Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	1993/0465(COD)	Procedure completed
Biocidal products for non-agricultural uses: common rules for national authorisations Amended by 2005/0263(COD) Amended by 2006/0288(COD) Amended by 2008/0188(COD) Repealed by 2009/0076(COD) Subject 3.10.09.02 Plant health legislation 4.20.05 Health legislation and policy		

Key players

European Parliament	Former committee responsible		
	ENVI Environment, Public Health and Consumer Protection	PSE JENSEN Kirsten M.	27/07/1994
Council of the European Union	Council configuration	Meeting	Date
	Fisheries	2063	18/12/1997
	Agriculture and Fisheries	2025	22/07/1997
	Fisheries	1983	20/12/1996
	Environment	1939	26/06/1996
	Environment	1905	04/03/1996
	Environment	1895	18/12/1995
	Environment	1817	16/12/1994

Key events

27/07/1993	Legislative proposal published	COM(1993)0351	Summary
13/09/1993	Committee referral announced in Parliament, 1st reading		
16/12/1994	Debate in Council	1817	
20/07/1995	Modified legislative proposal published	COM(1995)0387	Summary
18/12/1995	Debate in Council	1895	
22/02/1996	Vote in committee, 1st reading		Summary
22/02/1996	Committee report tabled for plenary, 1st reading	A4-0056/1996	

04/03/1996	Debate in Council	1905	Summary
17/04/1996	Debate in Parliament		
18/04/1996	Decision by Parliament, 1st reading	T4-0189/1996	Summary
24/06/1996	Modified legislative proposal published	COM(1996)0312	Summary
20/12/1996	Council position published	11310/1996	Summary
16/01/1997	Committee referral announced in Parliament, 2nd reading		
16/04/1997	Vote in committee, 2nd reading		
16/04/1997	Committee recommendation tabled for plenary, 2nd reading	A4-0137/1997	
13/05/1997	Debate in Parliament		Summary
13/05/1997	Decision by Parliament, 2nd reading	T4-0219/1997	Summary
22/07/1997	Parliament's amendments rejected by Council		Summary
11/11/1997	Formal meeting of Conciliation Committee		Summary
11/12/1997	Final decision by Conciliation Committee		Summary
16/12/1997	Joint text approved by Conciliation Committee co-chairs	3633/1997	
18/12/1997	Decision by Council, 3rd reading		
08/01/1998	Report tabled for plenary, 3rd reading	A4-0011/1998	
13/01/1998	Debate in Parliament		Summary
14/01/1998	Decision by Parliament, 3rd reading	T4-0014/1998	Summary
16/02/1998	Final act signed		
16/02/1998	End of procedure in Parliament		
24/04/1998	Final act published in Official Journal		

Technical information

Procedure reference	1993/0465(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amended by 2005/0263(COD) Amended by 2006/0288(COD) Amended by 2008/0188(COD) Repealed by 2009/0076(COD)
Legal basis	EC before Amsterdam E 100A
Stage reached in procedure	Procedure completed

