30 September 2015

Antifouling products - applications for approval and tests

1 GENERAL

This guide introduces regulations relating to the approval of antifouling products, application procedures, and detailed instructions for data requirements. Its purpose is to make applying easier, harmonise the application procedures, and thus promote the rapid processing of applications by the responsible authority, Finnish Safety and Chemicals Agency (Tukes).

Finnish national advance approval procedure will be replaced by a procedure according to Biocidal Products Regulation (EU) 528/2012 by the end of the transitional period of the BPR.

Tests or experiments with antifouling products for research and development purposes require either a notification to or an authorisation from Tukes (Chemicals Act 599/2013 34 §). Regulations concerning research and development are described in chapter 4 of this guide.

Besides the advance approval procedure described in this guide, also general provisions according to REACH regulation (1907/2006/EU) and CLP regulation (1272/2008/EU) apply to antifouling products.

1.1 Which antifouling products need to have an approval

According to Chemicals Act 599/2013 27 §, antifouling products cannot be placed on the market or used without the approval of the product. The approval is applied from Finnish Safety and Chemicals Agency (Tukes).

Antifouling products are products with a chemical or biological effect, used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures in water. The most used antifouling products are coatings for boats and ships and products used in fish farming.

An antifouling product contains one or several active substances that have been notified for product type 21 in the review programme of biocidal active substances (Commission delegated regulation (EU) No 1062/2014, annex II). If an antifouling product contains an active substance that has not been notified in product type 21, the active substance is a so called new substance and needs to be applied for approval as a new biocidal product within the EU. In this case the product can be approved only after the active substance has been evaluated and approved on the EU level.

Antifouling products that do not contain an active substance with a biocidal effect are not covered by the authorisation obligation. In ambiguous situations it is recommended to negotiate with Tukes whether the product is subject to the BPR or not.

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1.2 Who can apply for approval

Approval has to be applied for by a person who is responsible for the first placing of the product on the market in Finland. If the applicant is not the manufacturer of a product or its active substance, the person applying for approval has to present a letter of access providing for the applicant the right to represent its principal in Finland in matters concerning the product or the active substance. The applicant may be either Finnish or foreign but he shall have a permanent office within the European Community, Norway or Switzerland.

Companies other than the holder of the approval may market the product. If the product is marketed with many trade names, all of them must be declared to Tukes.

2 CONTENTS OF THE APPLICATION AND THE DATA REQUIRED

The applicant shall submit to Tukes all data on toxicological and ecotoxicological effects, efficacy, leaching and other properties of the chemical and its active substances that are necessary for the assessment of the conditions for issue an approval. The data requirements are listed in The Ministry of the Environment Decree concerning applications and notifications of biocidal products and their active substances (419/2014).

The application dossier consists of the product application form and a data package (see Table 1.). The applicant is responsible for filling correct information in the application dossier. The original tests and study reports shall be attached to the application. The application form is available at website http://www.tukes.fi/en/Palvelut/Forms/Biocides/ . The data requirements are listed in Annex 1 of this guide.

Table 1. Dossier for the antifouling product

Advance approval of an antifouling product		
Data package for the product	Product application form	Filled and signed in English/Finnish/Swedish
	Product studies or a letter of access to the product dossier	LoA if the dossier is not owned by the applicant
	Health and environmental effects and exposure assessment	EU risk assessment form Doc IIB and IIC or similar information in English/Finnish/Swedish
	Safety Data Sheet	in Finnish (in Swedish when necessary)
	Label	in Finnish and Swedish
	Instructions for use	in Finnish (in Swedish when necessary)

	Product studies	in English/Finnish/Swedish
	Reference list	in English/Finnish/Swedish
Data package for the active substance	A letter of access to the active substance dossier on art. 95 list of the BPR	

Original studies and other data based on the product shall be attached to the application. The attachments shall be numbered using the numbering in the data requirement list. If there are several studies in one attachment, they shall be separated with a minuscule (f. ex. 6.1.1a, 6.1.1b).

In the application, the applicant must clearly identify any information which is considered to involve business and professional secrets and justify each claim made taking into consideration 58 § of the Chemicals Act. This information can be presented in separate appendixes which are marked confidential.

Studies to be submitted must be conducted and reported either according to the methods mentioned in the Commission Decree (EC) Nr 440/2008 or according to the OECD (Organisation for Economic Co-operation and Development) guidelines for testing of chemicals. The studies must also comply with the principles of Good Laboratory Practice and the study report shall contain a certificate of this.

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, Tukes 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 decision on the application may be taken even in that case that supplementary data are not delivered in due time (Administrative Act 434/2003 33 §).

