Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2009/0076(COD)
Making available on the market and use of biocidal products Repealing Directive 98/8/EC 1993/0465(COD) Amended by 2013/0150(COD) Amended by 2017/0353(COD) Subject 2.10 Free movement of goods 3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 4.60.08 Safety of products and services, product liability	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PPE KLASS Christa	15/09/2009
Former committee responsible		
ENVI Environment, Public Health and Food Safety	PPE KLASS Christa	15/09/2009
Former committee for opinion		
IMCO Internal Market and Consumer Protection (Associated committee)	PPE SARTORI Amalia	28/09/2009
ITRE Industry, Research and Energy		
IMCO Internal Market and Consumer Protection		
ITRE Industry, Research and Energy	ECR KARIM Sajjad	17/09/2009
Former committee for opinion on the legal basis		
JURI Legal Affairs	PPE LECHNER Kurt	21/04/2010

Council of the European Union

Council configuration	Meeting	Date
Education, Youth, Culture and Sport	3164	10/05/2012
Environment	3103	21/06/2011
Environment	3061	20/12/2010
Environment	3021	11/06/2010
Environment	2988	22/12/2009

European Commission

Commission DG	Commissioner
Environment	POTOČNIK Janez

Key events

14/07/2009	Committee referral announced in Parliament, 1st reading		
17/12/2009	Referral to associated committees announced in Parliament		
22/12/2009	Debate in Council	2988	
11/06/2010	Debate in Council	3021	Summary
22/06/2010	Vote in committee, 1st reading		Summary
01/09/2010	Committee report tabled for plenary, 1st reading	A7-0239/2010	
21/09/2010	Debate in Parliament		
22/09/2010	Decision by Parliament, 1st reading	T7-0333/2010	Summary
29/09/2011	Committee referral announced in Parliament, 2nd reading		
04/10/2011	Vote in committee, 2nd reading		
18/01/2012	Debate in Parliament		
19/01/2012	Results of vote in Parliament		
19/01/2012	Decision by Parliament, 2nd reading	T7-0010/2012	Summary
10/05/2012	Act approved by Council, 2nd reading		
22/05/2012	Final act signed		
22/05/2012	End of procedure in Parliament		
27/06/2012	Final act published in Official Journal		

Technical information

Procedure reference	2009/0076(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 98/8/EC 1993/0465(COD) Amended by 2013/0150(COD) Amended by 2017/0353(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/04920

Documentation gateway

Legislative proposal		COM(2009)0267	12/06/2009	EC	Summary
Document attached to the procedure		SEC(2009)0773	12/06/2009	EC	

Document attached to the procedure		SEC(2009)0774	12/06/2009	EC	
Committee draft report		PE438.377	18/02/2010	EP	
Amendments tabled in committee		PE439.891	19/03/2010	EP	
Amendments tabled in committee		PE439.902	08/04/2010	EP	
Amendments tabled in committee		PE439.904	08/04/2010	EP	
Amendments tabled in committee		PE439.930	08/04/2010	EP	
Committee opinion	ITRE	PE430.878	22/04/2010	EP	
Committee opinion	IMCO	PE439.175	18/05/2010	EP	
Specific opinion	JURI	PE441.319	18/05/2010	EP	
Amendments tabled in committee		PE443.056	17/06/2010	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0239/2010	01/09/2010	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0333/2010	22/09/2010	EP	Summary
Council statement on its position		10974/2011	14/06/2011	CSL	
Council position		05032/2/2011	21/06/2011	CSL	Summary
Committee draft report		PE467.347	19/07/2011	EP	
Commission communication on Council's position		COM(2011)0498	11/08/2011	EC	Summary
Amendments tabled in committee		PE472.199	13/09/2011	EP	
Amendments tabled in committee		PE472.203	23/09/2011	EP	
Amendments tabled in committee		PE473.715	29/09/2011	EP	
Committee recommendation tabled for plenary, 2nd reading		A7-0336/2011	10/10/2011	EP	Summary
Text adopted by Parliament, 2nd reading		T7-0010/2012	19/01/2012	EP	Summary
Commission response to text adopted in plenary		SP(2012)171	06/03/2012	EC	
Commission opinion on Parliament's position at 2nd reading		COM(2012)0135	20/03/2012	EC	Summary
Draft final act		00003/2012/LEX	23/05/2012	CSL	
Follow-up document		COM(2016)0151	17/03/2016	EC	Summary
Follow-up document		COM(2016)0650	11/10/2016	EC	Summary
Follow-up document		COM(2018)0342	28/05/2018	EC	Summary
Follow-up document		COM(2021)0287	07/06/2021	EC	
Follow-up document		SWD(2021)0128	07/06/2021	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2012/528
OJ L 167 27.06.2012, p. 0001 Summary

Corrigendum to final act 32012R0528R(08)
OJ L 280 28.10.2017, p. 0057

Final legislative act with provisions for delegated acts

Delegated acts

2013/2688(DEA)	Examination of delegated act
2013/2689(DEA)	Examination of delegated act
2014/2642(DEA)	Examination of delegated act
2014/2797(DEA)	Examination of delegated act
2019/2787(DEA)	Examination of delegated act
2019/2791(DEA)	Examination of delegated act
2019/2788(DEA)	Examination of delegated act
2017/2822(DEA)	Examination of delegated act
2018/2916(DEA)	Examination of delegated act
2017/2555(DEA)	Examination of delegated act
2018/2961(DEA)	Examination of delegated act
2019/2790(DEA)	Examination of delegated act
2019/2789(DEA)	Examination of delegated act
2019/2786(DEA)	Examination of delegated act
2019/2785(DEA)	Examination of delegated act
2020/2849(DEA)	Examination of delegated act
2021/2597(DEA)	Examination of delegated act
2021/2598(DEA)	Examination of delegated act
2020/2857(DEA)	Examination of delegated act
2022/2603(DEA)	Examination of delegated act

Making available on the market and use of biocidal products

PURPOSE: to improve the safety of biocidal products used and placed on the market in the European Union and to simplify authorisation procedures.

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

BACKGROUND: Directive 98/8/EC establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products, the mutual recognition of these authorisations within the Community and the establishment at Community level of a positive list of active substances that may be used in biocidal products.

The review of the implementation of the Directive has indicated that for the evaluation of active substances, the simplified procedures provided for in the Directive, notably for low-risk products (Annex IA to the Directive), have no real effect. It has also indicated that the data requirements and data waiving

provisions may be unclear or inconsistently applied. In addition, although product authorisation has not yet started, simplification of the procedures concerning the authorisation of biocidal products in Member States may be beneficial in reducing costs and administrative burden for companies and public authorities alike.

IMPACT ASSESSMENT: the impact assessment covers **five main issues** requiring action:

1. **Scope**: including treated materials in the scope of the Directive would significantly increase the costs to industry. However, although the equal treatment of industry and environmental and human health benefits are difficult to quantify, they are likely to be significant;
2. **Product authorisation**: a combination of the Community authorisation for certain products with the strengthening of the mutual recognition process for other products appears to be the most realistic solution;
3. **Data sharing**: mandatory data sharing at product authorisation and active substance approval stage implies the highest total cost savings to applicants, possibly the highest number of safer products remaining on the market and the highest number of animals saved;
4. **Data requirements**: the best option seems to be a combination of data waiving with the use of existing information and a new approach to low risk biocidal products;
5. **Fees charged by Member States**: a partially harmonised fee structure may encourage the development of more new active substances and the retention of more existing active substances. Another option - specific provisions for SMEs - would make the procedure less costly for SMEs.