Committee dossier	CODE/4/09216

Documentation gateway

Legislative proposal		COM(1993)0351 OJ C 239 03.09.1993, p. 0003	27/07/1993	EC	Summary
Reconsultation		COM(1993)0570	10/11/1993	EC	
Economic and Social Committee: opinion, report		CES0574/1994 OJ C 195 18.07.1994, p. 0070	28/04/1994	ESC	Summary
Modified legislative proposal		COM(1995)0387 OJ C 261 06.10.1995, p. 0005	20/07/1995	EC	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0056/1996 OJ C 096 01.04.1996, p. 0003	22/02/1996	EP	
Economic and Social Committee: opinion, report		CES0415/1996 OJ C 174 17.06.1996, p. 0032	27/03/1996	ESC	Summary
Text adopted by Parliament, 1st reading/single reading		T4-0189/1996 OJ C 141 13.05.1996, p. 0166-0176	18/04/1996	EP	Summary
Modified legislative proposal		COM(1996)0312 OJ C 241 20.08.1996, p. 0008	24/06/1996	EC	Summary
Council position		11310/1996 OJ C 069 05.03.1997, p. 0013	20/12/1996	CSL	Summary
Commission communication on Council's position		SEC(1996)2399	10/01/1997	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A4-0137/1997 OJ C 150 19.05.1997, p. 0003	16/04/1997	EP	
Text adopted by Parliament, 2nd reading		T4-0219/1997 OJ C 167 02.06.1997, p. 0015-0024	13/05/1997	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(1997)0331	27/06/1997	EC	Summary
Joint text approved by Conciliation Committee co-chairs		3633/1997	16/12/1997	CSL/EP	
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A4-0011/1998 OJ C 034 02.02.1998, p. 0004	08/01/1998	EP	
Text adopted by Parliament, 3rd reading		T4-0014/1998 OJ C 034 02.02.1998, p. 0057-0069	14/01/1998	EP	Summary
Implementing legislative act		32000R1896 OJ L 228 08.09.2000, p. 0006-0017	07/09/2000	EU	Summary
Implementing legislative act		32003R2032 OJ L 307 24.11.2003, p. 0001-0096	04/11/2003	EU	Summary
Implementing legislative act		32005R1048 OJ L 178 09.07.2005, p. 0001-0098	13/06/2005	EU	Summary
Implementing legislative act		32006R1849 OJ L 355 15.12.2006, p. 0063-0071	14/12/2006	EU	Summary

Follow-up document		COM(2008)0620	08/10/2008	EC	Summary
Follow-up document		COM(2011)0050	10/02/2011	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 1998/8
OJ L 123 24.04.1998, p. 0001 Summary

Biocidal products for non-agricultural uses: common rules for national authorisations

OBJECTIVE: to ensure the freedom of movement of biocidal products and goods treated thereby, without risk to man and the environment. CONTENT 1. The Directive complements Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal L 230, 19 August 1991). It also sets out a comparable approach: establishment of a Community-wide positive list of active substances and, at in Member States, grant of authorisations and system of mutual recognition of authorisations. 2. Definition and scope of application: biocidal products cover pesticides for non-agricultural use, such as insecticides, disinfectants, products for the preservation of wood or other materials and biocides for industrial use. 3. The Directive draws up a positive Community list of active substances intended to combat harmful organisms and which may be used in biocidal products. 4. System of authorisation for placing on the market of the various biocidal products containing the active substances included in the positive list. This authorisation may be issued, modified and cancelled by the Member States in accordance with the common requirements set out in the Directive and the uniform principles to be drawn up by the Commission on the opinion of a Standing Committee on Biocidal Products composed of representatives of the Member States and chaired by a representative of the Commission. 5. Principle of mutual recognition of authorisations granted by the Member States, with a safeguard clause. 6. System of provisional authorisation (three years) of placing on the market by a Member State, in its territory, of biocidal products containing an active substance not yet included in the positive list, but satisfying its conditions. This period is extended to ten years when the biocidal product is not included in the positive list, but is already being placed on the market. 7. Ten-year programme for the evaluation of active substances being placed on the market and to be included in the positive list. 8. Possibility, for the Member States, to use an unauthorised active substance or biocidal product for research or development purposes, provided that strict conditions are respected. 9. Harmonised rules on the protection of confidentiality and information exchange. 10. As regards classification, packaging and labelling of biocidal products, the rules laid down in Directives 88/379/EEC and 78/631/EEC and some supplementary rules listed in the Directive are applicable. 11. Introduction of an information system for users on biocidal products by means of data-safety sheets. 12. Regulation of the advertising of biocidal products. 13. Obligation for Member States to take the measures needed for biocidal products placed on the market to be officially inspected as regards compliance with the conditions laid down in the Directive. Source: European Commission - Info92 08/95 ?

