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)

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)

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:

Modifications etc. (not altering text)

C1 Regulation applied (with modifications) (N.I.) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(a), **Sch. 1** (with regs. 7, 8)

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Purpose and subject matter

1 The purpose of this Regulation is to improve the functioning of the [F1]... market through [F2]... rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to

safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

2 This Regulation lays down rules for:

a the establishment at **[**F3Great Britain**]** level of a list of active substances which may be used in biocidal products;

b the authorisation of biocidal products;

F4c . . . . . .

d the making available on the market and the use of biocidal products within **[**F5Great Britain**]**;

e the placing on the market of treated articles.

Textual Amendments

F1 Word in Art. 1(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 62(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Art. 1(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 62(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 1(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 62(3)(a)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 21(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Art. 1(2)(c) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 62(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 1(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 62(3)(c)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 21(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 2

Scope

1 This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2 Subject to any explicit provision to the contrary in this Regulation or other F6... legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:

a Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[14];

b **[**F7the Medical Devices Regulations 2002**]**;

c **[**F8the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012**]**;

d Regulation (EC) No 1831/2003;

e Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(15)] and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[(16)];

f Regulation (EC) No 1333/2008;

g Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[(17)];

h Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed[(18)];

i Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[(19)];

j Regulation (EC) No 1223/2009;

[[F9]k the Toys (Safety) Regulations 2011.**]**

Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.

3 Subject to any explicit provision to the contrary in this Regulation [F10]..., this Regulation shall be without prejudice to the following instruments:

a Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(20)];

b Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[(21)];

c Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work[(22)];

d Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[(23)];

e Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(24)];

f Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work[(25)];

g Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[(26)];

h Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[(27)];

i Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants[(28)];

j Regulation (EC) No 1907/2006;

k Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising[(29)];

l Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals[(30)];

m Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[31];

n Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[32];

o Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer[33];

p Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[34];

q Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions[35].

4 Article 69 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5 This Regulation shall not apply to:

a food or feed used as repellents or attractants;

[F11b biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008.**]**

6 Biocidal products which obtained final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under **[**F12Chapter VI**]** of this Regulation. Articles 47 and 68 shall apply accordingly.

7 Nothing in this Regulation shall prevent **[**F13the competent authority or any other relevant authority from**]** from restricting or banning the use of biocidal products in the public supply of drinking water.

8 **[**F14The Secretary of State**]** 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.

9 The disposal of active substances and biocidal products shall be carried out in accordance with F15... national waste legislation in force.

Textual Amendments

F6 Word in Art. 2 omitted (31.12.2020) by virtue of S.I. 2019/720, **Sch. 2 para. 63(2)(a)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 22**)

F7 Words in Art. 2(2)(b) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 63(2)(b)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 22**)

F8 Words in Art. 2(2)(c) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 63(2)(c)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 22**)

F9 Art. 2(2)(k) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 63(2)(d)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 22**)

F10 Words in Art. 2(3) omitted (1.11.2022) by virtue of The Chemicals (Health and Safety) Trade and Miscellaneous Amendments Regulations 2022 (S.I. 2022/1037), regs. 1(2), **9(2)**

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market

and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F12 Words in Art. 2(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 63(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in Art. 2(7) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 63(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Art. 2(8) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 63(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in Art. 2(9) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 63(6)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 3

Definitions

1 For the purposes of this Regulation, the following definitions shall apply:

a ‘biocidal product’ means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, 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,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, 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.

A treated article that has a primary biocidal function shall be considered a biocidal product.

b ‘micro-organism’ means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

c ‘active substance’ means a substance or a micro-organism that has an action on or against harmful organisms;

d ‘existing active substance’ means a substance which was on the market on 14 May 2000 **[**F16, in a country which was a Member State of the EU on that date,**]** as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

e ‘new active substance’ means a substance which was not on the market on 14 May 2000 **[**F17in a country which was a Member State of the EU on that date**]** as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

f ‘substance of concern’ means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is

present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

Such a substance would, unless there are other grounds for concern, normally be:

— F18...

— a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,

— a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;

g ‘harmful organism’ means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

h ‘residue’ means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance’s metabolites, breakdown or reaction products;

i ‘making available on the market’ means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

j ‘placing on the market’ means the first making available on the market of a biocidal product or of a treated article;

k ‘use’ means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside **[**F19Great Britain**]**;

l ‘treated article’ means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

m ‘national authorisation’ means an administrative act by which the competent authority F20... authorises the making available on the market and the use of a biocidal product or a biocidal product family F21...;

[F22n ‘Union authorisation’ means the administrative act by which the Commission authorised the making available on the market and use of a biocidal product or a product family in the territory of the Union or part thereof before IP completion day;**]**

o ‘authorisation’ means national authorisation F23... or authorisation in accordance with Article 26;

p ‘authorisation holder’ means the person established **[**F24in the United Kingdom**]** who is responsible for the placing on the market of a biocidal product in **[**F25Great Britain**]** and specified in the authorisation;

q ‘product-type’ means one of the product-types specified in Annex V;

r ‘single biocidal product’ means a biocidal product with no intended variations as to the percentage of the active or non-active substances it contains;

[F11s ‘biocidal product family’ means a group of biocidal products having:

(i) similar uses;

(ii) the same active substances;

(iii) similar composition with specified variations; and

(iv) similar levels of risk and efficacy;**]**

t ‘letter of access’ means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by **[**F26the competent authority**]** for the purposes of this Regulation;

u ‘food’ and ‘feed’ mean food as defined in Article 2 of Regulation (EC) No 178/2002 and feed as defined in Article 3(4) of that Regulation;

F27v . . . . . .

w ‘technical equivalence’ means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;

F28x . . . . . .

y ‘advertisement’ means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

z ‘nanomaterial’ means 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 1-100 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 as follows:

— ‘particle’ means a minute piece of matter with defined physical boundaries,

— ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

— ‘aggregate’ means a particle comprising strongly bound or fused particles;

aa ‘administrative change’ means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

ab ‘minor change’ means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;

ac ‘major change’ means an amendment of an existing authorisation which is neither an administrative change nor a minor change;

ad ‘vulnerable groups’ means persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents;

ae ‘small and medium-sized enterprises’ or ‘SMEs’ means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[(36)].

[F29af ‘the consent requirement’ means the requirement for consent in accordance with Article 83B;

ag 'the UK List' means the list of approved substances established and maintained in accordance with Article 8A;

ah 'the Simplified Active Substance List' means the list of active substances which can be used in biocidal products that qualify for the simplified authorisation procedure, established and maintained in accordance with Article 24A.

ai "appropriate fee" means the fee payable for the activity concerned in regulations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;

aj "Devolved Authority" means—

i the Scottish Ministers, or

ii the Welsh Ministers.**]**

2 For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:

a 'substance';

b 'mixture';

c 'article';

d 'product and process-orientated research and development';

e 'scientific research and development'.

[F30 3 The Secretary of State may issue a decision which is to be published, as to whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial and whether a specific product or group of products is a biocidal product or a treated article or neither.

4 A decision issued under paragraph 3 above is subject to the consent requirement.

5 The Secretary of State may by regulations adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress, taking into account the Recommendation referred to in paragraph 3 above.

6 Regulations made under paragraph 5 above are subject to the consent requirement.

7 Where any of the Devolved Authorities makes proposals in relation to adaptations under paragraph 5 above, the Secretary of State must have regard to such proposals in deciding whether to exercise functions in that paragraph.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F16 Words in Art. 3(1)(d) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in Art. 3(1)(e) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in Art. 3(1)(f) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in Art. 3(1)(k) substituted (31.12.2020) by S.I. 2019/720, Sch. 2 para. 64(2)(d) (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(a)**)

F20 Words in Art. 3(1)(m) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Words in Art. 3(1)(m) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F22 Art. 3(1)(n) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(f)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 23(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in Art. 3(1)(o) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

F24 Words in Art. 3(1)(p) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(h)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F25 Words in Art. 3(1)(p) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(h)(ii)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 23(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 Words in Art. 3(1)(t) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Deleted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F28 Art. 3(1)(x) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(j)**; 2020 c. 1, Sch. 5 para. 1(1)

F29 Art. 3(1)(af)-(aj) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(2)(k)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 23(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Art. 3(3)-(7) substituted for Art. 3(3) (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 64(3)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER II

APPROVAL OF ACTIVE SUBSTANCES

Article 4

Conditions for approval

1 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 point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.

2 The approval of an active substance shall be restricted to those product-types for which relevant data have been submitted in accordance with Article 6.

3 The approval shall specify the following conditions, as appropriate:

a the minimum degree of purity of the active substance;

b the nature and maximum content of certain impurities;

c the product-type;

d manner and area of use including, where relevant, use in treated articles;

e designation of categories of users;

f where relevant, characterisation of the chemical identity with regard to stereoisomers;

g other particular conditions based on the evaluation of the information related to that active substance;

h the date of approval and the expiry date of the approval of the active substance.

4 The approval of an active substance shall not cover nanomaterials except where explicitly mentioned.

Article 5

Exclusion criteria

1 Subject to paragraph 2, the following active substances shall not be approved:

a 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 category 1A or 1B;

b active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;

c active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;

d active substances which **[**[F31]meet the criteria in Regulation (EU) No 2100/2017**]** are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;

e active substances which meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006.

2 Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:

a the risk to humans, animals 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 into the environment;

b it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

c not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal 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 a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. [F32]...

[F33]3 . . . . . .