CONTENT: on 8 October 2008, the Commission submitted a report on the implementation of Directive 98/8/EC and the functioning of the simplified procedures (see COD/1993/0465 under follow-up documents). Based on the conclusions of the report, the present proposal for a revision of Directive 98/8/EC aims to tackle the identified weaknesses of the regulatory 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. The main elements of the revision are as follows:

Legal form: the Directive is turned into a Regulation. As a result, there will be no need for national transposition measures, which is also expected to ensure more harmonised implementation of the regulatory framework in the Member States.

Scope: the scope is extended to biocides in materials that might come into contact with food. With regard to materials containing biocidal products, under the current situation, if an article is treated in the EU, then only a biocidal product that is authorised for that purpose may be used. However, if the article is treated with a biocidal product outside the EU and then imported, there is no control over the substance it may incorporate. This could represent risks for human health or for the environment. In addition, this situation is discriminatory to the EU industry, and could lead to the production of treated articles or materials being moved out of the EU in order to circumvent restrictions on certain substances. As part of the revision of the Biocides Directive, it is proposed that **all articles or materials** must be treated only with biocidal products authorised for that purpose in at least one Member State .

Labelling requirements: these have two objectives: (i) to inform consumers that the article was treated with a biocidal product; and (ii) to alert competent authorities in the Member States and trigger any existing inspection provisions aimed at ensuring compliance. The labelling provisions apply equally to EU and non EU manufacturers.

Authorisation: the proposal provides for harmonised procedures for the authorisation of biocidal products. The provisions regarding mutual recognition of authorisations are reworked and clarified, in particular the resolution of disputes between Member States, or between Member States and applicants. Apart from authorisations granted by Member States, a **centralised authorisation system** is proposed. This will be available for products identified as low-risk - without having to go through a separate evaluation of the active substance first- and for products containing new active substances.

The technical and scientific tasks relevant to this centralised system will be carried out by the **European Chemicals Agency (ECHA)**. In addition, ECHA will undertake the coordination of organisational and technical tasks for the evaluation of all applications for inclusion of active substances in Annex I (the Community positive list for active substances) which were until now attributed to the Commission Joint Research Centre.

The **simplified procedures** involving the current Annex IA and IB are repealed, as very little use has been made of them so far. The simplified procedure involving frame formulations is modified so as to allow, within a group of products belonging to the same frame formulation, the replacement of any non-active ingredient by other non-active ingredients (currently, this is restricted to pigments, dyes, and perfumes).

The **rules on comparative assessment** are also modified: the proposed system comprises a first stage where active substances that still give rise to concern and are listed in Annex I, but are also flagged for substitution. Biocidal products containing these active substances may be compared with others that are available on the market for the same or similar use pattern, and if they present significantly higher risk than the latter, their authorisations are refused or cancelled at national level.

Research on animals: the new proposal will also reduce the number of tests on animals. In line with recent policy developments, animal testing may only be carried out once. Following the example of REACH (Community legislation on chemicals), the proposed Regulation shall force undertakings, that make a request for an authorisation, to share the results of their studies on animals, in exchange for equitable compensation. Moreover, tests proving the safety and effectiveness of a biocidal product shall only be required when there is a real need.

Data protection: the data protection system is significantly simplified, without cutting back on any acquired rights under the current system. It also grants protection to data submitted after the inclusion of the active substance in Annex I (mainly during product authorisation): these studies are not protected by the current legislation. The proposed data protection system also covers the case of newly generated studies.

Data requirements: these are modified: (i) the principle of proposing adaptations to the data requirements is formalised and Member States have to inform and assist the applicants with their adaptation requests; (ii) the grounds for waiving of data provided for in REACH will apply also for the proposed Regulation; (iii) the core data requirements are modified and certain long-term animal studies are only required when necessary. Lastly, the **confidentiality** provisions are slightly modified and aligned with those of REACH. This is to facilitate their application by ECHA.

Specific parallel trade rules: for the purpose of facilitating the movement of biocidal products in the EU territory, the proposal provides for specific parallel trade rules: authorised biocidal products that have the same use, contain the same active substance and have essentially identical composition to products authorised in another Member State may be placed on the market of that other Member State via a simplified administrative procedure.

BUDGETARY IMPLICATION: the proposal will have budgetary implications as there is a need to support the European Chemicals Agency (the Agency) in taking up the additional tasks related to the assessment and inclusion of active substances used in biocidal products in Annex I of the Regulation and the centralised authorisation of certain biocidal products. The Agency will receive specific fees from applicants for certain of these activities as well as an annual fee on products centrally authorised by the Community. The revenue from the fees will have to be supplemented by a subsidy from the Community.

Making available on the market and use of biocidal products

The Committee on Environment, Public Health and Food Safety adopted the report drawn up by Christa KLASS 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. It recommended that the European Parliament?s position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Precautionary principle and special vulnerability of children: the purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, animals and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Nanomaterials: there is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety, the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.

Exclusion from the scope: the Regulation will not apply to biocidal products within the scope of Regulation (EC) No 1935/2004 (Food Contact Regulation), Council Directive 98/83/EC on the quality of water intended for human consumption and Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

Inclusion of an active substance in Annex I: Members specify that substances that fall under the exclusion criteria should only be included in Annex I for a maximum period of 5 years. This is in line with the PPP regulation.

Furthermore, active substances as such or in biocidal products may be placed on the market in the Union for use in biocidal products only if they have been included in Annex I in accordance with the provisions of this Regulation. Unless otherwise provided in this Regulation, all manufacturers of an active substance, as such or in a biocidal product, shall submit to the Agency an application for inclusion in Annex I. The committee states that only if manufacturers are obliged to comply with the same data requirements in Annex II will fair treatment be possible.

With regard to exclusion criteria: not later than 13 December 2013, the Commission shall adopt, by means of delegated acts, measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties. In addition, substances such as those that have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered as having such endocrine-disrupting properties.

With regard to data requirements for an application, the report specifies that a letter of access to a dossier may be part of the application. Members state that the applicants might not own the data required to support an application. They also make several amendments to provisions on the submission and validation of applications, with particular reference to the time limits, and state that the Agency should observe the same timeframes for the validation of applications as those introduced under Article 20 of REACH.

With respect to active substances which are candidates for substitution, Members consider that the criteria for identifying candidates of substitution should be aligned with the criteria for substances to be authorised under Regulation (EC) No 1907/2006 (REACH) (Article 57). Since the Agency will carry out the task of examining if an active substance fulfils any of the criteria, the committee states that consistency between the two regulations is advisable. It also considers that non-active isomers do not pose a danger to health or the environment. There is therefore no need to include them among substances that are candidates for substitution.

