Basic information

2013/0150(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Making available on the market and use of biocidal products: conditions for access to the market Amending Regulation (EU) No 528/2012 2009/0076(COD) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 4.60.02 Consumer information, advertising, labelling	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	GROOTE Matthias (S&D)	30/05/2013
	Shadow rapporteur KLASS Christa (PPE) LEPAGE Corinne (ALDE) RIVASI Michèle (Verts/ALE) GIRLING Julie (ECR) WILS Sabine (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	3301	2014-03-10

European

Commission DG	Commissioner

Commission	Environment	POTOČNIK Janez
European Economic and Social Committee		

Key events

Date	Event	Reference	Summary
16/05/2013	Legislative proposal published	COM(2013)0288	Summary
23/05/2013	Committee referral announced in Parliament, 1st reading		
17/10/2013	Vote in committee, 1st reading		
25/10/2013	Committee report tabled for plenary, 1st reading	A7-0354/2013	Summary
25/02/2014	Decision by Parliament, 1st reading	T7-0125/2014	Summary
25/02/2014	Results of vote in Parliament		
10/03/2014	Act adopted by Council after Parliament's 1st reading		
11/03/2014	Final act signed		
11/03/2014	End of procedure in Parliament		
05/04/2014	Final act published in Official Journal		

Technical information

Procedure reference	2013/0150(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation (EU) No 528/2012 2009/0076(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/12784

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE516.835	11/09/2013	
Amendments tabled in committee		PE519.767	30/09/2013	
Committee report tabled for plenary, 1st reading/single reading		A7-0354/2013	25/10/2013	Summary

Text adopted by Parliament, 1st reading/single reading		T7-0125/2014	25/02/2014	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00140/2013/LEX	11/03/2014	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2013)0288	16/05/2013	Summary
Commission response to text adopted in plenary	SP(2014)446	20/05/2014	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2013)0288	04/08/2013	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES4753/2013	18/09/2013	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Regulation 2014/0334
OJ L 103 05.04.2014, p. 0022 Summary

Making available on the market and use of biocidal products: conditions for access to the market

2013/0150(COD) - 16/05/2013 - Legislative proposal

PURPOSE: to amend 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.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: an analysis of Regulation (EU) No 528/2012 on Biocidal Products has shown that certain provisions will lead to unforeseen consequences. The main problem identified is that the transitional rules of the Regulation will introduce 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. Other unintended market barriers for certain companies have also been identified. Furthermore, the Biocidal Products Regulation fails to define a protection period for data relating to those products with the most favourable risk profile.

IMPACT ASSESSMENT: the Commission did not undertake an impact assessment. The proposal has received the broad support of stakeholders and experts.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union.

CONTENT: this proposal seeks to amend the recently adopted Regulation (EU) No 528/2012 on Biocidal Products which has not yet come into force. It contains provisions that will remove market barriers for suppliers of new articles treated with biocidal products and for a large number of suppliers of biocidal active substances. It also defines the protection periods for the data relating to those biocidal products with the best profile.

BUDGETARY IMPACT: the proposal has no impact of the budget of the European Union.

Making available on the market and use of biocidal products: conditions for access to the market

2013/0150(COD) - 25/10/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Matthias GROOTE (S&D, DE) 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.

The committee recommended that the European Parliament's position adopted at first reading, following the ordinary legislative procedure, should amend the Commission proposal. The main amendments, of a technical nature, were as follows:

Processing aids: Members highlighted that Regulation (EU) No 528/2012 excludes from its application biocidal products used as processing aids. They proposed to amend the Regulation to clarify beyond doubt that 'processing aids' means those defined in Regulation (EC) No 1831/2003 of the European Parliament and Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Consistency with the legislation on classification, labelling and packaging of substances and mixtures: in order to ensure consistency between Regulation (EU) No 528/2012 and Regulation (EC) No 1272/2008, Article 19(4)(b) of Regulation (EU) No 528/2012 should also be amended to include specific target organ toxicity by single or repeated exposure category 1 as a classification criterion in order to preclude authorisation for the making available on the market of a biocidal product containing such substances for use by the general public.

Biocidal products with less severe classification: Regulation 528/2012/EU should allow biocidal products with less severe classification to be part of a family based on higher risk formulations if they have similar composition, exposure levels, and proven efficacy.

