ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 25(A)

EC number	Name/group	Restriction	Comment
Category 1 — Substances authorised as food additives according to Regulation (EC) No 1333/2008			
200-018-0	Lactic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 270
204-823-8	Sodium acetate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 262
208-534-8	Sodium benzoate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 211
201-766-0	(+)-Tartaric acid	Concentration to be limited so that each biocidal product does not require classification	E 334

a **[**[F1]The date of approval of vinegar for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

b **[**[F2]The date of approval of *Saccharomyces cerevisiae* for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

c **[**[F3]The date of approval of powdered egg for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

d **[**[F4]The date of approval of honey for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

e **[**[F5]The date of approval of D-fructose for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

f **[**[F6]The date of approval of cheese for product-type 19 for the purposes of Article 89(3) is 1 June 2021.**]**

g **[**[F7]The date of approval of concentrated apple juice for product-type 19 for the purposes of Article 89(3) is 1 June 2021.

h Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).**]**

		according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	
200-580-7	Acetic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 260
201-176-3	Propionic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 280
Category 2 — Substances included in Annex IV to Regulation (EC) No 1907/2006			
200-066-2	Ascorbic acid		
232-278-6	Linseed oil		

Category Weak acids
3 —

Category 4 — Traditionally used substances of natural origin			
Natural oil	Lavender oil		CAS 8000-28-0
Natural oil	Peppermint oil		CAS 8006-90-4
[[F1]Not available	Vinegar[a]	Excluding vinegar that is not food and excluding vinegar that contains more than 10 % acetic acid	CAS No 8028-52-2**]**

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g **[**[F7]The date of approval of concentrated apple juice for product-type 19 for the purposes of Article 89(3) is 1 June 2021.

h Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).**]**

		(whether or not it is food).	
[F2Not available	*Saccharomyces cerevisiae* (yeast)[b]	Excluding *Saccharomyces cerevisiae* that is not food or feed.	CAS No 68876-77-7]
[F3Not available	Powdered egg[c]	Excluding powdered egg that is not food or feed.	]
[F4Not available	Honey[d]	Excluding honey that is not food or feed.	CAS No 8028-66-8]
[F5200-333-3	D-Fructose[e]	Excluding D-fructose that is not food or feed.	CAS No 57-48-7]
[F6Not available	Cheese[f]	Excluding cheese that is not food or feed.	]
[F7Not available	Concentrated apple juice[g]	Excluding concentrated apple juice that does not fall within the definition in point (2) of Part I of Annex I to Council Directive 2001/112/EC[h].	]
Category 5 — Pheromones			
222-226-0	Oct-1-en-3-ol		
Mixture	Webbing clothes moths pheromone		
[F8Category 6 —Substances for which a Member State has validated an active substance dossier in accordance with Article 7(3) of this Regulation or accepted such a dossier in accordance with Article 11(1) of Directive 98/8/EC]			
204-696-9	Carbon dioxide	Only for use in ready-for-use gas canisters functioning together	

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h Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).]

		with a trapping device	
231-783-9	Nitrogen	Only for use in limited quantities in ready-for-use canisters	
[X1Not available	(9Z,12E)-tetradeca-9,12-dien-1-yl acetate		CAS 30507-70-1]
Category 7 — Other			
	Baculovirus		
215-108-5	Bentonite		
203-376-6	Citronellal		
231-753-5	Iron sulphate		

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h Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).]

Editorial Information

X1 Substituted by Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Official Journal of the European Union L 167 of 27 June 2012).

Textual Amendments

F1 Inserted by Commission Delegated Regulation (EU) 2019/1819 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include vinegar as an active substance in Annex I thereto (Text with EEA relevance).

F2 Inserted by Commission Delegated Regulation (EU) 2019/1820 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include Saccharomyces cerevisiae as an active substance in Annex I thereto (Text with EEA relevance).

F3 Inserted by Commission Delegated Regulation 2019/1821 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include powdered egg as an active substance in Annex I thereto (Text with EEA relevance).

F4 Inserted by Commission Delegated Regulation (EU) 2019/1822 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include honey as an active substance in Annex I thereto (Text with EEA relevance).

F5 Inserted by Commission Delegated Regulation (EU) 2019/1823 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include D-fructose as an active substance in Annex I thereto (Text with EEA relevance).

F6 Inserted by Commission Delegated Regulation (EU) 2019/1824 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include cheese as an active substance in Annex I thereto (Text with EEA relevance).

F7 Inserted by Commission Delegated Regulation (EU) 2019/1825 of 8 August 2019 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council to include concentrated apple juice as an active substance in Annex I thereto (Text with EEA relevance).

F8 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation of the dossier referred to in point (a) of Article 6(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all active substances. However, in some cases the physical or chemical properties of the substance may mean that it is impossible or unnecessary to provide specific data elements belonging to the CDS.

With regard to the ADS, the data elements to be provided for a specific active substance shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the substance, existing data, information which is part of the CDS and the types of products in which the active substance will be used and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex II table. The general considerations regarding adaptation of information requirements as set out in Annex IV shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the Annex II table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates. The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in Article 4(1) are met.

The applicant should consult the detailed technical guidance regarding the application of this Annex and the preparation of the dossier referred to in point (a) of Article 6(1), which is available on the website of the Agency.

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

Additional information may need to be submitted if it is necessary to carry out the evaluation as indicated in Article 8(2).

3. A detailed and full description of the studies conducted or referred to and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements. Evidence should also

be provided to demonstrate that the active substance upon which the tests have been carried out is the same as the substance for which the application has been submitted.

4. The formats made available by the Agency must be used for submission of the dossiers. In addition, IUCLID must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the website of the Agency.

5. Tests submitted for the purpose of the approval of an active substance shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[(1)]. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes[(2)] and in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances[(3)] or other international standards recognised as being equivalent by the Commission or the Agency. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

7. Where testing is done, a detailed description (specification) of the active substance used and its impurities must be provided. Testing should be performed with the active substance as manufactured or, in the case of some of the physical and chemical properties (see indications given in column I of the table), with a purified form of the active substance.

8. Where test data exist that have been generated before 1 September 2013 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State concerned, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrates.

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In-vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

TITLE 1

CHEMICAL SUBSTANCES

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 and are not repeated in column 3, also apply.

Column 1Information required	**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Active substance manufacturer (name, address and location of manufacturing plant(s))		
2. IDENTITY OF THE ACTIVE SUBSTANCE		
For the active substance, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated		
2.1. Common name proposed or		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	accepted by ISO and synonyms (usual name, trade name, abbreviation)		
2.2.	Chemical name (IUPAC and CA nomenclature or other international chemical name(s))		
2.3.	Manufacturer's development code number(s)		
2.4.	CAS number plus EC, INDEX and CIPAC numbers		
2.5.	Molecular and structural formula (including SMILES notation, if available and appropriate)		
2.6.	Information on optical activity and full details of any isomeric composition (if applicable and appropriate)		
2.7.	Molar mass		
2.8.	Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents		

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c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	including suppliers, specifications and commercial availability		
2.9.	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		
2.10.	The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances		
2.11.	Analytical profile of at least five representative batches (g/kg active substance) including information on content of the impurities referred to in 2.10.		
2.12.	The origin of the natural active		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	substance or the precursor(s) of the active substance, e.g. an extract of a flower		
3. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE			
3.1. Appearance[a]			
3.1.1.	Aggregate state (at 20 °C and 101,3 kPa)		
3.1.2.	Physical state (i.e. viscous, crystalline, powder) (at 20 °C and 101,3 kPa)		
3.1.3.	Colour (at 20 °C and 101,3 kPa)		
3.1.4.	Odour (at 20 °C and 101,3 kPa)		
3.2.	Melting/freezing point[b]		
3.3.	Acidity, alkalinity		
3.4.	Boiling point[b]		
3.5.	Relative Density[b]		
3.6.	Absorption spectra data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient at relevant		

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b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	wavelengths, where relevant[b]		
3.7. Vapour pressure[b]			
3.7.1.	Henry's law constant must always be stated for solids and liquids if it can be calculated		
3.8.	Surface tension[b]		
3.9.	Water solubility[b]		
3.10.	Partition coefficient (n-octanol/ water) and its pH dependency[b]		
3.11.	Thermal stability, identity of breakdown products[b]		
3.12.	Reactivity towards container material		
3.13.	Dissociation constant	ADS	
3.14.	Granulometry		
3.15.	Viscosity	ADS	
3.16.	Solubility in organic solvents, including effect of temperature on solubility[b]	ADS	
3.17.	Stability in organic solvents used in	ADS	

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e OJ L 348, 24.12.2008, p. 84.

	biocidal products and identity of relevant breakdown products[a]		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Self-reactive substances and mixtures		
4.9.	Pyrophoric liquids		
4.10.	Pyrophoric solids		
4.11.	Self-heating substances and mixtures		
4.12.	Substances and mixtures which in contact with water emit flammable gases		
4.13.	Oxidising liquids		

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b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

4.14.	Oxidising solids		
4.15.	Organic peroxides		
4.16.	Corrosive to metals		
4.17. Additional physical indicators for hazards			
4.17.1.	Auto-ignition temperature (liquids and gases)		
4.17.2.	Relative self ignition temperature for solids		
4.17.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	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 ≥ 1 g/kg		
5.2. Analytical methods for monitoring purposes including recovery rates and the limits			

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
b	The information provided should be for the purified active substance of stated specification.
c	OJ L 20, 26.1.1980, p. 43.
d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

of quantification and detection for the active substance, and for residues thereof in/on the following where relevant			
5.2.1.	Soil		
5.2.2.	Air		
5.2.3.	Water (surface, drinking etc.) and sediment		
5.2.4.	Animal and human body fluids and tissues		
5.3.	Analytical methods for monitoring purposes including recovery rates and the 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)	ADS	

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e OJ L 348, 24.12.2008, p. 84.

