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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concerning the making available on the market and use of biocidal products

(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.

(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

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

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

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.

(33) In the light of the diversity of both active substances and biocidal products not subject to the simplified authorisation procedure, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request the adaptation of the data requirements, as appropriate, including the waiving of data requirements which are not necessary or are impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide appropriate technical and scientific justification to support their requests.

(34) In order to help applicants, and in particular small and medium-sized enterprises (SMEs), to comply with the requirements of this Regulation, Member States should provide advice, for example by establishing helpdesks. This advice should be in addition to the operational guidance documents and other advice and assistance provided by the Agency.

(35) In particular, to ensure that applicants can effectively exercise the right to request the adaptation of data requirements, Member States should provide advice on this possibility and the grounds on which such requests could be made.

(36) To facilitate access to the market it should be possible to authorise a group of biocidal products as a biocidal product family. Biocidal products within a biocidal product family should have similar uses and the same active substances. Variations in the composition or the replacement of non-active substances should be specified, but may not adversely affect the level of risk or significantly reduce the efficacy of the products.

(37) When authorising biocidal products it is necessary to ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, or, in the case of vertebrates, unnecessary suffering and pain. Furthermore, they may not have, in the light of current scientific and technical knowledge, any unacceptable effect on human health, animal health or on the environment. Where appropriate, maximum residue limits for food and feed should be established with respect to active substances contained in a biocidal product to protect human and animal health. When these requirements are not met, biocidal products shall not be authorised unless their authorisation is justified because of the disproportionate negative impact for society of not authorising them when compared to the risks arising from their use.

(38) Where possible, the presence of harmful organisms should be avoided by means of suitable precautionary steps, such as proper warehousing of goods, compliance with relevant hygiene standards and immediate disposal of waste. As far as possible, biocidal products that pose lower risks for humans, animals and the environment should be used whenever they provide an effective remedy, and biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used only as a last resort.

(39) Some authorised biocidal products may present certain risks if used by the general public. It is therefore appropriate to provide that certain biocidal products should not generally be authorised for making available on the market for use by the general public.

(40) To avoid duplication of the evaluation procedures and to ensure free movement of biocidal products within the Union, procedures should be established to ensure that product authorisations granted in one Member State are recognised in other Member States.

(41) To enable closer cooperation between Member States in the evaluation of biocidal products and to facilitate biocidal products' market access, it should be possible to launch the mutual recognition procedure when applying for the first national authorisation.

(42) It is appropriate to lay down procedures for the mutual recognition of national authorisations and, in particular, to resolve any disagreements without undue delay. If a competent authority refuses mutual recognition of an authorisation or proposes to restrict it, a coordination group should try to reach an agreement on the action to be taken. If the coordination group does not succeed in finding an agreement within a specified time limit, the Commission should be empowered to take a decision. In case of technical or scientific questions, the Commission may consult the Agency before preparing its decision.

(43) However, considerations related to public policy or public security, environmental and human and animal health protection, the protection of national treasures and the absence of the target organisms might justify, following agreement with the applicant, Member States' refusal to grant an authorisation or decision to adjust the terms and conditions of the authorisation to be granted. If no agreement with the applicant can be found, the Commission should be empowered to take a decision.

(44) The use of biocidal products of certain product-types might give rise to animal welfare concerns. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products falling under such product-types, in so far as such derogations are justified and do not jeopardise the purpose of this Regulation regarding an appropriate level of protection of the internal market.

(45) In order to facilitate the functioning of the authorisation and mutual recognition procedures, it is appropriate to establish a system for the mutual exchange of information. To accomplish this, a Register for Biocidal Products should be established. Member States, the Commission and the Agency should use this Register to make available to each other the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.

(46) If the use of a biocidal product is in the interests of a Member State, but there is no applicant interested in making available on the market such a product in the Member State, official or scientific bodies should be able to apply for an authorisation. If they are granted an authorisation, they should have the same rights and obligations as any other authorisation holder.

(47) To take account of scientific and technical developments as well as the needs of authorisation holders, it is appropriate to specify under which conditions authorisations can be cancelled, reviewed or amended. The notification and exchange of information

which may affect authorisations is also necessary to enable competent authorities and the Commission to take appropriate action.

(48) In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to permit, for a limited period of time, the making available on the market of biocidal products which do not comply with the requirements of this Regulation.

(49) To encourage research and development in active substances and biocidal products, it is necessary to establish rules concerning the making available on the market and use of unauthorised biocidal products and non-approved active substances for the purposes of research and development.

(50) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade in identical biocidal products authorised in different Member States.

(51) To determine, where necessary, the similarity of active substances, it is appropriate to lay down rules concerning technical equivalence.

(52) To protect human health, animal health and the environment, and to avoid discrimination between treated articles originating in the Union and treated articles imported from third countries, all treated articles placed on the internal market should contain only approved active substances.

(53) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled.

(54) Applicants that have invested in supporting the approval of an active substance or the authorisation of a biocidal product in accordance with this Regulation or Directive 98/8/EC should be able to recover part of their investment by receiving equitable compensation whenever use of proprietary information which they submitted in support of such approval or authorisation is made for the benefit of subsequent applicants.

(55) With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

(56) To encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the approval of such active substances or the authorisation of biocidal products containing them which is longer than the period of protection for information concerning existing active substances and biocidal products containing them.

