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 (Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

(2) Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation.

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

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(4) To ensure a high level of protection for human health, animal health and the environment, this Regulation should apply without prejudice to Union legislation on safety in the workplace and environmental and consumer protection.

(5) Rules concerning the making available on the market of biocidal products within the Community were established by Directive 98/8/EC of the European Parliament and of the Council[3]. It is necessary to adapt those rules in the light of experience and in particular the report on the first seven years of the implementation submitted by the Commission to the European Parliament and the Council, which analyses problems with and weaknesses of that Directive.

(6) Taking into account the main changes that should be made to the existing rules, a regulation is the appropriate legal instrument to replace Directive 98/8/EC to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.

(7) A distinction should be drawn between existing active substances which were on the market in biocidal products on the transposition date set in Directive 98/8/EC and new active substances which were not yet on the market in biocidal products on that date. During the ongoing review of existing active substances, Member States should continue to allow biocidal products containing such substances to be made available on the market according to their national rules until a decision is taken on approval of those active substances. Following such a decision Member States, or, where appropriate, the Commission, should grant, cancel or modify authorisations as appropriate. New active substances should be reviewed before biocidal products containing them are placed on the market, so as to ensure that new products that are placed on the market comply with the requirements of this Regulation. However, to encourage the development of new active substances, the evaluation procedure for new active substances should not prevent Member States or the Commission from authorising, for a limited period of time, biocidal products containing an active substance before it is approved, provided that a full dossier has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set out in this Regulation.

(8) To ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier, or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products. Biocidal products containing active substances for which the relevant person does not comply with that obligation should no longer be made available on the market. In such cases, there should be appropriate phase-out periods for disposal and use of existing stocks of biocidal products.

(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.

(10) In order to ensure legal certainty, it is necessary to establish a Union list of active substances approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information

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that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.

(11) This Regulation applies without prejudice to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency[(4)]. Under certain conditions, biocidal active substances are exempt from the relevant provisions of that Regulation.

(12) With a view to achieving a high level of protection of human health, animal health and the environment, active substances with the worst hazard profiles should not be approved for use in biocidal products except in specific situations. These should include situations when approval is justified because of the negligible risk from exposure to the substance, human health, animal health or environmental reasons or the disproportionate negative impact for society of non-approval. When deciding if such active substances may be approved, the availability of suitable and sufficient alternative substances or technologies should also be taken into account.

(13) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are significant indications that an active substance used in biocidal products or treated articles does not meet the requirements of this Regulation, the Commission should be able to review the approval of the active substance.

(14) Active substances should be designated as candidates for substitution if they have certain intrinsic hazardous properties. In order to allow for a regular examination of substances identified as candidates for substitution, the approval period for those substances should not, even in the case of renewal, exceed seven years.

(15) In the course of granting or renewing the authorisation of a biocidal product that contains an active substance that is a candidate for substitution, it should be possible to compare the biocidal product with other authorised biocidal products, non-chemical means of control and prevention methods with regard to risks they pose and benefits from their use. As a result of such a comparative assessment, a biocidal product containing active substances identified as candidates for substitution should be prohibited or restricted where it is demonstrated that other authorised biocidal products or non-chemical control or prevention methods that present a significantly lower overall risk for human health, animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages. Appropriate phase-out periods should be provided for in such cases.

(16) In order to avoid unnecessary administrative and financial burdens for industry and competent authorities, a full in-depth evaluation of an application to renew the approval of an active substance or the authorisation of a biocidal product should be carried out only if the competent authority that was responsible for the initial evaluation decides that this is necessary on the basis of the available information.

(17) There is a need to ensure effective coordination and management of the technical, scientific and administrative aspects of this Regulation at Union level. The European

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Chemicals Agency set up under Regulation (EC) No 1907/2006 ('the Agency') should carry out specified tasks with regard to the evaluation of active substances as well as the Union authorisation of certain categories of biocidal products and related tasks. Consequently, a Biocidal Products Committee should be established within the Agency to carry out certain tasks conferred on the Agency by this Regulation.

(18) Certain biocidal products and treated articles as defined in the Regulation are also regulated by other Union legislation. It is therefore necessary to draw clear borderlines in order to ensure legal certainty. A list of product-types covered by this Regulation with an indicative set of descriptions within each type should be set out in an Annex to this Regulation.

(19) Biocidal products intended to be used not only for the purposes of this Regulation, but also in connection with medical devices, such as disinfectants used to disinfect surfaces in hospitals and medical devices, may pose risks other than those with which this Regulation is concerned. Therefore, such biocidal products should comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements set out in Annex I to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(5)], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(6)] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[(7)].

(20) Where a product has a biocidal function that is inherent to its cosmetic function, or where that biocidal function is considered to be a secondary claim of a cosmetic product and is therefore regulated under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[(8)], that function and the product should remain outside the scope of this Regulation.

(21) The safety of food and feed is subject to Union legislation, in particular Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(9)]. Therefore, the present Regulation should not apply to food and feed used as repellents or attractants.

(22) Processing aids are covered by existing Union legislation, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(10)] and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(11)]. Therefore, it is appropriate to exclude them from the scope of this Regulation.

(23) As products used for the preservation of food or feed by the control of harmful organisms, previously covered by product-type 20, are covered by Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008, it is not appropriate to maintain that product-type.

(24) As the International Convention for the Control and Management of Ships' Ballast Water and Sediments provides for an effective assessment of the risks posed by ballast

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water management systems, the final approval and subsequent type-approval of such systems should be considered equivalent to the product authorisation required under this Regulation.

(25) To avoid possible negative effects on the environment, biocidal products that can no longer lawfully be made available on the market should be dealt with in accordance with Union legislation on waste, in particular Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste[(12)], as well as national legislation implementing that legislation.

(26) To facilitate the making available on the market throughout the Union of certain biocidal products with similar conditions of use in all Member States, it is appropriate to provide for Union authorisation of those products. In order to allow some time for the Agency to build up the necessary capacity and to gain experience with this procedure, the possibility to apply for Union authorisation should be extended through a step-wise approach to further categories of biocidal products with similar conditions of use in all Member States.

(27) The Commission should review experience with the provisions on Union authorisations and report to the European Parliament and the Council by 31 December 2017, accompanying its report with proposals for changes if appropriate.

(28) To ensure that only biocidal products that comply with the relevant provisions of this Regulation are made available on the market, biocidal products should be subject to authorisation either by competent authorities for making available on the market and use within the territory of a Member State or part of it, or by the Commission for making available on the market and use within the Union.

(29) To encourage the use of products with a more favourable environmental or human or animal health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products. Once authorised in at least one Member State, those products should be allowed to be made available on the market in all Member States without the need for mutual recognition, under certain conditions.

(30) To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

(31) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.

(32) To evaluate the risks that would arise from proposed uses of biocidal products, it is appropriate that applicants submit dossiers which contain the necessary information. Defining a data set for active substances and for biocidal products in which they are contained is necessary so as to assist both applicants seeking authorisation and competent authorities carrying out an evaluation to decide on authorisation.