Renewal and review of an active substance inclusion: unless more strictly specified in the decision to renew the inclusion of an active substance in Annex I, the renewal may be renewed for a period not exceeding 10 years (rather than an indefinite period, as stated in the proposal.) The committee considers that indefinite authorisations of new active substances will limit the incentive to conduct new research and provide new scientific data. In line with the current directive on biocides as well as the pesticides/plant protection legislation, there is a need for review of the active substances on a regular basis.

The committee also made amendments to the clauses on the submission and validation of applications, and aligned comitolgy provisions with the TFEU.

General principles of authorisation: application for authorisation shall be submitted to the Agency. When an applicant submits an application for national authorisation, that applicant shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify the evaluating competent authority in the application itself. The committee considers that the ECHA should conduct the initial validation of all applications.

Conditions for authorisation include a consideration of cumulative or synergistic effects. Where nanomaterials are used, the risk to the environment and to health has been assessed separately.

The report states that infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel these organisms. In addition, other precautionary steps have to be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if these measures show no effect shall further steps be taken. Biocidal products that pose low risks for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall only be applied as a last resort.

Mandatory measures shall be established with a framework directive for Union action in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.

With respect to the criteria for low-risk biocidal products, the committee states that the Commission's proposal does not contain any kind of evaluation at EU-level of low risk active substances. It is completely unclear what active substances a low-risk product can contain. In order to categorise anything as a low-risk product, it is crucial to know what it contains. Therefore, the active substances of a low risk product should as a very minimum be evaluated at an EU-level and be included on Annex I in order for the product to be recognised as a low-risk product.

Members go on to specify that low-risk products that are based on active substances included in Annex I or that are being evaluated with a view to inclusion in Annex I should require access to the data for the active substance. Property and data protection for active substances that have been included in Annex I should not be undermined.

The Commission should, provide technical and scientific guidance and tools, above all for SMEs.

Comparative assessment must be carried out in relation to all biocidal products having the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years. The aim is to provide a clearer definition of how the comparative assessment should be carried out. One element to be taken into consideration is the need for sufficient experience in the use of the product. This should be the rule and not the exception.

Members state that the Commission shall adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. These measures shall define the criteria and algorithms to be used in a comparative assessment to ensure that there is a uniform application throughout the Union.

National authorisations: the person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national or Union authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (the 'evaluating competent authority'). The Agency shall, within three weeks after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database. Members state that the ECHA should carry out the initial validation of all applications throughout the Union, so that the evaluating competent authorities can concentrate on actual assessment of the applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach. The Agency should observe the same timeframes for the validation of applications as those introduced under REACH.

Mutual recognition procedures: applications for a national authorisation which involve a mutual recognition procedure may be submitted to the competent authority in English. A single authorisation number shall be used in all the Member States involved.

The report sets out procedures and the time period for the resolution of disputes between Member States.

Community authorisations: the Union authorisation may be granted to any category of biocidal products. The report states that a centralised authorisation system has clear benefits for the functioning of the internal market by ensuring consistent assessments and a harmonised implementation of the requirements in all Member States, driving best practices and same standards of consumer protection across Europe. The Community authorisation procedure should therefore extend to all product categories instead of only a small minority of products (low risk biocidal products and products with new active substances).

A new clause is inserted on biocidal products with similar conditions of use.

The report makes several amendments to provisions on the cancellation, review and amendments of authorisations. It notes that in addition to revision of the inclusion of an active substance in Annex I, an indication (from practical measurements) that the aims of the Water Framework Directive are jeopardised must also be grounds for cancelling or amending the authorisation of a biocidal product.

Derogations and research: under the Commission proposal, a test on an unauthorised biocidal product for research and development purposes which involved the release of the product into the environment would require prior national authorisation. The time required in order to obtain it could hamper innovation. It is proposed instead that a 30-day period be set to allow the authority to assess whether the proposed test gives rise to any concern and to deliver its opinion. The report also makes some amendments to the provisions on data protection and data sharing.

Report: the Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Union authorisation procedure and mutual recognition, by 1 January 2016 (instead of 1 January 2023).

Information: the label must show whether the product contains nanomaterials and any specific related risks and, following each reference to nanomaterials, the word "nano" in brackets. Safety data sheets must contain specified information. The report states that Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products. The Commission shall make available on the internet a list of all active substances available within the internal market.

National helpdesks in Member States: Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. These shall be in addition to any assistance provided by the Agency.

Comitology: Members made certain amendments in order to align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU, and provided for transitional measures until the new rules on implementing acts are adopted.

Making available on the market and use of biocidal products

The European Parliament adopted by 550 votes in favour to 22 against with 80 abstentions, a resolution under the ordinary legislative procedure (formerly the co decision procedure).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. The main points are as follows:

Precautionary principle and special vulnerability of children: the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Nanomaterials: there is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order better to assess their safety, the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

AFS Convention: in view of the environmental impact that anti-fouling products can have in the water, the Commission must take steps at international level to ensure that the AFS Convention (International Convention on the Control of Harmful Anti-Fouling Systems on Ships) is ratified worldwide and adapted to the Regulation.

Exclusion from the scope: active substances which shall not be included in Annex I include active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen/ mutagen/oxic for reproduction category 1A or 1B. They also include: active substances which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are identified under Regulation (EC) No 1907/2006 as having endocrine disrupting properties; persistent, bio-accumulative and toxic; and persistent organic pollutants (POP).

However, these may be included in Annex I under certain specified circumstances ? for example, if it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.

Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this provision shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

Lastly, not later than 13 December 2013, the Commission shall adopt, by means of delegated acts measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties. Substances such as those that are classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered as having such endocrine-disrupting properties.

With regard to data requirements for an application, the resolution specifies that a letter of access to a dossier may be part of the application. They also make several amendments to provisions on the submission and validation of applications, with particular reference to the time limits, and state that the Agency should observe the same timeframes for the validation of applications as those introduced under Article 20 of REACH.

With respect to active substances which are candidates for substitution, Members considers that non-active isomers do not pose a danger to health or the environment. There is therefore no need to include them among substances that are candidates for substitution.

Renewal and review of an active substance inclusion: unless more strictly specified in the decision to renew the inclusion of an active substance in Annex I, the renewal may be renewed for a period not exceeding 10 years (rather than an indefinite period, as stated in the proposal.)

Parliament also made amendments to the clauses on the submission and validation of applications, and aligned comitolgy provisions with the TFEU.

General principles of authorisation: application for authorisation shall be submitted to the Agency. When an applicant submits an application for national authorisation, that applicant shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify the evaluating competent authority in the application itself. Parliament considers that the ECHA should conduct the initial validation of all applications.

Conditions for authorisation include a consideration of cumulative or synergistic effects. Where nanomaterials are used, the risk to the environment and to health has been assessed separately. The resolution states that infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel these organisms. In addition, other precautionary steps have to be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if these measures show no effect shall further steps be taken. Biocidal products that pose low risks for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall only be applied as a last resort.

Within two years of the date of adoption of the Regulation, mandatory measures shall be established and implemented with a framework directive for Union action in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.

With respect to the criteria for low-risk biocidal products, Parliament expanded the criteria for those substances which should not be considered as low risk, including substances that are corrosive, explosive, contain a nanomaterial, and very toxic or toxic. It deleted the derogation in cases of negligible exposure.

