the application.

The CA confirms the receipt of the application via the R4BP. After evaluation of the dossier the CA issues a decision on the registration with a national number and updates the R4BP accordingly within 60 days.

### ***3.2 Mutual recognition of registration***

The concept of mutual recognition is applied to the registration also. General principles of mutual recognition explained in Chapter 2.9 apply to mutual recognition of registration.

#### **When to apply**

Timelines for application are as described in Chapter 2.2.

## **How to apply**

For mutual recognition of registration of low-risk biocidal products, the application shall include:

- application forms (see Chapter 2.4.1)
- certified copy of the first registration granted detail of the applicant and manufacturers of the biocidal product and the active substance(s)
- a letter of access to any relevant data needed, where appropriate
- identity of the biocidal product
- physical and chemical properties of the product
- intended uses
- summary of the efficacy data
- analytical methods
- classification, packaging and labelling, including a draft label and use instructions in Estonian
- Safety Data Sheet (SDS) in Estonian.

Application for mutual recognition takes place in two phases.

In a first step the following is submitted by the deadline mentioned above:

- A filled in and signed paper copy of the application forms generated via the R4BP in Estonian or English (see Chapter 2.4.1).

In a second step following is submitted within two months of the having obtained the first registration:

- a certified copy of the first authorisation granted including translation into Estonian or English,
- product assessment report by the reference MS
- one electronic copy of the summary dossier, where the first member state has filled in the evaluation boxes
- draft label, use instructions and SDS in Estonian.
- Fee for handling the application has to be paid (see Chapter 4).

### **Practical details on submission of the application**

- see Chapter 2.4.1/ Practical details on submission of the application

The CA confirms the receipt of the application via the R4BP. Within 60 days the CA issues decision with a national number and updates the R4BP accordingly.

### **3.3 Basic substance**

According to the BPD a basic substance is listed in Annex IB if its major use is non-pesticidal but it has some minor use as a biocide either directly or in a product consisting of this substance and a simple diluent which itself is not a substance of concern. Basic substances cannot be marketed for biocidal use. Inclusion of a basic substance in Annex IB takes place according to the same procedure described in Article 11 of the BPD and at the web-site of the European Commission: <http://ec.europa.eu/environment/biocides/index.htm> .

### ***3.4 Frame formulation: establishment, authorisation and registration***

Frame formulations are defined in Article 2 of the BPD:

“Specifications for a group of biocidal products having the same use and user type. This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a previously authorised biocidal product which does not affect the level of risk associated with them and their efficacy.

In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.”

On applicants' request and based on the applicant's proposal and supportive data CA shall establish a frame formulation in connection of granting an authorisation for a biocidal product. CA may also on its own initiative establish a frame formulation.

Subsequent application for authorisation for a new biocidal product based on existing frame formulation may be made also by other applicants. They need a LoA to the dossier on the original frame formulation. The CA shall take a decision with regard to this application within 60 days. The fee (see Chapter 4) is invoiced in connection to the decision.

#### **How to establish**

Please see guidance which is available at the CIRCA public website: [http://circa.europa.eu/Public/irc/env/bio\\_reports/library?l=/documents\\_finalised&vm=detailed&sb=Title](http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/documents_finalised&vm=detailed&sb=Title)

### ***3.5 Temporary use of biocidal product***

In case of unforeseen danger (e.g. pathogen) which cannot be contained by other means a MS may temporarily authorise a biocidal product not complying with the provisions of the BPD for a limited and controlled use (BPD Art 15). The temporary authorisation may only be granted for 120 days. It is resolved in the Standing Committee for Biocides (SCB) at the EU level whether, and, if so, under what conditions, the temporary authorisation granted by a MS may be extended for a determined period, be repeated or revoked.

#### **How to apply**

The application shall consist of similar data and dossier required for tests and experiments with possible release to the environment (see Chapter 3.7).

### ***3.6 Placing new active substance on the market***

According to the Article 9 of the BPD new active substances, i.e. substances not on the EU market before 14 May 2000 and identified within the review programme of existing active substances, may not be placed on the market for biocidal use unless:

- a complete dossier has been forwarded to a MS and it is accompanied by the declaration that the active substance is intended for inclusion in a biocidal product. However, this not applied to substances used for research and development (see Chapter 3.7)
- the substance is classified, packaged and labelled in accordance with the provisions of Directive 67/548/EEC or CLP Regulation 1272/2008 (Art 61).

Use of such substances in biocidal products require inclusion in Annex I or IA and subsequent authorisation or registration of the product as explained elsewhere in this document.

### **How to apply**

Please contact the CA for further guidance.

## **3.7 Tests and experiments**

Tests and experiments for research and development with biocidal products and their active substances require recording, notification or authorisation.