Textual Amendments

F31 Words in Art. 5(1)(d) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 65(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Art. 5(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 65(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F33 Art. 5(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 65(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Data requirements for an application

1 An application for approval of an active substance shall contain at least the following elements:

a a dossier for the active substance satisfying the requirements set out in Annex II;

b a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and

c if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

2 Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:

a the data are not necessary owing to the exposure associated with the proposed uses;

b it is not scientifically necessary to supply the data; or

c it is not technically possible to generate the data.

However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1), if required by the [F34]... competent authority under Article 8(2).

3 An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed

adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

4 The **[**F35Secretary of State may by regulations amend the criteria**]** for determining what constitutes adequate justification to adapt the data requirements under paragraph 1 of this Article on the grounds referred to in point (a) of paragraph 2 of this Article.

[F36 5 Regulations made under paragraph 4 above are subject to the consent requirement.

6 Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 4 above, the Secretary of State must have regard to such proposals when deciding whether to exercise functions under that paragraph.**]**

Textual Amendments

F34 Word in Art. 6(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 66(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F35 Words in Art. 6(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 66(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F36 Art. 6(5)(6) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 66(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 7

Submission and validation of applications

[F37 1 The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, to the competent authority.**]**

F38 2 . . . . . .

3 Within 30 days of the **[**F39competent authority receiving**]** an application, **[**F40it**]** shall validate the application if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1), and any justifications for the adaptation of data requirements, have been submitted.

In the context of the validation referred to in the first subparagraph, the F41... competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The F42... competent authority shall, as soon as possible after **[**F43it has received**]** an application, inform the applicant of the fees payable F44... and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

4 Where the F45... competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The [F45]... competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The [F45]... competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant [F46].... In such cases, part of the fees paid [F47]... shall be reimbursed.

5 On validating an application in accordance with paragraph 3 or 4, the [F48]... competent authority shall without delay inform the applicant [F49]... accordingly, indicating the date of the validation.

[F50]6 . . . . . .

Textual Amendments

F37 Art. 7(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F38 Art. 7(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F39 Words in Art. 7(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F40 Word in Art. 7(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F41 Word in Art. 7(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F42 Word in Art. 7(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in Art. 7(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F44 Words in Art. 7(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(4)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F45 Word in Art. 7(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F46 Words in Art. 7(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(5)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F47 Words in Art. 7(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(5)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F48 Word in Art. 7(5) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F49 Words in Art. 7(5) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F50 Art. 7(6) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 67(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Evaluation of applications

1 The [F51]... competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3), and **[**[F52]produce**]** an assessment report and **[**[F53]evaluation conclusions**]**.

[[F54]The competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The competent authority shall take due account of those comments.**]**

2 Where it appears that additional information is necessary to carry out the evaluation, the [F55]... competent authority shall ask the applicant to submit such information within a specified time limit [F56].... As specified in the second subparagraph of Article 6(2), the [F55]... competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

[[F57]2A The competent authority may request from the applicant available information on, and take into account, evaluations undertaken by third countries in order to complete its evaluation. The weight given to those third country evaluations shall take into account the equivalence of the evaluation process.**]**

3 Where the [F58]... competent authority considers that there are concerns for human health, animal 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 in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

[[F59]4 Within 270 days of producing its assessment reports and evaluation conclusions the competent authority shall prepare and submit an opinion on the approval of the active substance to the Secretary of State and the Devolved Authorities.**]**

Textual Amendments

F51 Word in Art. 8(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F52 Word in Art. 8(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in Art. 8(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F54 Words in Art. 8(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F55 Word in Art. 8(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F56 Words in Art. 8(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F57 Art. 8(2A) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F58 Word in Art. 8(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(6)**; 2020 c. 1, Sch. 5 para. 1(1)

F59 Art. 8(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 68(7)**; 2020 c. 1, Sch. 5 para. 1(1)

[F60 Article 8A

The GB List

The competent authority shall establish, maintain and make electronically available to the public a list of approved active substances ("the GB List").**]**

Textual Amendments

F60 Art. 8A inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 69** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 9

Approval of an active substance

1 The **[**F61Secretary of State**]** shall, on receipt of the opinion of the **[**F62competent authority**]** referred to in Article 8(4), either:

a **[**F63issue a decision**]** providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or

b in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, **[**F64issue a**]** decision that an active substance is not approved.

F65 …

[F66 1A. A decision issued under paragraph 1 is subject to the consent requirement.**]**

[F67 2 Approved active substances shall be included in the GB List established under Article 8A of this Regulation.**]**

Textual Amendments

F61 Words in Art. 9(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F62 Words in Art. 9(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F63 Words in Art. 9(1)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F64 Words in Art. 9(1)(b) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(2)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F65 Words in Art. 9(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(2)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F66 Art. 9(1A) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F67 Art. 9(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 70(4)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 25**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 10

Active substances which are candidates for substitution

1 An active substance shall be considered a candidate for substitution if any of the following conditions are met:

a it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);

b it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

c its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;

d it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006;

e there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;

f it contains a significant proportion of non-active isomers or impurities.

2 When preparing its opinion on the approval or renewal of the approval of an active substance, the **[**[F68]competent authority**]** shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

3 Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the **[**[F69]Secretary of State and the Devolved Authorities**]**, the **[**[F70]competent authority**]** shall make publicly available, without prejudice to Articles 66 and 67, information on potential candidates for substitution during a period of no more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The **[**[F70]competent authority**]** shall take due account of the information received when finalising its opinion.

4 By way of derogation from Article 4(1) and Article 12(3), the approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.

5 Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in the relevant **[**[F71]decision issued**]** in accordance with Article 9.

Textual Amendments

F68 Words in Art. 10(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 71(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F69 Words in Art. 10(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 71(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F70 Words in Art. 10(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 71(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F71 Words in Art. 10(5) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 71(4)**; 2020 c. 1, Sch. 5 para. 1(1)

[F72]Article 11

Technical guidance notes

. . . . . .

Textual Amendments

F72 Art. 11 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 72**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

RENEWAL AND REVIEW OF APPROVAL OF AN ACTIVE SUBSTANCE

Article 12

Conditions for renewal

1 The **[**F73Secretary of State**]** shall renew the approval of an active substance if the active substance still meets the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

2 In the light of scientific and technical progress, the **[**F74Secretary of State**]** shall review and, where appropriate, amend the conditions specified for the active substance referred to in Article 4(3).

3 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 **[**F75decision issued**]** in accordance with point (a) of Article 14(4) renewing such an approval.

[F76**]**4 The renewal of an approval under paragraph 1 or amendment of the conditions in paragraph 2 is subject to the consent requirement.**]**

Textual Amendments

F73 Words in Art. 12(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 73(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F74 Words in Art. 12(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 73(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F75 Words in Art. 12(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 73(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F76 Art. 12(4) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 73(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Submission and acceptance of applications

1 Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the **[**F77competent authority**]** at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

2 When applying for the renewal of the approval of the active substance, the applicant shall submit:

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial approval or, as appropriate, previous renewal; and

b its assessment of whether the conclusions of the initial or previous assessment of the active substance remain valid and any supporting information.

F78 3 . . . . . .

F79 4 . . . . . .

Textual Amendments

F77 Words in Art. 13(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 74(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F78 Art. 13(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 74(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F79 Art. 13(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 74(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 14

Evaluation of applications for renewal

1 On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the F80... competent authority shall, within 90 days of **[**F81receiving**]** an application in accordance with Article **[**F82 13**]**, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

2 Where the F83... competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1, 2 and 3 of Article 8.

Where the F83... competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of **[**F84receiving**]** the application in accordance with Article **[**F85 13**]**, prepare and submit to the **[**F86Secretary of State and the Devolved Authorities**]** a recommendation on the renewal of the approval of the active substance. It shall provide the applicant with a copy of its recommendation.

The F83... competent authority shall, as soon as possible after **[**F87it has received**]** an application, notify the applicant of the **[**F88appropriate fees**]**. The F83... competent authority shall reject the application if the applicant fails to pay the fees within 30 days of the notification and shall inform the applicant accordingly.

3 Within 270 days of **[**F89the completion of the evaluation conclusions**]**, if it has carried out a full evaluation of the application, or 90 days otherwise, the **[**F90competent authority**]** shall prepare and submit to the **[**F91Secretary of State and the Devolved Authorities**]** an opinion on renewal of the approval of the active substance.

4 The **[**F92Secretary of State**]** shall, on receipt of the opinion of the **[**F93competent authority**]**, **[**F94issue**]**:

a **[**F95a decision**]** providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or

b **[**F96a**]** decision that the approval of an active substance is not renewed.

F97 …

Article 9(2) shall apply.

[F98 4A The competent authority shall update the GB List with details of the renewal of the approval of the active substance**]**

[F99 5 Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Secretary of State shall issue a decision postponing the expiry date of approval for a period sufficient to enable the competent authority to examine the application.**]**

[F100 5A A decision issued under paragraph 4 or 5 above is subject to the consent requirement.**]**

6 Where the **[**F101 Secretary of State**]** decides not to renew or decides to amend the approval of an active substance for one or more product-types, the **[**F102 competent authority**]** shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Textual Amendments

F80 Word in Art. 14(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F81 Word in Art. 14(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F82 Word in Art. 14(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F83 Word in Art. 14(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F84 Word in Art. 14(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F85 Word in Art. 14(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F86 Words in Art. 14(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F87 Words in Art. 14(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F88 Words in Art. 14(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(3)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F89 Words in Art. 14(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F90 Words in Art. 14(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F91 Words in Art. 14(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F92 Words in Art. 14(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F93 Words in Art. 14(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F94 Word in Art. 14(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F95 Words in Art. 14(4)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F96 Word in Art. 14(4)(b) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in Art. 14(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(5)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F98 Art. 14(4A) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(6)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 26**); 2020 c. 1, **Sch. 5 para. 1(1)**

F99 Art. 14(5) substituted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(7)**; 2020 c. 1, Sch. 5 para. 1(1)

F100 Art. 14(5A) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(8)**; 2020 c. 1, Sch. 5 para. 1(1)

F101 Words in Art. 14(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F102 Words in Art. 14(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 75(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

I[F103] Article 15

Review of approval of an active substance

1 The Secretary of State 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 Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met. The Secretary of State may also review the approval of an active substance for one or more product-types at the request of the competent authority if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. The Secretary of State shall make publically

available the information that it is carrying out a review and shall provide an opportunity for the applicant to submit comments. The Secretary of State shall take due account of those comments in the review.