Comparative assessment must be carried out in relation to all biocidal products having the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years. Members state that the Commission shall adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. These measures shall

define the criteria and algorithms to be used in a comparative assessment to ensure that there is a uniform application throughout the Union.

National authorisations: the person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national or Union authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (the 'evaluating competent authority'). The Agency shall, within three weeks after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

Mutual recognition procedures: applications for a national authorisation which involve a mutual recognition procedure may be submitted to the competent authority in English. A single authorisation number shall be used in all the Member States involved.

Community authorisations: from 2013 the Community authorisation may be granted to the following categories of biocidal products: (a) biocidal products containing one or more new active substances; (b) low-risk biocidal products. From 2017 the Community authorisation may be granted to all categories of biocidal products with the exception of biocidal products that contain active substances that fall under the provisions on the exclusion criteria. A Member State shall notify the Commission where it restricts or prohibit the Union authorisation for certain biocidal products in the territory of that Member State. Such restriction or prohibition must be justified on specified grounds.

Parliament makes several amendments to provisions on the cancellation, review and amendments of authorisations.

Labelling: the label must show whether the product contains nanomaterials and any specific related risks and, following each reference to nanomaterials, the word "nano" in brackets. Safety data sheets must contain specified information. The resolution states that Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products. The Commission shall make available on the internet a list of all active substances available within the internal market.

Treated articles or material: these must contain the words "treated with biocidal products", followed by the name, using wherever possible common nomenclature (e.g. INCI), of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials, where relevant, and for all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material, unless at least equivalent labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation ; the names of all nanomaterials followed by the word "nano" in brackets. They must also contain any hazard statement or precautionary statement set out in the authorisation for the biocidal product but only if the biocidal product is intended to be released under normal or reasonably foreseeable conditions of use.

National helpdesks in Member States: Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. These shall be in addition to any assistance provided by the Agency under the terms of the Regulation.

Comitology: Members made certain amendments in order to align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU, and provided for transitional measures until the new rules on implementing acts are adopted.

Reports: the Commission must submit the following reports:

- a report on the implementation of the Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by 1 January 2019 and every three years thereafter ;
- at the latest two years after the entry into force of the Regulation, a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them;
- not later than five years after the entry into force of the Regulation, a report on the impact of the spread of biocidal products in the environment.

Animal testing: given that animal testing should be avoided, testing on vertebrate animals shall be undertaken only as a last resortwhere no alternative solution can be employed without producing an impact on humans or animals. Testing on vertebrate animals shall not be repeated for the purposes of the Regulation. Where those tests or studies have already been submitted in connection with a previous application, the competent authority or the Agency shall, without delay, assess technical equivalence in relation to the comparison source. If the technical equivalence assessment is positive, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Annexes: Parliament made certain amendments to the Annexes.

Making available on the market and use of biocidal products

The Council adopted its position on first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

The European Parliament adopted several hundred amendments to the Commission proposal. Many are acceptable to the Council and it has therefore included them in its position at first reading (wholly, in part, or in principle).

The following points should be mentioned:

- while the Council accepts the need to address nanomaterials, because of rapid developments in the field, at this stage it has only included a definition, a statement that approval of active substances does not cover nanomaterials, except where explicitly mentioned, and a reference to the need for technical guidance to be elaborated to take account of the latest scientific information;
- the Council considers that requiring a substitution plan for biocidal products containing active substances meeting the exclusion criteria would unnecessarily duplicate the requirement for a comparative assessment ;
- the Council?s position at first reading would open the Union authorisation procedure to all other biocidal products except for those of certain product-types. It also provides for the Commission to make a report on the application of the Union authorisation procedure by the end of 2017, in which report the Commission can review whether adjustments are needed to the scope in 2020;
- only those Annexes containing technical provisions (i.e., Annexes II, III and IV) should be adapted to scientific and technical progress via delegated acts;

- helpdesks should not be mandatory, but an option that Member States can choose as a way to fulfil their obligation to provide advice to applicants.

The Council's position at first reading also includes a number of changes other than those envisaged in the European Parliament's position. The changes of substance compared to the Commission's initial proposal concern principally the following points:

1) Consequences of the Lisbon Treaty: like the European Parliament, the Council had to adapt the text of the original proposal to the new regime laid down by the Lisbon Treaty regarding powers conferred by the legislator on the Commission. However, the Council considered certain matters which the Parliament was prepared to delegate to the Commission, to be of such importance that they should be decided at the legislative level, i.e. by Parliament and Council jointly. The Council also considered certain decisions for which the Parliament had considered delegated acts appropriate to be in the nature of implementing measures rather than acts which supplement or amend the basic act.

2) Procedure for the approval of active substances: approval of active substances will, as at present, require the Commission to adopt a legal act. However, rather than amending the basic act repeatedly, the Council considered free-standing implementing measures preferable to a list of approved active substances in an annex to the basic act. This change to the procedure for the approval of active substances parallels that recently agreed for plant protection products. While they were listed in Annex I to Directive 91/414/EEC, Regulation (EC) No 1107/2009 provides for their approval via implementing acts, for their compilation into a free-standing list and for electronic public access to that list.

3) ECHA's role: ECHA will have an essential coordination role to play in the approval of active substances and the Union authorisation of biocidal products. However, the Council considers that:

- all stages of the evaluation of an application should remain the responsibility of the evaluating competent authority;
- all Member States be able to appoint a member of the Biocidal Products Committee and that there be close links between this committee and Member States' competent authorities.

4) Products subject to a simplified authorisation procedure: the Council suggests the establishment of a specific list of active substances presenting low concern and a simplified authorisation procedure for biocidal products containing those active substances. To encourage widespread marketing and use of such products, they could as a general rule circulate throughout the Union after authorisation by a single Member State and a simple notification procedure in other Member States. If another Member State raises objections, the dispute settlement mechanisms of the mutual recognition procedure would be applicable.

5) Fees: the Council considers that a different approach needs to be taken for fees payable to ECHA from those payable to Member States' competent authorities. While it is appropriate for the Commission to adopt an implementing act laying down the fees payable to ECHA (rather than delegated acts, as the Commission proposed), Member States should be free to set national fees.

Making available on the market and use of biocidal products

The Commission accepted in full, in part or in principle 193 of the 309 amendments adopted by the European Parliament in its first reading. Around half of these 193 amendments are already reflected, at least in part, in the common position.

The Commission accepted amendments, either fully or in principle or in part, relating to modifications to the definition of biocidal products, the scope of derogations under exclusion criteria, the extension of the scope of the Union authorisation, the criteria for low-risk biocidal products and the provisions on treated articles.

A certain number of amendments (11 in total) were rejected by the Commission but incorporated in the Council's position in full, in part or in principle. These amendments mainly concern reduced time limits for the inclusion and renewal of inclusion of candidates for substitution as well as other active substances and shorter deadlines for certain tasks to be carried out by the European Chemicals Agency. While the Commission rejected them on grounds that they would increase the administrative and regulatory burden by adding to the workload of the Agency, Member States and economic operators without clear benefits in terms of improved levels of protection, the Council considered them acceptable.