6. EFFECTIVENESS AGAINST TARGET ORGANISMS

6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organism(s)		
6.4.	Likely concentration at which the active substance will be used in products and, where appropriate, in treated articles		
6.5.	Mode of action (including time delay)		
6.6.	Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including		

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e OJ L 348, 24.12.2008, p. 84.

	any available standard protocols, laboratory tests or field trials used including performance standards where appropriate		
6.7. Any known limitations on efficacy			
6.7.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.7.2.	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms		
7. INTENDED USES AND EXPOSURE			
7.1.	Field of use(s) envisaged for biocidal products and, where appropriate, treated articles		
7.2.	Product-type(s)		
7.3.	Detailed description of the intended use pattern(s) including in treated articles		

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e OJ L 348, 24.12.2008, p. 84.

7.4.	Users e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Likely tonnage to be placed on the market per year and, where relevant, for the envisaged major use categories		
7.6. Exposure data in conformity with Annex VI to this Regulation			
7.6.1.	Information on human exposure associated with the intended uses and disposal of the active substance		
7.6.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance		
7.6.3.	Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.6.4.	Information on exposure from		

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b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

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e OJ L 348, 24.12.2008, p. 84.

treated articles including leaching data (either laboratory studies or model data)		
8. TOXICOLOGICAL PROFILE FOR HUMAN AND ANIMAL INCLUDING METABOLISM		
8.1. Skin irritation or skin corrosion 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)		
8.2. 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)		
8.3. Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available		Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for

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c OJ L 20, 26.1.1980, p. 43.

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e OJ L 348, 24.12.2008, p. 84.

2.	human, animal and alternative data 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		— skin sensitisation or corrosivity, or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)
8.4.	Respiratory sensitisation	ADS	
8.5. 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 positive result in any of the in vitro genotoxicity studies			

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
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c	OJ L 20, 26.1.1980, p. 43.
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e	OJ L 348, 24.12.2008, p. 84.

8.5.1.	In vitro gene mutation study in bacteria		
8.5.2.	In vitro cytogenicity study in mammalian cells		
8.5.3.	In vitro gene mutation study in mammalian cells		
8.6.	In vivo genotoxicity study 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	ADS	The study/ies do(es) not generally need to be conducted if: — the results are negative for the three in vitro tests and if no metabolites of concern are formed in mammals or — valid in vivo micronucleus data is generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

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c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

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		
8.7. Acute toxicity In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 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 the likely route of human exposure — Gases and volatile liquids should be administered by the inhalation route		The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin

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e OJ L 348, 24.12.2008, p. 84.

— 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		
8.7.1. By oral route The Acute Toxic Class Method is the preferred method for the determination of this endpoint		The study need not be conducted if: — the substance is a gas or a highly volatile substance
8.7.2. 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		

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e OJ L 348, 24.12.2008, p. 84.

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 micrometers 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 micrometers) — the Acute Toxic Class Method is the preferred method for the determination of this endpoint		
8.7.3. By dermal route 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		

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e OJ L 348, 24.12.2008, p. 84.

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		
8.8. Toxicokinetics and metabolism studies in mammals		
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		
8.8.1. Further toxicokinetic and metabolism studies in mammals Additional studies might be required based on the outcome of the toxicokinetic and metabolism study conducted in rat. These further studies shall be required if: — there is evidence that metabolism in the rat is not relevant for human exposure — route-to-route extrapolation from oral to dermal/	ADS	

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e OJ L 348, 24.12.2008, p. 84.

inhalation exposure is not feasible Where it is considered appropriate to obtain information on dermal absorption, the assessment of this endpoint shall proceed using a tiered approach for assessment of dermal absorption		
8.9. 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 Testing by the dermal route shall be considered 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		The repeated dose toxicity study (28 or 90 days) does not need to be conducted if: — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products for systemic and local effects and no synergistic effects are expected, or — relevant human exposure can be excluded in accordance with Section 3 of Annex IV In order to reduce testing carried out on vertebrates and in particular the need for free-standing single-endpoint studies, the design of the repeated dose toxicity studies shall take account of the possibility to explore several endpoints within the framework of one study

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e	OJ L 348, 24.12.2008, p. 84.

	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 for example is 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		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	— gases have 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 micrometers)		
8.9.1.	Short-term repeated dose toxicity study (28 days), preferred species is rat		The short-term toxicity study (28 days) does not need to be conducted if: (i) a reliable sub-chronic (90 day) study is available, provided that the most appropriate species, dosage, solvent and route of administration were used, (ii) the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: — other available data indicate that the substance may have a dangerous property that cannot be detected in a short-

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e OJ L 348, 24.12.2008, p. 84.

			term toxicity study, or — appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short term toxicity study but which are liable to result in adverse effects after prolonged exposure
8.9.2.	Sub-chronic repeated dose toxicity study (90 days), preferred species is rat		The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

			H372 and H373 (Regulation (EC) No 1272/2008), for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor allows the extrapolation towards the NOAEL-90 days for the same route of exposure, and — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — the substance is unreactive, insoluble, not bioaccumulative and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure
8.9.3.	Long-term repeated dose toxicity (≥ 12 months)		The long-term toxicity study (≥ 12 months) does not need to be conducted if: — Long-term exposure can be excluded and no effects have been seen at the limit dose in the 90-day study or

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d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

		— a combined long-term repeated dose/ carcinogenicity study (8.11.1) is undertaken
8.9.4. Further repeat dose studies 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	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	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		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made.		
8.10. Reproductive toxicity 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		The studies need not be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

		that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure — If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered — If a substance is known to cause developmental toxicity, meeting the criteria for classification as

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

		Reproductive toxicity Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered
8.10.1. 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		
8.10.2. 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		

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d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

8.10.3. 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 the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration	ADS	
8.11. Carcinogenicity See 8.11.1 for new study requirements		A carcinogenicity study does not need to be conducted if: — the substance is classified as mutagen category 1A or 1B. The default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required
8.11.1. Combined carcinogenicity study and long-term repeated dose toxicity Rat, oral route of administration is the preferred route. If an		

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e OJ L 348, 24.12.2008, p. 84.

alternative route is 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		
8.11.2. Carcinogenicity testing in a second species — 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		
8.12. Relevant health data, observations and treatments		
Justification should be provided if data is not available		
8.12.1. Medical surveillance data on manufacturing plant personnel		
8.12.2. Direct observation, e.g. clinical cases, poisoning incidents		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

8.12.3. Health records, both from industry and any other available sources		
8.12.4. Epidemiological studies on the general population		
8.12.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests		
8.12.6. Sensitisation/ allergenicity observations		
8.12.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
8.12.8. Prognosis following poisoning		
8.13. Additional studies Additional data which may be required depending on the characteristics and intended use of the active substance Other available data: Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic' (genomic, proteomic, metabolomic,	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel		
8.13.1. Phototoxicity	ADS	
8.13.2. Neurotoxicity including developmental neurotoxicity — The preferred test species is the rat unless another test species is justified to be more appropriate — For delayed neurotoxicity tests the preferred species will be the adult hen — If anticholinesterase activity is detected a test for response to reactivating agents should be considered If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties then additional information or specific studies will be required. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

conduct toxicity studies by the oral route		
8.13.3. Endocrine disruption If there is any evidence from in vitro, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required to: — elucidate the mode/ mechanism of action — provide sufficient evidence for relevant adverse effects 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	ADS	
8.13.4. Immunotoxicity including developmental immunotoxicity If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required to: — elucidate the mode/ mechanism of action — provide sufficient evidence for	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

relevant adverse effects in humans 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		
8.13.5. Mechanistic data — any studies necessary to clarify effects reported in toxicity studies	ADS	
8.14. Studies related to the exposure of humans to the active substance	ADS	
8.15. Toxic effects on livestock and pets	ADS	
8.16. Food and feeding stuffs studies including for food-producing animals and their products (milk, eggs and honey) Additional information related to the exposure of humans to the active substance contained in biocidal products	ADS	
8.16.1. Proposed acceptable residue levels i.e. maximum residue limits (MRL) and the justification of their acceptability	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

