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**

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

			require recourse to testing of vertebrates
1. APPLICANT			
1.1.	Name and address, etc.		
1.2.	Contact person		
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		

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

quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in the case of a reaction mixture, the final composition of the biocidal product shall be given		
2.4. Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution		
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		

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

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		
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		

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

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		
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		

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

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		
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		

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

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 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	

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

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 treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISMS			
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting		

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

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 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		

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

	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		
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		

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

	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 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		

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

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		
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

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

		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 sensitisationThe assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is used justification shall be provided		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 — the available information indicates that the product should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH

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

			< 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 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		Testing on the mixture of products 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.

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		— 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: — 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 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)

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

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			
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 required for the biocidal product In addition, for certain biocides which are applied directly or around livestock (including horses) residue studies might be needed	ADS	
9. ECOTOXICOLOGICAL STUDIES			

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

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 9 of Annex II for relevant components of the biocidal product or the		

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

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		
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		

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

	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	
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	ADS	

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

	or plants under field conditions		
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; emergency measures to protect the environment		
11.4. Possibility of destruction or decontamination following release in or on the following:			

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

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		
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			

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

(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 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.

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		
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) of concern or a mixture that a substance(s) of concern is a component of		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

8.8. 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		