NB: Unofficial translation; legally binding texts are those in Finnish and Swedish
Ministry of the Environment, Finland

Ministry of the Environment Decree on the Applications and Notifications Concerning Biocidal Products and Their Active Substances

419/2014

Section 1
Authorisation application for a biocidal product

(1) In addition to what is stipulated in section 28(3) of the Chemicals Act (599/2013), an application concerning the authorisation of a biocidal product shall include the following information:

1) on each of the biocidal product's chemical active substances, the information specified in Annex 1 of this Decree
2) on chemical biocidal products, the information specified in Annex 2
3) on products with a microorganism as the active substance, the information in title 2 of Annex II of the Biocidal Products Regulation and title 2 of Annex III.

Section 2
Research

(1) The information specified in Annexes 1 and 2 as required for biocidal products and their active substances shall be based on reliable and well-documented research or analyses. With this information, a detailed and complete description of the studies and methods used shall be provided, along with references to literature where they appear.

(2) Information on the physical and chemical properties of chemical biocidal products and their active substances as well as effects on health and the environment shall be based on research conducted using the methods described in Council Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), or the test guidelines issued by the Organisation for Economic Co-operation and Development OECD (OECD Decision C(81)30 Annex 1) in accordance with the requirements set for test laboratories in section 24 of the Chemicals Act. If equally reliable information can be obtained by using test methods others than those mentioned above, their use shall be justified in the application.

Section 3
Deviations regarding the provision of information

Any information specified in Annexes 1 and 2 that is not required in terms of exposure associated with the proposed uses does not need to be supplied. This also applies to

information that is not scientifically justified or technically possible to acquire. In these cases, justifications shall be presented in the application.

Section 4
Use of information provided by another applicant

(1) If an application refers to information provided by another applicant, a written letter of access of the owner for the information shall be appended to the application. Section 33 of the Chemicals Act contains stipulations regarding the right of the Finnish Safety and Chemicals Agency to use such information in the processing of an application.

(2) Upon referring to information submitted by another applicant, the applicant shall demonstrate that the biocidal product in question is identical in composition to the previously authorised product, and that the active substances, including purity and impurities, are the same.

(3) As regards dossier concerning the active substance, references may also be made to documents delivered to the authority for the purposes of the work programme for biocidal active substances specified in article 89 of the Biocidal Product Regulation.

Section 5
Information requirements concerning test activities

(1) With regard to the production research and development work notification referred to in section 34(1) of the Chemicals Act, a test plan shall be submitted to the Finnish Safety and Chemicals Agency before the commencement of the testing. The following information shall be included in the plan:

1) name and contact information of the person responsible for the test and the person conducting it
2) purpose and location of the test
3) planned time and duration of the test
4) names and amounts of biocidal products used and their active substances, information on their manufacturer or importer, and the identity information of biocidal products and active substances in accordance with Annexes 1 and 2, excluding information on manufacturing methods and exposure
5) labelling required for the safe use of the biocidal products or active substances in question
6) material safety data sheet or other comparable information available on the effects of the biocidal products and active substances on health and the environment
7) other information important for the assessment of the acceptability of the test or the hazardous nature of the biocidal products or active substances.

(2) If so requested, the corresponding information shall also be provided on scientific tests requiring a record to be kept, as specified in section 34(1) of the Chemicals Act.

Section 6
Test requiring a permission

When applying for the permission described in section 34(2) of the Chemicals Act for a biocidal product, the information listed in section 5(1) shall be provided to the Finnish Safety and Chemicals Agency no less than 60 days before the commencement of the test. Furthermore, information on the precautions required for the safe performance of the test shall be appended to the application.

Section 7
Entry into force

(1) This Decree enters into force on 15 June 2014.