In the case of scientific research and development experiments require written records. The person supplying the product or the active substance for the experiment or the person responsible for the experiment has to draw up and maintain written records containing the following information:

- identity of the product or the active substance,
- quantities supplied,
- information on labelling and contact information of those persons to which the product or the active substance has been submitted.
- a dossier containing all available data on possible effects on human or animal health or impact on the environment shall be compiled.

This information shall be delivered to the CA if requested.

In the case of process-oriented research and development with no release into the environment tests require notification. The information listed above shall be delivered to the CA a minimum of 4 weeks before the active substance or product is placed on the market and the test is started.

In the case of research and development with possible release into the environment tests require authorisation. This applies both to scientific and process-orientated experiments and tests. The person responsible of the experiment/test shall apply for authorisation from the CA a minimum of 4 weeks before the experiment/test is to be started. In the application for authorisation of research and development with possible release into the environment, in addition to the above mentioned data, information about any precautions necessary for the safe performance of the experiment shall be submitted to the CA. Separate authorisation is not needed on every single experiment/test if the CA in its decision has permitted a set of tests and defined the conditions for the performance of the tests.

If the proposed experiments or tests are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the CA may either prohibit them or only allow them subject to such conditions as it considers necessary to prevent those consequences (e.g. quantities of product or active substance that can be used in the experiment/test or on the areas to be treated).

### **How to apply**

#### **Practical details on submission of the application**

- see Chapter 2.4.1/ Practical details on submission of the application.

### 3.8 Parallel import

To be added later.

### 4 FEES

According to Article 25 of the BPD, MS have to establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances on Annex I, IA or IB to pay charges, corresponding as far as possible to the costs caused for the authorities when carrying out all the different procedures associated with the provisions of the BPD.

The statutory basis for these fees in Estonia consists of a Biocides Act and a State Fees Act.

Table 3 Fees for biocides in Estonia (EUR)

1. Application for an active substance for inclusion in Annexes I, IA or IB the first product type	9088,23 <sup>1</sup>
2. Application for an active substance for inclusion in Annexes I, IA or IB the second and subsequent product types	8493,85 <sup>1</sup>
3. Authorisation of a biocidal product for the first time in the EU	4780,59 <sup>1</sup>
4. Mutual recognition of a biocidal product	958,67
5. Registration of a low risk biocidal product for the first time in the EU	3636,57 <sup>1</sup>
6. Mutual recognition of registration of a low risk biocidal product	696,63
7. Notification on process-oriented R & D	1879
8. Establishment of a frame formulation	345,12
9. Authorisation of a (established) frame formulation product	293,99
10. Provisional authorisation	1879
11. Administrative changes (e.g. change of the name of the product, change of the applicant)	249,25
12. Significant modification of a decision (e.g. extension of uses, considerable change of formulation)	677,46

<sup>1</sup> There are two different types of fees in the Biocides Act:

1. For the inclusion of active substance and the authorisation/registration in addition to the State fees also fees for evaluation of a dossier shall be paid. The applicant of the dossier shall get an agreement for evaluation of the dossiers with a skilled expert(s) with relevant experiences and notify about the choice of expert to get an acceptance from the Health Board. Thus the fee for the evaluation of the dossier bases on the agreement between the applicant and the relevant expert accepted by the Health Board. The price for the evaluation shall be paid directly to the expert.
2. State fees, which shall be paid before submitting the documents to the Health Board. The state fee is paid for checking the completeness of the dossier as well as for other relevant administrative procedures. The state fees shall be paid according to the State Fees Act.

## 5 FURTHER INFORMATION

### *5.1 Estonia CAs: Contact details*

Health Board, Department of Chemical Safety  
Postal address: Gonsiori 29, Tallinn 10147, Estonia  
e-mail: [biotsiid@terviseamet.ee](mailto:biotsiid@terviseamet.ee)  
web: [www.terviseamet.ee](http://www.terviseamet.ee)

### *5.2 Useful links*

European Commission, DG Environment:  
<http://ec.europa.eu/environment/biocides/>

European Commission, Joint Research Centre, Institute for Health and Consumer Protection:  
<http://ihcp.jrc.ec.europa.eu/>