8.16.2. Behaviour of the residue of the active substance on the treated or contaminated food or feeding stuffs including the kinetics of disappearance Residue definitions should be provided where relevant. It is also important to compare residues found in toxicity studies with residues formed in food-producing animals and their products, as well as food and feed	ADS	
8.16.3. Overall material balance for the active substance Sufficient residue data from supervised trials on food-producing animals and their products, as well as food and feed, to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	ADS	
8.16.4. Estimation of potential or actual exposure of humans to the active substance and residues through diet and other means	ADS	
8.16.5. If residues of the active substance occur in or on feeding stuffs	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

for a significant period of time or are found in food of animal origin after treatment on or around food-producing animals (e.g. direct treatment on animals or indirect treatment of animal houses or surroundings) then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin		
8.16.6. Effects of industrial processing and/ or domestic preparation on the nature and magnitude of residues of the active substance	ADS	
8.16.7. Any other available information that is relevant It may be appropriate to include information on migration into food, especially in the case of treatment of food contact materials	ADS	
8.16.8. Summary and evaluation of data submitted under 8.16.1 to 8.16.8	ADS	

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d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

It is important to establish whether the metabolites found in food (from animals or plants) are the same as those tested in toxicity studies. Otherwise values for risk assessment (e.g. ADI) are not valid for the residues found		
8.17. If the active substance is to be used in products for action against plants including algae then tests shall be required to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals	ADS	
8.18. Summary of mammalian toxicology Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL		
9. ECOTOXICOLOGICAL STUDIES		
9.1. Toxicity to Aquatic Organisms		
9.1.1. Short-term toxicity testing on fish When short-term fish toxicity data is required the threshold		The study does not need to be conducted if: — a valid long-term aquatic toxicity

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e OJ L 348, 24.12.2008, p. 84.

approach (tiered strategy) should be applied		study on fish is available
9.1.2. Short-term toxicity testing on aquatic invertebrates		
9.1.2.1. Daphnia magna		
9.1.2.2. Other species	ADS	
9.1.3. Growth inhibition study on algae		
9.1.3.1. Effects on growth rate of green algae		
9.1.3.2. Effects on growth rate of cyanobacteria or diatoms		
9.1.4. Bioconcentration		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
9.1.4.1. Estimation methods		
9.1.4.2. Experimental determination		
9.1.5. Inhibition of microbial activity The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

9.1.6. Further Toxicity Studies on Aquatic Organisms If the results of the ecotoxicological studies, studies on fate and behaviour and/or the intended use(s) of the active substance indicate a risk for the aquatic environment, or if long-term exposure is expected, then one or more of the tests described in this Section shall be conducted	ADS	
9.1.6.1. Long term toxicity testing on Fish (a) Fish Early Life Stage (FELS) Test (b) Fish short term toxicity test on embryo and sack fry stages (c) Fish juvenile growth test (d) Fish full life cycle test	ADS	
9.1.6.2. Long term toxicity testing on invertebrates (a) Daphnia growth and reproduction study (b) Other species reproduction and growth (e.g. Mysid) (c) Other species development and emergence (e.g. Chironomus)	ADS	
9.1.7. Bioaccumulation in an appropriate aquatic species	ADS	

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d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

9.1.8.	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	
9.1.9.	Studies on sediment- dwelling organisms	ADS	
9.1.10.	Effects on aquatic macrophytes	ADS	
9.2.	Terrestrial toxicity, initial tests	ADS	
9.2.1.	Effects on soil micro-organisms		
9.2.2.	Effects on earthworms or other soil- dwelling non-target invertebrates		
9.2.3.	Acute toxicity to plants		
9.3.	Terrestrial tests, long term	ADS	
9.3.1.	Reproduction study with earthworms or other soil-dwelling non-target invertebrates		
9.4.	Effects on birds	ADS	For endpoint 9.4.3 the study does not need to be conducted if: — the dietary toxicity study shows that the LC_{50} is above 2 000 mg/kg
9.4.1.	Acute oral toxicity		
9.4.2.	Short-term toxicity — eight-		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	day dietary study in at least one species (other than chickens, ducks and geese)		
9.4.3.	Effects on reproduction		
9.5.	Effects on arthropods	ADS	
9.5.1.	Effects on honeybees		
9.5.2.	Other non-target terrestrial arthropods, e.g. predators		
9.6.	Bioconcentration, terrestrial	ADS	
9.7.	Bioaccumulation, terrestrial	ADS	
9.8.	Effects on other non-target, non-aquatic organisms	ADS	
9.9.	Effects on mammals	ADS	Data are derived from the mammalian toxicological assessment. The most sensitive relevant mammalian long-term toxicological endpoint (NOAEL) expressed as mg test compound/kg bw/ day shall be reported
9.9.1.	Acute oral toxicity		
9.9.2.	Short term toxicity		
9.9.3.	Long term toxicity		
9.9.4.	Effects on reproduction		
9.10.	Identification of endocrine activity	ADS	

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

10. ENVIRONMENTAL FATE AND BEHAVIOUR		
10.1. Fate and behaviour in water and sediment		
10.1.1. Degradation, initial studies		
If the 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 the tests described in 10.1.3 and 10.3.2 and where appropriate — in 10.4 shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed		
10.1.1.1. 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 %		
(b) Phototransformation in water, including identification of transformation products		
10.1.1.2. Biotic		

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

(a)	Ready biodegradability		
(b)	Inherent biodegradability (where appropriate)		
10.1.2.	Adsorption/ desorption		
10.1.3. Rate and route of degradation including identification of metabolites and degradation products			
10.1.3.1.	Biological sewage treatment		
(a)	Aerobic biodegradation	ADS	
(b)	Anaerobic biodegradation	ADS	
(c)	STP simulation test	ADS	
10.1.3.2.	Biodegradation in freshwater		
(a)	Aerobic aquatic degradation study	ADS	
(b)	Water/sediment degradation test	ADS	
10.1.3.3.	Biodegradation in sea water	ADS	
10.1.3.4.	Biodegradation during manure storage	ADS	

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
b	The information provided should be for the purified active substance of stated specification.
c	OJ L 20, 26.1.1980, p. 43.
d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

10.1.4. Adsorption and desorption in water/ aquatic sediment systems and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.1.5. Field study on accumulation in sediment	ADS	
10.1.6. Inorganic substances: information on fate and behaviour in water	ADS	
10.2. Fate and behaviour in soil	ADS	
10.2.1. Laboratory study on rate and route of degradation including identification of the 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	ADS	
10.2.2. Field studies, two soil types	ADS	

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

10.2.3. Soil accumulation studies	ADS	
10.2.4. Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.2.5. Further studies on sorption		
10.2.6. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	ADS	
10.2.6.1. Column leaching studies		
10.2.6.2. Lysimeter studies		
10.2.6.3. Field leaching studies		
10.2.7. Extent and nature of bound residues The determination and characteristics of bound residues is recommended to be combined with a soil simulation study	ADS	
10.2.8. Other soil degradation studies	ADS	

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

10.2.9. Inorganic substances: information on fate and behaviour in soil		
10.3. Fate and behaviour in air		
10.3.1. Phototransformation in air (estimation method) Identification of transformation products		
10.3.2. Fate and behaviour in air, further studies	ADS	
10.4. Additional studies on fate and behaviour in the environment	ADS	
10.5. Definition of the residue	ADS	
10.5.1. Definition of the residue for risk assessment		
10.5.2. Definition of the residue for monitoring		
10.6. Monitoring data	ADS	
10.6.1. Identification of all degradation products (> 10 %) must be included in the studies on degradation in soil, water and sediments		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

11. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
11.1.	Recommended methods and precautions concerning handling, use, storage, transport or fire		
11.2.	In case of fire, nature of reaction products, combustion gases etc.		
11.3.	Emergency measures in case of accident		
11.4.	Possibility of destruction or decontamination following release in or on the following:		
(a)	air		
(b)	water, including drinking water		
(c)	soil		
11.5.	Procedures for waste management of the active substance for industry or professional users		
11.6.	Possibility of reuse or recycling		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