(2) This Decree repeals the Ministry of the Environment Decree on the Applications and Notifications Concerning Biocidal Products and Their Active Substances (467/2000)

Annex 1. Information required for chemical biocidal products referred to in section 26 of the Chemicals Act

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
1. ACTIVE SUBSTANCE MANUFACTURER (name, address and location of manufacturing plant(s)	X	X	X	X
2. IDENTITY OF THE ACTIVE SUBSTANCE				
Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)	X	X	X	X
Chemical name (IUPAC and CA nomenclature or other international chemical name(s))	X	X	X	X
CAS number and EC number	X	X	X	X
Molecular and structural formula	X	X	X	X
Information on optical activity and full details of any isomeric composition (if applicable and appropriate)	X	X	X	X
Molar mass	X	X	X	X
Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability	X	X	X	X
Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit	X	X	X	X
The identity of any impurities and additives including by-products of synthesis,	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substance				
The origin of the natural active substance or the precursor(s) of the active substance, e.g. a n extract of a flower	X	X		
3. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE				
Physical state (i.e. viscous, crystalline, powder) (at 20°C and 101,3 kPa; information for the purified active substance of stated specification, or the active substance as manufactured, if different)	X	X	X	X
Colour (at 20°C and 101,3 kPa; information for the purified active substance of stated specification, or the active substance as manufactured, if different)	X	X	X	X
Melting/freezing point (information for the purified active substance of stated specification)	X	X	X	X
Boiling point (information for the purified active substance of stated specification)	X	X	X	X
Relative density (information for the purified active substance of stated specification)	X	X	X	X
Absorption spectra data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient at relevant wavelengths, where relevant (information for the purified active substance of stated specification)	X	X	X	X
Vapour pressure (information for the purified active substance of stated specification	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Henry's law constant must always be stated for solids and liquids if it can be calculated	X	X	X	X
Surface pressure (information for the purified active substance of stated specification)	X	X	X	X
Water solubility (information for the purified active substance of stated specification)	X	X	X	X
Partition coefficient (n-octanol/water) and its pH dependency (information for the purified active substance of stated specification)	X	X	X	X
Thermal stability, identity of breakdown products (information for the purified active substance of stated specification)	X	X	X	X
Reactivity towards container material	X	X	X	X
Dissociation constant	X	X	X	X
Solubility in organic solvents, including effect of temperature on solubility (information for the purified active substance of stated specification)	X	X	X	X
Stability in organic solvents used in biocidal products and identity of relevant breakdown products (information for the purified active substance of stated specification, or the active substance as manufactured, if different)	X	X		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS				
(The information in section 4 may be necessary for classifying a substance in accordance with Regulation (EC) No 1272/2008 (CLP). Only the information				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
appropriate for the substance in question is provided.)				
Explosives	X	X	X	X
Flammable gases	X	X	X	X
Flammable aerosols	X	X	X	X
Oxidising gases	X	X	X	X
Gases under pressure	X	X	X	X
Flammable liquids	X	X	X	X
Flammable solids	X	X	X	X
Self-reactive substances and mixtures	X	X	X	X
Pyrophoric liquids	X	X	X	X
Pyrophoric solids	X	X	X	X
Self-heating substances and mixtures	X	X	X	X
Substances and mixtures which in contact with water emit flammable gases	X	X	X	X
Oxidising liquids	X	X	X	X
Oxidising solids	X	X	X	X
Organic peroxides	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Corrosive to metals	X	X	X	X
Additional physical indicators of hazard:				
a) Auto-ignition temperature (liquids and gases)	X	X	X	X
b) Relative self-ignition temperature for solids	X	X	X	X
c) Dust explosion hazard	X	X	X	X
5. METHODS OF DETECTION AND IDENTIFICATION				
Analytical methods including validation parameters for the determination of active substance as manufactured and, where appropriate, for relevant residues, isomers and impurities of the active substance and additives (e.g. stabilisers). For impurities other than relevant impurities this only applies if they are present at ≥ 1g/kg.		X		
Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in/on the following where relevant:				
a) Soil	X	X		X
b) Air	X	X		
c) Water (surface, drinking etc.) and sediment	X	X	X	X
d) Animal and human body fluids and tissues	X	X	X	X
Analytical methods for monitoring purposes including recovery rates and the	X			