The Commission considers that the common position does not alter the key objectives of the proposal and can thus support it. Nevertheless, the Commission considers that certain aspects of the text should be improved and would be happy to work with the other institutions in order to make such improvements. In particular, with regard to the procedures for the establishment of Maximum Residue Levels, the wording of the common position is not compatible with Regulation (EC) No 470/2009 and this inconsistency should be addressed as a priority.

The Commission made two declarations :

1) Comitology: in a spirit of compromise, the Commission will not stand against a qualified majority vote in favour of the Presidency text. However, the Commission would underline that it does not share the views of the Council that the measures for the approval of active substances and for rules on fees payable to the European Chemicals Agency are of an implementing nature and thus fall under Article 291 TFEU. As regards both these matters, the Commission is of the view Article 290 (delegated acts) is the appropriate procedure given that they entail measures of general application which would modify or supplement the non-essential elements of the Regulation.

2) Resource implications: the extension of the scope of the Union authorisation together with additional tasks allocated to the European Chemicals Agency, the shorter deadlines and the increased frequency of renewals for active substances will necessarily result in a significant increase in the workload of the Agency and the Commission. At the same time, the workload for national authorities will be reduced as a result of a wider scope of Union authorisation. In light of the increased workload, the Agency and the Commission will need additional financial and human resources to ensure effective implementation of the Regulation. In view of this, the Commission calls on the Council to address these requirements under the new financial perspectives.

To take account of the resource implications resulting from the changes introduced by the Council and the Parliament in the first reading, including the need to adjust the fee system as a way to reduce the impact on the Union budget, the Commission has prepared a revised financial statement which is attached to the Communication.

The total amount of operational appropriations is estimated at EUR 9.108 million in commitment appropriations until 2013 (EUR 2.756 million in 2012 and EUR 6.352 million in 2013).

Expenditure for 2012 is based on the subsidy to ECHA from the date of adoption onwards. Some preparatory measures are also financed in 2011 and 2012 under the LIFE Programme (budget line 07 03 07) for an estimated amount of EUR 1.5 million.

In light of the additional tasks allocated to the Agency and the time needed to prepare all aspects of its future work as well as the fact that the legislative process is taking longer than initially anticipated, the Commission considers it necessary to postpone the date of applicability of the proposed regulation to 1 September 2013 with the exception of provisions which allow the Commission and the Agency to take preparatory steps (e.g. delegated/implementing acts, guidance documents).

Making available on the market and use of biocidal products

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading in the report by Christa KLASS (EPP, DE) regarding the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

The committee reinserted several amendments adopted by the European Parliament in forst reading. It recommended that Parliaments position on second reading should modify the Councils position as follows:

Purpose of the Regulation: Members want to specify that the purpose of protecting both human and animal health and the environment is at an equal level as the purpose of the functioning of the internal market, and not just an ancillary purpose. In view of the precautionary principle, it is necessary to ensure that active substances or products placed on the market do not have harmful effects on humans, on-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Scope: Council Directive 98/83/EC on the quality of water intended for human consumption should remain the main legislation applicable biocidal products used for drinking water treatment.

Furthermore, materials and articles intended to come into contact with food, including any biocidal products linked to such materials, are already covered by Regulation (EC) No 1935/2004, and should be excluded from the scope of this regulation.

The report specifies that Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence or of animal disease control.

Dangerous substances: a substance which fulfils the criteria for being a POP under Regulation (EC) No 850/2004, or which fulfils the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006 should be considered a dangerous substance.

Nanomaterials: Members consider that the definition of nanomaterials is an essential element of the regulation and thus needs to be adopted by the legislator. No later than six months after the adoption of the Recommendation concerning the definition of nanomaterials, the Commission shall make a legislative proposal to amend this Regulation to include that definition in this Regulation.

Nanomaterials can have very different characteristics to the same substances in normal form. The risks posed by nanomaterials in biocidal products to the environment and to health must therefore be investigated separately.

Furthermore, in light of the current lack of appropriate risk assessment of nanomaterials, they should not qualify for the simplified authorisation procedure. Where a treated article contains a biocidal product, the person responsible for the placing on the market of that treated article shall ensure that the label provides certain specified information including the name of all nanomaterials, followed by the word "nano" in brackets.

Inclusion of active substances: an active substance may not be placed on the market for use in a biocidal product unless it is included in Annex I, in accordance with the Regulation. An active substance referred to in Article 5 may only be included in Annex -I for an initial period of 5 years. Substances that come under the exclusion criteria may only be included in Annex 1 for an initial period of 5 years.

Exclusion criteria: Members specify that active substances shall not be approved for inclusion in Annex I if, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, they are considered as having endocrine-disrupting properties that may cause adverse effects in humans.

No later than 13 December 2013, the Commission shall adopt delegated acts specifying scientific criteria for the determination of endocrine disrupting properties.

Members suggest that active substances may not be included in Annex I unless at least one of the following conditions is fulfilled:

- the exposure of humans or the environment to the active substance in question in a biocidal product, under normal conditions of use, is negligible, meaning that the product is used in closed systems or under other conditions excluding contact with humans;
- it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.

The use of any biocidal product containing active substances included in Annex I shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.

Member State authorising a biocidal product containing an active substance included in Annex I shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

Approval of an active substance: in order to preserve Parliaments rights of control, active substances should continue to be included in an Annex to the Regulation and decided by means of delegated acts. The act should include the conditions and relevant dates of inclusion and expiry of inclusion. There should also be a decision in its own right if a substance is not included in Annex I, in order to have a record of all decisions.

Active substances for substitution: active substances must be candidates or substitution if (i) it meets the criteria to be classified, in

accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser; (ii) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects.

Renewal and review of approval: unless more strictly specified in the decision to renew the approval of an active substance, the renewal shall be for ten years (and not 15 as the Council had prescribed) for all product-types to which the approval applies.

The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications, not only serious indications, that any of the conditions laid down) are no longer met. The Commission may also inclusion where there are significant indications that the objectives of Directive 2000/60/EC on water may not be achieved.

General conditions of authorisation: Members consider that the notification of products should be made at least 30 days in advance to allow a real market monitoring. They made certain amendments to make it easier for biocidal products with the same formulation and intended use to be marketed under different brand names and by different manufacturers. As such authorisations relate to biocidal products whose formulations are identical, there is no need to assess their impact on human health and the environment again.

Measures geared to the sustainable use of biocidal products: the committee states that Member States shall establish and implement mandatory measures on the basis of a Union framework directive in order to achieve the sustainable professional use of biocidal products, including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.

The Commission shall submit a legislative proposal for the framework directive within two years of adoption of the regulation.

Mutual recognition: for the purposes of simplification, Members state that in the case of a biocidal product family, one single authorisation number shall be provided for all biocidal products which belong to that product family.

Union authorisations: the amended text stipulates that applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 (exclusion criteria):

- from 2013 the Union authorisation may be granted to biocidal products containing one or more new active substances;
- from 2017 the Union authorisation may be granted to all categories of biocidal products.

Treated articles or materials: the labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the national language or languages of the Member State on whose market the treated article is to be placed. In the case of treated goods which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

Animal testing: any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, ("the prospective applicant"), shall submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency, or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC for an identical or technically equivalent product.