11.7.	Possibility of neutralisation of effects		
11.8.	Conditions for controlled discharge including leachate qualities on disposal		
11.9.	Conditions for controlled incineration		
11.10.	Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances[c], of Annexes I and II to Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration[d], of Annex I to Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	the field of water policy[e], of Part B of Annex I to Directive 98/83/EC or Annexes VIII and X to Directive 2000/60/EC		
12. CLASSIFICATION, LABELLING AND PACKAGING			
12.1.	State any existing classification and labelling		
12.2. The hazard classification of the substance resulting from the application of Regulation (EC) No 1272/2008			
In addition, for each entry, the reasons why no classification is given for an endpoint should be provided			
12.2.1.	Hazard classification		
12.2.2.	Hazard pictogram		
12.2.3.	Signal word		
12.2.4.	Hazard statements		
12.2.5.	Precautionary statements including prevention, response, storage and disposal		
12.3.	Specific concentration		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	limits, where applicable, resulting from the application of Regulation (EC) No 1272/2008		
13.	SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
b	The information provided should be for the purified active substance of stated specification.
c	OJ L 20, 26.1.1980, p. 43.
d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in Regulation (EC) No 440/2008 that are not repeated in column 3, also apply.

Column 1Information required	**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Manufacturer (name, address and location of manufacturing plant)		

2. IDENTITY OF THE MICRO-ORGANISM			
2.1.	Common name of the micro-organism (including alternative and superseded names)		
2.2.	Taxonomic name and strain		
2.3.	Collection and culture reference number where the culture is deposited		
2.4.	Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
2.5.	Specification of the technical grade active ingredient		
2.6.	Method of production and quality control		
2.7.	Content of the micro-organism		
2.8.	Identity and content of impurities, additives, contaminating micro-organisms		
2.9.	Analytical profile of batches		
3. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM			
3.1. General information on the micro-organism			

3.1.1.	Historical background		
3.1.2.	Historical uses		
3.1.3.	Origin, natural occurrence and geographical distribution		
3.2.	Development stages/life cycle of the micro-organism		
3.3.	Relationships to known plant or animal or human pathogens		
3.4.	Genetic stability and factors affecting it		
3.5.	Information on the production of metabolites (especially toxins)		
3.6.	Production and resistance to antibiotics and other anti-microbial agents		
3.7.	Robustness to environmental factors		
3.8.	Further information on the micro-organism		
4. METHODS OF DETECTION AND IDENTIFICATION			
4.1.	Analytical methods for the analysis of the micro-organism as manufactured		

4.2.	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)		
5. EFFECTIVENESS AGAINST TARGET ORGANISM			
5.1.	Function and mode of control e.g. attracting, killing, inhibiting		
5.2.	Infectiveness, dispersal and colonisation ability		
5.3.	Representative organism(s) controlled and products, organisms or objects to be protected		
5.4.	Effects on representative target organism(s) Effects on materials, substances and products		
5.5.	Likely concentration at which the micro-organism will be used		
5.6.	Mode of action (including time delay)		
5.7.	Efficacy data		
5.8. Any known limitations on efficacy			
5.8.1.	Information on the occurrence or possible occurrence		

	of the development of resistance of the target organism(s) and appropriate management strategies		
5.8.2.	Observations on undesirable or unintended side effects		
5.8.3.	Host specificity, range and effects on species other than the target organism		
5.9.	Methods to prevent loss of virulence of seed stock of the micro-organism		
6. INTENDED USES AND EXPOSURE			
6.1.	Field of use(s) envisaged		
6.2.	Product-type(s)		
6.3.	Detailed description of the use pattern(s)		
6.4.	Category of users for which the micro-organism should be approved		
6.5. Exposure data applying, as appropriate, the methodologies described in Section 5 of Annex I to Regulation (EC) No 1907/2006			
6.5.1.	Information on human exposure associated with the intended uses and disposal of the active substance		

6.5.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance		
6.5.3.	Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.	EFFECT ON HUMAN AND ANIMAL HEALTH		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
7.1. Basic information			
7.1.1.	Medical data		
7.1.2.	Medical surveillance on manufacturing plant personnel		
7.1.3.	Sensitisation/ allergenicity observations		
7.1.4.	Direct observation, e.g. clinical cases Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression		
7.2. Basic studies			
7.2.1.	Sensitisation		
7.2.2. Acute toxicity, pathogenicity, and infectiveness			

7.2.2.1.	Acute oral toxicity, pathogenicity and infectiveness		
7.2.2.2.	Acute inhalatory toxicity, pathogenicity and infectiveness	ADS	
7.2.2.3.	Intraperitoneal/ subcutaneous single dose	ADS	
7.2.3.	In vitro genotoxicity testing		
7.2.4.	Cell culture study		
7.2.5.	Information on short-term toxicity and pathogenicity	ADS	
7.2.5.1.	Health effects after repeated inhalatory exposure	ADS	
7.2.6.	Proposed treatment: first aid measures, medical treatment		
7.3.	Specific toxicity, pathogenicity and infectiveness studies	ADS	
7.4.	Genotoxicity — in vivo studies in somatic cells	ADS	
7.5.	Genotoxicity — in vivo studies in germ cells	ADS	
7.6.	Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation		

7.7.	Residues in or on treated articles, food and feedingstuffs	ADS	
7.7.1.	Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs	ADS	
7.7.2.	Further information required	ADS	
7.7.2.1.	Non-viable residues	ADS	
7.7.2.2.	Viable residues	ADS	
7.8.	Summary and evaluation of residues in or on treated articles, food and feedingstuffs	ADS	
8.	EFFECTS ON NON-TARGET ORGANISMS		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
8.1. Effects on aquatic organisms			
8.1.1.	Effects on fish		
8.1.2.	Effects on freshwater invertebrates		
8.1.3.	Effects on algae growth		
8.1.4.	Effects on plants other than algae	ADS	
8.2.	Effects on earthworms		
8.3.	Effects on soil micro-organisms		

8.4.	Effects on birds		
8.5.	Effects on bees		
8.6.	Effects on arthropods other than bees		
8.7.	Further studies	ADS	
8.7.1.	Terrestrial plants	ADS	
8.7.2.	Mammals	ADS	
8.7.3.	Other relevant species and processes	ADS	
8.8.	Summary and evaluation of effects on non-target organisms		
9. ENVIRONMENTAL FATE AND BEHAVIOUR			
9.1. Persistence and multiplication			
9.1.1.	Soil		
9.1.2.	Water		
9.1.3.	Air		
9.1.4.	Mobility		
9.1.5.	Summary and evaluation of fate and behaviour in the environment		
10. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
10.1.	Recommended methods and precautions concerning		

	handling, storage, transport or fire		
10.2.	Emergency measures in case of an accident		
10.3.	Procedures for destruction or decontamination		
10.4.	Procedures for waste management		
10.5.	Monitoring plan to be used for the active micro-organism including handling, storage, transport and use		
11. CLASSIFICATION, LABELLING AND PACKAGING OF THE MICRO-ORGANISM			
11.1.	Relevant risk group specified in Article 2 of Directive 2000/54/EC		
12.	SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with point (b) of Article 6(1) and the dossier accompanying an application for the authorisation of a biocidal product in accordance with point (a) of Article 20(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex III table. The general considerations regarding adaptation of information requirements as set out in Annex IV to this Regulation shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates.

For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation.

The relevant calculation methods used for the classification of mixtures as laid down in Regulation (EC) No 1272/2008 shall, where appropriate, be applied in the hazard assessment of the biocidal product. Such calculation methods shall not be used if, in relation to a particular hazard, synergistic and antagonistic effects between the different substances contained in the product are considered likely.

Detailed technical guidance regarding the application of this Annex and the preparation of the dossier is available on the website of the Agency.

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

Additional information may need to be submitted if necessary to carry out the evaluation as indicated in Article 29(3) or Article 44(2).

The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria in Article 19(1)(b) are met.

3. A detailed and full description of studies conducted and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements.

4. The formats made available by the Agency shall be used for submission of the dossiers. In addition, IUCLID shall be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness

must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

7. Where testing is done, a detailed quantitative and qualitative description (specification) of the product used for each test and its impurities must be provided.

8. Where test data exist that have been generated before 17 July 2012 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State, on a case-by-case basis, taking into account, among other factors, the need to avoid unnecessary testing.