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor articles treated with it come into contact with food-producing animals, food of plant or animal origin or feeding stuffs)				
6. EFFECTIVENESS AGAINST TARGET ORGANISMS				
Function and mode of control		X		
Representative organism(s) controlled and products, organisms or objects to be protected		X		
Effects on representative target organism(s)		X		
Likely concentration at which the micro-organism will be used		X		
Mode of action (including time delay)		X		
Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and appropriate management strategies		X		
7. INTENDED USES AND EXPOSURE				
Field(s) of use envisaged for biocidal products		X		
Likely tonnage to be placed on the market per year in Finland and, where relevant, the primary use categories envisaged		X		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS INCLUDING METABOLISM				
Skin irritation or skin corrosion	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)				
Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)	X	X	X	X
Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided	X	X	X	X
Mutagenicity The assessment of this endpoint shall comprise the following consecutive steps: - an assessment of the available in vivo genotoxicity data - an in vitro test for gene mutations in bacteria, an in vitro cytogenicity test in mammalian cells and an in vitro gene mutation test in mammalian cells are required - appropriate in vivo genotoxicity studies shall be considered in case of a				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
positive result in any of the in vitro genotoxicity studies				
a) In vitro gene mutation study in bacteria	X	X	X	X
b) In vitro cytogenicity study in mammalian cells	X	X	X	X
c) In vitro gene mutation study in mammalian cells	X	X	X	X
d) In vivo genotoxicity study	X	X	X	X
The assessment of this endpoint shall comprise the following consecutive steps: - If there is a positive result in any of the in vitro genotoxicity studies and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed/conducted by the applicant. - If either of the in vitro gene mutation tests is positive, an in vivo test to investigate unscheduled DNA synthesis shall be conducted. - A second in vivo somatic cell test may be necessary, depending on the results, quality and relevance of all the available data. - If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered				
Acute toxicity In addition to the oral route of administration, for substances other than gases, information shall be provided for at least one other route of administration. - The choice for the second route will depend on the nature of the substance and				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
the likely route of human exposure - Gases and volatile liquids should be administered by the inhalation route. If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered. Before a new dermal acute toxicity study is carried out, an in vitro dermal penetration study (OECD 428) should be conducted to assess the likely magnitude and rate of dermal bioavailability. - There may be exceptional circumstances where all routes of administration are deemed necessary				
a) By oral route The Acute Toxic Class Method is the preferred method for the determination of this endpoint.	X	X	X	X
b) By inhalation Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account: - the vapour pressure of the substance (a volatile substance has vapour pressure > 1 × 10–2 Pa at 20 °C) and/or - the active substance is a powder containing a significant proportion (e.g. 1% on a weight basis) of particles with particle size MMAD < 50 micrometres or - the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometres)	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
- the Acute Toxic Class Method is the preferred method for the determination of this endpoint.				
c) By dermal route	X	X	X	X
Testing by the dermal route is necessary only if:				
- inhalation of the substance is unlikely, or				
- skin contact in production and/or use is likely, and either				
- the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin, or				
- the results of an in vitro dermal penetration study (OECD 428) demonstrate high dermal absorption and bioavailability				
Toxicokinetics and metabolism studies in mammals	X	X		X
The toxicokinetics and metabolism studies should provide basic data about the rate and extent of absorption, the tissue distribution and the relevant metabolic pathway including the degree of metabolism, the routes and rate of excretion and the relevant metabolites				
Repeated dose toxicity				
In general, only one route of administration is necessary and the oral route is the preferred route. However, in some cases it may be necessary to evaluate more than one route of exposure.				
