Manual of EUROPEAN ENVIRONMENTAL POLICY

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

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This section is the text of the Manual as published in 2012. It is therefore important to note the following:

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Institute for European Environmental Policy

Authorization and marketing of biocides

Formal references	
Directive 98/8/EC (OJ L123 24.4.1998)	Directive on placing of biocidal products on the market
Proposed – COM(2006)373	
Amended by	
Regulation (EC) No 1896/2000 (OJ L228 8.9.2000)	Regulation on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC on Biocidal products
Regulation (EC) No 2032/2003 (OJ L307/1 24.11.2003)	Regulation on the second phase of the programme referred to in Article 16(2) of Directive 98/8/EC on Biocidal products
2007/226/EC (OJ L97/47 12.4.2007)	Council Decision concerning the extension of the deadline for placing on the market of biocidal products containing certain active substances not examined during the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council
2008/31/EC (OJ L81/57 20.3.2008)	Directive amending Directive 98/8/EC concerning the placing of biocidal products on the market, as regards the implementing powers conferred on the Commission
2009/84/EC (OJ L197 29.7.2009)	Directive amending Directive 98/8/EC to include sulphuryl fluoride as an active substance in Annex I
2009/85/EC (OJ L198 30.7.2009)	Directive amending Directive 98/8/EC to include coumatetralyl as an active substance in Annex I
2009/86/EC (OJ L198 30.7.2009)	Directive amending Directive 98/8/EC to include fenpropimorph as an active substance in Annex I
2009/87/EC (OJ L198 30.7.2009)	Directive amending Directive 98/8/EC to include indoxacarb as an active substance in Annex I
2009/88/EC (OJ L199 31.7.2009)	Directive amending Directive 98/8/EC to include ithiacloprid as an active substance in Annex I
2009/89/EC (OJ L199 31.7.2009)	Directive amending Directive 98/8/EC to include nitrogen as an active substance in Annex I
2009/91/EC (OJ L201 31.7.2009)	Directive amending Directive 98/8/EC to include disodium tetraborate as an active substance in Annex I
2009/92/EC (OJ L 201 1.8.2009)	Directive amending Directive 98/8/EC to include bromadiolone as an active substance in Annex I
2009/93/EC (OJ L201 1.8.2009)	Directive amending Directive 98/8/EC to include alphachloralose as an active substance in Annex I
2009/94/EC (OJ L201 1.8.2009)	Directive amending Directive 98/8/EC to include boric acid as an active substance in Annex I
2009/95/EC (OJ L201, 1.8.2009)	Directive amending Directive 98/8/EC to include aluminium phosphide as an active substance in Annex I
2009/96/EC (OJ L201 1.8.2009)	Directive amending Directive 98/8/EC to include disodium octaborate tetrahydrate as an active substance in Annex I
2009/98/EC (OJ L203 5.8.2009)	Directive amending Directive 98/8/EC to include boric oxide as an active substance in Annex I

