Daniele Ferrario and Richard R. Rabbit

t4 Report

Analysis of the Proposed EU Regulation Concerning Biocide Products and its Opportunities for Alternative Approaches and a Toxicology for the 21st Century

Supplementary Data

Tab. A: Comparison between the proposed Regulation concerning the placing on the market and use of biocidal products with the current Directive 98/8/EC
Only articles more relevant for the purpose of this paper have been extracted and commented on.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
Article 1: Subject matter This Regulation lays down rules for: (1) the placing on the market and use of biocidal products within the Member States or the Community; (2) the mutual recognition of authorisations within the Community; (3) the establishment at Community level of a list of active substances which may be used in biocidal products.	**Article 1: Scope** 1. This Directive concerns: (a) the authorisation and the placing on the market for use of biocidal products within the Member States; (b) the mutual recognition of authorisations within the Community; (c) the establishment at Community level of a positive list of active substances which may be used in biocidal products.	The proposal is turned into a Regulation; it will ensure the uniform application of the new instrument throughout the EU, in particular the procedures and the deadlines for authorisation of biocide products and mutual recognition of these authorisations.
Article 3: Definitions 1. For the purposes of this Regulation, the following definitions shall apply: (a) “biocidal products” mean active substances or mixtures containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. All substances, mixtures and devices placed on the market with the intention to generate active substances shall also be considered biocidal products	**Article 2** 1. For the purposes of this Directive the following definitions shall apply: (a) Biocidal products Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Annex V.	All substances placed on the market with the intent to generate active substances are now considered biocidal products
(b) “micro-organism” means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;	(d) Active substance A substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.	

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
(c) "active substance" Means a substance or a micro-organism having an action against harmful organisms; (d) "existing active substance" means a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development; (e) "new active substance" means a substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;	(d) Active substance A substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms.	Directive 98/8/EC concerning Biocidal Products entered into force on 14 May 2000; a marked distinction between existing active substances from before this date and new active substances has now been made.
(f) "substance of concern" means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect;	(e) Substance of concern Any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect. Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (39), and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (40).	
(g) "harmful organism" means organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, or on animals or the environment;	(f) Harmful organism Any organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment.	
(h) "residues" means substances present in or on plants or products of plant origin, edible animal products, drinking water or elsewhere in the environment and resulting from	(g) Residues One or more of the substances present in a biocidal product which remains as a result of its use including the metabolites of such substances and products resulting	

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
the use of a biocidal product, including their metabolites, breakdown or reaction products;	from their degradation or reaction.	
(i) "placing on the market" means the first supply of a biocidal product for distribution or for use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;	(h) Placing on the market Any supply, whether in return for payment or free of charge, or subsequent storage other than storage followed by consignment from the customs territory of the Community or disposal. Importation of a biocidal product into the customs territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive.	
(j) "use" means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with view to export of the biocidal product outside the Community;		
(k) "treated material or article" means any substance, mixture, material or article which was treated with or incorporates one or more biocidal products with the intention to protect the substance, mixture, material or article from deterioration caused by harmful organisms;		For the first time any substance entered into the production of goods has to be declared.
(l) "national authorisation" means an administrative act by which the competent authority of a Member State authorises the placing on the market and the use of a biocidal product in its territory or in a part thereof; (m) "Community authorisation" means an administrative act by which the Commission authorises the placing on the market and the use of a biocidal product in the territory of the Community or in a part thereof; (n) "authorisation" means national authorisation or Community authorisation;	(i) Authorisation An administrative act by which the competent authority of a Member State authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof.	A Regulation shall have general application, in which every Member States has to accept the same definition. The Commission will have now more power as to the authorization and use of biocidal products.
(o) "unique product formulation" means a biocidal product with no variations as to the percentage of the active substance, the percentage composition of the non-active substances, or the perfumes, dyes or pigments it contains; (p) "frame formulation" means a group of biocidal products having	(j) Frame-formulation Specifications for a group of biocidal products having the same use and user type. This group of products must contain the same active substances of the same specifications, and their compositions must present only variations from a	