2 Where any of the Devolved Authorities proposes that an active substance should be reviewed the Secretary of State shall have regard to such proposals in deciding whether to review the approval of an active substance.

3 Where those indications are confirmed, the Secretary of State shall issue a decision amending the conditions of approval of an active substance or cancelling its approval. Article 9(2) shall apply. The competent authority shall inform the initial applicants for the approval accordingly.

4. On duly justified imperative grounds of urgency the Secretary of State may issue immediately applicable decisions.

5. Paragraphs 1, 3 and 4 are subject to the consent requirement.

6. Where the Secretary of State decides to cancel or amend the approval of an active substance for one or more product-types the competent authority shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.**]**

Textual Amendments

F103 Art. 15 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 76**; 2020 c. 1, Sch. 5 para. 1(1)

F104 Article 16

Implementing measures

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Textual Amendments

F104 Art. 16 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 77**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

1 Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.

2 Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder **[**F105to the competent authority**]**.

F106 …

F107 …

3 An authorisation may be granted for a single biocidal product or a biocidal product family.

4 An authorisation shall be granted for a maximum period of 10 years.

5 Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.

Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.

[F108The competent authority**]** shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

6 The **[**F109biocidal product family authorisation holder shall notify the competent authority**]** of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. F110...

F1117 . . . . . .

Textual Amendments

F105 Words in Art. 17(2) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F106 Words in Art. 17(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F107 Words in Art. 17(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F108 Words in Art. 17(5) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F109 Words in Art. 17(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F110 Words in Art. 17(6) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F111 Art. 17(7) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 78(5)**; 2020 c. 1, Sch. 5 para. 1(1)

I[F112] Article 17A

NI Product Market Access

1 Subject to paragraphs 5-8, a biocidal product is to be treated as if it was authorised by the competent authority under Article 30 or, where relevant, Article 26, under the same terms and conditions as the product is authorised or permitted in Northern Ireland where—

a each of the following conditions are met—

i the biocidal product—

aa is a qualifying Northern Ireland good, and

bb has a Relevant NI Permission at that time;

ii the authorisation holder or the person with a Relevant NI Permission (as the case may be) is established in Northern Ireland;

iii all the active substances in the biocidal product are entered in—

aa the list prepared pursuant to Article 8A (the GB List), or

bb the list prepared pursuant to Article 24A (the Simplified Active Substance List);

iv the person referred to in point (a)(ii) notifies the competent authority no later than 90 days in advance of making the biocidal product available on the market by submitting in full to the competent authority the information that the person submitted in their application under Regulation (EU) No 528/2012 as it has effect in EU law to the evaluating competent authority, reference Member State or Northern Ireland competent authority (as the case may be), for the Relevant NI Permission together with a copy of any relevant NI authorisation or permit;

v the competent authority takes no action pursuant to paragraph 2;

b if the person referred to in point (a)(ii) intends to make any changes to the product, that person notifies the competent authority no later than 90 days in advance of the date on which such changes will apply, with the information submitted to the reference Member State pursuant to Article 5 of Commission Implementing Regulation (EU) No 354/2013 as it has effect in EU law, or for administrative changes other than those referred to in the second subparagraph of Article 6(2) of that Regulation, that person notifies the competent authority within 12 months of making the change;

c if the person referred to in point (a)(ii) intends to renew the authorisation of the product in Northern Ireland, that person notifies the competent authority no later than 90

days in advance of the date of renewal by submitting in full the information that the person submitted to the reference Member State pursuant to Articles 31(1) or 45(1) of Regulation (EU) No 528/2012 as it has effect in EU law or, where relevant, Article 2 of Commission Delegated Regulation (EU) No 492/2014 as it has effect in EU law.

2 The competent authority may prohibit a biocidal product notified under paragraph 1 from being made available on the market in Great Britain where—

a such action can be justified on any of the following grounds—

i the protection of the environment,

ii public policy or security,

iii the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants,

iv the protection of national treasures possessing artistic, historic or archaeological value,

v the target organisms not being present in harmful quantities, or

b the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

3 The competent authority may amend the terms and conditions under which a biocidal product may be made available on the market in Great Britain where—

a this can be justified on the grounds in paragraph 2(a), or

b the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

4 Where the competent authority intends to take action under paragraphs 2 or 3, or identifies concerns as to whether the biocidal product meets the criteria in Articles 19 or 25, the competent authority—

a must inform the notifier, and

b may request additional information.

5 The period of 90 days referred to in paragraphs 1(a)(iv), (b) and (c) is suspended—

a where the competent authority takes action under paragraph 4(b), until the competent authority receives the additional information, and

b from the point when the competent authority receives the additional information, for a further period of 90 days to allow the competent authority to consider that additional information.

6 Where any information submitted to the competent authority under this Article includes one or more letters of access, the competent authority may reject the letter of access where it does not hold the relevant data.

7 Where the additional information has not been submitted to the competent authority within 90 days of a request under paragraph 4(b), the notification made under paragraph 1 is to be treated as withdrawn.

8 Where the competent authority has amended the terms and conditions under which a biocidal product may be made available on the market under paragraph 3, that product must not be made available and used in Great Britain other than under those amended terms and conditions.

9 Where a biocidal product has been treated as authorised due to meeting the requirements of paragraph 1 but ceases to satisfy those requirements—

a there is deemed to be a cancellation of the authorisation of that product by the competent authority, and

b the period of grace provided for in Article 52 applies.

10 For the purposes of this Article—

a "NI competent authority" means the competent authority appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013;

b "qualifying Northern Ireland good" has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

c "Relevant NI Permission" means any of the following—

i a national authorisation granted by the NI competent authority under Article 30 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 5 of Regulation (EU) No 414/2013 as it has effect in EU law;

ii an authorisation granted by mutual recognition by the NI competent authority under Articles 33 or 34 of Regulation (EU) No 528/2012 as it has effect in EU law;

iii a Union authorisation granted by the Commission under Article 44 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 6 of Regulation (EU) No 414/2013 as it has effect in EU law;

iv an authorisation granted by the NI competent authority under the simplified procedure in accordance with Article 26 of Regulation (EU) No 528/2012 as it has effect in EU law or Article 6a of Regulation (EU) No 414/2013 as it has effect in EU law;

v a biocidal product permitted on the market by the NI competent authority under the Parallel Trade procedure in Article 53(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

vi a critical use permit granted in Northern Ireland under Article 55(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

vii a provisional authorisation under Article 55(2) of Regulation (EU) No 528/2012 as it has effect in EU law;

viii a cultural heritage authorisation granted under Article 55(3) of Regulation (EU) No 528/2012 as it has effect in EU law;

ix an essential use authorisation granted under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013.**]**

Textual Amendments

F112 Art. 17A inserted (31.12.2020) by S.I. 2019/720, Sch. 2 para. 78A (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 27**)

F113 Article 18

Measures geared to the sustainable use of biocidal products

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Textual Amendments

F113 Art. 18 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 79**; 2020 c. 1, Sch. 5 para. 1(1)

Article 19

Conditions for granting an authorisation

1 A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

[[F11]a the active substances are included in **[**[F114]the Simplified Active Substance List**]** or approved for the relevant product-type and any conditions specified for those active substances are met;**]**

b it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;

(ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

(iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— the fate and distribution of the biocidal product in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— the impact of the biocidal product on non-target organisms,

— the impact of the biocidal product on biodiversity and the ecosystem;

c the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

d the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product;

[[F11]e where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93[(37)], Regulation (EC) No 396/2005 of the European

Parliament and of the Council[38], Regulation (EC) No 470/2009 of the European Parliament and of the Council[39] or Directive 2002/32/EC of the European Parliament and of the Council[40], or specific migration limits or limits for the residual content in food contact materials have been established with respect to such active substances in accordance with Regulation (EC) No 1935/2004 of the European Parliament and of the Council[41];**]**

f where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

2 The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

a realistic worst case conditions under which the biocidal product may be used;

b the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

c the consequences of use and disposal of the biocidal product;

d cumulative effects;

e synergistic effects.

3 A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20.

4 A biocidal product shall not be authorised for making available on the market for use by the general public where:

F115a . . . . . .

[F11b it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:

— acute oral toxicity category 1, 2 or 3,

— acute dermal toxicity category 1, 2 or 3,

— acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,

— acute inhalation toxicity (vapours) category 1 or 2,

— specific target organ toxicity by single or repeated exposure category 1,

— a category 1A or 1B carcinogen,

— a category 1A or 1B mutagen, or

— toxic for reproduction category 1A or 1B;

c it consists of, contains or generates, a substance that meets the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;**]**

d it has endocrine-disrupting properties; or

e it has developmental neurotoxic or immunotoxic effects.

5 Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. F116...