2009/107/EC (OJ L262 6.10.2009)	Directive amending Directive 98/8/EC as regards the extension of Certain time periods
2009/150/EC (OJ L313 28.11.2009)	Directive amending Directive 98/8/EC to include flocumafen as an active substance in Annex I
2009/151/EC (OJ L313 28.11.2009)	Directive amending Directive 98/8/EC to include tolyfluanid as an active substance in Annex I
2010/7/EU (OJ L37 10.2.2010)	Directive amending Directive 98/8/EC to include aluminium phosphide releasing phosphine. as an active substance un Annex I.
2010/8/EU (OJ L37 10.2.2010)	Directive amending Directive 98/8/EC to include warfarin sodium. as an active substance un Annex I.
2010/9/EU (OJ L36 9.2,2010)	Directive amending Directive 98/8/EC to include aluminium phosphide releasing phosphine to product type 18 as defined in Annex V. as an active substance un Annex I.
2010/10/EU (OJ L37 10.2.2010)	Directive amending Directive 98/8/EC to include brodifacoum. as an active substance un Annex I.
2010/11/EU (OJ L37 10.2.2010)	Directive amending Directive 98/8/EC to include warfarin, as an active substance un Annex I.
2010/50/EU (OJ L210 11.7.2010)	Directive amending Directive 98/8/EC to include dazomet, as an active substance un Annex I.
2010/51/EU (OJ L210 11.7.2010)	Directive amending Directive 98/8/EC to include N,N-diethyl-meta-toluamide, as an active substance un Annex I.
2010/72/EU (OJ L288 5.11.2010)	Directive amending Directive 98/8/EC to include spinosad, as an active substance in Annex I.
2010/74/EU (OJ L292 10.11.2010)	Directive amending Directive 98/8/EC to extend the inclusion in Annex I thereto of the active substance carbon dioxide to product type 18.
2011/10/EU (OJ L34 9.2.2011)	Directive amending Directive 98/8/EC to include bifenthrin, as an active substance in Annex I.
2011/11/EU (OJ L34 9.2.2011)	Directive amending Directive 98/8/EC to include (Z,E)-tetradeca-9,12-dienyl acetate, as an active substance in Annex I.
2011/12/EU (OJ L34 9.2.2011	Directive amending Directive 98/8/EC to include fenoxycarb, as an active substance in Annex I.
2011/13/EU (OJ L34 9.2.2011)	Directive amending Directive 98/8/EC to include nonanoic acid, as an active substance in Annex I.
2011/391/EU (OJ L175 2.7.2011)	Commission Decision concerning the non-inclusion of certain substances in Annex I, IA or IB
2011/78/EU (OJ L243 21.9.2011)	Commission Directive amending Directive 98/8/EC to include Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52 as an active substance in Annex I
2011/80/EU (OJ L243 21.9.2011)	Commission Directive amending Directive 98/8/EC to include lambda- cyhalothrin as an active substance in Annex I
2011/81/EU (OJ L243 21.9.2011)	Commission Directive amending Directive 98/8/EC to include deltamethrin as an active substance in Annex I
Legal base	Article 114 TFEU (originally Article 95 TEC)
Binding dates	
Entry into force	14 May 1998

Formal compliance	14 May 2000
National rules for the placing on the market of biocidal products will cease to apply	14 May 2010

Purpose of the Directive

The Directive sets controls over the marketing and use of biocides to manage the associated risks to the environment and to human and animal health. Directive 91/414/EEC on placing plant protection products on the market established a common European system for the authorization and placing on the market of plant protection products. The Directive 98/8/EC establishes a similar common framework of rules relating to the authorization and placing on the market of biocidal products. The framework will replace existing rules and procedures in the Member States, removing potential barriers to trade in biocides and in products treated with them.

Summary of the Directive

The Directive has three main purposes:

- to establish 'positive' Community lists of all active ingredients which can be used in biocides, authorized under a new common procedure;
- to establish a common procedure for the authorization of biocide products in Member States;
- to establish the principle of mutual recognition, so that Member State authorizations are recognized across the Community.

This Directive mirrors the purpose and structure of Directive 91/414/EEC on the marketing of plant protection products, requiring Community approval of all active ingredients for biocide products, but leaving approval of the product formulations with Member States acting in accordance with the common framework. Because the Directive post-dates the established national authorization, marketing and use of many of these products, there is a ten-year transition period from 2000 to 2010, during which the Commission undertook a work programme to list all approved active ingredients. Member States have been able to continue to permit the marketing and use of existing and new products during that period, using the main criteria established by the Directive.

Scope of the Directive

Biocidal products are defined as those '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'. As with the Directive 91/414/EEC, active ingredients in biocides are referred to as 'active substances' while marketed products are 'preparations'.

A full list of 23 product types and descriptions for biocides is provided in an Annex. Active substances used in biocide products are to be listed in three separate 'positive lists' annexed to the Directive, the first of which covers most biocidal substances. A second category of 'low-risk' biocides is also defined by reference to a second 'positive' list of less harmful

active substances. The Directive also allows for ‘basic substances’ whose major uses are non-pesticidal but which have minor uses as biocides, to be covered by the same procedures under a third ‘positive list’.

The Directive defines a ‘substance of concern’, which is ‘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’. No substance of concern can be listed for inclusion in ‘low-risk’ biocides, or as a ‘basic’ substance. The Directive also defines the concept of a ‘frame formulation’ as a group of biocides with the same active substances of the same specification designed for the same use and user type, such that their risk to human and animal health and to the environment is the same.

The Directive does not apply to products already defined or within the scope of other Directives, namely: proprietary medicinal and veterinary products (including homeopathic products and implantable devices); products defined or within the scope of Directives on food additives; materials intended to come into contact with foodstuffs; health rules for milk and milk products, egg products and fishery products; feedingstuffs and cosmetics; derogations for production and marketing of products of animal origin; and the placing of plant protection products (agricultural pesticides) on the market.