The request shall be accompanied by fees in accordance with the text.

Furthermore, Members want to align the text relating to data sharing with the provisions in REACH.

Reports: every three years, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The implementation reports shall be published on the relevant website of the Commission. The report shall include information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases, and information on the impact on the environment.

- Not later than five years after the entry into force of this Regulation, the Commission shall draw up a report on the impact of the spread of biocidal products in the environment.
- At the latest two years after the entry into force of the Regulation, the Commission shall submit a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.

Public access: the Commission shall make available on the internet a list of all active substances available within the internal market. The persons responsible for the placing on the market of biocidal products shall make available on the internet a list of such products. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Comitology: the amended text contains several amendments with a view to aligning the comitology procedure to the new system on delegated acts in accordance with Article 290 TFEU. The Regulation must contain detailed provisions on the delegation of power.

Making available on the market and use of biocidal products

The European Parliament adopted a legislative resolution on the Council position with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Parliament adopted its position in second reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between Parliament and Council. They amend the Councils position as follows:

Purpose and scope: as required by Parliament, the amended text clarifies that special attention shall be paid to the protection of vulnerable groups.

The Regulation shall not apply to biocidal products or treated articles that are within the scope of the instruments specified in the text, amongst which is Directive 2009/48/EC on the safety of toys.

It will not apply to: (i) food or feed used as repellents or attractants; (ii) biocidal products when used as processing aids.

Nothing in the Regulation shall prevent Member States from restricting or banning the use of biocidal products in the public supply of drinking water.

Biocidal product: the definition in the amended text covers any substance or mixture generated from substances or mixtures which are not themselves biocidal products in the meaning of the Regulation to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Substance of concern: this means a substance which fulfils the criteria for being a POP under Regulation (EC) No 850/2004, or which fulfils the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006.

Nanomaterial: this is defined as a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, particle, agglomerate and aggregate are defined.

The Commission shall be empowered to adopt delegated acts in order to adapt the definition of nanomaterial in view of technical and scientific progress and taking into account the Commission Recommendation 2011/696/EU.

With regard to authorisation, the text conforms to Parliaments request and states that risks posed by nanomaterials in biocidal products to health and the environment must be examined separately.

A biocidal product shall be eligible for the simplified procedure only if the biocidal product does not contain a nanomaterial.

With regard to treated articles, the person responsible for the placing on the market of that treated article shall ensure that the label states the name of all nanomaterials contained in biocidal products, followed by the word nano in brackets.

Approval of active substances: an active substance may only be approved for an initial period not exceeding 5 years. The approval shall specify the date of approval and the expiry date of the approval of the active substance.

Exclusion criteria: active substances which are considered as having endocrine-disrupting properties that may cause adverse effects in humans shall not be approved. No later than 13 December 2013, the Commission shall adopt delegated acts specifying scientific criteria for the determination of endocrine disrupting properties.

Active substances may be approved if it is shown that at least one of the following conditions is met:

- the risk to humans or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release to the environment;
- it is shown by evidence that the active substance is essential to prevent or to control a serious danger to public or animal health or to the environment; or not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.

The use of any biocidal product containing active substances approved in accordance with the regulation shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.

Submission and validation of applications: the evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under the regulation and shall reject the application if the applicant fails to pay the fees within 30 days.

Where the evaluating competent authority considers that there are concerns for human health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns and include this as part of its conclusions.

Active substances which are candidates for substitution: an active substance shall be considered a candidate for substitution if it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser.

Renewal and review of approval: the renewal shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the Regulation renewing the approval of an active substance.

The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in the regulation are no longer met.

General conditions of authorisation: as Members had asked, the notification of products should be made at least 30 days in advance to allow a real market monitoring. The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions.

For applications for Union authorisations, the summary of the characteristics of the biocidal product shall be provided in one of the official languages of the Union accepted by the evaluating competent authority at the time of application and in all official languages of the Union before the authorisation of the product.

Measures geared to the sustainable use of biocidal products: three years after the entry into force of the Regulation, the Commission shall, on the basis of experience gained with the application of the Regulation, present a report on how the Regulation contributes to a sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to

human and animal health and the environment by biocidal products. That report shall, inter alia, examine:

- the promotion of best practices as a means of reducing the use of biocidal products to the minimum;
- the most effective approaches for monitoring the use of biocidal products;
- the development and application of integrated pest management principles with respect to the use of biocidal products;
- the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface or groundwater and whether additional measures are needed to address them;
- the role that the improved performance of the equipment used for the application of biocidal products could make to sustainable use.

On basis of that report, the Commission shall, if appropriate, present a legislative proposal.

Union authorisations: the amended text stipulates that applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 (exclusion criteria) and certain product types:

- from 1 September 2013, the Union authorisation may be granted to biocidal products containing one or more new active substances and biocidal products of product-types 1 (human hygiene), 3 (veterinary hygiene), 5 (drinking water), 18 (insecticides, acaricides and products to control other arthropods) and 19 (repellents and attractants);
- from 1 January 2017, the Union authorisation may be granted to biocidal products of product-types 2 (Disinfectants and algaecides not intended for direct application to humans or animals) , 6 (preservatives for products during storage) and 13 (working or cutting fluid preservatives);
- from 1 January 2020, the Union authorisation may be granted to all categories of biocidal products.

Derogation from the requirements: by way of derogation, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in the Regulation, for a limited and controlled use under the supervision of the competent authority , if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

Research and development: any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make any other information available to the competent authorities on request.

Labelling: the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans and the environment. The supplier of a treated article shall, upon request by a consumer, provide, within 45 days, free of charge, information on the biocidal treatment of the treated article.

The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise.

Animal testing: in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. Any person intending to perform tests or studies shall, in the case of data involving tests on vertebrate animals, submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under the Regulation or Directive 98/8/EC.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, the Agency shall, without delay, communicate the name and contact details of the data submitter(s) and data owner(s) to the prospective applicant.

Data owners must share information in exchange for equitable compensation.

The Regulation shall apply from 1 September 2013.

Making available on the market and use of biocidal products

Pursuant to Article 293(2) of the Treaty on the Functioning of the European Union, the Commission will not stand against the amendments voted by the European Parliament in second reading on the basis of the compromise text negotiated between Parliament and Council.

The amendments adopted by the European Parliament at its plenary session of 19 January 2012 concern essentially:

- the criteria for the exclusion of active substances from the approval process;
- the scope of the EU centralized procedure for biocidal products;
- greater flexibility in relation to the data requirements and a reduction in the testing of vertebrate animals;
- the labelling requirements for treated articles;
- the publication of reports and the dissemination of information;
- the tasks attributed of the European Chemicals Agency and the basis for the payment of fees to that Agency.

The Commission will not stand against the compromise package as it is generally in line with the overall purpose and the general characteristics of the proposal. The Commission has made declarations regarding the use of implementing acts for the setting of the fees payable to the European Chemicals Agency, the definition of nanomaterial and the fees for mutual recognition applications.

Making available on the market and use of biocidal products

PURPOSE: to improve free movement of biocidal products in the Union whilst ensuring a high level of human, animal and environmental protection.