[F116 The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health

and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

A biocidal product family shall be authorised only if:

a the application explicitly identifies the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the assessment is based, as well as the permitted variations in composition and uses referred to in point (s) of Article 3(1) together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and

b it can be established based on the assessment referred to in the first subparagraph of this paragraph that all the biocidal products within the family comply with the conditions set out in paragraph 1.

7 Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of maximum residue limits with respect to active substances contained in a biocidal product in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 or Directive 2002/32/EC, or for the establishment of specific migration limits or limits for the residual content in food contact materials with respect to such substances in accordance with Regulation (EC) No 1935/2004.**]**

F1178 . . . . . .

9 Where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009.

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F114 Words in Art. 19(1)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 80(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F115 Art. 19(4)(a) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 80(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F116 Words in Art. 19(5) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 80(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F117 Art. 19(8) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 80(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 20

Requirements for applications for authorisation

1 The applicant for an authorisation shall submit the following documents together with the application:

a for biocidal products other than biocidal products meeting the conditions laid down in Article 25:

i a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;

ii a summary of the biocidal product characteristics including the information referred to in points (a), (b) and (e) to (q) of Article 22(2), as applicable;

iii a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product;

[F118the competent authority may refuse to accept a letter of access for the purposes of this Article if it does not hold the relevant data.**]**

b for biocidal products that the applicant considers meet the conditions laid down in Article 25:

(i) a summary of the biocidal product characteristics as referred to in point (a) (ii) of this paragraph;

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

[F119 2 Applications must be submitted in English.**]**

F120 3 . . . . . .

Textual Amendments

F118 Words in Art. 20(1) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 81(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F119 Art. 20(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 81(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F120 Art. 20(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 81(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 21

Waiving of data requirements

1 By way of derogation from Article 20, the applicant need not provide data required under that Article where any of the following applies:

a the data are not necessary owing to the exposure associated with the proposed uses;

b it is not scientifically necessary to supply the data; or

c it is not technically possible to generate the data.

2 The applicant may propose to adapt the data requirements of Article 20 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

F121 3 . . . . . .

Textual Amendments

F121 Art. 21(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 82**; 2020 c. 1, Sch. 5 para. 1(1)

Article 22

Content of authorisation

1 An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.

2 Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:

a trade name of the biocidal product;

b name and address of the authorisation holder;

c date of the authorisation and its date of expiry;

d authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

e qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %;

f manufacturers of the biocidal product (names and addresses including location of manufacturing sites);

g manufacturers of the active substances (names and addresses including location of manufacturing sites);

h type of formulation of the biocidal product;

i hazard and precautionary statements;

j product-type and, where relevant, an exact description of the authorised use;

k target harmful organisms;

l application doses and instructions for use;

m categories of users;

n particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;

o instructions for safe disposal of the product and its packaging;

p conditions of storage and shelf-life of the biocidal product under normal conditions of storage;

q where relevant, other information about the biocidal product.

Article 23

Comparative assessment of biocidal products

1 The **[**F122competent authority**]** shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).

F123 2 . . . . . .

[F11 3 The **[**F124competent authority **]**, shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment F125... demonstrates that both of the following criteria are met:**]**

a for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;

b the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

4 By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.

F126 5 . . . . . .

6 Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years.

7 Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect four years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F122 Words in Art. 23(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 83(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F123 Art. 23(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 83(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F124 Words in Art. 23(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 83(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F125 Words in Art. 23(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 83(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F126 Art. 23(5) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 83(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F127 Article 24

Technical guidance notes

. . . . . .

Textual Amendments

F127 Art. 24 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 84**; 2020 c. 1, Sch. 5 para. 1(1)

I F128 Article 24A

The Simplified Active Substance List

The competent authority must establish, maintain and make electronically available "the Simplified Active Substance List" of active substances that can be used in products that qualify for the simplified authorisation procedure under Article 25 of this Regulation.**I**

Textual Amendments

F128 Art. 24A inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 85**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER V

SIMPLIFIED AUTHORISATION PROCEDURE

Article 25

Eligibility for the simplified authorisation procedure

For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible if all the following conditions are met:

(a) all the active substances contained in the biocidal product appear in **[**F129the Simplified Active Substance List**]** and satisfy any restriction specified in **[**F130that list**]**;

(b) the biocidal product does not contain any substance of concern;

(c) the biocidal product does not contain any nanomaterials;

(d) the biocidal product is sufficiently effective; and

(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Textual Amendments

F129 Words in Art. 25(1)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 86(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F130 Words in Art. 25(1)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 86(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 26

Applicable procedure

1 Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the **[**F131competent authority**]**, F132....

2 The F133... competent authority shall inform the applicant of the **[**F134appropriate fees**]** and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the **[**F134appropriate fees**]**, the F133... competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

[F1352A Where the application is one to which paragraph 2B applies, paragraph 2 applies as if for "shall inform the applicant of the appropriate fees" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fees".

2B This paragraph applies to—

a an application in respect of a relevant category B product that is resubmitted by virtue of Article 95E; or

b an application that is resubmitted under Article 95FA.

2C A "relevant category B product" is a product containing an active substance falling within category B of the Simplified Active Substance List that before IP completion day was—

a approved; or

b included in Annex 1 to 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.**]**

3 **[**F136Subject to paragraph 3A,**]** within 90 days of accepting an application, the F133... competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25.

[F137 3A Where a relevant application is accepted before 2nd October 2027, the competent authority must authorise the application before 31st December 2027 if it is satisfied that the product meets the conditions laid down in Article 25.

3B In paragraph 3A, "relevant application" is one that is submitted in respect of a product containing an active substance that before IP completion day was—

a approved; or

b included in Annex 1 to 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.**]**

4 Where the F133... competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The F133... competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25.

[F138 Where paragraph 3A applies, the deadline of 31st December 2027 referred to in that paragraph is to be extended by a number of days equal to the number of days beginning with the date on which the competent authority requested additional information and ending with the date on which the information was received by the competent authority plus 90 days.**]**

The F133... competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees F139... shall be reimbursed.

Textual Amendments

F131 Words in Art. 26(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 87(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F132 Words in Art. 26(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 87(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F133 Word in Art. 26 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 87(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F134 Words in Art. 26(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 87(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F135 Art. 26(2A)-(2C) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(2)(a)**

F136 Words in Art. 26(3) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(2)(b)**

F137 Art. 26(3A)(3B) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(2)(c)**

F138 Words in Art. 26(4) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(2)(d)**

F139 Words in Art. 26(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 87(5)**; 2020 c. 1, Sch. 5 para. 1(1)

[F140 Article 27

Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure

. . . . . .

Textual Amendments

F140 Art. 27 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 88**; 2020 c. 1, Sch. 5 para. 1(1)

Article 28

Amendment of [F141 the Simplified Active Substance List]

[F142 1 The competent authority must, after receiving the decision of the Secretary of State, update the Simplified Active Substance List in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article.**]**

2 Active substances give rise to concern where:

a they meet the criteria for classification according to Regulation (EC) No 1272/2008 as:
- explosive/highly flammable,
- organic peroxide,
- acutely toxic of category 1, 2 or 3,
- corrosive of category 1A, 1B or 1C,
- respiratory sensitiser,
- skin sensitiser,
- germ cell mutagen of category 1 or 2;
- carcinogen of category 1 or 2,
- human reproductive toxicant of category 1 or 2 or with effects on or via lactation,
- specific target organ toxicant by single or repeated exposure, or
- toxic to aquatic life of acute category 1;

b they fulfil any of the substitution criteria set out in Article 10(1); or

c they have neurotoxic or immunotoxic properties.

Active substances also give rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

[F143 3 The Secretary of State may agree to the restriction or removal of an entry of an active substance to the Simplified Active Substance List on the recommendation of the competent

authority if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 25.

4 Paragraph 1 or 3 shall apply at the initiative of the Secretary of State or at the request of an economic operator or at the request of a Devolved Authority providing the necessary evidence as referred to in those paragraphs.

5 The Secretary of State may make regulations to further specify the procedures to be followed with respect to the amendment of the Simplified Active Substance List.

6 A decision issued or a function carried out under paragraph 1, 3 or 5 is subject to the consent requirement.

7 Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 5 above, the Secretary of State must have regard to such proposals when deciding whether to exercise functions under that paragraph.**]**

Textual Amendments

F141 Words in Art. 28 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 89(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F142 Art. 28(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 89(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F143 Art. 28(3)-(7) substituted for (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 89(c)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VI

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 29

Submission and validation of applications

1 Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the [F144]... competent authority. The [F144]... competent authority shall inform the applicant of the **[**[F145]appropriate fees**]**, and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the **[**[F145]appropriate fees**]**, the [F144]... competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

[[F146]1A Where the application is one that has been resubmitted by virtue of any of the Articles listed in paragraph 1B, paragraph 1 applies as if for "shall inform the applicant of the appropriate fees" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fees".

1B The Articles are—

a Article 95B;

b Article 95D;

c Article 95F;

d Article 95H.**]**

2 Within 30 days of acceptance, the [F144]... competent authority shall validate the application if **[**[F147]the relevant information referred to in Article 20 has been submitted**]**

[F148]a . . . . . .

[F149]b . . . . . .

In the context of the validation referred to in the first subparagraph, the [F144]... competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

3 Where the [F144]... competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The [F144]... competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in paragraph 2.

The [F144]... competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly.

[F150]4 . . . . . .

5 If paragraph 3 does not apply and the [F144]... competent authority considers that the application is complete, it shall validate the application and without delay inform the applicant accordingly, indicating the date of the validation.