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
similar uses and presenting limited variations in their composition with regard to a reference biocidal product belonging to that group which contains the same active substances of the same specifications where such permitted variations do not adversely affect the level of risk or the efficacy of these products;	previously authorised biocidal product which do not affect the level of risk associated with them and their efficacy. In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy.	
(q) “letter of access” means an original document, signed by the owner or owners of information, which states that the information may be used by the competent authorities, the European Chemicals Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation;	(l) Letter of access A document, signed by the owner or owners of relevant data protected under the provisions of this Directive, which states that these data may be used by the competent authority for the purpose of granting an authorisation or a registration of a biocidal product under this Directive	The European Chemicals Agency will be now responsible for chemical evaluation and registration
(r) “food and feedingstuff” means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [42] and feedingstuff as defined in Article 3(4) of that Regulation. (s) “food contact materials” means any material and article intended to come into contact with food which are covered by Regulation (EC) No 1935/2004 [43]; (t) “processing aid” means any substance which: (i) is not consumed as a food or feedingstuff by itself; (ii) is intentionally used in the processing of raw materials, foods or feedingstuff or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;.		Inclusion of material that might come into contact with food, feedstuff or processing aid.
(u) “technical equivalence” means Similarity as regards the chemical composition and hazard profile of a substance produced from a new manufacturing source, compared to the substance of the reference source		

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
with respect to which the initial risk assessment was carried out.		
2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms: (a) substance; (b) mixture; (c) article; (d) product and process-orientated research and development; (e) scientific research and development. Chapter II Inclusion of an active substance in Annex I	2. For the purposes of this Directive the definitions for: (a) substance, (b) preparation, (c) scientific research and development, (d) process-orientated research and development laid down in Article 2 of Council Directive 67/548/EEC shall apply.	
Article 4 Conditions for inclusion 1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if the biocidal products containing that active substance fulfil the conditions laid down in point (b) of Article 16(1). 2. The inclusion in Annex I of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 6. 3. An active substance shall, where appropriate, be included in Annex I together with any of the following conditions: (a) the minimum degree of purity of the active substance; (b) the nature and maximum content of certain impurities; (c) the product type as outlined in Annex V; (d) manner and area of use; (e) designation of categories of users; (f) other particular conditions based on the evaluation of the information related to that active substance. 4. Where appropriate, maximum residue limits shall be established with respect to active substances included in Annex I in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council [44] [and Council Regulation (EEC) No 2377/90].		Active substances are included in Annex I for maximum 10 years
Article 5 Exclusion criteria	**Article 10** Inclusion of an active substance in Annex	The exclusion of substances will be

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
1. Notwithstanding Article 4(1), active substances referred to in paragraph 2 shall be included in Annex I only if at least one of the following conditions is met: (a) the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions; (b) it is shown that the active substance is necessary to control a serious danger to public health; (c) it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies. Point (c) shall not apply to active substances for product types 4 and 14 to 19. 2. The following active substances shall be included in Annex I where at least one of the conditions set out in paragraph 1 is met: (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, carcinogen category 1A or 1B; (b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B; (c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B; (d) active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.	I, IA or IB (a) An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as: – carcinogenic, – mutagenic, – toxic for reproduction, – sensitising, or – is bioaccumulative and does not readily degrade. 5. (i) An entry of an active substance in Annex I and, where relevant, IA or IB may be refused or removed, – if the evaluation of the active substance in accordance with Article 11(2) shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern, and – if there is another active substance on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment.	more strict. Active substances classified in accordance to REACH as carcinogen toxic to the reproduction mutagen 1A or 1B will be excluded from Annex I. Active substances classified in accordance to REACH as toxic to the reproduction 1A or 1B will be excluded from Annex I Active substances classified in accordance to article 57 (f) of Regulation (EC) No 1907/2006 as endocrine disruptors will be excluded from Annex I
Article 7 Submission and validation of applications 1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European	**Article 2** (k) Registration An administrative act by which the competent authority of a Member State, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements	The European Chemicals Agency will be now responsible for all submission evaluations.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
Chemicals Agency (hereinafter referred to as “the Agency”) and inform it of the name of the competent authority of the Member State that he chooses to evaluate his application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.	of this Directive, allows the placing on the market of a low-risk biocidal product in its territory or in a part thereof.	
Article 9 Active substances which are candidates for substitution		Comparative assessment between substance candidates for substitution
(a) its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type; (b) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006; (c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, even with very restrictive risk management measures; (d) it contains a significant proportion of non-active isomers; (e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B; (f) it is considered to have endocrine disrupting properties that may cause adverse effect on humans on the basis of the assessment of Community or internationally agreed test guidelines or other available data.		Particular concerns have been raised for active substances that are likely to induce Immunotoxicity, Neurotoxicity and Endocrine disruptors activity. All active substances capable of producing such patterns of toxicity are candidates for substitution with active substances showing less toxicity. Isomers are also included in the evaluation of possible toxic active substances In accordance with the Regulation (EC) No 1272/2008 on classification, labelling and packaging substances likely to be classified as carcinogen, mutagen or toxic for the reproductive system should be pointed to as candidate for substitution.
Article 16 Conditions for granting an authorisation 1. A biocidal product shall be authorised only if the following conditions are met: (a) the active substances included therein	**Article 5** Conditions for issue of an authorisation 1. Member States shall authorise a biocidal product only if	Biocidal producs shall not be authorized if, according to Regulation (EC) No 1272/2008, they might decrease the fertility, and damage unborn child

