Opinion of the European Economic and Social Committee on the 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products with regard to certain conditions for access to the market'

COM(2013) 288 final — 2013/0150 (COD)

(2013/C 341/10)

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On 23 May 2013 the European Parliament and on 6 June 2013 the Council decided to consult the European Economic and Social Committee, under Article 114 of the Treaty on the Functioning of the European Union, on the

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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 17 July 2013.

At its 492nd plenary session, held on 18 and 19 September 2013 (meeting of 18 September), the European Economic and Social Committee adopted the following opinion by 154 votes to 2 with 7 abstentions.

1. **Conclusions and recommendations**

1.1 The European Commission's proposal helps to improve substantially the practical application from 1 September 2013 of the new Biocidal Products Regulation, clarifies the arrangements for the transitional rules and provides greater legal certainty for operators.

1.2 The EESC regrets that, during the long and complex process of adopting the new European legislation on biocidal products, the Commission, the Council and Parliament have not given prior consideration to the distortions that confused and unclear transitional rules could create.

1.3 The EESC agrees that changes need to be made to the Biocidal Products Regulation before it enters into force ([1]), so as to facilitate the transition from Directive 98/8/EC. In order to ensure that the system runs smoothly, a coherent framework of transitional measures enabling the system to change gradually for operators and Member States is crucial.

1.4 The EESC welcomes the changes made to the transitional measures concerning treated articles, and the evaluation of existing active substance and biocidal products. These modifications will prevent the de facto freezing of the placing on the market of many new treated articles, to allow them on the market provided that a complete dossier to assess the active substance(s) contained in these treated articles has been submitted by 1 September 2016 ([2]). These modifications will also allow a better transition to the harmonised authorisation system for existing biocidal products ([3]).

1.5 With regard to the innovative provision on the mandatory sharing of studies on environmental fate and behaviour relating to Annex II of Regulation (EC) No 1451/2007, the EESC calls on the Commission to ensure that the new obligation does not distort competition or have a detrimental impact on companies' innovation capacity.

1.6 The EESC is in favour of dealing with other important matters in the context of this legislative modification, such as access to information, the definition of products of the biocidal products family and the obligation to share data.

2. **Introduction**

2.1 A biocidal product is any active substance or mixture 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

([1]) It is due to enter into force on 1 September 2013.

([2]) Article 94 of Regulation (EU) No 528/2012.

([3]) Article 89 of Regulation (EU) No 528/2012.

exert a controlling effect on any harmful organism by chemical or biological means; all substances, mixtures and products placed on the market with the intention to generate active substances shall also be considered biocidal products ([4]). Biocidal products are present in our daily lives, preventing the spread of diseases and promoting a high degree of hygiene in areas with high population densities.

2.2 Directive 98/8/EC of the European Parliament and of the Council laid down rules concerning the placing of biocidal products on the market within the Community ([5]). This Directive harmonises at European level the legislation on these products, establishing common principles for the evaluation and authorisation of biocidal products, thus preventing economic or administrative barriers.

2.3 On 16 May 2013, the European Commission presented a new proposal amending Regulation (EU) No 528/2012, concerning the making available on the market and use of biocidal products with regard to certain conditions for access to the market ([6]). This "Biocidal Products Regulation" was approved on 22 May 2012 ([7]) and is due to enter into force on 1 September 2013. The new legislation will replace Directive 98/8/EC and is the result of an intense public consultation and a detailed impact assessment drawn up by the European Commission ([8]).

2.4 The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. The Regulation, which maintains the structure of Directive 98/8, is underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not have harmful effects on health or the environment.

2.5 This legislation is intended to fill the gaps found in the previous legislative framework and to streamline the functioning of the authorisation system through simplification, the removal of obstacles to trade in biocidal products and the harmonisation of certain provisions.