Textual Amendments

F144 Word in Art. 29 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F145 Words in Art. 29(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F146 Art. 29(1A)(1B) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(3)**

F147 Words in Art. 29(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F148 Art. 29(2)(a) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F149 Art. 29(2)(b) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F150 Art. 29(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 90(5)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 30

Evaluation of applications

1 **[**F151Subject to paragraph 1A,**]** the F152... competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

[F153 1A Where an application for a relevant product is validated in accordance with Article 29 before 31st December 2026, the competent authority must decide before 31st December 2027 whether to grant an authorisation in accordance with Article 19. It must take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

1B In paragraph 1A a "relevant product" is a product containing an active substance in respect of which the implementing regulation providing that the substance is approved entered into force before IP completion day.

1C In paragraph 1B "implementing regulation" has the same meaning as in 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 as it had effect immediately before IP completion day.**]**

2 **[**F154Subject to paragraph 2A,**]** where it appears that additional information is necessary to carry out the evaluation, the F152... competent authority shall ask the applicant to submit such information within a specified time limit. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

The F152... competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly.

[F155 2A Where paragraph 1A applies and it appears that additional information is necessary to carry out the evaluation, the competent authority must ask the applicant to submit such information within a specified time limit. The deadline of 31st December 2027 referred to in paragraph 1A is to be extended by a period equal to the number of days beginning with the date on which the applicant is asked for additional information and ending with the date on which that information is received by the competent authority. But the deadline may not be extended by more than 180 days in total, unless it is justified by the nature of the data requested or by exceptional circumstances.

The competent authority must reject the application if the applicant fails to submit the requested information within the specified time limit and must inform the applicant accordingly.**]**

3 **[**F156Subject to paragraph 4,**]** within the 365-day period referred to in paragraph 1, the F152... competent authority shall:

a draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the 'assessment report');

b send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and

c take due account of those comments when finalising its assessment.

[F157 4 Where paragraph 1A applies, the competent authority must comply with the requirements in paragraph 3(a), (b) and (c)—

a before 31st December 2027; or

b where the applicant has been asked to submit additional information under paragraph 2A, before the date to which the deadline of 31st December 2027 has been extended under that paragraph.**]**

Textual Amendments

F151 Words in Art. 30(1) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(a)**

F152 Word in Art. 30 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 91**; 2020 c. 1, Sch. 5 para. 1(1)

F153 Art. 30(1A)-(1C) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(b)**

F154 Words in Art. 30(2) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(c)**

F155 Art. 30(2A) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(d)**

F156 Words in Art. 30(3) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(e)**

F157 Art. 30(4) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(4)(f)**

Article 31

Renewal of a national authorisation

1 An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the **F158**... competent authority at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date.

2 The **F158**... competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

3 When applying for renewal, the applicant shall submit:

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

b its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

4 The **F158**... competent authority shall inform the applicant of the **[**F159 appropriate fees**]** and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the **[**F159 appropriate fees**]**, the **F158**... competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

5 On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the [F158]... competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

6 Where the [F158]... competent authority decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 30.

Where the [F158]... competent authority decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of this Article.

7 Where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the [F158]... competent authority shall grant a renewal for the period necessary to complete the evaluation.

Textual Amendments

F158 Word in Art. 31 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 92(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F159 Words in Art. 31(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 92(b)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VII

MUTUAL RECOGNITION PROCEDURES

[F160]*Article 32*

Authorisation through mutual recognition

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

[F160]*Article 33*

Mutual recognition in sequence

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 34

Mutual recognition in parallel

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 35

Referral of objections to the coordination group

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 36

Referral of unresolved objections to the Commission

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 37

Derogations from mutual recognition

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 38

Opinion of the Agency

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 39

Application for mutual recognition by official or scientific bodies

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 40

Supplementary rules and technical guidance notes

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VIII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

SECTION 1

Granting of Union authorisations

F160 Article 41

Union authorisation

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 42

Biocidal products for which Union authorisation may be granted

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 43

Submission and validation of applications

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 44

Evaluation of applications

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2

Renewal of Union authorisations

F160 Article 45

Submission and acceptance of applications

. . . . . .

Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

F160 Article 46

Evaluation of applications for renewal

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Textual Amendments

F160 Arts. 32-46 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 93**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IX

CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

Article 47

Obligation for notification of unexpected or adverse effects

1 On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, that may affect the authorisation, the holder of an authorisation shall without delay notify the competent authority [F161].... In particular, the following shall be notified:

a new data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, animals or the environment;

b any data indicating the potential of the active substance for the development of resistance;

c new data or information indicating that the biocidal product is not sufficiently effective.

2 The competent authority [F162]..., shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

[F163]3 . . . . . .

Textual Amendments

F161 Words in Art. 47(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 94(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F162 Words in Art. 47(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 94(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F163 Art. 47(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 94(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 48

Cancellation or amendment of an authorisation

1 Without prejudice to Article 23, the competent authority [F164]... shall at any time cancel or amend an authorisation it has granted where it considers that:

a the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;

b the authorisation was granted on the basis of false or misleading information; or

c the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

2 Where the competent authority [F165]... intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The **[**[F166]competent authority**]** shall take due account of those comments when finalising its decision.

3 Where the competent authority [F167]... cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder [F168]....

[F169]...

[F170]...

Textual Amendments

F164 Words in Art. 48(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F165 Words in Art. 48(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F166 Words in Art. 48(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F167 Words in Art. 48(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F168 Words in Art. 48(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F169 Words in Art. 48(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F170 Words in Art. 48(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 95(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 49

Cancellation of an authorisation at the request of the authorisation holder

At the reasoned request of an authorisation holder, the competent authority [F171]... shall cancel the authorisation. [F172]...

Textual Amendments

F171 Words in Art. 49 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 96(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F172 Words in Art. 49 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 96(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 50

Amendment of an authorisation at the request of the authorisation holder

F173 1 . . . . . .

2 An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent **[**F174authority**]**. **[**F175The competent authority shall**]** decide whether the conditions of Article 19 or, where relevant, Article 25 are still met and whether the terms and conditions of the authorisation need to be amended.

The application shall be accompanied by the **[**F176appropriate fees**]**.

3 An amendment to an existing authorisation shall fall under one of the following categories of changes:

a administrative change;

b minor change; or

c major change.

Textual Amendments

F173 Art. 50(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 97(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F174 Word in Art. 50(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 97(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F175 Words in Art. 50(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 97(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F176 Words in Art. 50(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 97(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F177 Article 51

Detailed rules

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Textual Amendments

F177 Art. 51 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 98**; 2020 c. 1, Sch. 5 para. 1(1)

[F11 Article 52

Period of grace

Notwithstanding Article 89, where the competent authority F178... cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

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

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F178 Words in Art. 52 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 99**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER X

PARALLEL TRADE

F179 Article 53

Parallel trade

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Textual Amendments

F179 Art. 53 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 100**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XI

TECHNICAL EQUIVALENCE

Article 54

Assessment of technical equivalence

[F11 1 Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the **[**F180 competent authority**]**.**]**

2 The applicant shall submit all data that the **[**F180 competent authority**]** requires to assess technical equivalence.

[F11 3 The **[**F180 competent authority**]** shall inform the applicant of the **[**F181 appropriate fees**]** and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.**]**

4 After giving the applicant the opportunity to submit comments, the **[**F180 competent authority**]** shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it F182 ... to the applicant.

5 Where, in the opinion of the **[**F180 competent authority**]**, additional information is necessary to carry out the assessment of technical equivalence, the **[**F180 competent authority**]** shall ask the applicant to submit such information within a time limit specified by the **[**F180 competent authority**]**. The **[**F180 competent authority**]** shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

F183 6 . . . . . .

7 An appeal may be brought, in accordance with Article 77, against decisions of the **[**F180 competent authority**]** under paragraphs 3, 4 and 5 of this Article.

F184 8 . . . . . .

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F180 Words in Art. 54 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 101(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F181 Words in Art. 54(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 101(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F182 Words in Art. 54(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 101(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F183 Art. 54(6) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 101(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F184 Art. 54(8) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 101(e)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XII

DEROGATIONS

I[F185] Article 55

Derogation from the requirements

1 By way of derogation from Articles 17 and 19, the 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 this 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.

On receipt of a reasoned request from the competent authority, the Secretary of State or a Devolved Authority shall issue a decision, with or without conditions, on whether the action taken may be extended for a period not exceeding 550 days if they have competence to exercise the derogation within the meaning in paragraphs 4 to 8.

2 By way of derogation from point (a) of Article 19(1) and until an active substance is approved, the competent authority may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the competent authority has produced an assessment report and evaluation conclusions on the new active substance and consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

If the Secretary of State decides not to approve the new active substance, the competent authority shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been made by the Secretary of State when the period of three years expires, the competent authority may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

3 By way of derogation from point (a) of Article 19(1), the Secretary of State or a Devolved Authority shall issue a decision allowing the competent authority to authorise a biocidal product containing a non-approved active substance if the Secretary of State or a Devolved Authority is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. To obtain such a derogation, the competent authority shall apply to the Secretary of State or a Devolved Authority providing due justification.

4. The Secretary of State has competence to grant a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure—

a relates to England;

b relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);

c relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

5. The Scottish Ministers have competence to grant a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

6. The Welsh Ministers have competence to exercise a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

7. Where the Secretary of State grants a derogation, the Secretary of State must immediately inform the Devolved Authorities giving reasons for the decision. Where a Devolved Authority exercises a derogation, it must immediately inform the other Devolved Authority and the Secretary of State giving reasons for the decision.**]**

Textual Amendments

F185 Art. 55 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 102** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 28**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 56

Research and development

[F11 1 By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ('experiment' or 'test') may take place only under the conditions provided for in this Article.**]**

Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.

2 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 competent authority F186.... 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 available any other information requested by the competent **[**F187authority**]**.

In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.

3 If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the **[**F188competent authority**]** may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. F189...

F190 4 . . . . . .

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F186 Words in Art. 56(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 103(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F187 Word in Art. 56(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 103(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F188 Words in Art. 56(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 103(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F189 Words in Art. 56(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 103(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F190 Art. 56(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 103(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 57

Exemption from registration under Regulation (EC) No 1907/2006

In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products authorised for placing on the market in accordance with Article F191... 55 or 56 shall be regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of Regulation (EC) No 1907/2006.

Textual Amendments

F191 Word in Art. 57 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 104**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XIII

TREATED ARTICLES

Article 58

Placing on the market of treated articles

1 This Article shall apply exclusively to treated articles that are not biocidal products. It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

2 A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in **[**F192the Simplified Active Substance List**]**, and any conditions or restrictions specified therein are met.

[F113 The person responsible for the placing on the market of a treated article shall ensure that the label provides the information listed in the second subparagraph, where:**]**

— in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or

— in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.

The label referred to in the first subparagraph shall provide the following information:

a a statement that the treated article incorporates biocidal products;

b where substantiated, the biocidal property attributed to the treated article;

c without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

d the name of all nanomaterials contained in the biocidal products, followed by the word ‘nano’ in brackets;

e any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.

4 Notwithstanding the labelling requirements set out in paragraph 3, 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, animals and the environment.

5 Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article.

6 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 **[**F193English**]**. In the case of treated articles that 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.

[F194]7 . . . . . .

8 Where there are significant indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), Article 5(2) or Article 25, **[**[F195]the Secretary of State**]** shall review the approval of that active substance or its inclusion in **[**[F196]the Simplified Active Substance List**]** in accordance with Article 15(1) or Article 28(2).

[[F197]9 Where any of the Devolved Authorities proposes that an active substance should be reviewed in accordance with paragraph 8 above, the Secretary of State shall have regard to such proposals in deciding whether to review the active substance.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F192 Words in Art. 58(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F193 Word in Art. 58(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F194 Art. 58(7) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F195 Words in Art. 58(8) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F196 Words in Art. 58(8) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F197 Art. 58(9) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 105(6)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XIV

DATA PROTECTION AND DATA-SHARING

Article 59

[[F198]**Protection of data held by the competent authority]**

1 Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by **[**[F199]the competent authority**]** for the benefit of a subsequent applicant, except where:

a the subsequent applicant submits a letter of access; or

b the relevant time limit for data protection has expired.

2 When submitting data to **[**F200the**]** competent authority F201... for the purposes of this Regulation the applicant shall, where relevant, indicate the name and contact details of the data owner for all data submitted. The applicant shall also specify whether it is the data owner or holds a letter of access.

3 The applicant shall, without delay, inform the competent authority F202... about any changes to the ownership of the data.

F2034 . . . . . .

Textual Amendments

F198 Art. 59 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F199 Words in Art. 59(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F200 Word in Art. 59(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F201 Words in Art. 59(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F202 Words in Art. 59(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F203 Art. 59(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 106(6)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 60

Data protection periods

1 Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.

Data protected under this Article or for which the protection period under this Article has expired shall not be protected again.

2 The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of

adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end five years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

[[F11]3 The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3) **[**[F204]or 30(1)**]**.

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3) **[**[F204]or 30(1)**].]**

The protection period for new data submitted with a view to the renewal or amendment of the authorisation of a biocidal product shall end five years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.

[[F205]4 The protection period for data submitted for biocidal products containing only existing active substances which were authorised in the United Kingdom prior to IP completion day shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5) of this Regulation as it had effect immediately before IP completion day.

5 The protection period for data submitted for biocidal products containing a new active substance which were authorised in the United Kingdom prior to IP completion day shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5) of this Regulation as it had effect immediately before IP completion day.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F204 Words in Art. 60(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 107(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F205 Art. 60(4)(5) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 107(3)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 29**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 61

Letter of access

1 A letter of access shall contain at least the following information:

a the name and contact details of the data owner and the beneficiary;

b the name of the active substance or biocidal product for which access to the data is authorised;

c the date on which the letter of access takes effect;

d a list of the submitted data to which the letter of access grants citation rights.

2 Revocation of a letter of access shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

Article 62

Data sharing

1 In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation.

2 Any person intending to perform tests or studies ('the prospective applicant')

a shall, in the case of data involving tests on vertebrates; and

b may, in the case of data not involving tests on vertebrates,

submit a written request to the **[**F206competent authority**]** to determine whether such tests or studies have already been submitted to the F207... competent authority in connection with a previous application under this Regulation **[**F208or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day**]** or Directive 98/8/EC. **[**F209The competent authority must**]** verify whether such tests or studies have already been submitted **[**F210and whether the competent authority has access to the tests or studies**]**.

Where such tests or studies have already been submitted to the F211... competent authority in connection with a previous application, under this Regulation **[**F212or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day**]** or Directive 98/8/EC, **[**F213and where the competent authority has access to the tests or studies the competent authority must**]**, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant.

The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner.

Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant:

a shall, in the case of data involving tests on vertebrates; and

b may, in the case of data not involving tests on vertebrates,

request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.

Textual Amendments

F206 Words in Art. 62(2) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(a)(i)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F207 Words in Art. 62(2) omitted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(a)(ii)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F208 Words in Art. 62(2) inserted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(a)(iii)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F209 Words in Art. 62(2) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(a)(iv)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F210 Words in Art. 62(2) inserted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(a)(v)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F211 Words in Art. 62(2) omitted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(b)(i)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F212 Words in Art. 62(2) inserted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(b)(ii)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

F213 Words in Art. 62(2) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 108(b)(iii)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**)

Article 63

Compensation for data sharing

1 Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.

2 Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation.

3 Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the **[**F214competent authority**]** and the data owner thereof, at the earliest one month after the prospective applicant receives the name and address of the data submitter from the **[**F214competent authority**]**.

Within 60 days of being informed, the **[**F214competent authority**]** shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred. Where the prospective applicant and data owner cannot agree,

national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.

The data owner shall not refuse to accept any payment offered pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court, in accordance with the second subparagraph.

4 Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner, having regard to the guidance **[**F215either specified or referred to by the competent authority**]**. The prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of this Regulation.

5 An appeal may be brought, in accordance with Article 77, against decisions of the **[**F216competent authority**]** under paragraph 3 of this Article.

Textual Amendments

F214 Words in Art. 63(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 109(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F215 Words in Art. 63(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 109(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F216 Words in Art. 63(5) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 109(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 64

Use of data for subsequent applications

1 Where the relevant data protection period according to Article 60 has expired in relation to an active substance, **[**F217the competent authority**]** may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant **[**F218, where the data was provided to the competent authority,**]** in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.

Where the relevant data protection period according to Article 60 has expired in relation to a biocidal product, **[**F217the competent authority**]** may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant **[**F218, where the data was provided to the competent authority,**]** in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.

An appeal may be brought, in accordance with Article 77, against decisions of the **[**F219competent authority**]** under the first and second subparagraphs of this paragraph.

2 Notwithstanding paragraph 1, subsequent applicants shall provide the following data accordingly to the **[**F220competent authority**]**F221...:

a all necessary data for the identification of the biocidal product, including its composition;

b the data needed to identify the active substance and to establish technical equivalence of the active substance;

c the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of the authorised biocidal product.

Textual Amendments

F217 Words in Art. 64(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 110(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F218 Words in Art. 64(1) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 110(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F219 Words in Art. 64(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 110(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F220 Words in Art. 64(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 110(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F221 Words in Art. 64(2) omitted (1.11.2022) by virtue of The Chemicals (Health and Safety) Trade and Miscellaneous Amendments Regulations 2022 (S.I. 2022/1037), regs. 1(2), **9(3)**

CHAPTER XV

INFORMATION AND COMMUNICATION

SECTION 1

Monitoring and reporting

Article 65

Compliance with requirements

1 **[**F222The competent authority**]** shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(42)] shall apply accordingly.

2 **[**F223The competent authority**]** shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.

In order to facilitate such enforcement, manufacturers of biocidal products placed **[**F224on the market in Great Britain**]** shall maintain, in relation to the manufacturing process,

appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

a safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

b records of the various manufacturing operations performed;

c results of internal quality controls;

d identification of production batches.

F225...

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and **[**F226the competent authority**]**.

F2273 . . . . . .

F2284 . . . . . .

Textual Amendments

F222 Words in Art. 65(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F223 Words in Art. 65(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F224 Words in Art. 65(2) substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 111(3)(b)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 31**)

F225 Words in Art. 65(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F226 Words in Art. 65(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(3)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F227 Art. 65(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F228 Art. 65(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 111(5)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 66

Confidentiality

F2291 . . . . . .

2 The **[**F230competent authority**]** shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned:

a details of the full composition of a biocidal product;

b the precise tonnage of the active substance or biocidal product manufactured or made available on the market;

c links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

d names and addresses of persons involved in testing on vertebrates.

However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the **[**F231competent authority**]** shall disclose the information referred to in this paragraph.

3 Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

a the name and address of the authorisation holder;

b the name and address of the biocidal product manufacturer;

c the name and address of the active substance manufacturer;

d the content of the active substance or substances in the biocidal product and the name of the biocidal product;

e physical and chemical data concerning the biocidal product;

f any methods for rendering the active substance or biocidal product harmless;

g a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

h recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;

i safety data sheets;

j methods of analysis referred to in Article 19(1)(c);

k methods of disposal of the product and of its packaging;

l procedures to be followed and measures to be taken in the case of spillage or leakage;

m first aid and medical advice to be given in the case of injury to persons.