Active ingredients used in biocides

Positive lists of active ingredients are established under the Directive in Annexes I, IA and IB. These are very similar in purpose to the positive list which already applies to the authorization and marketing of plant protection products. Article 10 of the Directive establishes rules for the inclusion of both ‘active’ and ‘basic’ substances ‘with requirements agreed at Community level’ in these annexes. Annex I is for active substances in biocides, IA is for active substances in low-risk biocides, and IB is for basic substances which may have a biocidal action.

All the active ingredients used in biocides must be listed in one of these three Annexes. In order to get a particular substance listed, Article 11 specifies that applicants must send a detailed dossier for that substance to the ‘competent authority’ of one of the Member States, plus a dossier for at least one biocidal product containing the substance. Dossiers must be compiled in accordance with detailed specifications set out in Annexes to the Directive. Summaries of these dossiers must also be forwarded, with the competent authority's permission, to the Commission and other Member States. The competent authority must then evaluate the dossiers within 12 months and copy its evaluation to the Commission and all other Member States with a recommendation for inclusion or exclusion of the substance on one of the three lists. To spread the workload, evaluations can be carried out by any of the competent authorities in different Member States, not necessarily the one which receives the initial application.

Decisions about whether or not to accept the recommendations of ‘competent authorities’ rest with the Commission, as advised by the Standing Committee on Biocidal Products, composed of representatives of the Member States and chaired by a representative of the Commission.

An active substance cannot be included in the Annex IA list if it is classified according to Directive 67/548/EEC on classification, labelling and packaging of dangerous substances as

carcinogenic, mutagenic, toxic for reproduction, sensitizing, or bio-accumulative and not readily degradable. The positive lists can include conditions on the degree of purity, permitted product type, category of users, manner, area and concentration ranges of use. Where appropriate, acceptable exposure levels, daily intakes and knock-on environmental effects will need to be established before the substance is listed.

Under Article 10, entry of an active substance onto the lists can be refused or removed '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'. This concept of comparative evaluation is included in order to try and minimize additional risks from a proliferation of new chemicals. However, the clause is qualified by a requirement that when such a refusal or removal is considered, 'an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment'.

Authorization of biocides

Member States are to ensure that no biocidal products are placed on the market and used in their territory unless authorized in accordance with this Directive. Low-risk biocides containing only less harmful substances (listed in Annex IA) can be authorized in a simplified procedure, and new biocides which are based upon a previously approved 'frame-formulation' of active substances can expect a swifter approval process than others. Authorizations are granted for up to ten years from the date when their active substances were listed in the Directive's Annexes. Member States must ensure that the classification, packaging, labelling and use of biocides are in line with the provisions of the Directive.

The Directive requires mutual recognition of authorizations between Member States so that a product which is approved and registered in one Member State can be quickly approved and registered in any other Member State, whenever this is applied for. However, if a Member State can show that its own circumstances differ significantly from another state in which the biocide is already authorized and these differences represent an unacceptable risk to humans or to the environment, they can refuse authorization.

Biocides can only be authorized by Member States if their active ingredients appear in the positive lists in Annex IA of the Directive and any conditions of use laid down in these annexes are met. Applicants are required to present a detailed dossier for evaluation of the product and a dossier or letter of access for each active substance in the product, each of which must satisfy the particular requirements detailed in annexes to the Directive. Member States must establish, in the light of current scientific and technical knowledge, that the product is effective, that it has no unacceptable effects on human or animal health or on the environment either directly or indirectly (e.g. through its use and distribution into water, air, etc.), that it contains no toxic impurities or residues, and it can be stored, used and transported safely.

Authorizations can be reviewed at any time – for example, in the light of new research data – in which case Member States can require authorization holders to submit further information. They can be cancelled in the event of any constituent active substance being taken off the lists annexed to the Directive, or if any conditions are broken, or at the request of the applicant who holds the authorization. Member States must also ensure that any active

substances that have not previously been authorized as biocides are not used as biocides until they have been brought into line with the procedures of this Directive.

Review programmes

According to Article 16(2) the Commission and the Member States have to embark on a programme of work with the aim of systematically examining the risks associated with active substances that may be authorized for use in biocidal products. The programme was set up under Regulation (EC) No 1896/2000, which laid down the rules for the first phase of the review of active substances. During this phase, the industry had to identify the active ingredients they used in their products, and if they wished to continue using them for biocidal purposes, to notify them for evaluation by providing initially a limited dossier with information on the substances.