The test methods and guidelines must, whenever possible, be chosen so that the use of laboratory animals is minimised or totally avoided (The Act on protection of animals used for scientific or educational purposes 497/2013 11 §). 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. If information is available, but it is inadequate, the scope of the additional studies required will be considered on a case-by-case basis.

3 HANDLING OF THE APPLICATION

The first step Tukes will take when processing the application is to check that all the required documents have been submitted and the technical quality is acceptable. When necessary, the applicant will be asked to complete his application. When new appendixes are submitted, updated reference lists shall also be attached. If the application is not completed before a set deadline, Tukes can reject an insufficient application.

The risks to the environment and human health from the product and its active substance will be evaluated and the biological efficacy and other conditions of approval will be checked at Tukes using the material provided by the applicant. Tukes will decide upon the approval of the product in accordance with 29 § of the Chemicals Act and confirm its intended use and the instructions for use. Conditions and instructions can also be attached to the approval decision. In cases where the applicant disagrees with a decision, he may appeal the decision to the County Administrative Court (Administrative Appeals Act 586/1996).

3.1 Duration of the approval

Approval can be granted until the end of the transitional period of BPR (December 31, 2024) or until the decision on the product has been made according to the BPR.

The applicant is responsible for submitting information of hazardous chemicals for registration to the Chemical Products Register of Tukes according to The Ministry of Social Affairs and Health decree 553/2008. The information shall be sent after the approval decision. Further guidance and forms can be requested from:

Finnish Safety and Chemicals Agency (Tukes)
Chemical Products Register
Kalevantie 2
FI-33100 Tampere
Finland

e-mail: **tuoterekisteri@tukes.fi**

3.2 Altering and cancelling of the approval

Any changes in the antifouling product have to be notified to Tukes.

Any **changes in the applicant**, i.e. if the identity of the company responsible for placing the antifouling product on the Finnish market changes, have to be notified to Tukes without delay. 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 of **the product name** shall be notified in advance to Tukes. In this case any renewed labels, safety data sheets and instructions for use must also be submitted to Tukes. Tukes will confirm the change of the product name in writing.

If **the composition of the product** is to be changed, a written request to Tukes must be made in good time. The request shall include detailed information on the new composition and any possible changes in classification and labelling, the leaching of the active substance, the efficacy of the product etc. The planned timetable for the change shall also be presented as well as a clearly reasoned account of the feasibility of using the documentation for the previous formulation in the evaluation of health and environmental effects of the new formulation. Tukes will make a decision on the composition change. If the suggested change is, however, fundamental, i.e. the risks to health or the environment or the efficacy cannot 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 an approval must be applied for it.

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

3.3 Fees

Tukes will charge for processing an application when the dossier has arrived. Charges are determined by the Decree of the Ministry of Employment and the Economy on the charges of Finnish Safety and Chemicals Agency (636/2013). The basic fee is not refundable.

4 RESEARCH AND DEVELOPMENT

According to the Chemicals Act (34 §) certain tests and experiments for research and development with antifouling products and their active substances require either notification or authorisation from Tukes.

Procedures described here apply to antifouling products containing existing active substances and of which no application for approval has been submitted to Tukes.

Tests and experiments are divided into three categories. In the case of scientific research and development **tests require written records** according to 34 § of the Chemicals Act. The person providing the product or the active substance for the test or the person responsible of the test has to draw up and maintain written records containing the following information: identity of the product or the active substance, amounts provided, information on labelling and contact information of those establishments to which the product or the active substance has been submitted. In addition, a dossier shall be compiled with all available data on possible human or animal health effects or impacts on the environment. This information shall be delivered to Tukes by request.

If there is **no release into the environment** in process-oriented research and development, tests require **notification** according to the Chemicals Act 34 §. The following information shall be delivered to Tukes before the active substance or product is placed on the market (Ministry of the Environment Decree 419/2014 5 §):

- Name and contact information of the person who will be responsible for the test and the person conducting the test
- Purpose of the test and where the test is to be conducted
- Expected time and duration of the test
- The names and quantities of the products and active substances involved and information concerning their manufacturer or importer; identity of products and active substances, excluding data on method of manufacture and data on exposure
- Labelling of the product or the active substance
- Safety data sheet or other similar available data on the effect on health and the impact on the environment of the product and/or the active substance
- Other necessary information from the viewpoint of acceptability of the test or the hazard assessment of the product or the active substance.