Biocidal products for non-agricultural uses: common rules for national authorisations

$summary.text

Biocidal products for non-agricultural uses: common rules for national authorisations

During its debates, the European Parliament called for common principles for evaluating dossiers to be established as soon as possible and included in the main proposal in the form of an annex. The Council was of the same opinion. The Commission's amended proposal thus included a new Annex VI setting out the common principles. It referred to the annex in a new recital, which stated that common rules should be established to assess biocidal products in order to guarantee a harmonised approach in the Member States. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The report by Mrs K. JENSEN (PSE, DK) was adopted. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The discussion focused on Annexes II, III and IV (information to be provided to gain authorization) of the Commission's initial proposal on the one hand, and on Annex V (scope of the directive, with a breakdown by product types)on the other hand. The Council reached a political agreement, on the basis of the Presidency's suggestions, regarding the structure of these annexes and the procedures to be followed for compiling annexes and for future adjustments to their content. The Permanent Representatives Committee was instructed to continue working on the directive, taking account of the results achieved thus far and the orientations given by today's discussion, with a view to achieving results at the Environment Council's meeting in June 1996.

Biocidal products for non-agricultural uses: common rules for national authorisations

The Committee has already issued an Opinion (OJ C195 of 18/7/94) on the original Commission Proposal, concerning the placing of biocidal products on the market; the Opinion was generally favourable while suggesting a number of improvements. The Committee has no objection to establishing common principles for evaluating dossiers (for the authorization of biocidal products) under the current Amended Proposal, which it approved, subject to several comments designed to clarify and/or emphasize the contents of the Annex.?

Biocidal products for non-agricultural uses: common rules for national authorisations

In adopting the report by Mrs Kirsten JENSEN (PSE, DK), by 310 votes to 27 and 11 abstentions, Parliament opposed the idea that it should be possible for a biocidal product authorized by a single national authority to be authorized automatically by other national authorities within 60 days. It wished national authorities, which at present had to rely on information made available by companies, to have access to sufficient documentation. The EP considered that the levying of green taxes could help limit and bring about change in the use of biocides, and called for the implementation by the Member States of action plans designed to reduce consumption of biocidal products. The EP approved Article 9(7) of the proposal concerning alternative evaluation allowing the authorities to reconsider an authorization granted. Also adopted was an amendment providing that the Member States may authorize antifouling products used on seagoing vessels of over 25 metres for a period of ten years from the directive's entry into force. If legislation is adopted by the IMO within this time limit, this provision will lapse. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The amended proposal for a directive on the marketing of biocidal products incorporates a number of amendments adopted by the European Parliament at first reading. The main changes made to the initial proposal are designed to: - state that the directive helps to cut down the number of experiments carried out on animals; - change the scope of the directive so that it applies to all the relevant products not covered by other legislation, while avoiding duplication with existing legislation (there must be careful coordination, inter alia, with the directives on the protection of water and the continued use and release into the environment of genetically modified organisms); - introduce the idea of a 'general formula', defined as a category of products designed for the same use and the same type of user; - state the period of time laid down for the processing of requests for authorization for biocidal products: any request for authorization must be decided upon within a reasonable period of time. Requests for authorization for biocidal products to which the general formula applies must be processed within 60 days; - stipulate that specific account must be taken of the effects of biocidal products on air and surface water and that methods of application must be included in requests for authorization; - state that the labels on biocidal products must not be misleading or give an exaggeratedly favourable impression of the product; - change the requirements regarding the information to be provided when requesting authorization: the file must contain supporting data but must also correspond to the current state of technological progress; - provide for the authorization of a biocidal product is subject to a fee; - authorize the use of anti-soiling agents on sea-going vessels during a ten-year period from the entry into force of the directive. The amended proposal did not incorporate the European Parliament's amendments aimed at: - changing the scope of the directive by changing the definition of 'harmful organisms', including products intended for export and bringing within the scope of the directive materials treated with biocidal products; - provide for the drawing up of action plans to limit the use of biocidal products; - propose that all biocidal product labels recommend that they be used in moderation; - remove the reference to the 5th environmental action programme; - propose limiting the types of substance which can be included in the composition of biocidal products; - change the committee procedure laid down for the adoption of the regulation governing the programme of systematic examination. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The common position concerning the placing of biocidal products on the market, adopted unanimously, included 27 of the 28 amendments proposed by Parliament as incorporated by the Commission in its second modified proposal. It also included several amendments rejected by the Commission. The common position does not alter the basic aims of the proposal, but certain aspects of the text have been clarified and the number of recitals reduced. The scope of the proposal has been better defined and more specific cases for derogation from the principle of mutual recognition have been introduced. Practical aspects of authorization procedures have been introduced, e.g. frame-formulations and commodity substances, as well as a procedure for low-risk products. The conditions for the operation of the principle of comparative assessment have been clarified. The annexes have been restructured to provide a common core data set for all active substances and biocidal products. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The Commission supports the common position. The changes made were suggested by the Member States in order to clarify or simplify certain aspects of the authorization procedures. As a result the text is simpler but still highlights the main objectives of the proposal, i.e. environmental protection, while guaranteeing the free movement of biocidal products.?