[F114 Any person submitting information related to an active substance or a biocidal product to the F232... competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F229 Art. 66(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 112(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F230 Words in Art. 66(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 112(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F231 Words in Art. 66(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 112(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F232 Words in Art. 66(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 112(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 67

Electronic public access

[F11 1 From the date on which the **[**F233 Secretary of State issues a decision**]** providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information **[**F234, where**]** held by the **[**F235 competent authority**]** on that active substance shall be made publicly and easily available free of charge:**]**

a where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;

b if applicable, the name as given in the European Inventory of Existing Commercial Chemical Substances;

c the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);

d physicochemical endpoints and data on pathways and environmental fate and behaviour;

e the result of each toxicological and ecotoxicological study;

f acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;

g the guidance on safe use provided in accordance with Annexes II and III;

h analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.

2 **[**F236 From the date on which a biocidal product is authorised, the following up-to-date information, where held by the competent authority, shall be made publicly and easily available free of charge—**]**

a the terms and conditions of the authorisation;

b the summary of the biocidal product characteristics; and

c analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.

[F11 3 From the date on which the **[**F237 Secretary of State issues a decision**]** providing that an active substance is approved, as referred to in point (a) of Article 9(1), the **[**F238 competent authority**]** shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority F239 ... as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information **[**F240 where held by the competent authority**]** on that active substance:**]**

a if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;

b the study summaries or robust study summaries of studies submitted to support the approval of the active substance;

c information, other than that listed in paragraph 1 of this Article, contained in the safety data sheet;

d the trade name(s) of the substance;

e the assessment report.

4 From the date on which a biocidal product is authorised, the **[**F241competent authority**]** shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority F242... as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information **[**F243where held by the competent authority**]**:

a study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and

b the assessment report.

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F233 Words in Art. 67(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F234 Word in Art. 67(1) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F235 Words in Art. 67(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F236 Words in Art. 67(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F237 Words in Art. 67(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F238 Words in Art. 67(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F239 Words in Art. 67(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F240 Words in Art. 67(3) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F241 Words in Art. 67(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F242 Words in Art. 67(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F243 Words in Art. 67(4) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 113(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 68

Record-keeping and reporting

1 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. They shall make available the relevant information contained in these records to the competent authority on request.

F244 2 . . . . . .

Textual Amendments

F244 Art. 68(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 114**; 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2

Information about biocidal products

Article 69

Classification, packaging and labelling of biocidal products

1 Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2) F245... and, where applicable, Regulation (EC) No 1272/2008.

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

2 In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or similar indications. In addition, the label must show clearly and indelibly the following information:

a the identity of every active substance and its concentration in metric units;

b the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

c the authorisation number allocated to the biocidal product by the competent authority [F246]...;

d the name and address of the authorisation holder;

e the type of formulation;

f the uses for which the biocidal product is authorised;

g directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorisation;

h particulars of likely direct or indirect adverse side effects and any directions for first aid;

i if accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups;

j directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;

k the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

l where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

m where applicable, the categories of users to which the biocidal product is restricted;

n where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;

o for biocidal products containing micro-organisms, labelling requirements in accordance with **[**[F247]the Control of Substances Hazardous to Health Regulations 2002**]**.

By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (e), (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3 **[**[F248]The competent authority**]** may require:

a the provision of models or drafts of the packaging, labelling and leaflets;

b that biocidal products made available on the market **[**[F249]be labelled in English**]**.

Textual Amendments

F245 Words in Art. 69(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 115(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F246 Words in Art. 69(2)(c) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 115(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F247 Words in Art. 69(2)(o) substituted (31.12.2020) by virtue of S.I. 2019/720, Sch. 2 para. 115(3)(b) (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 32**)

F248 Words in Art. 69(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 115(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F249 Words in Art. 69(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 115(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F250 Article 70

Safety data sheets

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Textual Amendments

F250 Art. 70 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 116**; 2020 c. 1, Sch. 5 para. 1(1)

Article 71

[F251 Exchange of information]

[F252 1 The competent authority shall establish and maintain a system for the exchange of information between the competent authority and applicants.]

F253 2 . . . . . .

3 Applicants shall use the [F254 system referred to in paragraph 1] to submit applications and data for all procedures covered by this Regulation.

4 Upon submission of applications and data by applicants, the [F255 competent authority] shall check that these have been submitted in the correct format F256 ....

Where the [F255 competent authority] decides that the application has not been submitted in the correct format, it shall reject the application and inform the applicant accordingly.

F257 5 . . . . . .

F257 6 . . . . . .

F257 7 . . . . . .

F257 8 . . . . . .

F257 9 . . . . . .

Textual Amendments

F251 Art. 71 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F252 Art. 71(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F253 Art. 71(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F254 Words in Art. 71(3) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F255 Words in Art. 71(4) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F256 Words in Art. 71(4) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F257 Art. 71(5)-(9) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 117(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 72

Advertising

1 Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences ‘Use biocides safely. Always read the label and product information before use.’. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2 Advertisers may replace the word ‘biocides’ in the prescribed sentences with a clear reference to the product-type being advertised.

3 Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or any similar indication.

Article 73

Poison control

Article 45 of Regulation (EC) No 1272/2008 shall apply for the purposes of this Regulation.

CHAPTER XVI

THE AGENCY

[F258] *Article 74*

Role of the Agency

. . . . . .

Textual Amendments

F258 Arts. 74-76 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 118**; 2020 c. 1, Sch. 5 para. 1(1)

[F258] *Article 75*

Biocidal Products Committee

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Textual Amendments

F258 Arts. 74-76 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 118**; 2020 c. 1, Sch. 5 para. 1(1)

[F258] *Article 76*

Secretariat of the Agency

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Textual Amendments

F258 Arts. 74-76 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 118**; 2020 c. 1, Sch. 5 para. 1(1)

[F259 Article 77

Appeals

1 Decisions of the competent authority taken pursuant to this Regulation may be appealed against in accordance with regulation 14 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

2 Fees may be payable as appropriate by the person bringing an appeal.

3 An appeal lodged pursuant to paragraph 1 shall have suspensive effect.**]**

Textual Amendments

F259 Art. 77 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 119** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 33**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F260 Article 78

The budget of the Agency

. . . . . .

Textual Amendments

F260 Art. 78 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 120**; 2020 c. 1, Sch. 5 para. 1(1)

[F261 Article 79

Formats for submission of information to the competent authority

The competent authority shall specify formats for submission of information. Applicants shall use these formats in their submissions to the competent authority pursuant to this Regulation.**]**

Textual Amendments

F261 Art. 79 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 121**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XVII

FINAL PROVISIONS

[F262 Article 80

Fees and charges

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Textual Amendments

F262 Art. 80 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 122**; 2020 c. 1, Sch. 5 para. 1(1)

Article 81

[F263The competent authority]

[F264]1 The competent authority responsible for the application of this Regulation—

a is the competent authority as appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013, and

b must have a sufficient number of suitably qualified and experienced staff to enable the obligations provided for in this Regulation to be carried out efficiently and effectively. **]**

2 **[**F265The competent authority**]** shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Regulation. That shall include the provision of advice about the possibility of adapting the data requirements of Articles 6 and 20, the grounds on which such an adaptation can be made, and on how to prepare a proposal. F266...

[F267The competent authority**]** may in particular provide advice by establishing **[**F268a helpdesk**]**. Helpdesks already established under Regulation (EC) No 1907/2006 may act as helpdesks under this Regulation.

F269]3 . . . . . .

Textual Amendments

F263 Art. 81 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F264 Art. 81(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(3)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 34**); 2020 c. 1, **Sch. 5 para. 1(1)**

F265 Words in Art. 81(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F266 Words in Art. 81(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F267 Words in Art. 81(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(4)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F268 Words in Art. 81(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(4)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F269 Art. 81(3) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 123(4)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F270 Article 82

Committee procedure

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Textual Amendments

F270 Art. 82 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 124**; 2020 c. 1, Sch. 5 para. 1(1)

F271 Article 83

Exercise of the delegation

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Textual Amendments

F271 Art. 83 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 124**; 2020 c. 1, Sch. 5 para. 1(1)

I F272 Article 83A

Regulation procedure

1. Regulations made by the Secretary of State under this Regulation are to be made by statutory instrument.

2. Such regulations may—

a contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);

b make different provision for different purposes.

3. A statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

Textual Amendments

F272 Arts. 83A, 83B inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 125** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 35**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 83B

The consent requirement

1. Where any provision of this Regulation states that a function is subject to the consent requirement, the function may be exercised in a particular instance only if the person exercising it has obtained the consent or consents (if any) required by paragraphs 2 and 3.

2. The consent of the Scottish Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998) whether or not the exercise of the function also relates to a part of the United Kingdom other than Scotland.

3. The consent of the Welsh Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.**]**

Textual Amendments

F272 Arts. 83A, 83B inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 125** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 35**); 2020 c. 1, **Sch. 5 para. 1(1)**

F273 Article 84

Urgency procedure

. . . . . .

