COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.10.2008
COM(2008) 618 final

2008/0188 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods

(Text with EEA relevance)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Grounds for and objectives of the proposal

This proposal for a European Parliament and Council Directive to amend Directive 98/8/EC of 16 February 1998 concerning the placing of biocidal products on the market (hereinafter, 'the Directive') is submitted following a report forwarded by the Commission to the European Parliament and the Council on the progress with the 10-year work programme for the evaluation of active substances used in biocidal products, referred to in Article 16(2) of the Directive and on the implementation of the Directive in accordance with its Article 18(5).

General context

As set out in the above-mentioned report, the current progress rate of the review programme will not permit its completion by 14 May 2010 as planned. This is mainly due to the fact that, before any review could start, it was necessary to establish an inventory of active substances used in biocidal products placed on the European market of biocidal products, and list the ones that the industry or specific Member States were interested to have examined in view of their possible inclusion into Annex I or IA of the Directive (the Community positive list). This elaborate exercise has taken three full years to complete. It was only at the end of 2003 that the timetable, priorities and list of Rapporteur Member States for the review programme could be set, while the first dossiers with studies for evaluation were not submitted before 2004. Overall, 964 active substances were identified, of which 468 were notified for evaluation.

The experience so far with the review programme indicates that the evaluation of a regular active substance dossier never takes less than three years, even under optimum conditions, and the average time required is in the order of four years.

Article 16(1) of the Directive provides for a transitional period of ten years (14.5.2000-14.5.2010), during which the biocides market will continue to be regulated by national rules. Gradually, as more and more active substances are evaluated and included in the Community positive list, the national rules for biocidal product authorisations are replaced by the harmonised conditions established by the Directive. However, as the end of the transitional period coincides with the end of the review programme, this means in practice that, on the very next day, only products that contain active substances included in the Community positive list *and* are authorised in accordance with the Directive can be legally placed on the market. For the reasons explained above, it is almost certain that the review of a great part of the active substances will not be finalised by 14.5.2010. As a consequence, all products containing active substances not yet evaluated would have to be withdrawn from the market.

Even if all the active substances were evaluated and a decision was adopted for their inclusion, or not, in the Directive's positive list by 14 May 2010, these decisions would need to be transposed by the Member States and authorisations or registrations for biocidal products containing the substances concerned would have to be issued in accordance with Article 16(3) of the Directive. This implies the preparation and submission by the industry of complete dossiers on specific biocidal products, their evaluation by the competent authorities, and the issuance of new authorisations or registrations at Member State level and subsequent mutual recognition in other Member States. Only then would be the market regulated by harmonised

rules. However, the Directive, as it is now, does not allow for such a period, but requires that the market be fully harmonised by 14 May 2010.

Article 12 of the Directive, on data protection, will need to be adjusted as well to the new deadline of the review programme, because otherwise there is a risk that the information submitted for the purposes of the Directive from 14 May 2010 until the proposed new deadline for the completion of the review programme - that is, on 14 May 2013, will not be protected.

Considering the findings of the above-mentioned report, the proposed extension of three years might not be enough to finalise the review programme. However, providing for a significantly longer extension might work against intensifying the efforts to complete the evaluation work in a timely manner. For this reason, it is proposed to provide for an implementing measure procedure to allow for flexibility in the review programme and corresponding transitional period for any remaining dossiers.

Existing provisions in the area of the proposal

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Certain dates and one procedure in Directive 98/8/EC are to be amended by the present proposal.

Consistency with the other policies and objectives of the Union

Not applicable.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

There has been extensive informal consultations with the Member States about the foreseen progress with the review programme, in particular during the Competent Authorities' meetings in Brussels (4 per year), where industry representatives are also present as observers. Ways to speed up the evaluation of active substances and to organise a co-ordinated authorisation of biocidal products were also explored and discussed during a special seminar titled "Post Annex I Inclusion" that took place on 13 March 2007, in the margin of the 24th Competent Authorities meeting in Brussels.

Summary of responses and how they have been taken into account

The Member States also believe that completion of the review programme of all notified active substances is highly unlikely to happen by 14 May 2010. They underlined as reasons the lack of quality or completeness of the submitted information, which considerably delays the procedure; the insufficient resources to deal with the current and the foreseen amount of work, in particular considering the additional needs for scientific personnel created recently by REACH; and the difficulty with regard to the implementation of very demanding technical provisions of the Directive. All these opinions expressed by the Member States have been fully taken into account, together with the aim to accomplish, as fast as possible, the harmonisation of the biocides market.