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
are listed in Annex I and any conditions included in that Annex together with those active substances are complied (b) it is established according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2, complies with the following criteria: (i) it is sufficiently effective; (ii) it has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates; (iii) it has no unacceptable effects itself or as a result of its residues, directly or indirectly, on human or animal health; (iv) it 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; – its impact on non-target organisms; – its impact on biodiversity and the ecosystem; (c) the nature, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III; (d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product. 2. The evaluation of the compliance of the biocidal product with the criteria set out in point (b) of paragraph 1 shall take into account the following factors: (a) all normal conditions under which the biocidal product may be used; (b) how any material or article treated with	(a) the active substance(s) included therein are listed in Annex I or IA and any requirements laid down in these Annexes are fulfilled; (b) it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier provided for in Article 8, according to the common principles for the evaluation of dossiers as laid down in Annex VI, that, when used as authorised and having regard to: – all normal conditions under which the biocidal product may be used, – how the material treated with it may be used, – the consequences from use and disposal, the biocidal product: (b) it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier provided for in Article 8, according to the common principles for the evaluation of dossiers as laid down in Annex VI, that, when used as authorised and having regard to: – all normal conditions under which the biocidal product may be used, – how the material treated with it may be used, – the consequences from use and disposal, the biocidal product: (i) is sufficiently effective, (ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates, (iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater, (iv) has no unacceptable effect 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; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water,	(reproduction category 1A or 1B)