For the evaluation of the safety of consumers in relation to active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Testing by the dermal route shall be concider‌d if: - skin contact in production and/or use is likely, and - inhalation of the substance is unlikely, and - one of the following conditions is met: i) toxicity is observed in an acute dermal toxicity test at lower doses than in the oral toxicity test, or ii) information or test data indicate dermal absorption is comparable or higher than oral absorption, or (iii) dermal toxicity is recognised for structurally related substances and is, for example, observed at lower doses than in the oral toxicity test, or dermal absorption is comparable or higher than oral absorption. Testing by the inhalation route shall be considered if: - exposure of humans via inhalation is likely taking into account the vapour pressure of the substance (volatile substances and gases with vapour pressure > 1 × 10–2 Pa at 20°C), and/or - there is the possibility of exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometres)				
a) a reliable sub-chronic (90 day) study is available, preferred species is rat	X	X	X	X
b) Long-term repeated dose toxicity (≥ 12 months)	Combined with a carcinogenicity study	Combined with a carcinogenicity study		Combined with a carcinogenicity study
c) Further repeat dose studies	X	X		X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of administration shall be undertaken in case of: - no other information on toxicity for a second non-rodent species is provided for, or - failure to identify a no observed adverse effect level (NOAEL) in the 28- or the 90-day study, unless the reason is that no effects have been observed at the limit dose, or - substances bearing positive structural alerts for effects for which the rat or mouse is an inappropriate or insensitive model, or - toxicity of particular concern (e.g. serious/severe effects), or - indications of an effect for which the available data is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, hormonal activity), or - concern regarding local effects for which a risk characterisation cannot be performed by route-to-route extrapolation, or - particular concern regarding exposure (e.g. use in biocidal products leading to exposure levels which are close to the toxicologically relevant dose levels), or - effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28- or the 90-day study, or - the route of administration used in the initial repeated dose study was				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made.				
Reproductive toxicity For the evaluation of the safety of consumers in relation to active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.				
a) Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route. The study shall be initially performed on one species.	X	X		X
b) Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route. If another reproductive toxicity test is used, justification shall be provided. The extended one-generation reproductive toxicity study adopted at OECD level shall be considered as an alternative approach to the multi-generation study.	X	X		X
c) Further pre-natal developmental toxicity study. A decision on the need to perform additional studies on a second species or mechanistic studies should be based on the outcome of reproductive toxicity test a) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration.	X	X		X
Carcinogenicity See a) for new study requirements				
a) Combined carcinogenicity study and long-term repeated dose toxicity Rat, oral route of administration is the preferred route. If an alternative route is	X	X		X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
proposed a justification must be provided. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.				
b) Carcinogenicity testing in a second species	X	X		X
- A second carcinogenicity study should normally be conducted using the mouse as test species.				
- For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.				
Relevant health data, observations and treatments, if available:				
a) Medical surveillance data on manufacturing plant personnel	X	X	X	X
b) Direct observation, e.g. clinical cases, poisoning incidents	X	X	X	X
c) Health records, both from industry and any other available sources	X	X	X	X
d) Epidemiological studies on the general population	X	X	X	X
e) Diagnosis of poisoning including specific signs of poisoning and clinical tests	X	X	X	X
f) Sensitisation/allergenicity observations	X	X	X	X
g) Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known; prognosis following poisoning	X	X	X	X
Additional data which may be required depending on the characteristics and intended use of the active substance.				
Mechanistic data: any studies necessary to clarify effects reported in toxicity studies, if studies are available	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Studies related to the exposure of humans to the active substance, where relevant.	X	X	X	X
9. ECOTOXICOLOGICAL STUDIES				
Toxicity to aquatic organisms				
a) Short-term toxicity testing on fish The study does not need to be conducted if a valid long-term aquatic toxicity study on fish is available. When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied	X	X	X	X
b) Short-term toxicity testing on aquatic invertebrates (*Daphnia magna*)	X	X	X	X
c) Effects on growth rate of green algae	X	X	X	X
Bioconcentration, experimental determination where relevant; - The experimental determination may not need to be carried out if it can be demonstrated on the basis of physico-chemical properties (e.g. log Kow < 3) or other evidence that the substance has a low potential for bioconcentration	X	X	X	X
Inhibition of microbial activity	X The study is conducted with rotentice active substances if the product is used in waste water sewers or	X	X	