2.6 The Commission has decided to present a formal modification, before its entry into force, of the Biocidal Products Regulation, No 528/2012, having detected that some of its provisions could lead to distortions in its operation. The fundamental purposes of this modification are:

— to prevent the transitional rules of the Biocidal Products Regulation from introducing an unintended market freeze of up to eleven years for articles treated with biocidal substances which are legal on the EU market, but which have not yet been evaluated at EU level;

— to remove unintended market barriers resulting from the Regulation's application which could harm certain operators.

3. **General observations**

3.1 In 2010, the EESC adopted its opinion on Regulation (EU) No 267/2009 concerning the making available on the market and use of biocidal products ([9]). The Committee expressed its support for replacing the Directive with a Biocidal Products Regulation with a view to achieving simplification and harmonisation of the legislation.

3.2 Despite the impact assessment, the public consultation and the various reports drawn up in the context of the approval of the Biocidal Products Regulation, the criticisms of mainly small and medium-sized suppliers regarding the possibility of significant restrictions and dysfunctions on the market as a result of the implementation of the Regulation have required the European Commission to react urgently by presenting a series of modifications to remove the possible harmful effects of the European biocidal products legislation, in particular its transitional provisions.

3.3 The EESC is pleased that the Commission has amended certain articles with a view to the more rational application of the legislation. However, the EESC believes that, once the procedure to revise the Regulation had been launched, certain gaps in the original legislation should have been dealt with more fully and systematically, regarding access to information, the obligation to share data and the definition of products of the biocidal products family.

3.4 The modifications to the transitional rules, in particular Articles 86, 89 and 94 of Regulation (EU) No 528/2012, will prevent the market-freezing of certain existing active substances and a de facto prohibition of new treated articles, between 1 September 2013 and the approval of the last active substance contained in the articles. The EESC believes that these changes to the transitional rules prevent significant collateral damage which the original wording of the said articles would have produced.

([4]) Directive 98/8/EC
([5]) OJ L 123, 24.4.1998.
([6]) COM(2013) 288 final.
([7]) OJ L 167, 27.6.2012.
([8]) SEC(2009) 773.
([9]) OJ C 347, 18.12.2010, p. 62.

4. **Specific comments**

4.1 Article 89(4) and Article 93(2) of Regulation (EU) No 528/2012 provide for phase-out periods for biocidal products for which no authorisation is granted. The new text proposes that the same periods should apply for phasing out biocidal products already on the market, where an authorisation is granted but the conditions of the authorisation require the product to be changed. The EESC considers that, in such cases, there should be a derogation from the periods laid down by the general rule in the event that a request is rejected. The EESC suggests that, when a product is approved with changes, the phase-out period should be extended so that it can be used and made available on the market until it has run out.

4.2 The European Chemicals Agency (ECHA) must ensure that the list it publishes (Article 95) only contains information on the corresponding suppliers supporting the renewal of a certain active substance.

4.3 With regard to access to information in accordance with Article 66(3), the EESC believes that a correct balance should be struck between public interest and legitimate private interests. The automatic and systematic disclosure of information regarding the name and address of the manufacturer of an active substance to any third party requesting it could undermine the protection of the commercial interest of the holder of the authorisation.

4.4 In its opinion on the Biocidal Products Regulation, the EESC welcomed the mandatory sharing of data on animal tests. In fact, one of the most positive aspects of the new regulation is that it prevents the unnecessary suffering of vertebrates through the continuous repetition of toxicological studies. In any event, the Commission should assess whether the obligation to share data, in addition to toxicological and ecotoxicological data, is balanced and favours the development of new active substances, particularly studies on environmental fate and behaviour relating to substances in Annex II of Regulation (EC) No 1451/2007. Effective compensation and protection of data until 2025 are crucial in order to prevent improper use of work.

4.5 The EESC is in favour of extending from 2 to 3 years the time limit for Member States to decide on the authorisation of a biocidal product following a decision to approve a particular active substance for a specific product-type (Article 89, Regulation (EU) No 528/2012). If the change had not been made, due to the different stages of the authorisation process, there would have been a risk of systematic non-compliance with time limits, thus paralysing the process.

Brussels, 18 September 2013.

The President
of the European Economic and Social Committee
Henri MALOSSE