Facilitate the enforcement of the Regulation: REACH has established the so-called "Forum" to coordinate enforcement activities amongst Member States with the support of the Agency and the Commission. The Forum should also be used to facilitate enforcement of the Biocidal Products Regulation by providing support and assistance to Member States with regard to control and enforcement activities.

Making available on the market and use of biocidal products: conditions for access to the market

2013/0150(COD) - 25/02/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 658 votes to 14 with 9 abstentions, a legislative resolution 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.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement between Parliament and Council. The main amendments were as follows:

Processing aids: Members clarified that the Regulation should not apply to biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008.

Biocidal product family: this means a group of biocidal products having: (i) similar uses, (ii) the same active substances, (iii) similar composition with specified variations, and (iv) similar levels of risk and efficacy.

The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall **consider the maximum risks to human health, animal health and the environment** and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

Conditions for granting an authorisation: a biocidal product shall be authorised provided the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met.

The product must also meet the **criteria** according to Regulation (EC) No 1272/2008 for classification as:

- **acute toxicity by**: (i) acute oral toxicity category 1, 2 or 3; (ii) acute dermal toxicity category 1, 2 or 3; (iii) acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3; (iv) acute inhalation toxicity (vapours) category 1 or 2;
- **specific target organ toxicity by single or repeated exposure category 1;**
- **a category 1A or 1B carcinogen or mutagen;**
- **toxic for reproduction category 1A or 1B.**

Period of grace: where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed **180 days** for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.

Assessment of technical equivalence: where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence shall submit an application to the Agency. The latter shall inform the applicant of the fees payable and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Placing on the market: the amended text states that he person responsible for the placing on the market of a treated article shall ensure that the **label** provides the information listed in the Regulation.

Confidentiality: any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that certain information **not be made available**, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.

Transitory provisions on treated articles: Members introduced amendments to avoid potentially serious adverse effects on economic operators whilst fully respecting the principle of legal certainty. They apply from 1 September 2013.

With regard to access to the dossier, the text provided that the **Agency shall regularly update** the list of active substances for which a dossier has been accepted or validated by a Member State. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data.

Facilitate enforcement of the Regulation: in order to facilitate good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement, the Agency should also be given the task of providing support and assistance to Member States with regard to control and enforcement activities by making use of existing structures, where appropriate.

Making available on the market and use of biocidal products: conditions for access to the market

2013/0150(COD) - 11/03/2014 - Final act

PURPOSE: to improve the functioning of the internal market by ensuring a high level of protection for the environment and for human health.

LEGISLATIVE ACT: Regulation (EU) No 334/2014 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

CONTENT: the amending Regulation aims to solve problems relating to certain provisions of Regulation (EU) No 528/2012 concerning biocidal products which has been in force since September 2013. In particular, it deletes unforeseen obstacles in terms of market access for new products treated with biocidal products as well as for new active biocidal substances.

The amendments aim, in particular, to:

- clarify that the Regulation should not apply to biocidal products when the latter are used as **'processing aids'** within the meaning of Regulations (EC) No 1831/2003 (4) and (EC) No 1333/2008;

- ensure that similar biocidal products are considered as part of a **biocidal product family** if they can be satisfactorily assessed based on identifiable maximum risks and minimum level of efficacy;

- provide that a biocidal product will only be authorised if the active substances are **listed in Annex I** of the Regulation or approved for the types of products concerned and if any conditions specified for those active substances are met;

- include specific target organ toxicity by single or repeated exposure category 1 **as a classification criterion**, in order to preclude authorisation for the making available on the market for use by the general public of a biocidal product meeting the criteria for this classification according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;

- provide a **period of grace not exceeding 180 days** for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it;

- extend the scope of **transitional measures concerning treated articles** (the current provisions apply only to treated articles already placed on the market) and provide for a phasing-out period for treated articles for which no application for the approval of the active substance for the relevant product-type is submitted by 1 September 2016;

- ensure the Agency **regularly updates a list of all active substances** for which a complete substance dossier has been submitted and accepted or validated by a Member State. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data

- **facilitate good cooperation**, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement.

ENTRY INTO FORCE: 25/04/2014. Amendments made to article 94 (Transitional measures concerning treated articles) and 95 (Transitional measures concerning access to the active substance dossier) of the Regulation will apply from 01/09/2013.