Biocidal products for non-agricultural uses: common rules for national authorisations

The European Parliament adopted the recommendation for second reading by Mrs Kirsten JENSEN (PSE, DK) after rejecting most of the amendments tabled by its environment committee. Parliament did, however, call for the deletion of two new annexes (content unknown) which

were added to the proposal during the second reading. The subject matter of these annexes was: (a) a list of active substances and the requirements relating to them approved at Community level for inclusion among low-risk biocidal products; (b) a list of basic substances and the requirements relating to them approved at Community level. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The rapporteur stressed the effects of chemical products on human health and particularly highlighted the findings made with regard to the diminishing quality of male sperm. Mrs Jensen particularly deplored the attachment to the proposal, during second reading, of two new annexes whose content was unknown. She condemned the fact that, as a result of this manoeuvre, Parliament would have to accept framework provisions with governments being able to choose the most appropriate solution in terms of how to implement these. Replying to the criticisms made about the lack of transparency, Commissioner Bjerregaard explained that the annex?s wording would be based on a complete risk assessment. The problem was complex as it did not just relate to environmental proposals. Of the 41 amendments tabled, 21 were acceptable to the Commission.

Biocidal products for non-agricultural uses: common rules for national authorisations

The Commission modified its proposal to include two of the amendments adopted by the European Parliament at second reading. These amendments introduce specific references to Annexes IVB and IVA which specify the data requirements necessary for the products and for the active substances based on micro-organisms. It should be noted that the Commission did not accept the amendments seeking to: - reduce from 24 to 18 months the time period for transposition of the directive; - delete Annex IA which lists the active substances posing a low risk to humans, animals and the environment; - delete Annex IB which lists the 'Commodity' substances which have a minor use as biocides. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

The Council was unable to accept all the European Parliament's second reading amendments to its common position on the proposal for a Directive concerning the placing of biocidal products on the market. The Conciliation Committee will therefore be convened.?

Biocidal products for non-agricultural uses: common rules for national authorisations

Europe's first attempt at producing harmonized Union-wide legislation on biocides (the new name for non-agricultural pesticides) has just received the go-ahead in the Parliament/Council Conciliation Committee following an exchange of letters between the two parties. Agricultural pesticides are covered by other legislation. The directive establishes a system for the authorization of biocidal products. Industry sources suggest that there are currently around 10 000 biocidal products on the market. Under the principle of mutual recognition, if a biocidal product is authorized for sale in one Member State, it can also be sold in any other Member State - subject to certain environmental conditions. However, MEPs refused to give Council and Commission a blank cheque to create lists of approved biocides without parliament being involved. Council had wanted to leave Parliament without any say in the compilation of lists of biocides which are to be authorized. Parliament will now be involved in this process and so will be able to keep an eye on the legislation after it has been adopted. The text must now be formally approved by Council and the House. Member States will have 24 months in which to transpose the directive into national law. The EP's rapporteur was Kirsten JENSEN (PES, Dk). The conciliation committee was co-chaired by EP vice-president Josep VERDE I ALDEA (PES, Sp) and Mr Johny LAHURE, President of the Council and Luxembourg's Health and Environment Minister.