If there is **a possible release into the environment** in process-oriented research and development, tests require **authorisation** according to the Chemicals Act 34 §. An authorisation should be applied for from Tukes 60 days before the planned start of the test. In the terms of approval there are conditions given e.g. on the volume of product or active substance used in the test or on the size of the treated areas. If Tukes has permitted a set of tests in the approval decision and defined the conditions for performing them, a separate authorisation is not needed for single tests.

In the application for authorisation of process-oriented research and development with possible release into the environment, in addition to the above mentioned information concerning any precautions necessary for the safe performance of the experiment or test shall be submitted to Tukes (Ministry of the Environment Degree 419/2014, 6 §).

The forms for notification/authorisation of tests are available in English and Finnish and they are retrievable at our Internet pages. The annexes shall be numbered and send together with the forms.

Tukes will charge the handling of the test application according to Decree of the Ministry of Employment and the Economy on the charges of Finnish Safety and Chemicals Agency (636/2013)

5 FURTHER INFORMATION

Contact information

Approval and notification procedures for antifouling products, health and environmental assessment, efficacy, physical -chemical properties and classification and labelling of chemicals:

Finnish Safety and Chemicals Agency (Tukes)
P.O. Box 66 (Opastinsilta 12 B)
FI-005210 Helsinki
Finland

Tel. +358 29 5052 000 (exchange)
e-mail: **biosinfo@tukes.fi**
www.tukes.fi/biocides

Safety Data Sheets, submission of information on hazardous chemicals for registration:

Finnish Safety and Chemicals Agency (Tukes)
Chemical Product Register
Kalevantie 2
FI-33100 Tampere
Finland

Tel. +358 29 5052 000 (exchange)
e-mail: **tuoterekisteri@tukes.fi**
http://www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Submitting-information-on-chemicals-/

Legislation

Biocidal Products Regulation (BPR), Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal product

The Finnish legislation (in Finnish and in Swedish) is available e.g. in the internet-address: http://www.finlex.fi

- Chemicals Act (599/2013)
- The Council of State Decree on biocidal products (418/2014)
- The Ministry of the Environment Decree concerning applications and notifications of biocidal products and their active substances (419/2014)
- The Ministry of the Environment Decree concerning approval or registration of biocidal product, phasing out and special requirements (20/2008 and its amendments)
- The Ministry of Social Affairs and Health decree concerning packaging and labelling of biocidal products (422/2000)
- The Ministry of Employment and the Economy Decree on the Charges of Finnish Safety and Chemicals Agency (636/2013)

Annex 1. Data requirements

Application forms are available at http://www.tukes.fi/en/Palvelut/Forms/Biocides/ .

Signs in the table:
X = mandatory information
(X) = to be submitted if available

Data requirements for antifouling product		
1 General information		
1.1	Name, address, telephone number, e-mail, and other contact information of the applicant	X
1.2	Product manufacturer: name, address and location of manufacturing plant	X
	Active substance manufacturer: name, address and location of manufacturing plant	X
	Authorisation by the manufacturer of the active substance of use of the dossier	X
2 Identity		
2.1	Trade name or proposed trade name, and manufacturer's development code number of the preparation	X
2.2	Composition of the product • active substances, their contents and classifications • other components, their contents and classifications	X
2.3	Physical state and nature of the biocidal product	X
3 Physical, chemical and technical properties		
3.1	Appearance	X
3.2	Explosive properties	X
3.3	Oxidising properties	X
3.4	Flash point and other indications of flammability or spontaneous ignition	X
3.5	Acidity/alkalinity and, if necessary, pH value (1 % in water)	X
3.6	Relative density	X

3.7	Storage stability - stability and shelf-life. The effects of light, temperature and humidity to the technical properties of biocidal product; reactivity with the container material.	X
3.8	Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability	X
3.9	Physical and chemical compatibility with other products including other biocidal prod¬ucts with which its use is to be authorised	X
3.10	*Surface tension and viscosity where appropriate*	X
3.11	*Particle size distribution where appropriate*	X
4 Analytical methods for detection and identification		
4.1	Analytical method for determining the concentrations of the active substance) in the biocidal product	X
4.2	In so far as not covered by data set for the active substance, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the soil, air and water	X
5 Intended uses and efficacy		
5.1	Product type and field of use envisaged	X
5.2	Method of application including description of system used	X
5.3	Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used	X
5.4	Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals	X
5.5	Function, for example fungicide, algicide, insecticide, bactericide	X
5.6	Pest organisms to be controlled and products, organisms or objects to be protected	X
5.7	Effects on target organisms	X
5.8	Mode of action (including time delay) in so far as not covered by data set for the active substance	X
5.9	User: industrial, other professional, general public (nonprofessional)	X