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
it or containing it may be used; (c) the consequences of its use and disposal. 3. An authorisation to place a low-risk biocidal product on the market shall be subject to compliance with the requirements of points (b), (c) and (d) of paragraph 1. 4. A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 18. 5. A biocidal product shall not be authorised for placing on the market to, or use by, the general public if it fulfils any of the following criteria for classification: (a) toxic, very toxic or a category 1 or 2 carcinogen, or a category 1 or 2 mutagen or toxic for reproduction category 1 or 2 according to Directive 1999/45/EC; (b) toxic, very toxic or a category 1A or 1B carcinogen, or a category 1A or 1B mutagen or toxic for reproduction category 1A or 1B according to Regulation (EC) No 1272/2008. 6. In the case of a frame formulation, a reduction in the percentage of the active substance in the reference biocidal product may be allowed, and/or an alteration in percentage composition of one or more non-active substances, and/ or the replacement of one or more non-active substances by others presenting the same or lower risk.	– its impact on non-target organisms; (c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the relevant requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB; (d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product. 2. A biocidal product classified according to Article 20(1) as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2, shall not be authorised for marketing to, or use by the general public. 3. Authorisation may be conditional on, and must stipulate the conditions relating to marketing and use necessary to ensure compliance with the provisions of paragraph 1. 4. Where other Community provisions impose requirements relevant to the conditions for the issue of an authorisation and for use of the biocidal product, and particularly where these are intended to protect the health of distributors, users, workers and consumers or animal health or the environment, the competent authority shall take these into account when issuing an authorisation and where necessary shall issue the authorisation subject to those requirements	
Article 17 Criteria for low-risk biocidal products 1. A biocidal product shall be considered a low-risk biocidal product if both the following conditions are fulfilled: (a) for any given environmental compartment, the ratio of the predicted environmental concentration (PEC) to predicted no-effect concentration (PNEC) may be derived and does not exceed 0.1; (b) for any effect to human health, the margin of exposure (the ratio of no observed adverse effect level (NOAEL) and exposure concentration) is higher	**Article 10** (b) Low-risk biocidal product A biocidal product which contains as active substance(s) only one or more of those listed in Annex I A and which An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as: – carcinogenic, – mutagenic, – toxic for reproduction, – sensitising, or	Provisions for PNEC and NOAEL have been added. Concerns as to the persistence of the substance (bio-accumulation) was added referring to REACH Annex XIII of Regulation (EC) No 1907/2006. Concerns on endocrine disruptors, immunotoxic and neurotoxic compounds have been added in accordance with Regulation (EC) No 1272/2008.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
than 1,000. However, a biocidal product shall not be considered a low-risk biocidal product if at least one of the following conditions is present: (a) it contains one or more active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006; (b) it contains one or more active substances qualified as endocrine disrupters; (c) it contains one or more active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as or which meets the criteria to be classified as one of the following: (i) carcinogenic; (ii) mutagenic; (iii) neurotoxic; (iv) immunotoxic; (v) toxic to reproduction; (vi) sensitising.	– is bioaccumulative and does not readily degrade. (b) Low-risk biocidal product A biocidal product which contains as active substance(s) only one or more of those listed in Annex I A and which does not contain any substance(s) of concern. Under the conditions of use, the biocidal product shall pose only a low risk to humans, animals and the environment. (c) Basic substance A substance which is listed in Annex I B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use. The substances, which could potentially enter Annex IB in accordance with the procedure laid down in Articles 10 and 11, are inter alia the following: – carbon dioxide, – nitrogen, – ethanol, – 2-propanol, – acetic acid, – kieselguhr.	
Article 19 Waiving of data requirements 1. Notwithstanding Article 18, the applicant need not provide data required under that Article if any of the following grounds applies: (a) the information is not necessary owing to the exposure associated with the proposed uses; (b) it is not scientifically necessary to supply the information; (c) it is not technically possible to supply the information. 2. The applicant may propose to adapt the data required under Article 18 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV. The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such		Inclusion of "data waiving" when the information is not scientifically necessary, or whenever technically impossible to supply information.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal. 3. The Commission shall adopt the measures designed to set the criteria defining what constitutes adequate justification to adapt the data required under Article 18 on the ground referred to in paragraph 1(a). Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4)		
Article 21 Comparative assessment of biocidal products 1. The receiving competent authority or, in the case of evaluation of an application for a Community authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1). 2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Community authorisation, also to the Commission. 3. The receiving competent authority or, in the case of a decision on an application for a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met: (a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents significantly lower risk for human or animal health or the environment;		In course of renewal of authorization if comparison between current active substances and candidates as substitute shows that the latter have less hazardous profiles or side effects to humans and/or environment than the former, replacement should be granted.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
Article 33 Biocidal products for which Community authorisation may be granted 1. The Community authorisation may be granted to the following categories of biocidal products: (a) biocidal products containing one or more new active substances; (b) low-risk biocidal products. 2. Following the report of the Commission on the implementation of this Regulation referred to in Article 54(4) and in light of the experience gained with the Community authorisations, the Commission may add other categories of biocidal products in paragraph 1 of this Article. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).		Under the current Directive, all biocidal products are authorised at Member State level. This will change for two types of biocidal products biocidal products based on new active substances and low-risk biocidal products – which will have access to a Community authorisation allowing them to be placed on the market throughout the Community
Article 47 Placing on the market of treated articles or materials. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the biocidal product(s) used for treating the materials or articles are authorised for this use in the Community or in at least one Member State. 2. Treated articles or materials shall be labelled with the following information: (a) the name of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials; (b) where relevant, the biocidal property attributed to treated articles or materials; (c) the authorisation number of all biocidal products that were used for the treatment or were incorporated in the articles or materials; (d) any hazard statement or precautionary statement set out in the authorisation for the biocidal product. The labelling shall be clearly visible, easily legible and appropriately durable.		For the first time complete information about treated articles or materials authorized for use in the Community will be required. The new proposal aims for authorizing the production and the distribution of all articles that are being treated with biocides in at least one Member State.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
Article 51 Mandatory information sharing 1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation. 2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, hereinafter "the prospective applicant," shall ask the competent authority or the Agency whether such tests or studies have already been submitted in connection with a previous application. The competent authority or the Agency shall verify if there is any data on such tests or studies in the Biocides Data Sharing Register. Where those tests or studies have already been submitted in connection with a previous application, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant. Where the data acquired under those tests or studies are still protected under Article 49, and involve tests on vertebrate animals the prospective applicant shall request from the owner of the information the right to refer to the tests or studies. Where the data acquired under those tests or studies are still protected under Article 49, and do not involve tests on vertebrate animals, the prospective applicant may request from the owner of the information the right to refer to the tests or studies.		Sharing of vertebrate animal test data in order to decrease useless animal testing will be mandatory. ECHA should give information about the name and contact detail of the owner of the information to all applicants.
Article 52 Compensation for mandatory information sharing 1. Where a request has been made in accordance with Article 51(2), the prospective applicant and the owner of the information shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the		Compensation for data sharing to owners of the experimental test data will be granted.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
arbitration order. 2. Where such agreement is reached, the owner of the information shall make available to the prospective applicant the information and shall give the prospective applicant the permission to refer to the data owner's tests or studies. 4. The costs of sharing the tests or studies shall be determined in a fair, transparent and non-discriminatory manner		
Article 58 Classification, packaging and labelling of biocidal products 1. Biocidal products shall be classified, packaged, and labelled in accordance with Directive 1999/45/EC and, where applicable, Regulation (EC) 1272/2008 and the approved summary of the biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 20(2) of this Regulation. In addition, products which may be mistaken for food, drink or feedingstuffs shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption. 2. Labels shall not be misleading and, in any case, shall not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless' or similar indications. In addition, the label must show clearly and indelibly the following information: (a) the identity of every active substance and its concentration in metric units; (b) the authorisation number allocated to the biocidal product by the competent authority; (c) the type of mixture; (d) the uses for which the biocidal product is authorised; (e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation; (f) particulars of likely direct or indirect adverse side effects and any directions for first aid; (g) if accompanied by a leaflet, the sentence 'Read attached instructions	**Article 20** Classification, packaging and labelling of biocidal Products 1. Biocidal products shall be classified in accordance with the provisions relating to classification in Directive 88/379/EEC. 2. Biocidal products shall be packaged in accordance with Article 6 of Directive 88/379/EEC. In addition: (a) products which may be mistaken for food, drink or feedingstuff shall be packaged to minimize the likelihood of such a mistake being made; (b) products available to the general public which may be mistaken for food, drink or feedingstuff shall contain components to discourage their consumption. 3. Biocidal products shall be labelled in accordance with the provisions relating to labelling in Directive 88/379/EEC. Labels shall not be misleading or give an exaggerated impression of the product and, in any case, not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless' or similar indications. In addition, the label must show clearly and indelibly the following: (a) the identity of every active substance and its concentration in metric units; (b) the authorisation number allocated to the biocidal product by the competent authority; (c) the type of preparation (e.g. liquid concentrates, granules, powders, solids, etc.); (d) the uses for which the biocidal product is authorised (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc.);	Classification in accordance with Regulation (EC) 1272/2008.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
before use'; (h) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging; (i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage; (j) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport; (k) where applicable, the categories of users to which the biocidal product is restricted; (l) where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water; (m) for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC. By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (c), (e), (f), (h), (i), (j) and (l) may be indicated on the packaging or on an accompanying leaflet integral to the packaging. 3. Member States may require that biocidal products placed on the market of their territories are labelled in their national language or languages.	(e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation; (f) particulars of likely direct or indirect adverse side effects and any directions for first aid; (g) if accompanied by a leaflet, the sentence 'Read attached instructions before use'; (h) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging; (i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage; (j) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animals from being exposed); and where applicable: (k) the categories of users to which the biocidal product is restricted; (l) information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water; (m) for microbiological biocidal products, labelling requirements according to Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (1). Member States shall require that items 3(a), (b), (d) and where applicable (g) and (k) always be carried on the label of the product. Member States shall permit items 3(c), (e), (f), (h), (i), (j) and (l) to be carried elsewhere on the packaging or on an	