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
	comparable system or location through which it may be carries to sewage treatment plants			
Long-term toxicity test on aquatic invertebrates: a) Daphnia growth and reproduction study or b) Other species reproduction and growth (e.g. Mysid) or c) Other species development and emergence (e.g. Chironomus)		X	X	X
Effects on birds				
Acute oral toxicity	X (where relevant)			
Short-term toxicity – eight-day dietary study in at least one species (other than chickens, ducks and geese)	X (where relevant)			
10. ENVIRONMENTAL FATE AND BEHAVIOUR				
Fate and behaviour in water and sediment				
Degradation, initial studies If the initial assessment performed indicates the need to investigate further the degradation of the substance and its degradation products or the active substance has an overall low or absent abiotic degradation, then tests shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed.				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Abiotic				
a) Hydrolysis as a function of pH and identification of breakdown products. The identification of breakdown products is required when the breakdown products at any sampling time are present at ≥ 10%.	X	X	X	X
b) Phototransformation in water, including identification of transformation products	X	X	X	X
Biotic				
Ready biodegradability	X	X	X	X
Adsorption/desorption	X	X	X	X
Biodegradation in freshwater				
Degradation in water/sediment systems			X Required where relevant if there is evidence of the persistence of the substance in an aquatic environment, e.g. if the substance is not readily biodegradable.	
Fate and behaviour in soil				
Laboratory study on rate and route of degradation including identification of the				X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions Laboratory studies on rate of degradation in three additional soil types				Required where relevant if the active substance degrades slowly and may enter the soil.
Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products		X (where relevant)		
Phototransformation in air (estimation method), identification of transformation products		X (where relevant)		
Identification of all degradation products (> 10%) must be included in the studies on degradation in soil, water and sediments.	X	X	X	X
11. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT				
Recommended methods and precautions concerning handling, use, storage, transport or fire		X		
In case of fire, nature of reaction products, combustion gases etc		X		
Emergency measures in case of accident		X		
Possibility of destruction or decontamination following release in or on the following: a) air b) water, including drinking water				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
c) soil				
Procedures for waste management of the active substance for industry or professional users		X		
Possibility of reuse or recycling		X		
Possibility of neutralisation of effects		X		
Conditions for controlled discharge including leachate qualities on disposal		X		
Conditions for controlled incineration		X		
12. CLASSIFICATION, LABELLING AND PACKAGING				
State any existing classification and labelling.				
The hazard classification of the substance resulting from the application of Regulation (EC) No 1272/2008:				
Hazard classification, hazard pictogram, signal word, hazard statements, precautionary statements including prevention, response, storage and disposal	X	X	X	X
Specific concentration limits, where applicable, resulting from the application of Regulation (EC) No 1272/2008	X	X	X	X