(57) It is essential to minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products, to be carried out only when the purpose and use of a product so requires. Applicants should share, and not duplicate, studies on vertebrates in exchange for equitable compensation. In the absence

of an agreement on sharing of studies on vertebrates between the data owner and the prospective applicant, the Agency should allow the use of the studies by the prospective applicant without prejudice to any decision on compensation made by national courts. Competent authorities and the Agency should have access to the contact details of the owners of such studies via a Union register so as to inform prospective applicants.

(58) A level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of equitable compensation of the costs borne by data owners.

(59) The generation of information by alternative means not involving tests on animals which are equivalent to prescribed tests and test methods should also be encouraged. In addition, the adaptation of data requirements should be used to prevent unnecessary costs related to testing.

(60) To ensure that the requirements laid down with respect to the safety and quality of authorised biocidal products are satisfied when they are made available on the market, Member States should take measures for appropriate control and inspection arrangements and manufacturers should maintain a suitable and proportionate quality control system. To this end, it may be appropriate for Member States to take action together.

(61) Effective communication of information on risks resulting from biocidal products and risk management measures is an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful to the commercial interests of the person concerned, except where it is necessary for the protection of human health, safety or the environment or for other reasons of overriding public interest.

(62) To increase the efficiency of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, authorisation holders should keep records of the products they place on the market.

(63) It is necessary to specify that provisions concerning the Agency laid down in Regulation (EC) No 1907/2006 should apply accordingly in the context of biocidal active substances and products. Where separate provisions need to be made with respect to the tasks and functioning of the Agency under this Regulation, they should be specified in this Regulation.

(64) The costs of the procedures associated with the operation of this Regulation need to be recovered from those making biocidal products available on the market and those seeking to do so in addition to those supporting the approval of active substances. To promote the smooth operation of the internal market, it is appropriate to establish certain common principles applicable both to fees payable to the Agency and to Member States' competent authorities, including the need to take into account, as appropriate, the specific needs of SMEs.

(65) It is necessary to provide for the possibility of an appeal against certain decisions of the Agency. The Board of Appeal set up within the Agency by Regulation (EC) No 1907/2006 should also process appeals against decisions adopted by the Agency under this Regulation.

(66) There is scientific uncertainty about the safety of nanomaterials for human health, animal health and the environment. 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, if possible based on the work of appropriate international forums and to specify that the approval of an active substance does not include the nanomaterial form unless explicitly mentioned. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(67) To ensure a smooth transition, it is appropriate to provide for a deferred application of this Regulation and to provide for specific measures concerning the assessment of applications for the approval of active substances and authorisation of biocidal products submitted before the application of this Regulation.

(68) The Agency should take over the coordination and facilitation tasks for new submissions for approval of active substances as of the date of applicability of this Regulation. However, in view of the high number of historical dossiers it is appropriate to allow some time for the Agency to prepare for the new tasks related to dossiers submitted under Directive 98/8/EC.

(69) To respect the legitimate expectations of companies with respect to the placing on the market and use of low-risk biocidal products covered by Directive 98/8/EC, those companies should be allowed to make such products available on the market if they comply with the rules on the registration of low-risk biocidal products under that Directive. However, this Regulation should apply after the expiry of the first registration.

(70) Taking into consideration that some products were not covered by Community legislation on biocidal products, it is appropriate to provide for transitional periods for such products and treated articles.

(71) This Regulation should take account, as appropriate, of other work programmes concerned with the review or authorisation of substances and products, or relevant international Conventions. In particular, it should contribute to the fulfilment of the Strategic Approach to International Chemicals Management adopted on 6 February 2006 in Dubai.

(72) In order to supplement or amend this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of certain non-essential elements of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely

and appropriate transmission of relevant documents to the European Parliament and to the Council.

(73) The Commission should adopt immediately applicable delegated acts where, in duly justified cases relating to the restriction of an active substance in Annex I or to the removal of an active substance from that Annex, imperative grounds of urgency so require.

(74) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[(13)].

(75) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the approval of an active substance or to the cancelling of an approval, imperative grounds of urgency so require.

(76) Since the objective of this Regulation, namely, to improve the functioning of the internal market for biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment cannot be sufficiently achieved by the Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 347, 18.12.2010, p. 62.

(**2**) Position of the European Parliament of 22 September 2010 (OJ C 50 E, 21.2.2012, p. 73) and position of the Council at first reading of 21 June 2011 (OJ C 320 E, 1.11.2011, p. 1). Position of the European Parliament of 19 January 2012 (not yet published in the Official Journal) and decision of the Council of 10 May 2012.

(**3**) OJ L 123, 24.4.1998, p. 1.

(**4**) OJ L 396, 30.12.2006, p. 1.

(**5**) OJ L 189, 20.7.1990, p. 17.

(**6**) OJ L 169, 12.7.1993, p. 1.

(**7**) OJ L 331, 7.12.1998, p. 1.

(**8**) OJ L 342, 22.12.2009, p. 59.

(**9**) OJ L 31, 1.2.2002, p. 1.

(**10**) OJ L 268, 18.10.2003, p. 29.

(**11**) OJ L 354, 31.12.2008, p. 16.

(**12**) OJ L 312, 22.11.2008, p. 3.

(**13**) OJ L 55, 28.2.2011, p. 13.