Collection and use of expertise

There was no need for external expertise.

Impact assessment

From the experience acquired so far with the review programme and by the most conservative estimations, it is expected that at least three more years will be necessary to complete the review programme and achieve effective harmonisation of the market. If no extension is given, the marketing of a substantial part of all biocidal products currently on the market will be illegal, as national rules will no longer apply after 14 May 2010, and as of that date, the Directive allows only the placing on the market of biocidal products that contain active substances included in the Community positive list and that have been authorised or registered in accordance with its provisions.

It is for this reason that the Commission decided to propose as a matter of urgency an amendment of the Directive with regard to the length of the review programme and of the transitional period, separately from the co-decision procedure on the revision of the Directive (foreseen to be launched at the end of 2008), which will follow later, once all options to remedy identified problems and weaknesses have been thoroughly investigated in an impact assessment.

Without these amendments, there will be significant adverse economic effects on the industry (who would no longer be allowed to market a large part of their products) and adverse effects on human health and on the environment, due to the lack of available products to combat many harmful organisms.

Given the relatively brief extension proposed for the review programme and the transitional period, and as a precautionary measure, the Commission also proposes to provide for the possibility to extend the review programme and corresponding transitional period for any remaining dossiers after 14.5.2013 by Comitology decisions.

3. LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

The proposed amendments to Directive 98/8/EC concern Articles 12(1)(c)(i), 12(2)(c)(i), 16(1) and 16(2). Basically, the 10-year work programme referred to in Article 16(2) becomes the 13-year programme, and the phrase "the date referred to in Article 34(1)" - i.e. 14 May 2000, the actual date of entry into force of the Directive - or the phrase "10 years from the date referred to in Article 34(1)" in the above-mentioned provisions is replaced by an actual date, in a way that, the expiry of the transitional period and the end of the review programme will be postponed by three years. As a necessary measure to cover the data ownership rights for information under evaluation during the period from the current end of the review programme (14.5.2010) until the proposed end (14.5.2013), the data protection rights referred to in Article 12(1)(c)(i) and 12(2)(c)(i) will also have to be extended by three years. Finally, a Comitology procedure is proposed to extend – if necessary - the review programme and transitional period for any remaining problematic active substance dossiers after 2013.

Legal basis

Article 95 TEC

Subsidiarity principle

The proposal falls under the exclusive competence of the Community. The subsidiarity principle therefore does not apply.

Proportionality principle

The proposal complies with the proportionality principle for the following reason(s).

If the current provisions of the Directive relating to the review programme and transitional period are not amended in time, there would be significant adverse economic effects on the industry (who would no longer continue to market a large part of their products) and adverse effects on human health and on the environment, as there would no longer be products available to combat many harmful organisms. The proposed amendments are the simplest solution to allow for a continuation of the status-quo until the review programme is concluded in an orderly fashion.

The proposed measures are not expected to create an additional financial or administrative burden on the Community, the national, regional or local authorities, nor for the economic operators or the citizens of the EU.

Choice of instruments

Proposed instruments: directive.

Other means would not be adequate for the following reason(s).

As the instrument to be amended is a Directive of the European Parliament and of the Council, the most appropriate legislative act to amend it would be another European Parliament and Council Directive, especially considering the very limited scope of the amendments. The choice of legal instrument may however be re-examined in the foreseen substantive revision of the Directive (planned for November 2008), which will amend the current provisions to a much wider extent.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget, other than the necessary resources for monitoring the implementation of the Directive and its review programme that are, or should have been, provided for.

5. ADDITIONAL INFORMATION

Correlation table

The Member States are required to communicate to the Commission the text of national provisions transposing the Directive as well as a correlation table between those provisions and this Directive.

European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) Article 16(1) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[5] provides for a transitional period of ten years, starting from 14 May 2000, the date of entry into force of that Directive during which Member States may apply their national rules or practices for placing biocidal products on the market, and in particular, authorise the marketing of biocidal products containing active substances that are not included in the positive list of that Directive, that is, its Annexes I, IA or IB.

(2) Article 16(2) of Directive 98/8/EC establishes a 10-year work programme, starting also from 14 May 2000, during which all the active substances contained in biocidal products that were present on the market before that date will be systematically examined and, if found acceptable from the point of view of human and animal health and the environment, they will be included in the Community positive list.

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ L 123, 24.4.1998, p. 1, Directive as last amended by Directive 2008/31/EC (OJ L 81, 20.3.2008, p. 57).

(3) Paragraphs 1(c)(i) and 2(c)(i) of Article 12 of Directive 98/8/EC provide for the protection of all information submitted for its purposes for a period of 10 years, starting also from 14 May 2000, unless a shorter period of protection has been granted in a particular Member State, in which case the latter will apply in its territory. That protection concerns only information submitted in support of the inclusion in the positive list of Directive 98/8/EC of active substances used in biocidal products that were present on the market before the date of entry into force of Directive 98/8/EC, i.e. the so-called 'existing' active substances.

(4) Once an existing active substance has been evaluated and included in the positive list of Directive 98/8/EC, its market is considered as harmonised, and the transitional rules for the placing on the market of products containing the active substance are replaced by the provisions of that Directive.

(5) In accordance with Article 16(2) of Directive 98/8/EC, the Commission has submitted a report[6] on the progress achieved with the 10-year work programme, two years before its completion. It is expected, based on the findings of that report, that the review of a significant number of active substances will not be finalised by 14 May 2010. Furthermore, even for the active substances for which a decision on their inclusion in the positive list of Directive 98/8/EC has been adopted by 14 May 2010, a sufficient time period is necessary for Member States to transpose the relevant acts and to grant, cancel or modify the relevant products authorisations, in order to comply with the harmonised provisions of Directive 98/8/EC. There is a serious risk that, at the end of the transitional period on 14 May 2010, national rules will no longer apply, while the relevant harmonised rules will not have been adopted yet. An extension of the 10-year work programme is therefore considered necessary, to permit the finalisation of the review of all active substances notified for evaluation.

(6) It is also necessary that the end of the review programme coincides with that of the transitional period, in a way that national systems or practices will regulate the placing of biocidal products on the market until they are ready to be replaced by harmonised provisions.

(7) Also for reasons of consistency and in order to avoid the loss of data protection while certain active substances are still under evaluation, the protection of all data submitted for the purposes of Directive 98/8/EC should be extended in order to coincide with the end of the review programme,

(8) The extension of the review programme proposed may not be enough to finalise the evaluation for a number of active substances. On the other hand, a significantly longer extension might work against intensifying the efforts to complete the review programme in a timely manner. Whereas a more flexible procedure to extend the review programme and the corresponding transitional period for any remaining active substances after 14.5.2013 should be provided for,

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[6] OJ C , , p. .

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/8/EC is hereby amended as follows:

1. Article 12 is amended as follows:

(a) paragraph 1(c)(i) is replaced by the following:

“(i) until 14 May 2013 for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, but not beyond 14 May 2013;”

(b) paragraph 2(c)(i) is replaced by the following:

“(i) until 14 May 2013 for any information submitted for the purposes of this Directive, except in the case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected in that Member State until the expiry of any remaining period of data protection provided for under those national rules, but not beyond 14 May 2013;”

2. Article 16 is amended as follows:

(a) in paragraph 1 the first sentence is replaced by the following:

"By way of further derogating from Articles 3(1), 5(1), 8(2) and 8(4), and without prejudice to paragraphs 2 and 3, a Member State may, until 14 May 2013, continue to apply its current system or practice of placing biocidal products on the market.”

(b) paragraph 2 is amended as follows :

(i) in the first subparagraph the first sentence is replaced by the following:

“Following the adoption of this Directive, the Commission shall commence a thirteen-year programme of work for the systematic examination of all active substances already on the market on the date referred to in Article 34(1) as active substances of a biocidal product for purposes other than those defined in Article 2(2)(c) and (d).”

(ii) at the end of the first subparagraph the following sentence is added:

"Depending upon the conclusions of the report, it may be decided, in accordance with the procedure laid down in Article 28(3), whether the transitional period referred to in the first paragraph and the 13-year period of the work programme is to be extended for a period to be determined."

(iii) in the second subparagraph, the words "During that 10-year period" are replaced by the words "During that thirteen-year period".

Article 2
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 14 May 2010 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*