Biocidal products for non-agricultural uses: common rules for national authorisations

At the Conciliation Committee meeting on 11 November 1997, agreement could not be reached on the question of appropriate information through Parliament on the decisions to be taken concerning the annexes to the Directive. Subsequently, at the meeting of 18 November, Parliament's delegation decided to pursue avenues for compromise with the Council on this point. Agreement was recorded by means of an exchange of letters on 10 December 1997 on a compromise arrangement giving Parliament the requisite guarantees that it would be fully notified in advance by the Commission on the proposals for the inclusion of substances in annexes Ia and Ib. The delegation will report on the outcome of conciliation to plenary in January 1998.?

Biocidal products for non-agricultural uses: common rules for national authorisations

Commissioner Bjerregaard expressed her satisfaction and announced that the Commission would present a new general text on comitology before June 1998.

Biocidal products for non-agricultural uses: common rules for national authorisations

In adopting the report by Mrs Kirsten JENSEN (PSE, DK), the European Parliament approved the decision of the EP/Council Conciliation Committee giving the green light to a first attempt to harmonize at European level legislation on biocides. Parliament secured agreement that it should be involved in drawing up lists of approved biocides, so that it can constantly monitor the application of the legislation. ?

Biocidal products for non-agricultural uses: common rules for national authorisations

OBJECTIVE: to harmonize regulations concerning the placing on the market of biocidal products and their active substances with a view to facilitating the proper operation of the internal market and ensuring a high level of protection of health and the environment.

COMMUNITY MEASURE: European Parliament and Council Directive 98/8/EC concerning the placing of biocidal products on the market.

SUBSTANCE: the Directive concerns a wide range of types of products (which are listed in Annex V to the Directive): disinfectants, preservatives, pest control products and antifouling products. It lays down a Community legislative framework of procedures and conditions for authorization enabling the national competent authorities to decide whether to authorize a product after assessing the technical information submitted by parties interested in placing biocidal products on the market. Once authorized in one Member State, a product must be mutually recognized and therefore authorized in any other Member State. As regards substances which serve as active ingredients of biocidal products, the Directive institutes a system of Community authorization. By means of positive lists, these substances are to be authorized as the occasion arises over a period of 10 years, after their risks have been assessed, and subject to any limits on their use to allow their inclusion in biocidal products.

ENTRY INTO FORCE: 14/05/1998

DEADLINE FOR TRANSPOSITION: 14/05/2000.

Biocidal products for non-agricultural uses: common rules for national authorisations

LEGISLATIVE ACT : Commission Regulation 1896/2000/EC on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products.

CONTENT : pursuant to Directive 98/8/EC, a programme of work is to be initiated for the review of all active substances of biocidal products already on the market on 14 May 2000.

The first phase of the review programme is intended to enable the Commission to identify existing active substances of biocidal products and specify those which should be evaluated for a possible inclusion in Annex I, Annex IA or Annex IB to the Directive. Given the expected high number of existing active substances which are candidates for such inclusion, information is needed to set priorities for a further phase of the review programme, which is planned to be initiated in 2002.

It is necessary to specify the relationship between producers, formulators, Member States and the Commission and the obligation on each of the parties for the implementation of the review programme.

In order to establish an exhaustive list of existing active substances, an identification procedure should be laid down by which all producers are to submit information on existing active substances of biocidal products to the Commission. Formulators should also have the opportunity of identifying existing active substances.

The present Regulation lays down provisions for the establishment and implementation of the first phase of the programme of work for the systematic examination of all active substances already on the market on 14 May 2000 as active substances of biocidal products.

ENTRY INTO FORCE : 28/09/2000.

Biocidal products for non-agricultural uses: common rules for national authorisations

LEGISLATIVE ACT : Commission Regulation 2032/2003/EC on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation 1896/2000/EC.

CONTENT : under Regulation 1896/2000/EC existing active substances for use in biocidal products had to be identified and those to be evaluated with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC in one or more product types had to be notified no later than 28 March 2002. An additional period for the submission of notifications for existing active substances that had been identified only or had been notified only in respect of certain product types was granted by Commission Regulation 1687/2002/EC of 25 September 2002 on an additional period for notification of certain active substances already on the market for biocidal use as established in Article 4(1) of Regulation 1896/2000/EC. That period expired on 31 January 2003.

It is necessary to establish an exhaustive list of existing active substances that have been identified in accordance with Article 3(1) or Article 5(2) of Regulation 1896/2000/EC or in respect of which equivalent information has been submitted in a notification in accordance with Article 4(1) of that Regulation.

It is also necessary to establish an exhaustive list of existing active substances in respect of which at least one notification has been accepted in accordance with Article 4(2) of Regulation 1896/2000/EC or in which a Member State has expressed an interest in accordance with Article 5(3) of that Regulation. That list should specify the product types concerned.

More specifically, as regards the second phase of the review programme, priorities for the evaluation of existing active substances should be established. The lists of prioritised substances and the dates for submission of complete dossiers should be specified. The task of evaluation should be distributed among the competent authorities of the various Member States. In order to enable new Member States to participate in the review programme after their accession, it is appropriate, for the time being, to designate Rapporteur Member States only in respect of certain product types. A Member State which has indicated an interest in seeking review of a particular active substance should not be designated Rapporteur Member State for that substance.

In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the requirements concerning preparation and submission of the complete dossier should be such as to encourage those whose notifications have been accepted, hereinafter

"participants", to act collectively, in particular by submitting collective dossiers. It should be possible for the Rapporteur Member State to make available the reference to any test involving vertebrate animals that has been carried out in respect of a notified existing active substance unless that reference is confidential under Article 19 of Directive 98/8/EC. Also, in order to gain experience on the appropriateness of data requirements and to ensure that the review of active substances is carried out in a cost-effective way, participants should be encouraged to provide information on the costs of compiling a dossier and on the need to carry out tests on vertebrate animals.

The present Regulation lays down detailed rules for the implementation of the second phase of the programme of work for the systematic examination of all active substances already on the market on 14 May 2000 as active substances of biocidal products referred to in Article 16(2) of Directive 98/8/EC.

ENTRY INTO FORCE : 14/12/2003.

Biocidal products for non-agricultural uses: common rules for national authorisations

LEGISLATIVE ACT : Commission Regulation 1048/2005/EC amending Regulation 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

CONTENT : Article 4 of Commission Regulation 2032/2003/EC lays down that, from the date of entry into force, any existing active substance not listed in Annex I to that Regulation is to be considered as not having been placed on the market for biocidal purposes before 14 May 2000. As a consequence biocidal products containing active substances not listed in Annex I may no longer be placed on the market, unless inclusion into Annex I or IA to Directive 98/8/EC is applied for in accordance with Article 11 of that Directive, and provisional authorisation has been received in accordance with Article 15(2) of that Directive. However, a limited number of active substances have been detected by the Member States which were not identified or notified before the time limit laid down in Commission Regulations 1896/2000/EC and 1687/2002/EC although there is evidence they were contained in biocidal products placed on the market before 14 May 2000. Some of these active substances are important from a socioeconomic perspective or for protection of public health. It is therefore appropriate to draw up a further list of active substances that should be allowed to remain on the market until 1 September 2006.

Certain substances not included in Annex II to Regulation 2032/2003/EC are applied in uses for which Member States claim that there is evidence demonstrating the essential need for reasons of health, safety, and protection of cultural heritage, or the use is critical for the functioning of society in the absence of technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment or health. It is therefore appropriate to introduce a system for applying for an extension of the period for marketing of biocidal products containing those substances. Such extensions should only be granted for the requesting Member States if the requests are justified, continued use does not give rise to concerns for human health and the environment, and, where appropriate, alternatives are being developed. The extension should only be allowed until 14 May 2010 at the latest.

In accordance with Article 4(2) of Regulation 2032/2003, placing on the market of biocidal products containing active substances not notified, or not notified for the appropriate product types, has to stop on 1 September 2006 at the latest. For certain substances or substance/product type combinations that have so far not been notified, there is now an interest by economic operators to prepare complete dossiers in view of their inclusion into Annex I or IA to Directive 98/8/EC. It is therefore appropriate, to introduce the possibility to prolong the marketing deadline for biocidal products containing such substances, in the product type concerned, provided interested operators submit complete dossiers well before 1 September 2006. If these dossiers are accepted, an extension of the period for placing those products on the market in the product types concerned should be allowed until the end of the evaluation of the complete dossiers, which should take place in parallel with the evaluation of the notified substances for the product types concerned.

For a number of notified existing active substances/product type combinations ? in particular those notified for product types 8 and 14 ? all participants have withdrawn or not complied with their obligations, and no other economic operator or Member State has expressed an interest to take over the role of participants within the given deadlines. Furthermore, following the recent classification by the competent authorities and the Commission of certain milk hygiene products as biocidal products in product type 3 as defined in Annex V to Directive 98/8/EC, it is appropriate to include into Annex II certain substances used in those milk hygiene products where producers, formulators or associations believing that these were not concerned by Directive 98/8/EC did not submit notifications before the deadlines established by Regulations 1896/2000/EC and 1687/2002/EC, but have done so before the adoption of this Regulation. Annexes II and III to Regulation 2032/2003/EC should therefore be amended accordingly. Annex V, Parts A, B, C, and D, and Annex VI should also be amended in the light of the provisions contained in this Regulation.

For one substance listed in Annexes I and II to Regulation 2032/2003/EC an incorrect CAS number and for another one an erroneous common name are indicated. Four substances are not listed in Annexes I and III, although they were identified within the deadlines set by Regulation 1896/2000/EC. This should be rectified.

Regulation 2032/2003/EC should therefore be amended accordingly.

This is the aim of the present Regulation.

ENTRY INTO FORCE : 29/07/2005.

Biocidal products for non-agricultural uses: common rules for national authorisations

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Biocidal products for non-agricultural uses: common rules for national authorisations

The aim of this report is to discuss the implementation of Directive 98/8/EC and the review programme referred to in Article 16(2), over the period from 14 May 2000 to 1 March 2008. It is noted, however, that the implementation of a significant part of the Directive's provisions has

not started. Notably, there have been no authorisations of biocidal products yet. The report includes the situation in the 10 Member States who joined the EU on 1 January 2004, but does not cover the situation in Bulgaria or Romania.

Progress made under the review programme to date: at the end of the first phase of the review programme, the 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. 548 (about 60%) 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%-33% of the biocidal products on the market. By 1 March 2008, half of the initially notified active substance/product-type combinations have been withdrawn from the review programme

Ongoing work under the review programme: the original timetable of the review programme (14/05/2010) was based on the assumption that two years would suffice from submission of the dossier by the participant to adoption of a decision on the inclusion of an active substance. In practice this proved impossible to achieve. No active substance has been evaluated to-date in less than three years and the average period of evaluation seems to be closer to approximately four to five years so far. The Commission discusses the factors responsible for the slower than scheduled pace of the review programme. It is estimated that the last decisions on the remaining active substances will be taken only in 2014.

The report goes on to discuss issues such as low-risk products, basic substances, frame formulations and data protection.

Conclusion: the Directive has set the foundations for improving environmental and public health in relation to biocidal products. During a five year effort before the effective start of the active substance review in 2004, the Commission has inventoried the European biocides market and put into place a structured procedure for the assessment and evaluation of the existing active substances. Although it has not been possible to meet the time lines originally envisaged, progress has been similar to if not faster than other comparable regulatory systems, such as for plant protection products (Directive 91/414/EEC) or existing chemical substances (Regulation (EC) n° 793/93).

The review programme will not be finalised by 14/05/2010, which is also the date by which the national rules for the placing on the market of biocidal products will cease to apply. Allowing the transitional period to elapse without completing the review programme for active substances would mean that the harmonised rules of the Directive about product authorisation could not apply for all the biocidal products already on the market. If neither set of rules ? harmonised or national ? could apply, there would be a legal void with regard to the placing on the market of biocidal products. This could have negative effects on public health and would have severe adverse economic effects on all companies operating in the biocides sector. Therefore, this paper is accompanied by a proposal for the revision of the Directive that would extend the review programme, the transitional period, and certain provisions on data protection that accompany this period for an additional three years (COD/2008/0188).

The substantive revision of the Directive: the Commission is also considering:

- the simplification and adaptation of the scope of the Directive;
- a tiered approach to data requirements that will take proportionality into consideration;
- a simplification of the data protection rules, including some mandatory data-sharing;
- greater harmonisation or co-ordination of fee structures;
- improvement of the simplified procedures;
- measures to facilitate complying with the Directive for SMEs, and measures to
- encourage innovation;
- measures to imptove the internal market in biocidal products.

Biocidal products for non-agricultural uses: common rules for national authorisations

The Commission presents a proposal for a Council Directive amending Directive 98/8/EC of the European Parliament and of the Council so as to include creosote as an active substance in Annex I. In accordance with the requirements of Directive 98/8/EC on biocidal products, a work programme was carried out concerning the review of all active substances contained in biocidal products already on the market on 14 May 2000 (existing active substances). Creosote was identified as an existing active substance and evaluated in the context of that work programme.

In the Commission?s view, the conclusions of the evaluation of creosote are that the conditions for the inclusion of the substance in Annex I are met under certain conditions. Accordingly, the Commission submitted a draft Directive for vote in the Committee established under Directive 98/8/EC. The Committee did not deliver a favourable opinion on the draft Directive in its meeting on 17 December 2010. Thus in accordance with the procedure set out in Article 5(a) of Decision 1999/468/EC this proposal for a Council Directive is submitted to Council and forwarded to the European Parliament.

It appears from the assessment report that wood preservatives containing creosote may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, when applied on wood in some of the scenarios evaluated. Furthermore, there were strong indications in the stakeholder consultation in 2008 that there are considerable socio-economic benefits of using creosote in certain applications. Life cycle analyses published in the context of the consultation have suggested that, in certain cases, no appropriate alternatives to creosote less damaging to the environment exist. However, for certain wood use scenarios presented in the assessment report, unacceptable risks for the environment were identified in the risk assessment.

Furthermore:

- creosote is considered to be a non-threshold carcinogen and is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008;
- creosote, which is a mixture of hundreds of compounds, contains mainly polycyclic aromatic hydrocarbons ('PAHs'). Some of these have been considered by the Committee for Risk Assessment of the European Chemicals Agency as persistent, bioaccumulative and toxic ('PBT'; anthracene) or very persistent and very bioaccumulative ('vPvB'; fluoranthene, phenanthrene and pyrene) in accordance with the criteria set out in Regulation (EC) No 1907/2006 (REACH);
- PAHs are listed as substances subject to release reduction provisions in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants ('POPs') and in Annex III to Regulation (EC) No 850/2004;
- Directive 2000/60/EC on water policy identifies PAHs as priority hazardous substances, from which pollution of surface waters through discharge, emission or loss must cease or be phased out.

The Commission considers that the conclusions of the evaluation of creosote are that the conditions for the inclusion of the substance in Annex I are met under certain conditions. These are as follows:

- biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available;
- the active substance is to be subject to a comparative risk assessment in accordance with Article 10(5)(i) before its inclusion in Annex I is renewed;
- when assessing the application for authorisation of a product, Member States shall assess those uses and those risks to environmental compartments and populations that have not been representatively addressed at the Union level risk assessment;

Member States shall ensure that authorisations are subject to the following conditions:

- creosote may only be used under the conditions mentioned in entry No 31 in Annex XVII to Regulation (EC) No 1907/2006 (REACH);
- creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to REACH;
- appropriate risk mitigation measures shall be taken to protect workers, including downstream users, from exposure during treatment and handling of treated wood in compliance with REACH and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens mutagens at work (Sixth individual Directive);
- appropriate risk mitigation measures must be taken to protect soil and aquatic compartments. In particular, labels and safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collected for re-use or disposal.