Annex 2. Information required for chemical biocidal products referred to in section 26 of the Chemicals

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
1. APPLICANT				
Name and address	X	X	X	X
Contact person	X	X	X	X
Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))	X	X	X	X
2. IDENTITY OF THE BIOCIDAL PRODUCT				
Trade name or proposed trade name	X	X	X	X
Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and non-active substances (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of the biocidal product shall be given.	X	X	X	X
Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES				
Appearance: colour and odour (at 20°C and 101,3 kPa)	X			
Physical state (at 20°C and 101,3 kPa)	X	X	X	X
Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1%) is outside the pH range 4–10	X	X	X	X
Relative density (liquids) and bulk, tap density (solids)	X	X	X	X
Storage stability, stability and shelf-life Effects on content of the active substance and technical characteristics of the biocidal product: light, temperature and humidity, reactivity towards container material	X	X	X	X
Technical characteristics of the biocidal product: Wettability	X	X		
Suspensibility, spontaneity and dispersion stability			X	X
Emulsifiability, re-emulsifiability and emulsion stability		X		
Particle size distribution, content of dust/fines, attrition and friability (information required only where relevant to the product in question)	X	X	X	X
Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised		X		
Surface tension	X	X		

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Viscosity	X	X	X	X
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS (The information in section 4 may be necessary for classifying a product in accordance with Regulation (EC) No 1272/2008 (CLP). Only the information appropriate for the product in question is provided.)				
Explosives	X	X	X	X
Flammable gases	X	X	X	X
Flammable aerosols	X	X	X	X
Oxidising gases	X	X	X	X
Gases under pressure	X	X	X	X
Flammable liquids	X	X	X	X
Flammable solids	X	X	X	X
Self-reactive substances and mixtures	X	X	X	X
Pyrophoric liquids	X	X	X	X
Pyrophoric solids	X	X	X	X
Self-reactive substances and mixtures	X	X	X	X
Substances and mixtures which in contact with water emit flammable gases	X	X	X	X
Oxidising liquids	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Oxidising solids	X	X	X	X
Organic peroxides	X	X	X	X
Corrosive to metals	X	X	X	X
Additional physical indications of hazard	X	X	X	X
Auto-ignition temperatures of products (liquids and gases)	X	X	X	X
Relative self-ignition temperature for solids	X	X	X	X
Dust explosion hazard	X	X	X	X
5. METHODS OF DETECTION AND IDENTIFICATION				
Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product.	X	X	X	X
In so far as not covered in connection to the active substance studies, analytical methods for monitoring purposes including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant, in or on the following:				
a) Soil		X		
b) Air		X		
c) Water (including drinking water) and sediment		X		
6. EFFECTIVENESS AGAINST TARGET ORGANISMS				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting	X	X	X	X
Representative organism(s) controlled and products, organisms or objects to be protected	X	X	X	X
Effects on representative target organisms	X	X	X	X
Likely concentration at which the active substance will be used	X	X	X	X
Mode of action (including time delay)	X	X	X	X
The proposed label claims for the product and, where label claims are made, for treated articles		X		X
Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		X	X	X
Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and appropriate management strategies	X (if available)	X	X (if available)	X (if available)
7. INTENDED USES AND EXPOSURE				
Field(s) of use envisaged for biocidal products and, where appropriate, treated articles	X	X	X	X
Product type	X	X	X	X
Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles	X	X	X	X
User e.g. industrial, trained professional, professional or general public (non-professional)	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Likely tonnage to be placed on the market per year and, where relevant, for different use categories		X	X	X
Method of application and a description of this method	X	X	X	X
Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes	X	X	X	X
Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal health and the environment	X	X	X	X
Proposed instructions for use	X	X	X	X
Exposure data in conformity with Annex VI to Regulation (EC) No 528/2012, if available:				
- Information on human exposure associated with production and formulation, proposed/expected uses and disposal	X	X	X	X
- Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal	X	X	X	X
- Information on exposure from treated articles including leaching data (either laboratory studies or model data)		X		X
- Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions			X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
8. TOXICOLOGICAL PROFILE FOR HUMAN AND ANIMAL INCLUDING METABOLISM				
Skin corrosion and skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008).	X	X	X	X
Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008).	X	X	X	X
Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided.	X		X	X
Acute toxicity - Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
a) By oral route	X	X	X	X
b) By inhalation	X	X	X	X
c) By dermal route	X	X	X	X
Information on dermal absorption	X	X		
Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach.				
Available toxicological data relating to	X	X	X	X
- non-active substance(s) (i.e. substance(s) of concern), or				
- a mixture that a substance(s) of concern is a component of				
If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of.				
Other test(s) related to the exposure to humans	X	X		
Suitable test(s) and a reasoned case will be required for the biocidal product				
9. ECOTOXICOLOGICAL STUDIES				
Where relevant, studies on substances of concern comparable to those on active substances	X	X	X	X
10. ENVIRONMENTAL FATE AND BEHAVIOUR				

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Where relevant, studies on substances of concern comparable to those on active substances	X	X	X	X
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT				
Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire	X	X	X	X
Identity of relevant combustion products in cases of fire	X	X	X	X
Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment	X (if information on active substance has not been provided)	X	X	X
Possibility of destruction or decontamination following release in or on the following:				
a) air	X	X	X	X
b) water, including drinking water	X	X	X	X
c) soil	X	X	X	X
Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)	X	X	X	X
Procedures for cleaning application equipment where relevant	X	X	X	X

Information required	Biocidal pesticides	Antifouling products	Slimicides	Wood preservatives
Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms	X	X		
12. CLASSIFICATION, LABELLING AND PACKAGING				
Proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Regulation (EC) No 1272/2008. Example labels, instructions for use and safety data sheets shall be provided.	X	X	X	X
Hazard classification, hazard pictogram, signal word, hazard statements, precautionary statements including prevention, response, storage and disposal	X	X	X	X
Proposals for safety-data sheets should be provided, where appropriate	X	X	X	X
Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included	X	X	X	X
13. EVALUATION AND SUMMARY				
Where relevant, the key information in the application documents shall be summarised and evaluated, and a draft risk assessment shall prepared	X	X	X	X