5.10	The proposed label claims for the product and efficacy data to support these claims including any available standard protocols used, laboratory tests, or field trials, where appropriate	X
5.11	Any other known limitations on efficacy including resistance	X
6 Toxicological studies		
6.1.1	Acute toxicity - oral	X
6.1.2-6.1.3	Acute toxicity - dermal on inhalation	X
6.2	Skin and eye irritation	X
6.3	Skin sensitisation	(X)
6.4	Information on dermal absorption	(X)
6.5	Available toxicological data relating to toxicologically relevant non-active substances	X
6.6	Information related to the human exposure of the biocidal product	X
7 Ecotoxicologicalt studies		
7.1	Foreseeable routes of entry into the environment on the basis of the use envisaged	X
7.2	Information on the ecotoxicology and residue of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself	X
	7.4.1.1 Acute toxicity to fish (marine /brackish water species)	X
	7.4.1.2 Acute toxicity to invertebrates (marine /brackish water species)	X
	7.4.1.3 Growth inhibition test on algae (marine /brackish water species)	X
	7.7.1.2 Residue data on fish concerning the active substance and including toxicological relevant metabolites	X
7.3	Available ecotoxicological information relating to ecotoxicological relevant non active substances (i.e. substances of concern), such as information from safety data sheets	X
8 Measures to be adopted to protect man, animals and the environment		
8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire	X

8.2	Specific treatment in case of an accident, for example, first aid measures following accidental eye or skin contact, ingestion or inhalation, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by data set for the active substance	X
8.3	Procedures, if any, for cleaning application equipment	X
8.4	Identity of relevant combustion products in cases of fire	X
8.5	Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (nonprofessional users),	X
8.6	Possibility of destruction or decontamination following release in or on the air, water and soil	X
8.7	Observations on undesirable or unintended side effects, for example, on beneficial and other non-target organisms	X
8.8	Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms	X
9 Classification, packaging and labelling		
	Safety data sheet	X
	Proposals including justification for the proposals for the classification and labelling of the biocidal product according to the provisions of the Chemicals Act and especially of the Ministry of Social Affairs and Health Decree on packaging and specific labelling of biocidal products	X
10	**Summary and evaluation of sections 2 to 9** This chapter refers to the risk assessment of the biocidal product, which must be attached to the application dossier. EU risk assessment form Doc IIB and IIC or similar information.	X

Data requirements for active substance **1 General information**		
1.1	Name, address, telephone number, e-mail, and other contact information of the applicant	X
1.2	Active substance manufacturer: name, address and location of manufacturing plant	X
	Authorisation by the manufacturer of the active substance of use of the dossier	X

2 Identity		
2.1	Common name proposed or accepted by ISO and synonyms	X
2.2	Chemical name according to IUPAC nomenclature and CAS-name, if different.	X
2.3	Manufacturer's development code numbers (if available)	X
2.4	CAS- and EC-numbers	X
2.5	Molecular and structural formula	X
2.6	Method of manufacture of the active substance (synthesis pathway in brief terms)	X
2.7	Specification of purity of the active substance, as appropriate (g/kg, g/l)	X
2.8	Identity and the typical concentration (g/kg, g/l) of impurities and additives, as appropriate	X
2.9	The origin of the natural active substance or the precursors of the active substance	X
2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC amending Council Directive 67/548/EEC	
3 Physical, chemical and technical properties		
3.1	Melting point, boiling point, relative density	X
3.2	Vapour pressure	X
3.3	Appearance	X
3.4	Absorption spectra	
3.5	Solubility in water including the effect of pH (5 to 9) and temperature	X
3.6	Dissociation constant	
3.7	*Solubility in organic solvents including the effect of temperature on solubility*	
3.8	*Stability in the organic solvents used in biocidal products and the identity of relevant breakdown products*	
3.9	Partition coefficient n-octanol/water	X
3.10	Thermal stability, identity of relevant breakdown products	X
3.11	Flammability including auto-flammability and identity of combustion products	X
3.12	Flash-point	