Proposal for Regulation concerning the placing on the market and use of biocidal products	Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market	Implementations / Comments The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
	accompanying leaflet integral to the packaging. These items of information shall be regarded as label information for the purposes of this Directive. 4. Where a biocidal product identified as insecticide, acaricide, rodenticide, avicide or molluscicide is authorised pursuant to this Directive and is also subject to classification, packaging and labelling according to Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) (2) by virtue of other Community provisions, Member States shall permit changes to the packaging and labelling of that product which may be required as a consequence of those provisions in so far as they do not conflict with the conditions of an authorisation issued under this Directive. 5. Member States may require the provision of samples, models or drafts of the packaging, labelling and leaflets. 6. Member States shall make the placing of biocidal products on the market in their territories subject to them being labelled in their national language or languages.	
ANNEX 2 Data requirements for active substances: 5. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [51], 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 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 [52] or other international	**Article 8** Requirements for authorisation As a general principle, tests must be conducted according to the methods described in Annex V to Directive 67/548/EEC. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognised and must be justified. Where appropriate, tests must be conducted in accordance with the provisions laid down in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (1) and Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative	Test should be conducted following good laboratory practice in accordance with Directive 2004/10/EC. Before conducting an experiment all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances should be avoided.

Proposal for Regulation concerning the placing on the market and use of biocidal products	**Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market**	**Implementations / Comments** The risks associated with the use and disposal of biocidal products are to be assessed and managed as they are in the Regulation1907/2006 (REACH).
standards recognised as being equivalent by the Commission or the Agency. Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex	provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances	