III

(Preparatory acts)

EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

460th PLENARY SESSION HELD ON 17 AND 18 FEBRUARY 2010

Opinion of the European Economic and Social Committee on the 'Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products'

COM(2009) 267 final — 2009/0076 (COD)

(2010/C 347/09)

Rapporteur: **Mr BIOT**

On 17 July 2009, the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products.

COM(2009) 267 final - 2009/0076 (COD).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 1 February 2010.

At its 460th plenary session, held on 17 and 18 February 2010 (meeting of 17 February), the European Economic and Social Committee adopted the following opinion by 180 votes to none, with 2 abstentions.

1. Conclusions and recommendations

1.1 The EESC welcomes the replacement of the current directive by a regulation to harmonise the placing on the market of biocidal products, which would be directly applicable in Member States' legislation.

1.2 The EESC notes that the Commission has made an effort to bring European legislation on biocidal products into line with the REACH regulation on chemicals, and considers it essential that the new regulation cover the harmonisation of data to be provided in accordance with Directive 88/379/EEC and Article 14(2) of the REACH regulation.

1.3 The EESC welcomes the changes regarding frame formulations, which should make it easier to develop and market variations in composition within a group of biocidal products. However, the degree of flexibility of composition must be clarified, both in terms of biocidal products and their inert components.

1.4 The EESC notes that the European Chemicals Agency (ECHA) has only been given a coordinating role. This body could play a more decisive role in order to help ensure the efficiency of the authorisation process for biocidal products at Community level and within the Member States. However, the EESC is concerned as to whether the Agency will have sufficient resources in time to carry out its mission effectively, given the extension of its remit to include biocidal products.

1.5 The EESC proposes maintaining the principle of risk assessment on a case-by-case basis as regards the decision to allow active substances in Annex I of the proposal ('List of active substances with requirements for inclusion in biocidal products'). However, the Committee believes that arbitrary discrimination is applied to certain disinfectant products for foodstuffs intended for human consumption and for cattle, to which the conditions set down in Article 5(c) cannot apply.

1.6 The EESC is pleased that the proposal provides for the mandatory sharing of data, particularly data from animal research.

1.6.1 The EESC endorses the Commission's proposal that authorised biocidal products must be used for any articles or materials that are treated. This is a fair measure that is mandatory within the EU.

1.7 The EESC welcomes the extension of this measure to materials and articles from non-EU countries in order to guarantee equal conditions in the market.

1.7.1 The EESC emphasises the need for the labelling of materials and processed products, to ensure that users have adequate and effective information. The Committee calls on the Commission, however, to study this matter further in order to limit the use of exhaustive labelling to cases where this would be of benefit to the consumer. The EESC suggests two levels of information. The first should provide information that is essential to consumer usage and protection. The second should include all known information and should be available in the event that consumers have to consult professionals (poison centres, doctors, etc.). This information could be made available via databases and Internet sites.

1.8 The EESC supports harmonising the fee system both for Member States and for the Agency, but is opposed to the levying of an annual fee without justification.

1.9 In line with the new regulation on the placing of plant protection products on the market, the EESC believes that to ensure the free movement of goods, parallel trade procedures should be restricted to identical products, based on the same sources of active substances and ingredients.

1.9.1 The EESC is pleased that the Commission recognises the phenomenon of 'free riders' and hopes that Article 83 can be developed in greater detail.

1.10 The EESC calls on the Commission to state how it would support Member States in effectively carrying out tests on biocidal products on the market.

1.11 Along the lines of the framework directive on the sustainable use of phytopharmaceutical products [1] and with a view to ensuring that biocidal products are used sustainably, the EESC proposes that in future, the Commission provide for these products to be used in a more rational way.

2. **Introduction**

2.1 The term 'biocides' refers to 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 [2].

2.2 When used judiciously, biocides contribute to the daily life of any civilised society. They prevent the spread of disease and promote a high level of hygiene in a highly populated environment. Every part of daily life is concerned by the use of biocides. Some of these products may be intrinsically hazardous, but aim to protect human and animal health and hygiene and the environment in a sustainable manner.

2.3 Current Directive 98/8/EC [3] of the Parliament and of the Council of 16 February 1998 establishes a harmonised legal framework for the authorisation and placing on the market of low-risk biocidal products and basic substances.

2.4 In this context, the EESC issued an opinion [4] approving the proposal for a directive insofar as it aimed to protect human and animal health and the environment.

2.5 Directive 98/8/EC requires the Commission to draw up a report seven years after its entry into force and to submit the report to the Council. The report shall address the implementation of the Directive and the functioning up to that date of the simplified procedures (frame formulations, low-risk biocidal products and basic substances).

2.6 Various consultations of stakeholders were held, followed by an impact assessment and a general consultation over the Internet.

2.7 The proposal is also backed by a number of studies, such as the study to assess the impact of the revision of Directive 98/8/EC which aimed to analyse the economic, social and environmental impacts of the different policy options. The conclusions of this study were directly reflected in the impact assessment.

2.8 The regulation proposed by the Commission aims to replace the afore-mentioned directive.

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[1] Directive 2009/128/EC – OJ L 309, 24.11.2009, p. 71.
[2] Directive 98/8/EC.
[3] OJ L 123, 24.4.1998, p. 1.
[4] OJ C 195, 18.7.1994, p. 70.

3. **Gist of the proposal**

3.1 The purpose of the proposal, which would replace Directive 98/8/EC, is to **increase the free movement of biocidal products within the Community**. It aims to tackle the identified weaknesses of the legal framework during the first eight years of its implementation, to improve and update certain elements of the system and to avoid problems anticipated in the future. It retains the structure of Directive 98/8/EC.

3.2 **Simplification of the procedures concerning the authorisation** of biocidal products in the Member States may help reduce the costs and administrative burden for economic operators, without lowering the safety level.

3.3 The proposal aims to be **consistent** with the other policies and objectives of the EU, taking account of:

— recent EU legislation on chemicals ([5]);

— Regulation 1272/2008 ([6]);

— horizontal EU legislation in the area;

— the general rules and obligations for Member States;

— a transitional period.

3.4 The aim of the proposal is to:

— simplify the data protection rules;

— avoid duplicating vertebrate animal studies through mandatory data-sharing ([7]);

— increase harmonisation of fees systems in the Member States and at EU level;

— establish rules for **parallel trade**;

— cover **articles** or materials treated with biocidal products.

3.5 Various articles of the proposal encourage research and innovation.

4. **General comments**

4.1 *New legislative proposal*

4.1.1 Directive 98/8/EC on biocidal products is to be replaced by a regulation.

4.1.2 The proposed regulation remains in line with the directive on biocidal products. It was preceded by an **impact assessment** focusing on the scope of the regulation, product authorisation, data-sharing, data requirements and fees charged by Member States.

4.1.3 The Commission has made an effort to **align** EU legislation on biocides with the **regulation on chemicals (REACH)**.

4.2 *Authorisation rules*

4.2.1 One element that, in principle, promotes harmonised implementation in all EU countries is the introduction of the concept of **Community authorisation**, with ECHA as the central regulator. The Commission argues that this system is the most efficient and therefore the most appropriate means of improving product availability and creating innovation incentives, thus making a greater contribution to protecting health and the environment. Nevertheless, fragmentation in the market for biocides, in terms both of producers (few global companies, a lot of SMEs) and of products and applications, would suggest a need to temper this viewpoint. The fact is that, since many companies in the sector are active in only a few countries, they are calling for **local authorisation**. Meanwhile, **mutual recognition** is demanded in cases where the volume of business in other Member States has increased.

4.2.2 The Commission's new approach, with the **Community authorisation** of **low-risk biocidal products** and **new substances**, may prove limited in impact, as it would affect only a minority of biocidal products and, as a result would lead to only limited administrative streamlining for companies and authorities alike. It would not, therefore, encourage companies to be more innovative.

4.2.3 The concept of low-risk biocidal products is dotted throughout the draft regulation. A better definition of low-risk biocidal products would be helpful.

4.3 *Data to be supplied*

4.3.1 Certain **criteria** for the definition of low-risk products may prove too restrictive. These criteria should be evaluated according to their impact before being adopted in the final regulation. Indeed, the study should be based on the risks, taking account of exposure and not just the inherent dangers. This measure would form an incentive for innovation in safer products whilst using existing substances. Products meeting these criteria should consequently be able to make use of the 'low-risk' label. Prohibiting the promotion of these products as low-risk products would be counter-productive.

([5]) Regulation EC 1907/2006 (REACH) – OJ L 396, 30.12.2006, p. 1.
([6]) OJ L 353, 31.12.2008, p. 1.
([7]) OJ C 94, 18.4.2002, p. 5 and OJ C 277, 17.11.2009, p. 51.

4.3.2 The Commission's proposal not to include low-risk products in Annex 1 provides an incentive for development and marketing. A number of points need to be clarified and examined, however, with a particular need for clear guidance on data for active substances and the format in which this data should be provided.

4.3.3 The general rules for adapting **data requirements** set out in **Annex IV** should be broadly welcomed. They offer guidance on sharing tests that are to be carried out.

4.3.4 The **data requirements for active substances** are included in **Annex II** of the proposal, which comprises two tiers, the first of which is defined as the standard. Tier II data may need to be submitted depending on the characteristics and intended use of the active substance, in particular if a danger for health or the environment has been identified.

4.3.5 Some toxicological studies are no longer necessary for the first tier, but might be for the second. Nevertheless, as it is the Member States that decide on the range of data required, on the basis of their evaluation, there is a risk that data requirements exceed what is necessary from the scientific point of view.

4.3.6 For reasons relating to competition, the data to be provided for alternative sources of active substances cannot be reduced, if these substances are included in Annex I and their protection has expired.

4.3.7 The level of **data requirements for biocidal products** included in **Article 18**, concerning **data requirements for an application for authorisation** and in **Annex III** of the proposal remains as high as under the current directive. No tests spread across different levels are stipulated and requirements are not lowered to what is strictly necessary. It will therefore be difficult for producers to develop innovative products for specific uses.

4.4 *Data sharing*

4.4.1 **Sharing data** on animal tests is mandatory, as is sharing - in a fair manner - the costs of producing and using the data for the purpose of demonstrating product safety under the terms of the current directive.

4.4.2 Whilst this concept of data sharing is in keeping with the REACH regulation, where data protection and the duration of protection are concerned, the proposal is not.

4.5 *Simplification measures*

4.5.1 Positive changes are put forward in the frame formulations, which should make it easier to develop varying compositions within a group of biocidal products. The degree of flexibility with regard to composition must be clarified, however, for both biocidal substances and their inert components.

4.6 *The role of ECHA*

4.6.1 ECHA's role will now consist merely of coordinating and validating Community authorisation for low-risk biocidal products and new substances.

4.6.2 The EESC considers that ECHA could act as a 'screening centre' that would group together similar applications. These could then be evaluated by a single authority, even if the dossier has been submitted in a number of different Member States.

4.7 *Parallel trade – data protection*

4.7.1 In line with the new regulation on the placing of plant protection products on the market, the EESC believes that to ensure the free movement of goods, parallel trade procedures should be restricted to identical products, based on the same sources of active substances and ingredients.

4.7.2 Where parallel trade is concerned, the data required should be afforded greater protection, at least for biocidal substances likely to be included in Annex 1.

4.7.3 In order to prevent the phenomenon of 'free riders', the industry has called for the relationship to the company of active substances contained in Annex I to be included, as a prerequisite for the ownership and protection of data. The biocides industry is pleased that the Commission recognises this phenomenon, but considers that Article 83 should be developed in greater detail, in order to address this phenomenon more effectively.

4.8 *Materials and articles treated*

4.8.1 The proposal stipulates that all **articles or materials** must be treated only with biocidal products authorised for that purpose in at least one Member State. The proposal also argues that this measure should be extended to materials and articles originating in non-EU countries, to ensure that the market is fair to everyone.

4.8.2 The EESC emphasises the need for treated materials and products to be labelled, to ensure that users have adequate and effective information. The Committee calls on the Commission to study this matter further in order to limit the use of labelling to cases where this would be of benefit to the consumer. The EESC suggests two levels of information. The first should provide information that is essential to consumer usage and protection. The second should provide all known information and should be available in the event that consumers have to consult professionals. This information could be made available via databases and Internet sites.

4.9 *Deadlines and implementation*

4.9.1 The failure to meet the deadlines for the evaluations set out in the directive is a major source of concern. These deadlines were extended in a mini-review of the directive, but little appears to have been done to withdraw from the market substances that have not been tested and which are potentially harmful. The uniform application of definitions and deadlines should enable the procedure to operate more smoothly between Member States.

4.9.2 Non-uniform and poor implementation of EU legislation by the Member States damages Community lawmaking.

4.10 *Payment procedures*

4.10.1 The Commission proposes harmonising the structure of **charges**, for both Member States and ECHA. Users face considerable differences in evaluation fees between Member States. There is often no correlation between the resources required and those actually used.

4.10.2 Charges should be more transparent and indicate the different stages and procedures involved in the evaluation. They should relate to a reasonable volume of work and can only be invoked where there is a real need to do so.

4.10.3 An annual charge should never be made without justification.

5. **Specific comments**

5.1 *The exclusion of biocidal substances from Annex 1*

5.1.1 Article 5(2) of the proposal excludes from Annex 1 active substances classified as carcinogenic, mutagenic, toxic for reproduction and those identified as having endocrine-disrupting properties.

5.1.2 Three derogations, which nevertheless make it possible to include such substances in Annex 1, are set out in Article 5(1) of the proposal:

— where human exposure to the substance is negligible;

— where the substance is necessary for public health;

— where a substance's risk/benefit ratio is favourable.

— The last paragraph of Article 5 nevertheless definitively excludes the application of the last derogation to active substances for product types 4 and 14 to 19 ([8]).

5.1.3 Some biocides can in themselves be dangerous, in line with their purpose, reflecting the definition of an active substance as *a substance or a micro-organism having an action against harmful organisms*; The benefits of using such products and the measures minimising their exposure to humans and the environment could enable them to be used as biocides.

5.1.4 Whilst occasional exposure is not a major cause for concern, the EESC would urge prudence as regards prolonged exposure to biocidal products without proper protection.

5.1.5 The Committee believes, however, that the types of product referred to above (4 and 14 to 19), to which the conditions set down in Article 5(c) cannot apply are discriminated against on an arbitrary basis. This measure is counter-productive as regards innovation and drastically reduces the portfolio of substances that could potentially be used as biocides in the future.

5.2 *Giving ECHA a greater role*

5.2.1 The EESC is in favour of extending ECHA's remit. It should be able to actively manage all procedures concerning the authorisation of biocidal products, at both the Community and national levels.

5.2.2 The advantages of a centralised evaluation system are as follows:

— ECHA would have all the requisite procedures in place for validating an application in the event that Community authorisation is granted;

— validation of the dossiers by a single body would help ensure greater consistency and more uniform and straightforward legislation on biocides;

— Member States could focus their resources on the current evaluation of the application;

([8]) Product type 4: Food and feed area disinfectants
Product type 14: Rodenticides
Product type 15: Avicides
Product type 16: Molluscicides
Product type 17: Piscicides
Product-type 18: Insecticides, acaricides and products to control other arthropods
Product type 19: Repellents and attractants
Product-types 14 to 19 fall under Group 3: Pest control.

— ECHA validation does not exclude the possibility of adding new data found during an evaluation procedure. This would remain a matter for the Member States.

5.2.3 In addition, if ECHA adopted the role of 'screening centre' whilst managing biocidal product dossiers:

— the Community Register for Biocidal Products, managed by ECHA, would make an excellent instrument for managing groups of biocides;

— biocidal products based on the same active substance or used in the same types of product would have the same deadline for submitting their applications;

— evaluation by a single competent authority of the main aspects of these products' dossiers would make legislation on biocides more consistent and more uniform;

— the effective management of an evaluation procedure would further encourage users to prepare dossiers proactively and would lower the threshold for the industry.

Brussels, 17 February 2010

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