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

TITLE 1

CHEMICAL PRODUCTS

Core data set and additional data set for chemical products

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1Information required:	**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT		
1.1. Name and address, etc.		
1.2. Contact person		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

1.3.	Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCT			
2.1.	Trade name or proposed trade name		
2.2.	Manufacturer's development code and number of the product, if appropriate		
2.3.	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		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	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		
2.4.	Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution		
[F9 2.5.	Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated		]

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

in accordance with Article 26 of Directive 98/8/EC		
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES		
3.1. Appearance (at 20 °C and 101,3 kPa)		
3.1.1. Physical state (at 20 °C and 101,3 kPa)		
3.1.2. Colour (at 20 °C and 101,3 kPa)		
3.1.3. Odour (at 20 °C and 101,3 kPa)		
3.2. 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		
3.3. Relative density (liquids) and bulk, tap density (solids)		
3.4. Storage stability, stability and shelf-life		
3.4.1. Storage stability tests		
3.4.1.1. Accelerated storage test		
3.4.1.2. Long term storage test at ambient temperature		
3.4.1.3. Low temperature stability test (liquids)		
3.4.2. Effects on content of the active substance and technical characteristics of the biocidal product		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

3.4.2.1.	Light		
3.4.2.2.	Temperature and humidity		
3.4.2.3.	Reactivity towards container material		
3.5. Technical characteristics of the biocidal product			
3.5.1.	Wettability		
3.5.2.	Suspensibility, spontaneity and dispersion stability		
3.5.3.	Wet sieve analysis and dry sieve test		
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability		
3.5.5.	Disintegration time		
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability		
3.5.7.	Persistent foaming		
3.5.8.	Flowability/ Pourability/ Dustability		
3.5.9.	Burning rate — smoke generators		
3.5.10.	Burning completeness — smoke generators		
3.5.11.	Composition of smoke — smoke generators		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

3.5.12.	Spraying pattern — aerosols		
3.5.13.	Other technical characteristics		
3.6. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised			
3.6.1.	Physical compatibility		
3.6.2.	Chemical compatibility		
3.7.	Degree of dissolution and dilution stability		
3.8.	Surface tension		
3.9.	Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Self-reactive substances and mixtures		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

4.9.	Pyrophoric liquids		
4.10.	Pyrophoric solids		
4.11.	Self-heating substances and mixtures		
4.12.	Substances and mixtures which in contact with water emit flammable gases		
4.13.	Oxidising liquids		
4.14.	Oxidising solids		
4.15.	Organic peroxides		
4.16.	Corrosive to metals		
4.17. Additional physical indications of hazard			
4.17.1.	Auto-ignition temperatures of products (liquids and gases)		
4.17.2.	Relative self-ignition temperature for solids		
4.17.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	concern in the biocidal product		
5.2.	In so far as not covered by Annex II 5.2 and 5.3, 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:	ADS	
5.2.1.	Soil	ADS	
5.2.2.	Air	ADS	
5.2.3.	Water (including drinking water) and sediment	ADS	
5.2.4.	Animal and human body fluids and tissues	ADS	
5.3.	Analytical methods for monitoring purposes including recovery rates and the 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 the material	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs)		
6. EFFECTIVENESS AGAINST TARGET ORGANISMS			
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which the active substance will be used		
6.5.	Mode of action (including time delay)		
6.6.	The proposed label claims for the product and, where label claims are made, for treated articles		
6.7.	Efficacy data to support these claims, including		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		
6.8. Any known limitations on efficacy			
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2.	Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms		
6.9.	Summary and evaluation		
7. INTENDED USES AND EXPOSURE			
7.1.	Field(s) of use envisaged for biocidal products and, where appropriate, treated articles		
7.2.	Product-type		
7.3.	Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Likely tonnage to be placed on the market per year and, where relevant, for different use categories		
7.6.	Method of application and a description of this method		
7.7.	Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes		
7.8.	Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	health and the environment		
7.9.	Proposed instructions for use		
7.10. Exposure data in conformity with Annex VI to this Regulation			
7.10.1.	Information on human exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.2.	Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.3.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
7.10.4.	Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS			

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

8.1. Skin corrosion or 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)		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.2. Eye irritation[a] 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)		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ECand Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.3. 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,		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	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		1272/2008 (CLP), and synergistic effects between any of the components are not expected — the available information indicates that the product should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)
8.4.	Respiratory sensitisation	ADS	Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.5. —	Acute toxicity Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

		of the components are not expected
8.5.1. By oral route		
8.5.2. By inhalation		
8.5.3. By dermal route		
8.5.4. For biocidal products that are intended to be authorised for use with other biocidal products, the risks to human health, animal health and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried out using combinations of the products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.6. Information on dermal absorption Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach		
8.7. Available toxicological data relating to:		Testing on the product/ mixture does not need to be conducted if:

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

— 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		— there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP)
8.8. Food and feedingstuffs studies	ADS	
8.8.1. If residues of the biocidal product remain in or on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	ADS	
8.9. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product	ADS	
8.10. Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	required for the biocidal product In addition, for certain biocides which are applied directly or around livestock (including horses) residue studies might be needed		
9.	**ECOTOXICOLOGICAL STUDIES**		
9.1.	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required		
—	Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP)		
—	Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/ or the biocidal product itself may be necessary		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

9.2. Further Ecotoxicological studies Further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4. If the biocidal product is in the form of bait or granules the following studies may be required:		
9.4.1. Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk		
9.5. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

The test requirements below are applicable only to the relevant components of the biocidal product		
10.1. Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2. Further studies on fate and behaviour in the environment Further studies chosen from among the endpoints referred to in Section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required. For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3. Leaching behaviour	ADS	
10.4. Testing for distribution and dissipation in the following:	ADS	
10.4.1. Soil	ADS	
10.4.2. Water and sediment	ADS	
10.4.3. Air	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

10.5.	If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions	ADS	
10.6.	If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
11.1.	Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire		
11.2.	Identity of relevant combustion products in cases of fire		
11.3.	Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available;		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	emergency measures to protect the environment		
11.4. Possibility of destruction or decontamination following release in or on the following:			
11.4.1.	Air		
11.4.2.	Water, including drinking water		
11.4.3.	Soil		
11.5.	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)		
11.6.	Procedures for cleaning application equipment where relevant		
11.7.	Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

12. CLASSIFICATION, LABELLING, AND PACKAGING		
As established in point (b) of Article 20(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted. Example labels, instructions for use and safety data sheets shall be provided		
12.1. Hazard classification		
12.2. Hazard pictogram		
12.3. Signal word		
12.4. Hazard statements		
12.5. Precautionary statements including prevention, response, storage and disposal		
12.6. Proposals for safety-data sheets should be provided, where appropriate		
12.7. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. EVALUATION AND SUMMARY The key information identified from the endpoints		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

Textual Amendments

F9 Inserted by Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products (Text with EEA relevance).

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1Information required:		**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT			
1.1.	Name and address		
1.2.	Contact person		
1.3.	Manufacturer and formulator of the biocidal product and the micro-organism(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCTS			
2.1.	Trade name or proposed trade name		

2.2.	Manufacturer's development code and number of the biocidal product, if appropriate		
2.3.	Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given		
2.4.	Formulation type and nature of the biocidal product		
[F9 2.5.	Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has		]

	been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC		
3. BIOLOGICAL, PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT			
3.1.	Biological properties of the micro-organism in the biocidal product		
3.2. Appearance (at 20 °C and 101,3 kPa)			
3.2.1.	Colour (at 20 °C and 101,3 kPa)		
3.2.2.	Odour (at 20 °C and 101,3 kPa)		
3.3.	Acidity, alkalinity and pH value		
3.4.	Relative density		
3.5. Storage stability, stability and shelf-life			
3.5.1.	Effects of light		
3.5.2.	Effects of temperature and humidity		
3.5.3.	Reactivity towards the container		

3.5.4.	Other factors affecting stability		
3.6. Technical characteristics of the biocidal product			
3.6.1.	Wettability		
3.6.2.	Suspensibility and suspension stability		
3.6.3.	Wet sieve analysis and dry sieve test		
3.6.4.	Emulsifiability, re-emulsifiability, emulsion stability		
3.6.5.	Particle size distribution content of dust/fines, attrition and friability		
3.6.6.	Persistent foaming		
3.6.7.	Flowability/ Pourability/ Dustability		
3.6.8.	Burning rate — smoke generators		
3.6.9.	Burning completeness — smoke generators		
3.6.10.	Composition of smoke — smoke generators		
3.6.11.	Spraying patterns — aerosols		
3.6.12.	Other technical characteristics		
3.7. Physical, chemical and biological compatibility with other products			

including biocidal products with which its use is to be authorised or registered			
3.7.1.	Physical compatibility		
3.7.2.	Chemical compatibility		
3.7.3.	Biological compatibility		
3.8.	Surface tension		
3.9.	Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS			
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Oxidising liquids		
4.9.	Oxidising solids		
4.10.	Organic peroxides		
4.11.	Corrosive to metals		
4.12. Other physical indications of hazard			
4.12.1.	Auto-ignition temperatures of		

	products (liquids and gases)		
4.12.2.	Relative self-ignition temperature for solids		
4.12.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	Analytical method for determining the concentration of the micro-organism(s) and substances of concern in the biocidal product		
5.2.	Analytical methods for monitoring purposes including recovery rates and the 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 the article treated with it does not come into contact with food-producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISM			