At the end of the first phase another Regulation (EC) No 2032/2003 was adopted on the second phase of the review programme, drawing up an inventory of the identified existing active substances; a timetable for the evaluation of the notified substances; a list of the designated Rapporteur Member States for the first two priority lists; and provisions regarding the procedural aspects of the review programme.

Development of the Directive

The need for a common procedure for authorization and marketing of biocides was first identified by the Council during its discussions on Directive 91/414/EEC, when it requested the Commission's intention on this issue. The proposal for a Directive was introduced in September 1993 (COM(93)351), but progress was delayed for many months as the European Parliament refused to take a position until the Commission provided it with the ‘common principles’ for assessing the safety of biocides and biocide products, which had been omitted from an annex to the proposal. In June 1996 the Commission amended the proposal and it received its second reading in Parliament in May 1997.

The proposal was the subject of much dispute, with industry concerned that it would involve them in significant increased costs and bureaucracy, and Parliament anxious to ensure the effectiveness of the Directive. In response to industry concerns the UK's Health and Safety Executive argued successfully for the inclusion of the two categories of ‘low-risk’ biocides (composed only of Annex IA active substances) and ‘frame formulations’ for which product approvals should be simpler, as well as a list of basic substances (Annex 1B list) where products will not require authorization.

During 1997, Parliament sought a greater role in the scrutiny and approval of active substances and products. Differences between the Parliament and the Council of Ministers were addressed through conciliation negotiations towards the end of 1997. Following these, the draft Directive was amended to strengthen the requirements for full dossiers for the listing of less harmful and basic substances under Annexes IA and IB, and to add the qualifying reference to ensure that these lists should not include any ‘substance of concern’.

Implementation of the Directive

Information on measures taken by the Member States to transpose the Driective can be found in their national execution measures.

In October 2008, the Commission prepared a report (COM(2008)620) on the evaluation of the implementation of the Directive and the review programme over the period from 14 May 2000 to 1 March 2008.

At the end of the first phase of the review programme, industry had identified 964 substances as active ingredients of biocidal products that were present on the market before 14 May 2000. Of these, 416 active substances were notified for evaluation in one or more product types. Totally, 548 (about 60 per cent) of the identified substances were not supported and were subsequently phased-out by 1 September 2006. It is estimated that these active substances were used in only 13 per cent to 33 per cent of the biocidal products on the market. Some of these active substances were no longer used in biocides, while others were not supported due to their unfavourable toxicity profile. In some cases, they were addressing a limited market that would not cover the evaluation cost. The implementation report did not identify any cases where the loss of these active substances left users without a substitute, or led to the proliferation of the target harmful organisms. By 1 March 2008, half of the initially notified active substance/product-type combinations had been withdrawn from the review programme.

The implementation report estimates that of the 472 dossiers submitted in support of the inclusion of an active substance/product-type combination, approximately 25 per cent of these dossiers were submitted either by a consortium or task force of enterprises or at least two enterprises that joined efforts. In 10 per cent of the cases more than one dossier was submitted for the same active substance/product-type combination, which means that the interested parties did not manage to come to an agreement to share data and submit a collective dossier.

Enforcement and court cases

According to the accompanying document of the 28th annual report on monitoring the application of Community law (SEC(2011)1093), in 2010 four non-communication cases were registered concerning the inclusion of active substances in Annex I. Furthermore, three non-communication cases were registered to include boric acid as an active substance in Annex I. All these cases have now been closed.

Further developments

On 12 June 2009, the European Commission adopted a proposal for a Regulation concerning the placing on the market and use of biocidal products (COM(2009)267). The proposed Regulation will repeal and replace Directive 98/8/EC.

The objective of the Proposal is to build on the principles laid down in the Directive 98/8/EC. The Proposal aims to address weaknesses identified in the implementation report (COM(2008)620), such as the costs of compiling a dossier in support of the inclusion of

active substance. For the first time the Proposal identifies which active substances may not be used in biocidal products. The Council adopted its position at the first reading on 21 June 2011 and the Commission Communication on the Council position at the first reading was adopted on 11 August 2011. The European Parliament adopted its position in January 2012. The proposed Regulation is scheduled to enter into force on 1 January 2013.

Related legislation

The following pieces of legislation interact with the Directive:

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP).
- Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (DSD).
- Directive 1999/45/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (DPD).
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive).
- Regulation (EC) No 689/2008 concerning the export and import of certain dangerous chemicals.
- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
- Regulation 1907/2009/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.
- Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.