LEGISLATIVE ACT: Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

CONTENT: following in second reading, the Council and the European Parliament adopted a regulation concerning the placing on the market and use of biocidal products. The provisions of the Regulation are based on the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment.

As required by the European Parliament, particular attention shall be paid to the protection of vulnerable groups.

The Regulation applies to insecticides, disinfectants and repellents, but not medicines or agricultural pesticides. It aims to simplify the authorisation procedures in the internal market through the harmonisation of legislation on biocidal products, while ensuring a high level of protection for both human and animal health and the environment.

The Regulation lays down certain principles.

(1) The establishment at Union level of a list of active substances which may be used in biocidal products.

(2) Conditions for the approval and renewal of approval of active substances :

- an active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in the text ;
- active substances that are classified as carcinogenic, mutagenic, toxic for reproduction or considered as having endocrine-disrupting properties, shall not be approved except in specified circumstances ;
- the approval of an active substance shall not cover nanomaterials except where explicitly mentioned ;
- an active substance that falls under the exclusion criteria may only be approved for an initial period not exceeding five years ;
- the renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation renewing such an approval ;
- the Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in the Regulation are no longer met.

(3) The granting of an authorisation for biocidal products: biocidal products should neither be made available on the market nor used unless authorised in accordance with the Regulation. As requested by the European Parliament, the authorisation holder shall notify each competent authority at least 30 days before placing it on the market.

(4) The mutual recognition of authorisations within the Union so as to reduce the administrative burden on producers.

(5) The making available on the market and the use of biocidal products within one or more Member States or the Union: the Regulation introduces the possibility of granting an Union authorisation for biocidal products, in addition to the current system of national product authorisation. A first series of product-types may be authorised at Union level as from 2013. From 2020 onwards, most biocidal products will qualify for this procedure.

(6) The placing on the market of treated articles which are not biocidal products: articles incorporating pest control chemicals may not be treated with unauthorised chemicals anymore and must be labelled under the conditions specified in the Regulation. These obligations apply to all articles treated with biocidal products on the EU market, including imported ones.

Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier.

The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products.

ENTRY INTO FORCE: 17/07/2012.

APPLICATION: from 01/09/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts to supplement or amend the Regulation. The power to adopt delegated acts is conferred on the Commission for a period of five years from 17 July 2012. This shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension. A delegated act shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification (this period may be extended by two months). If objections are made by the European Parliament or the Council, the delegated act shall not enter into force.

Making available on the market and use of biocidal products

The Commission presents a report on the sustainable use of biocides pursuant to the Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (the BPR).

The objective of the BPR is to improve the functioning of the internal market whilst ensuring a high level of protection of human health, animal health and the environment. It was applicable from 1 September 2013.

The BPR covers 4 main groups of biocidal products themselves divided into 22 product-types ranging from disinfectants for human hygiene to

embalming and taxidermist fluids, through in-can preservatives, insecticides, rodenticides and antifouling products.

The report is based on a preliminary study, which included a large survey of representatives from Member State Competent Authorities, industry and NGOs. It gives an overview of the findings of the study and shows how the BPR is contributing or can contribute to the sustainable use of biocides.

The main elements include:

- promotion of best practices to reduce the use of biocidal products;
- effective approaches for monitoring the use of biocidal products;
- best practices for integrated pest management principles (IPM) and use of biocidal products;
- risks in specific areas such as schools, workplaces, kindergartens etc.

The report also looks at the need to introduce additional measures, in particular for professional users, in view of reducing the risks posed to human health, animal health and the environment by biocidal products. It notes that the BPR has only been fully operational since 1 September 2013. This means that limited experience has been gained to date with the current legislation. However, the report draws the following conclusions:

Exclusion, substitution and comparative assessment: the exclusion and substitution criteria for active substances, and the comparative assessment for biocidal products containing active substance candidates for substitution, as provided by the BPR, provide very powerful mechanisms to phase out the use of substances of high and very high concern. In addition, this creates incentives to develop better alternatives. These mechanisms have not yet reached their full potential. Consequently:

- the completion of the on-going assessment of all the active substances that were already on the market when the BPD entered into force and the authorisation of biocidal products containing these active substances, must be the first and main priority with a view to promoting the sustainable use of biocidal products;
- Member States as well as industry need to concentrate their efforts and resources on substance approval and product authorisation. In addition, Member States will need to invest additional resources on enforcement activities to ensure that no product is illegally placed on their market and that biocidal products are properly labelled.

Additional measures to reduce the risks posed by biocidal products: the study concluded that the risks are already addressed appropriately by measures imposed through the conditions of approval of active substances or the authorisation of biocidal products.

- For professional users, the study concluded that the control measures applied under EU worker health and safety legislation as well as chemicals legislation combined with the risk mitigation measures specified at the stage of the biocidal product authorisation were sufficient if adhered to to address risk from exposure.
- Furthermore, due to the very diverse nature of biocidal products and the variety of applications, it does not seem appropriate to simply extend the scope of the Framework Directive on the Sustainable Use of Pesticides to biocidal products. Instead, the key objectives of that Directive in relation to biocidal products may be achieved through different means and more targeted actions.
- For the same reasons, extending the scope of the Machinery Directive to biocidal products does not seem appropriate either.

Dissemination of appropriate guidance or information: with regard to the means and targeted actions, the Commission considers that the correct, safe and sustainable use of biocidal products requires the availability and effective dissemination of appropriate guidance or information, whether that use be in a professional context or not:

- for industrial use, when the 'best available techniques reference documents' (BREFs) are developed under the framework of Directive 2010/75/EU on industrial emissions, best practice guidelines on the use of biocidal products should, where relevant, be incorporated;
- for professional use, developing guidance documents, providing training and certification of the users on application of best practices, go hand in hand;
- for non-professional use, the report emphasises the provisions on the authorisation and the labelling of the product. Technical solutions like smart tags or quick response codes (QR) providing a link to the authorisation holders website can be helpful to allow users to refer to specific product properties and use instructions.

Measures to be taken: the Commission will pursue the following actions, and invite Member States to do the same:

- focus and strengthen efforts on the review programme of existing active substances to ensure it is completed at the latest by end 2024;
- ensure that once active substances are approved, product authorisations are granted, amended or cancelled within 3 years;
- invest additional resources on enforcement activities;
- benefit from the legislative tools available, in particular by closely following the developments of BREFs that can be relevant for biocidal products used in industrial processes;
- encourage communication and awareness raising campaigns to inform end-users, through websites, in-store leaflets or videos, quick response codes on biocidal products, etc.;
- encourage the development and implementation of standards (e.g. under CEN) that could contribute to the sustainable use of biocidal products;
- welcome research initiatives on the sustainable use of biocides and alternatives to biocidal products.

Making available on the market and use of biocidal products

The Commission presented a report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

The report shall be drawn up not later than nine months before the end of the five-year period of the delegation, running from 17 July 2012.

The BPR empowers the Commission to adopt delegated acts in order to supplement or amend certain non-essential elements of the Regulation.