6.1.	Function and mode of control		
6.2.	Representative pest organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which micro-organism will be used		
6.5.	Mode of action		
6.6.	The proposed label claims for the product		
6.7.	Efficacy data to support these claims, including any available standard protocols, laboratory tests, or field trials used including performance standards, where appropriate and relevant		
6.8. Any other known limitations on efficacy including resistance			
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		

6.8.2.	Observations on undesirable or unintended side effects		
7. INTENDED USES AND EXPOSURE			
7.1.	Field of use envisaged		
7.2.	Product-type		
7.3.	Detailed description of intended use		
7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Method of application and a description of this method		
7.6.	Application rate and if appropriate the final concentration of the biocidal product or the micro-organism active substance in a treated article or the system in which the product is to be used (e.g. in the application device or bait)		
7.7.	Number and timing of applications and duration of protection Any particular information relating to the geographical location or climatic variations including necessary waiting periods for re-entry or necessary withdrawal period		

or other precautions to protect human health, animal health and the environment			
7.8.	Proposed instructions for use		
7.9. Exposure data			
7.9.1.	Information on human exposure associated with the proposed/expected uses and disposal		
7.9.2.	Information on environmental exposure associated with the proposed/ expected uses and disposal		
8.	TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected
8.1.	Skin corrosion or irritation		
8.2.	Eye irritation		
8.3.	Skin sensitisation		

8.4.	Respiratory sensitisation	ADS	
8.5. —	Acute toxicity Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		
8.5.1.	Oral		
8.5.2.	Inhalation		
8.5.3.	Dermal		
8.5.4.	Additional acute toxicity studies		
8.6.	Information on dermal absorption if required		
8.7. — —	Available toxicological data relating to: 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)		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected

	of concern or a mixture that a substance(s) of concern is a component of		
8.8.	Supplementary studies for combinations of biocidal products For biocidal products that are intended to be authorised for use with other biocidal products, the risks to humans, animals and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried using combinations of the products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.9.	Residues in or on treated articles, food and feedingstuffs	ADS	
9. ECOTOXICOLOGICAL STUDIES			
9.1.	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of		

	the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/ or the biocidal product itself may be necessary		
9.2.	Further ecotoxicological studies Further studies chosen from among the endpoints referred to in Section 8 of Annex II 'Micro-organisms' for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3.	Effects on any other specific non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4.	If the biocidal product is in the form of bait or granules	ADS	

9.4.1.	Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2.	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk		
9.5.	Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR			
10.1.	Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2.	Further studies on fate and behaviour in the environment Where relevant, all the information required in Section 9 of Annex II 'Micro-organisms' may be required for the product For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	

10.3.	Leaching behaviour	ADS	
10.4.	If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
11.1.	Recommended methods and precautions concerning: handling, storage, transport or fire		
11.2.	Measures in the case of an accident		
11.3. Procedures for destruction or decontamination of the biocidal product and its packaging			
11.3.1.	Controlled incineration		
11.3.2.	Others		
11.4.	Packaging and compatibility of the biocidal product with proposed packaging materials		
11.5.	Procedures for cleaning application equipment where relevant		

11.6. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use		
12. CLASSIFICATION, LABELLING AND PACKAGING		
Example labels, instructions for use and safety data sheets shall be provided		
12.1. Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC		
12.2. Precautionary statements including prevention, response, storage and disposal		
12.3. Proposals for safety-data sheets should be provided, where appropriate		
12.4. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. SUMMARY AND EVALUATION The key information identified from the endpoints		

in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This Annex sets out rules to be followed when the applicant proposes to adapt the data requirements set out in Annexes II and III in accordance with Article 6(2) and (3) or Article 21(1) and (2), without prejudice to the specific rules set out in Annex III on the use of the calculation methods for classification of mixtures to avoid testing on vertebrates.

The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) sufficient adequate and reliable documentation is provided to assess the equivalency of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters/endpoints foreseen to be investigated in the corresponding test methods;

(3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter;

(4) adequate and reliable documentation of the study is provided; and

(5) the study is performed using a system of quality assurance.

1.1.3. Historical human data

As a general rule, in accordance with Article 7(3) of Regulation (EC) No 1272/2008, tests on humans shall not be performed for the purposes of this Regulation. However, existing historical

human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered.

Data collected on humans shall not be used to lower the safety margins resulting from tests or studies on animals.

The strength of the data for a specific human health effect depends, among other things, on the type of analysis and the parameters covered, and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or does not have a particular dangerous property, while the information from each single source alone is considered insufficient to support this notion. There may be sufficient weight of evidence from the use of positive results of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the Commission as being equivalent, leading to the conclusion that a substance has a particular dangerous property. However, if the newly developed test method has been approved by the Commission, but has not yet been published, its results may be taken into account even where this leads to the conclusion that a substance does not have a particular dangerous property.

Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property:

— further testing on vertebrates for that property shall not be undertaken,

— further testing not involving vertebrates may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence, but not the absence of a given dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— the results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— the results are adequate for the purpose of classification and labelling and risk assessment, and

— adequate and reliable documentation of the applied method is provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on the use of (Q)SARs.

1.4. In vitro methods

Results obtained from suitable in vitro methods may indicate the presence of a given dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well-developed according to internationally agreed test development criteria.

Where such in vitro tests are positive, it is necessary to confirm the dangerous property by adequate *in vivo* tests. However, such confirmation may be waived if the following conditions are met:

(1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

(2) results are adequate for the purpose of classification and labelling and risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

In the case of negative results, these exemptions do not apply. A confirmation test may be requested on a case-by-case basis.

1.5. Grouping of substances and read-across approach

Substances whose physico-chemical, toxicological and ecotoxicological properties are similar or follow a regular pattern as a result of structural similarity may be considered as a group or 'category' of substances. Application of the group concept requires that physico-chemical properties, human and animal health effects, and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based on:

(1) a common functional group indicating the presence of dangerous properties;

(2) common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results shall:

— be adequate for the purpose of classification and labelling and risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method, and

— cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter.

In all cases, adequate and reliable documentation of the applied method shall be provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on technically and scientifically justified methodology for the grouping of substances.

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion, or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with some endpoints in Sections 8 and 9 of Annexes II and III, notwithstanding Article 6(2), may be omitted based on exposure considerations, where exposure data in accordance with Annex II or III are available.

In that case, the following conditions shall be met:

— An exposure assessment shall be performed, covering primary and secondary exposure under realistic worst case for all intended uses of the biocidal product that contains the active substance for which approval is applied, or of the biocidal product for which the authorisation is sought.

— If a new exposure scenario is introduced at a later stage, during the product authorisation process, additional data shall be submitted to assess whether the justification for data adaptation still applies.

— The reasons why the outcome of the exposure assessment justifies waiving of data requirements shall be clearly and transparently explained.

However, testing cannot be omitted for non-threshold effects. As a consequence, certain core data shall always be obligatory, e.g. genotoxicity testing.

If relevant, the Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the criteria established in accordance with Article 6(4) and Article 21(3).

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment, in accordance with the relevant Technical Notes for Guidance where available.

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1:Disinfectants

These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 3: Veterinary hygiene

Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

[[F8]Products used to be incorporated into materials which may enter into contact with food.**]**

Product-type 5: Drinking water

Products used for the disinfection of drinking water for both humans and animals.

MAIN GROUP 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

Product-type 6: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects.

This product-type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.

Product-type 10: Construction material preservatives

Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product-type 15: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.

Product-type 17: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.

Product-type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.

MAIN GROUP 4: Other biocidal products

Product-type 21: Antifouling products

Products 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 used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

TERMS AND DEFINITIONS

Correspondence with the criteria set out in Article 19(1)(b)

The subheadings ‘Effects on human and animal health’, ‘Effects on the Environment’, ‘Effects on Target Organisms’ and ‘Efficacy’ used in the Sections ‘Assessment’ and ‘Conclusions’ correspond to the four criteria set out in Article 19(1)(b) as follows:

‘Efficacy’ corresponds to criterion (i): ‘is sufficiently effective’.