3.13, *3.14*	Surface tension *and viscosity*	X
3.15	Explosive properties	
3.16	Oxidizing properties	
3.17	Reactivity towards container material	X
4 Analytical methods for detection and identification		
4.1	Analytical methods for the determination of pure active substances and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)	X
4.2	Analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the active substance and/or residues thereof, where relevant in soil, air and water	X
5 Effectiveness against target organisms and intended uses		
5.1	Function, for example fungicide, rodenticide, insecticide, bactericide	X
5.2	Organisms to be controlled and products, organisms or objects to be protected	X
5.3	Effects on target organisms, and likely concentration at which the active substance will be used	X
5.4	Mode of action (including time delay)	X
5.5	Field of use envisaged	X
5.6	User: industrial, professional, general public (non-professional)	X
5.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	X
5.8	Likely tonnage to be placed on the market in Finland per year	X
6 Toxicological and metabolic studies		
6.1.1	Acute Toxicity – oral	X
6.1.2-6.1.3	Acute Toxicity – dermal or inhalation	X
6.1.4	Skin and eye irritation	X
6.1.5	Skin sensitisation	X
6.2	Metabolism studies in mammals	X
6.3 – 6.4	Subchronic toxicity (90 d) or Short term repeated dose toxicity (28 days)	X

6.5	Chronic toxicity	(X)
6.6.1	*In vitro* gene mutation study in bacteria	X
6.6.2	*In vitro* cytogenicity study in mammalian cells	X
6.6.3	In vitro gene mutation assay in mammalian cells	X
6.6.4	If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in vivo* genotoxicity study will be required	X
6.6.5	If negative in 6.6.4 but positive in some of *in vitro* tests then undertake a second *in vivo* study	X
6.6.6	If positive result in 6.6.4 then a test to assess possible germ cell effects may be required.	X
6.7	Carcinogenicity study	X
6.8.1	Teratogenicity test	X
6.8.2	Two-generations reproduction study	X
6.9	*Neurotoxicity study where appropriate*	(X)
6.10	*Mechanistic study where appropriate*	(X)
6.11	Studies on other routes of administration where appropriate	
6.12.4	Epidemiological studies on the general population, if available	(X)
6.14	*Other test(s) related to the exposure of humans; toxicity of degradation products, by-products and reaction products related to human exposure*	(X)
6.15	*Test on food and feeding stuffs*	
6.16	*Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products*	
6.17	Summary of mammalian toxicology and conclusions	X
7 Ecotoxicological profile including environmental fate and behaviour		
7.1.1.1.1	Abiotic degradation - Hydrolysis as a function of pH and identification of breakdown products	X
7.1.1.1.2	Abiotic degradation - Phototransformation in water including identity of the products of transformation	X
7.1.1.2.1	Biotic degradation - Ready biodegradability	X
7.1.1.2.2	Biotic degradation - Inherent biodegradability, where appropriate	X
7.1.2	*Further studies on biodegradation according to the Technical Guidance Document*	(X)

7.1.3	Adsorption/desorption screening test	X
7.1.4	*Studies on adsorption and desorption in water/sediment systems according to the Technical Guidance Document*	(X)
7.2	*Studies on fate and behaviour in soil according to the Technical Guidance Document*	(X)
7.3	*Studies in fate and behaviour in the air according to the Technical Guidance Document*	(X)
7.4.1.1	Acute toxicity to fish (also marine /brackish water species)	X
7.4.1.2	Acute toxicity to invertebrates (also marine /brackish water species)	X
7.4.1.3	Growth inhibition test on algae (also marine /brackish water species)	X
7.4.1.4	Inhibition to microbiological activity	X
7.4.2	Estimation of bioconcentration	X
7.4.3	*Further studies on effects on aquatic organisms according to the Technical Guidance Document*	(X)
7.4.3.2	Effects on reproduction and the growth rate on an appropriate species of fish (marine /brackish water species)	(X)
7.4.3.3.1	Bioaccumulation in an appropriate species of fish (marine /brackish water species)	(X)
7.4.3.3.2	Bioaccumulation in an appropriate invertebrate species (marine /brackish water species)	(X)
7.4.3.4	Effects on reproduction and growth rate with an appropriate invertebrate species (marine /brackish water species)	X
7.4.3.5.1	Effects on sediment dwelling organisms (marine/ brackish water species)	(X)
7.4.3.5.2	Aquatic plant toxicity (marine /brackish water species)	(X)
7.5	*Effects on terrestrial organisms*	
7.6	Summary of ecotoxicological effects and fate and behaviour in the environment	X
8 Measures necessary to protect man, animals and the environment		
8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire	X
8.2	In case of fire, nature of reaction products, combustion gases, etc.	X
8.3	Emergency measures in case of an accident	X
8.4	Possibility of destruction or decontamination following release in or on the air, water and soil	X

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8.5	Procedures for waste management of the active substance for industry or professional users	X
8.6	Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms	X
9 Classification and labelling		
9	Proposals including justification for the proposals for the classification and labelling of the active substance according to the provisions of the Chemicals Act and especially of the Ministry of Social Affairs and Health Decree on packaging and specific labelling of biocidal products	X
10	**Summary and evaluation of sections 2 to 9**	X

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