Exercise of the delegation: during the period concerned by this report, the Commission adopted four delegated acts:

1. Commission Delegated Regulation (EU) No 736/2013: the BPR provides for the continuation of the work programme for the systematic examination of all existing active substances used in biocidal products commenced in accordance with Directive 98/8/EC. The Commission shall be empowered to adopt delegated acts concerning the extension of the duration of the work programme for a determined period.

The BPR provided the work programme to be achieved by 14 May 2014. However, the Commission pointed out that the examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024. As a consequence, Regulation (EU) No 736/2013 amended the BPR in order to extend the duration of the work programme until 31 December 2024.

The Commission adopted the delegated act on 17 May 2013 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 20 August 2013.

2. Commission Delegated Regulation (EU) No 837/2013: the Commission shall be empowered to adopt delegated acts concerning the adaptation of Annexes II, III and IV to such scientific and technical progress.

Regulation (EU) No 837/2013 amended Annex III to the BPR in order to include the proof of establishment of technical equivalence in the information requirement for authorisation of biocidal products. A biocidal product may be authorised even if one or more of the active substances contained therein has been manufactured in a different location or according a different process, including from different starting materials, than those of the substance evaluated for approval pursuant to Article 9 of the BPR. This delegated act was aimed at ensuring in such a situation that the active substance contained in a biocidal product does not have significantly more hazardous properties than the substance which has been evaluated for the purpose of approval.

The Commission adopted the delegated act on 25 June 2013 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 23 September 2013.

3. Commission Delegated Regulation (EU) No 492/2014: the Commission shall be empowered to adopt delegated acts laying down supplementary rules for the renewal of authorisations subject to mutual recognition.

The Commission adopted Regulation (EU) No 492/2014 in order to lay down supplementary rules for the renewal of authorisations subject to mutual recognition procedures, both in the Member State having granted the first authorisation and in those Member States having granted an authorisation through mutual recognition of that first authorisation. The delegated act provides that the European Chemicals Agency shall draw up guidelines on the details related to the handling of renewals.

The Commission adopted the delegated act on 7 March 2014 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 3 June 2014.

4. Commission Delegated Regulation (EU) No 1062/2014: the Commission adopted Regulation (EU) No 1062/2014 in order to supplement the BPR as regards the detailed rules for the continuation of the review programme which was previously carried out according to rules based on Directive 98/8/EC. S

Since the BPR repealed the Directive, the existing detailed rules had to be updated adapted to the provisions of the BPR. The delegated act defines the rights and obligations of competent authorities and of participants in the work programme. In addition, the delegated act specifies in which situations a prospective applicant would be allowed to join or replace an existing participant or to take over the support of an included substance in the review programme.

The Commission adopted the delegated act on 4 August 2014 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 30 October 2014.

Other delegations: experts are currently discussing a draft delegated regulation in line with the new inter-institutional agreement. It is going to adopt as soon as possible the delegated regulation supplementing the BPR and specifying scientific criteria for the determination of endocrine-disrupting properties.

Conclusion: the Commission considered that the delegated powers conferred on it should remain in force. The implementation of the BPR is advancing and technical and scientific progress takes place. Therefore the Commission may be required to adopt further delegated acts in the future in order to keep the legal framework up to date.

Making available on the market and use of biocidal products

In accordance with Regulation (EU) No 528/2012, the Commission presented a report on the authorisation of biocidal products by the Union.

Background to the report: as a reminder, Regulation (EU) No 528/2012, applicable since 1 September 2013, lays down rules on the placing on the market and use of biocidal products. It provides that active substances must be listed in Annex I to that Regulation (so-called 'low risk active substances') or approved at EU level and included in a Union list of approved active substances before they can be used in biocidal products. Secondly, biocidal products containing an active substance require authorisation before they can be placed on the market and used.

The procedure for Union authorisation is the following: the European Chemicals Agency (ECHA) receives the application and, following its assessment by an evaluating competent authority of a Member State, ECHA organises a peer review process resulting in an opinion delivered by its Biocidal Products Committee (BPC). This opinion will be the basis for the Commission to decide on whether or not to grant the Union authorisation, and under which conditions.

By 31 December 2017, no Union authorisation has been granted yet, as the regulatory process for the first applications requesting a Union authorisation has not been completed. Therefore, the Commission is not in a position to make a comprehensive analysis of the functioning of current provisions in the Regulation on Union authorisation.

Consequently, this report provides a factual overview of the applications for Union authorisation submitted until 1 October 2017 and some preliminary conclusions based on the limited experience gained so far with the existing applications for Union authorisation.

Number and types of applications: until the end of 2017, a total of 115 applications for Union authorisations have been submitted, 70 (60.9%) thereof under Regulation (EU) No 528/2012 while 45 (39.1%) have been submitted under Commission Implementing Regulation (EU) No 414/2013.

Regarding the type of authorisation sought, 20 applications (17.4%) involved single biocidal products while 95 (82.6%) involved biocidal product families. This latter figure is significantly higher than the estimates in a survey carried out by two industry associations in 2015. Furthermore, the trend in the submission of applications for EU authorisation in recent years shows that this procedure is increasingly being used.

This seems to indicate that Union authorisation is attractive under the current fee amounts laid down by the Commission Implementing Regulation (EU) No 564/2013, in particular for biocidal product families. However, it will only be possible to fully assess the success of this procedure a few years after the actual issue of Union authorisations.

Products covered: the main product-types covered by the current applications are disinfectants (48.7%), followed by applications including a combination of disinfectant and preservative uses (45.2%) and finally by insecticides (5.2%) which corresponds to product-type.

Therefore, Union authorisation seems to respond to the needs of applicants to reach the whole Union market for widely used biocidal products with similar conditions of use across EU.

Applications for Union authorisation concern 16 active substances representing 38 active substance/product-type combinations. All of these are existing active substances as defined in Article 3(1)(d) of Regulation (EU) No 528/2012.

Only 2 out of the 16 active substances fulfil one of the substitution criteria referred to in Article 10(1)(b) to (f) of Regulation (EU) No 528/2012. This finding is consistent with the objective of discouraging prospective applicants to submit applications for Union authorisation of products containing active substances fulfilling the substitution criteria.

The Union authorisation procedure is mainly used by applicants to request the authorisation of biocidal product families (82.6% of the applications) that cover a high number of existing products in the markets of Member States. Taking into account that most applications for Union authorisation are also intended for more than one product-type (85%), this may add a certain degree of difficulty for the evaluating competent authorities to timely validate and assess the applications.

The report also notes the following:

- 58% of applications are today assessed by one Member State only: the driving factors behind the applicants' choice of Member States should be further explored in order to find a more balanced distribution of the workload between Member States;
- a significant proportion of applications was incomplete and required further submission of information. In this respect, proper planning of early pre-submission meetings between the applicant and the evaluating competent authority should be further promoted;
- about 21% of the applicants having submitted Union authorisation applications are SMEs: the possibility to implement a system of payment of fees by instalments should be further considered in order to better understand their effect on the number of applications submitted by SMEs.

The Commission will include a more comprehensive assessment of the Union authorisation procedure in its composite report to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012. The composite report will be based on the reports submitted by Members States to the Commission on the implementation of the Regulation in their respective territories, which are due by 30 June 2020.