‘Effects on target organisms’ corresponds to criterion (ii): ‘has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross resistance or unnecessary suffering and pain for vertebrates’.

‘Effects on human and animal health’ corresponds to criterion (iii): ‘has no immediate or delayed unacceptable effects itself, or as a result of its residues, on human health, including that of vulnerable groups[(4)], or animal health, directly or through drinking water, food, feed, air, or through other indirect effects’.

‘Effects on the environment’ corresponds to criterion iv: ‘has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— its impact on non-target organisms,

— its impact on biodiversity and the ecosystem’.

Technical definitions

(a) Hazard identification

The identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) Dose (concentration) — response (effect) assessment

The estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) Exposure assessment

The determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) Risk characterisation

The estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include ‘risk estimation’, i.e. the quantification of that likelihood.

(e) Environment

Water, including sediment, air, soil, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex sets out the common principles for the evaluation of dossiers for biocidal products referred to in Article 19(1)(b). A decision by a Member State or the Commission to authorise a biocidal product shall be taken on the basis of the conditions set down in Article 19, taking account of the evaluation carried out according to this Annex. Detailed technical guidance regarding the application of this Annex is available on the website of the Agency.

2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials, the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.

3. In order to ensure a high and harmonised level of protection of human health, animal health and the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product, taking into account any cumulative and synergistic effects.

4. A risk assessment on the active substance(s) present in the biocidal product is always required. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

5. Additional risk assessments shall be carried out, in the same manner as described above, on any substance of concern present in the biocidal product. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

6. In order to carry out a risk assessment, data are required. These data are detailed in Annexes II and III and take account of the fact that there are a wide variety of applications as well as different product-types and that this has an impact on the associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. The evaluating body shall take due consideration of the requirements of Articles 6, 21 and 62 in order to avoid duplication of data submissions. Data may also be required on a substance of concern present in a biocidal product. For in-situ generated active substances, the risk assessment includes also the possible risks from the precursor(s).

7. The results of the risk assessments carried out on the active substance and on the substances of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

8. When making evaluations of a biocidal product the evaluating body shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

9. The application of these common principles shall, when taken together with the other conditions set out in Article 19, lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised. Such authorisation may include restrictions on use or other conditions. In certain cases the competent authorities may conclude that more data are required before an authorisation decision can be made.

10. In the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent authorities or the Commission shall also evaluate whether the conditions of Article 5(2) can be satisfied.

11. During the process of evaluation, applicants and the evaluating bodies shall cooperate in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

12. The judgments made by the evaluating body during the evaluation must be based on scientific principles, preferably recognised at international level, and must be made with the benefit of expert advice.

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be validated by the evaluating or receiving competent authority in accordance with the relevant articles of the Regulation. After validation of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any ‘treated articles’ treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.

15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the scientific definitions and methodologies for the assessment of cumulative and synergistic effects.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail hazard identification and the establishment of appropriate reference values for dose or effect concentrations such as NOAEL or Predicted No Effect Concentrations (PNEC), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the appropriate reference values for each of the active substances and for any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

(a) the hazards due to the physico-chemical properties,

(b) the risk to humans and animals,

(c) the risk to the environment,

(d) the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

20. The information provided on the biocidal product family shall permit the evaluating body to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 19(1)(b).

21. Where relevant the technical equivalence for every active substance contained in the biocidal product shall be established with reference to active substances already included in the list of approved active substances.

Effects on human and animal health

Effects on human health

22. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

23. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute toxicity,
— irritation,
— corrosivity,
— sensitisation,
— repeated dose toxicity,
— mutagenicity,
— carcinogenicity,
— reproductive toxicity,
— neurotoxicity,
— immunotoxicity,
— disruption of the endocrine system,

— any other special properties of the active substance or substance of concern,
— other effects due to physico-chemical properties.

24. The populations previously mentioned are:
— professional users,
— non-professional users,
— humans exposed directly or indirectly via the environment.

In considering these populations, particular attention should be given to the need to protect vulnerable groups within these populations.

25. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

26. The evaluating body shall apply points 27 to 30 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

27. For repeated dose toxicity and reproductive toxicity the dose-response relationship shall be assessed for each active substance or substance of concern and, where possible, a NOAEL identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

28. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or another appropriate dose-effect descriptor shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

29. For mutagenicity and carcinogenicity, a non-threshold assessment should be carried out if the active substance or substance of concern is genotoxic and carcinogenic. If the active substance or a substance of concern is not genotoxic a threshold assessment shall be carried out.

30. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur, particularly in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects as a result of the use of the biocidal product.

31. When carrying out the risk assessment special consideration shall be given to toxicity data derived from observations of human exposure where such data are available, e.g. information gained from manufacture, from poison centres or epidemiology surveys.

32. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed directly or indirectly via the environment), for which exposure to a biocidal product occurs or can reasonably be foreseen, with particular attention paid to the pathways of exposure relevant for vulnerable groups. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern, including relevant metabolites and degradation products to

which a population is, or may be exposed during use of the biocidal product and articles treated with that product.

33. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Articles 6 and 21 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,
— the form in which the biocidal product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties of the biocidal product,
— the likely routes of exposure and potential for absorption,
— the frequency and duration of exposure,
— maximum residue levels,
— the type and size of specific exposed populations, where such information is available.

34. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
— be subjected to an analysis taking into account possible elements of uncertainty,
— be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

35. Where, for any of the effects set out in point 23 a reference value has been identified, the risk characterisation shall entail comparison of the reference value with the evaluation of the dose/concentration to which the population will be exposed. Where a reference value cannot be established a qualitative approach shall be used.

Assessment factors account for the extrapolation from animal toxicity to the exposed human population. The setting of an overall assessment factor considers the degree of uncertainty in inter-species and intra-species extrapolation. In the absence of suitable chemical-specific data, a default assessment factor of 100 is applied to the relevant reference value. Additional elements can also be considered for assessment factors, including toxicokinetics and toxicodynamics, the nature and severity of the effect, human (sub-)populations, exposure deviations between study results and human exposure with regard to frequency and duration, study duration extrapolation (e.g. sub-chronic to chronic), dose-response relationship and the overall quality of the toxicity data package.

Effects on animal health

36. Using the same relevant principles as described in the section dealing with effects on humans, the evaluating body shall consider the risks posed to animals from the biocidal product.

Effects on the environment

37. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota, following the use of the biocidal product.

38. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as PNEC. However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Articles 6 and 20. It shall be calculated by applying an assessment factor to the reference values resulting from tests on organisms, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)). Where appropriate, other dose-effect descriptors may be used as reference values.

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller the degree of uncertainty and the size of the assessment factor.

42. For each environmental compartment, an exposure assessment shall be carried out in order to predict the likely concentration of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However, in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions (including any relevant contribution from articles treated with biocidal products) are known or are reasonably foreseeable.

44. The PEC, or the qualitative estimation of exposure, shall be determined taking account of, in particular and where appropriate:

— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties,
— breakdown/transformation products,
— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
— the frequency and duration of exposure,
— long range environmental transportation.

45. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 34. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

48. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) if it contains any substance of concern or relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006, or if it has endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on target organisms

49. An assessment shall be made to demonstrate that the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate, the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

50. The evaluating body shall, where relevant, evaluate the possibility of the development by the target organism of resistance or cross-resistance to an active substance in the biocidal product.

Efficacy

51. Data submitted by the applicant shall be sufficient to substantiate the efficacy claims for the product. Data submitted by the applicant or held by the evaluating body must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Union guidelines where these are available and applicable. Where appropriate, other methods from the list below can be used. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method
— national standard method
— industry standard method (if accepted by the evaluating body)
— individual producer standard method (if accepted by the evaluating body)
— data from the actual development of the biocidal product (if accepted by the evaluating body).

Summary

53. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects.

54. For biocidal product containing more than one active substance, any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

CONCLUSIONS

General principles

55. The purpose of the evaluation is to establish whether or not the product complies with the criteria set down in point (b) of Article 19(1). The evaluating body shall reach its conclusion as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product, based on the assessment carried out in accordance with points 13 to 54 of this Annex.

56. In establishing compliance with the criteria set out in point (b) of Article 19(1), the evaluating body shall arrive at one of the following conclusions for each product-type and each area of use of the biocidal product for which application has been made:

(1) that the biocidal product complies with the criteria;

(2) that, subject to specific conditions/restrictions, the biocidal product can comply with the criteria;

(3) that it is not possible, without additional data, to establish if the biocidal product complies with the criteria;

(4) that the biocidal product does not comply with the criteria.

57. The evaluating body shall, when seeking to establish whether a biocidal product complies with the criteria in point (b) of Article 19(1), take into account uncertainty arising from the variability in the data used in the evaluation process.

58. If the conclusion arrived at by the evaluating body is that additional information or data are required, then the evaluating body shall justify the need for any such information or data. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

Effects on human and animal health

Effects on human health

59. The evaluating body shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment. In reaching these conclusions, particular attention shall be paid to vulnerable groups among the different populations.

60. The evaluating body shall examine the relationship between exposure and effect. A number of factors need to be considered when examining this relationship. One of the most important factors is the nature of the adverse effect of the substance under consideration. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, immunotoxicity, reproductive toxicity, disruption of the endocrine system together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern, or of their relevant metabolites or degradation products.

61. Typically, the margin of exposure (MOE_{ref}) — the ratio between the dose descriptor and the exposure concentration — is in the region of 100, but a MOE_{ref} that is higher or lower than this may also be appropriate depending on, among other things, the nature of the critical effects and the sensitivity of the population.

62. The evaluating body shall, where appropriate, conclude that criterion (iii) under point (b) of Article 19(1) can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.

63. If, for non-professional users, the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population, the product shall not normally be considered as complying with criterion (iii) under point (b) of Article 19(1) for this population.

Effects on animal health

64. Using the same relevant criteria as described in the section dealing with effects on human health, the evaluating body shall consider whether criterion (iii) under point (b) of Article 19(1) is complied with for animal health.

Effects on the environment

65. The basic tool used in the decision-making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC, the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

66. For any given environmental compartment, if the PEC/PNEC ratio is equal to or less than 1, the risk characterisation shall be that no further information and/or testing is necessary. If the PEC/PNEC ratio is greater than 1, the evaluating body shall judge, on the basis of the size of that ratio and on other relevant factors, whether further information and/or testing is required to clarify the concern or appropriate risk reduction measures are necessary, or whether the biocidal product cannot comply with criterion (iv) under point (b) of Article 19(1).

Water

67. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target organisms in the aquatic, marine or estuarine environment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. In particular, the evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1), where under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments), would undermine the achievement of compliance with the standards laid down in:

— Directive 2000/60/EC,
— Directive 2006/118/EC,
— Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy[(5)],
— Directive 2008/105/EC, or
— international agreements on the protection of river systems or marine waters from pollution.

68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in groundwater, exceeds the lower of the following concentrations:
— the maximum permissible concentration laid down by Directive 98/83/EC, or
— the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological data,

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

69. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where the foreseeable concentration of the active substance or a substance of concern, or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:
— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by:
  — Directive 2000/60/EC,
  — Directive 98/83/EC, or
— has an impact deemed unacceptable on non-target organisms,

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

70. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that, if followed, they minimise the likelihood of accidental contamination of water or its sediments.

Soil

71. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in soil, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Air

72. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) of point (b) of Article 19(1) where there is a reasonably foreseeable possibility of unacceptable effect on the air compartment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Non-target organisms

73. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product, if for any active substance or substance of concern:

— the PEC/PNEC is above 1, or

— the concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

74. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product, if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1, unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Effects on target organisms

75. Where the development of resistance or cross-resistance to the active substance in the biocidal product is likely, the evaluating body shall consider actions to minimise the consequences of this resistance. This may involve modification of the conditions under which an authorisation is given. However, where the development of resistance or cross-resistance cannot be reduced sufficiently, the evaluating authority shall conclude that the biocidal product does not satisfy criterion (ii) under point (b) of Article 19(1).

76. A biocidal product intended to control vertebrates shall not normally be regarded as satisfying criterion (ii) under point (b) of Article 19(1) unless:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

77. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State or, where appropriate, in the Union, except where the biocidal product is intended for use in specific circumstances. The evaluating body shall evaluate dose-response data generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

78. In relation to the criteria set out in points (iii) and (iv) of Article 19(1)(b), the evaluating body shall combine the conclusions arrived at for the active substance(s) and the substances of concern to produce overall summary conclusions for the biocidal

product itself. A summary of the conclusions in relation to the criteria set out in points (i) and (ii) of Article 19(1)(b) shall also be made.

OVERALL INTEGRATION OF CONCLUSIONS

The evaluating body shall, on the basis of the evaluation carried out in accordance with the principles set down in this Annex, come to a conclusion as to whether or not it is established that the biocidal product complies with the criteria laid down under point (b) of Article 19(1).

ANNEX VII

CORRELATION TABLE

Directive 98/8/EC	**This Regulation**
—	Article 1
Article 1	Article 2
Article 2	Article 3
Article 10	Article 4
Article 10	Article 5
—	Article 6
Article 11(1)(a)	6(1)
Article 11(1)(a)(i) and (ii)	6(2)
—	6(3)
—	6(4)
—	Article 7
Article 11(1)(a)	7(1)
—	7(2)
—	7(3)
—	7(4)
—	7(5)
—	7(6)
—	Article 8
Article 11(2), first subparagraph	8(1)
Article 11(2), second subparagraph	8(2)
Article 10(1), first subparagraph	8(3)
—	8(4)
—	Article 9
11(4)	9(1)

—	9(2)
—	Article 10
Article 33	Article 11
Article 10(4)	Article 12
—	12(1)
—	12(2)
—	12(3)
—	Article 13
—	Article 14
—	Article 15
—	Article 16
—	Article 17
Article 3(1)	17(1)
Article 8(1)	17(2)
—	17(3)
Article 3(6)	17(4)
Article 3(7)	17(5)
—	17(6)
—	Article 18
—	Article 19
Article 5(1)	19(1)
Article 5(1)(b)	19(2)
—	19(3)
Article 5(2)	19(4)
—	19(5)
Article 2(1)(j)	19(6)
—	19(7)
—	19(8)
—	19(9)
—	Article 20
Article 8(2)	20(1)
Article 8(12)	20(2)
—	20(3)
—	Article 21

—	Article 22
Article 5(3)	22(1)
—	22(2)
—	Article 23
—	23(1)
Article 10(5)(i)	23(2)
—	23(3)
—	23(4)
—	23(5)
—	23(6)
Article 33	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28
—	Article 29
—	Article 30
—	Article 31
Article 4	Article 32
—	Article 33
—	Article 34
—	Article 35
Article 4(4)	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40
—	Article 41
—	Article 42
—	Article 43
—	Article 44
—	Article 45
—	Article 46
—	Article 47

Article 7	Article 48
Article 7	Article 49
Article 7	Article 50
—	Article 51
—	Article 52
—	Article 53
—	Article 54
Article 15	Article 55
Article 17	Article 56
—	Article 57
—	Article 58
Article 12	Article 59
—	Article 60
—	60(1)
Article 12(1)(c)(ii) and (1)(b) and (1)(d)(ii)	60(2)
Article 12(2)(c)(i) and (ii)	60(3)
—	Article 61
—	Article 62
—	Article 63
Article 13(2)	63(1)
—	63(2)
—	63(3)
Article 13(1)	Article 64
—	Article 65
Article 24	65(1)
—	65(2)
Article 24	65(3)
—	65(4)
—	Article 66
—	66(1)
—	66(2)
—	66(3)
Article 19(1)	66(4)
—	Article 67

—	Article 68
—	Article 69
Article 20(1) and 20(2)	Article 69(1)
Article 20(3)	Article 69(2)
Article 20(6)	Article 69(2)
Article 21, second subparagraph	Article 70
—	Article 71
—	Article 72
Article 22(1), first and second subparagraphs	72(1)
Article 22(1), third subparagraph	72(2)
Article 22(2)	72(3)
—	Article 73
—	Article 74
—	Article 75
—	Article 76
—	Article 77
—	Article 78
—	Article 79
—	Article 80
—	80(1)
Article 25	80(2)
—	80(3)
Article 26	Article 81
Article 28	Article 82
—	Article 83
—	Article 84
Article 29	Article 85
—	Article 86
—	Article 87
Article 32	Article 88
—	Article 89
—	Article 90
—	Article 91
—	Article 92

—	Article 93
—	Article 94
—	Article 95
—	Article 96
—	Article 97
Annex IA	Annex I
Annex II A, III A and IV A	Annex II
Annex II B, III B and IV B	Annex III
—	Annex IV
Annex V	Annex V
Annex VI	Annex VI

(**1**) OJ L 142, 31.5.2008, p. 1.

(**2**) OJ L 276, 20.10.2010, p. 33.

(**3**) OJ L 50, 20.2.2004, p. 44.

(**4**) See definition of vulnerable groups in Article 3.

(**5**) OJ L 164, 25.6.2008, p. 19.

Status:
Point in time view as at 20/11/2019.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 528/2012 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.