European Union Law (EUR-LEX):  
<http://eur-lex.europa.eu/en/index.htm>

## REFERENCES

### EU regulations and guidance documents

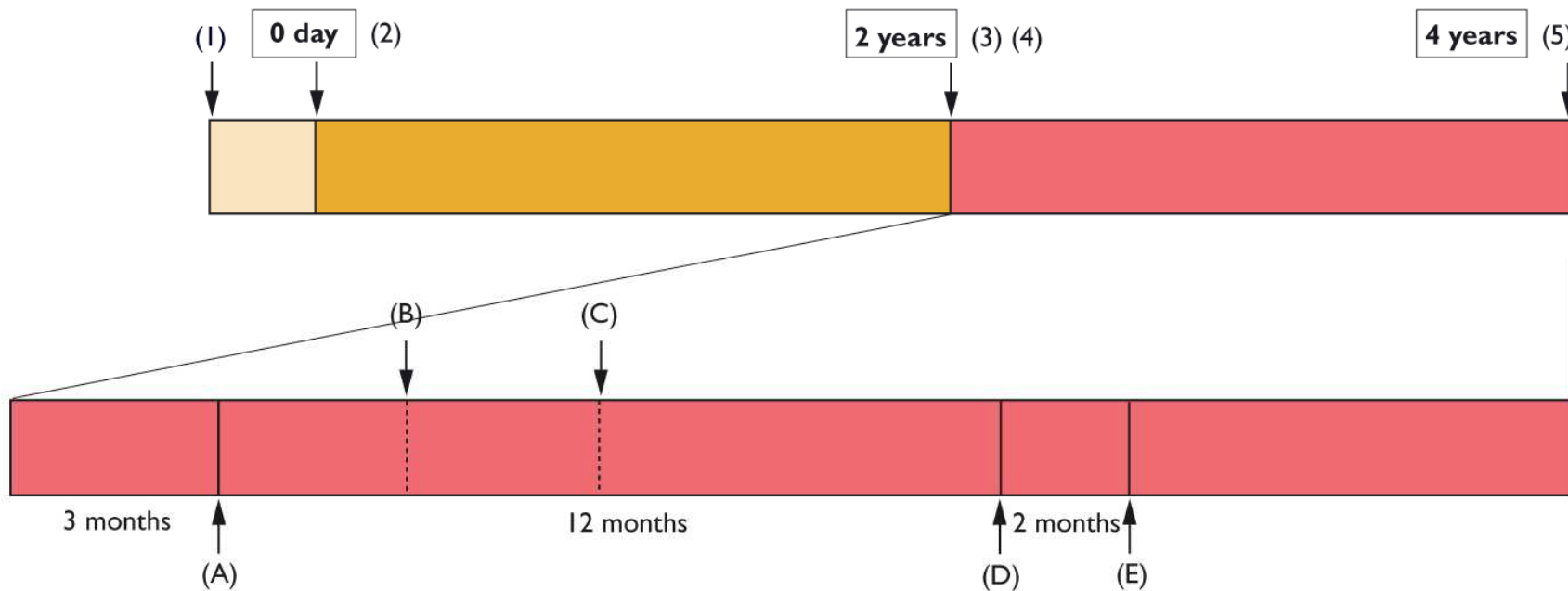
1. **Biocidal Products Directive, BPD:** Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal of the European Communities L 123, 24.4.1998.
2. **Amendment of the BPD:** Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods. Official Journal of the European Communities L 262, 6.10.2009.
3. **First Review Regulation:** Commission regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products). Official Journal of the European Communities L228, 8.9.2000.
4. **Second Review Regulation:** Commission regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products. Official Journal of the European Communities L307, 24.11.2003.
5. **Consolidated, Fifth Review Regulation:** Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market . Official Journal of the European Communities L 325, 11.12.2007.
6. **TNsG for Preparation of Dossiers and Study Evaluation:** Technical notes for guidance on dossier preparation including preparation and evaluation of study summaries under Directive 98/8/EC. Concerning the placing of biocidal products on the market. [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/guidance-documents)
7. **TNsG for Data Requirements:** Technical notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products. [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/guidance-documents)
8. **TNsG on Product Evaluation:** Technical notes for guidance in support of Annex VI of Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Common principles and practical procedures for the authorisation and registration of products. [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/guidance-documents)
9. **TGD:** Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. [http://ihcp.jrc.ec.europa.eu/our\\_activities/health-env/risk\\_assessment\\_of\\_Biocides/guidance-documents](http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/guidance-documents)

## **National legislation related to biocides**

- **Biocides Act**, (RTI, 09.06.2009, 29, 174), available only in Estonian.
- **Chemicals Act**, (RTI, 28.05.1998, 47, 697), available only in Estonian.
- **Regulation** of The Minister of Social Affairs **No. 122** (RTL, 21.12.2004, 154, 2326) "The requirements and procedures for identification, classification, packaging and labelling of dangerous chemicals", available only in Estonian.
- **State Fees Act** (RT I 2010, 21, 107), available only in Estonian.

## Post-Annex I timelines

- (1) Standing Committee on Biocides (SCB)
- (2) Directive on active substance comes into force
- (3) Active substance into Annex I
- (4) National authorisation has to be applied for (20/2008)
- (5) Decisions on the applications at latest



- (A) Completeness check
- (B) Withdrawal from the market in case of no application (6 months from application timeline)
- (C) Withdrawal from the market in case of incomplete application (6 months from rejection of application)
- (D) Decision on the first authorisation
- (E) Completing the application on mutual recognition