Textual Amendments

F273 Art. 84 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 124**; 2020 c. 1, Sch. 5 para. 1(1)

***[F274** Article 85*

Adaptation to scientific and technical progress

1. The Secretary of State may by regulations amend Annexes II, III and IV to this Regulation to take account of current scientific and technical knowledge.**]**

2. Regulations made under paragraph 1 above shall be subject to the consent requirement.

Textual Amendments

F274 Art. 85 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 126**; 2020 c. 1, Sch. 5 para. 1(1)

[F11 Article 86

Active substances included in Annex I to Directive 98/8/EC

Active substances **[**[F275]included**]** in Annex I to Directive 98/8/EC shall be deemed to have been approved under this Regulation on the date of inclusion and shall be included in the list referred to in Article 9(2). Approval shall be subject to the conditions set out in those Commission directives.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F275 Word in Art. 86 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 127**; 2020 c. 1, Sch. 5 para. 1(1)

[F276 Article 87

Penalties

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Textual Amendments

F276 Art. 87 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 128**; 2020 c. 1, Sch. 5 para. 1(1)

[F277 Article 88

Safeguard clause

1. Where on the basis of new evidence the competent authority has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment, it may take appropriate provisional measures.

2. The Secretary of State or a Devolved Authority shall issue a decision to either permit the provisional measure for a time period defined in the decision or require the competent

authority to revoke the provisional measure if they have competence to issue the decision within the meaning in paragraphs 3 to 5.

3. The Secretary of State has competence to issue a decision if, or to the extent that, the exercise of the function to take that measure—

a relates to England;

b relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);

c relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

4. The Scottish Ministers have competence to issue the decision if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

5. The Welsh Ministers have competence to issue a decision if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

6. Where the Secretary of State issues the decision under paragraph 2 the Secretary of State must immediately inform the Devolved Authorities giving reasons for the decision. Where a Devolved Authority issues the decision under paragraph 2, it must immediately inform the other Devolved Authority and the Secretary of State giving reasons for the decision.**]**

Textual Amendments

F277 Art. 88 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 129** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 36**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F278 Article 89

Existing transitional measures

1. The competent authority shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 31 December 2024.

2. The Secretary of State may by regulations—

a extend the date for the systematic examination of all existing active substances referred to in this Article;

b specify matters in relation to the carrying out of the work programme and the related rights and obligations of the competent authority and the participants in the programme.

3. Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 2, the Secretary of State must have regard to such proposals in deciding whether to exercise functions under that paragraph.

4. Regulations made under paragraph 2 above are subject to the consent requirement.

5. In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Secretary of State shall either issue decisions providing that an

active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, issue decisions stating that an active substance is not approved. Decisions approving an active substance shall specify the date of approval. Article 9(2) shall apply.

6. A decision made under paragraph 5 is subject to the consent requirement.

7. **[**F279Subject to paragraph 7A,**]** by way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1, 2 and 9 of this Article, the current system or practice of making available on the market or using a given biocidal product continues to apply for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The competent authority may, in accordance with the current system or practice, authorise the making available on the market or use of a biocidal product containing only—

a existing active substances which—

i have been evaluated under Commission Regulation (EC) No 1062/2014 but which have not yet been approved of that product-type;

ii are being evaluated under that Regulation but have not yet been approved for that product-type; or

b a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

[F280 7A By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1, 2 and 9 of this Article, where paragraph 7B or 7C applies the current system or practice of making available on the market or using a biocidal product is to apply until the relevant date or, if earlier, the date on which the product is authorised under this Regulation. The competent authority may, in accordance with the current system or practice, authorise the making available on the market or use of the biocidal product.

7B This paragraph applies to a biocidal product—

a that contains at least one existing active substance that was approved before IP completion day; and

b the application in respect of which—

i is one to which a relevant provision applies;

ii was received no later than the date of approval of the last of the active substances to be approved for that product-type; and

iii was resubmitted by virtue of Article 95B, 95D, 95E, 95F, 95FA or 95H.

7C This paragraph applies to a biocidal product—

a that contains at least one active substance in respect of which the implementing regulation providing that the substance is approved entered into force before IP completion day;

b to which paragraph 7B does not apply; and

c the application in respect of which—

i is one to which a relevant provision applies;

ii was received no later than the date of approval of the last of the active substances to be approved for that product-type; and

iii was received after IP completion day.**]**

8. By way of derogation from **[**F281paragraphs 7 and 7A**]**, in the case of a decision not to approve an active substance, the competent authority may continue to apply its current system

or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with paragraph 5, and may continue to apply the current system or practice of using biocidal products for up to 18 months after that decision.

9. Following a decision to approve a particular active substance for a specific product-type, the competent authority shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval **[**F282or, where paragraph 7A applies, before the relevant date**]**.

To that effect, those wishing to apply for the authorisation of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation no later than the date of approval of the active substance or substances. In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type.

[F2839A Where, in relation to a particular case the application in respect of which is one to which a relevant provision applies, the deadline by which a competent authority must authorise a biocidal product is extended under Article 26(4), Article 29(3) or Article 30(2A), the relevant date for the purposes of paragraphs 7A and 9 is to be extended by the same number of days in relation to that particular case.**]**

10. Where no application for authorisation has been submitted in accordance with paragraph 9 above—

a the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance or substances; and

b use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance or substances.

11. Where the competent authority decides to reject an application submitted in accordance with paragraph 9 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply—

a a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the competent authority; and

b use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the competent authority.**]**

[F28412 In this Article—

"implementing regulation" has the same meaning as in 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 as it had effect immediately before IP completion day;

"relevant date" means—

a where Article 26(2A) applies, 29th April 2028;

b where Article 26(3A) or 30(1A) applies, 31st December 2027;

c where Article 29(1A) applies, 1st March 2029; or

d where Article 5(2) or 6A(1A) of Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council applies, 31st December 2027;

"relevant provision" means—

a Article 26(2A);

b Article 26(3A);

c Article 29(1A);

d Article 30(1A);

e Article 5(2) of Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; or

f Article 6A(1A) of that Regulation.**]**

Textual Amendments

F278 Art. 89 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 130**; 2020 c. 1, Sch. 5 para. 1(1)

F279 Words in Art. 89(7) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(a)**

F280 Art. 89(7A)-(7C) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(b)**

F281 Words in Art. 89(8) substituted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(c)**

F282 Words in Art. 89(9) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(d)**

F283 Art. 89(9A) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(e)**

F284 Art. 89(12) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(5)(f)**

Article 90

Transitional measures concerning active substances evaluated under Directive 98/8/EC

F2851 . . . . . .

2 Applications submitted for the purposes of Directive 98/8/EC for which the **F286**... evaluation in accordance with Article 11(2) of Directive 98/8/EC **[F287**had**]** not been completed by 1 September 2013 shall be evaluated by the competent **[F288**authority**]** in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No **[F289**1062/2014**]**.

That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Every effort shall be made to avoid additional testing on vertebrates and to avoid causing delays to the review programme laid down in Regulation (EC) No **[**F289**]**1062/2014**]** as a result of these transitional arrangements.

F290 …

Textual Amendments

F285 Art. 90(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F286 Words in Art. 90(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F287 Word in Art. 90(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F288 Word in Art. 90(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F289 Word in Art. 90(2) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(3)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F290 Words in Art. 90(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 131(3)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 91

Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC

Applications for biocidal product authorisations submitted for the purposes of Directive 98/8/EC for which the evaluation **[**F291**]**had**]** not been completed by 1 September 2013 shall be evaluated by the competent **[**F292**]**authority**]** in accordance with that Directive.

Notwithstanding the first paragraph, the following shall apply:

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5(1) is met, the biocidal product shall be authorised in accordance with Article 19,

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Textual Amendments

F291 Word in Art. 91 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 132(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F292 Word in Art. 91 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 132(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 92

Transitional measures concerning biocidal products authorised/registered under Directive 98/8/EC

1 Biocidal products for which an authorisation or registration in accordance with Article 3, 4, 15 or 17 of Directive 98/8/EC was granted before 1 September 2013 can continue to be made available on the market and used subject, where applicable, to any conditions of authorisation or registration stipulated under that Directive until the expiry date of the authorisation or registration or its cancellation.

[F293 1A. The competent authority may request further data relating to the original authorisation as necessary.

1B. It is the duty of the authorisation holder to provide the necessary data within 60 days of such a request.

1C. The competent authority may cancel the authorisation if this Article is not complied with and the period of grace set out in the second paragraph of Article 52 shall apply.**]**

2 Notwithstanding paragraph 1, this Regulation shall apply to biocidal products referred to in that paragraph from 1 September 2013.

[F294 Biocidal products authorised in accordance with Article 3 or 4 of Directive 98/8/EC shall be considered as authorised in accordance with Article 17 of this Regulation.**]**

Textual Amendments

F293 Art. 92(1A)-(1C) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 133**; 2020 c. 1, Sch. 5 para. 1(1)

F294 Inserted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

[F11 Article 93

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

By way of derogation from Article 17(1), **[**F295the**]** current system or practice of making available on the market and using a biocidal product not covered by the scope of Directive 98/8/EC, but falling within the scope of this Regulation, and consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013 **[**F296, shall continue to apply—**]**F297...

(a) where applications for approval of all those active substances, which the biocidal product consists of, contains or generates, **[**F298were**]** submitted for the relevant product-type by 1 September 2016, the deadlines provided for in the second subparagraph **[**F299Article 89(7), in Article 89(8) to (10) and in Article 89(11); or**]**

(b) where an application **[**F300was**]** not submitted in accordance with point (a) for one of the active substances, until 1 September 2017.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F295 Word in Art. 93 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F296 Words in Art. 93 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F297 Words in Art. 93 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F298 Word in Art. 93(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F299 Words in Art. 93(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F300 Word in Art. 93(b) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 134(4)**; 2020 c. 1, Sch. 5 para. 1(1)

[F11 Article 94

Transitional measures concerning treated articles

1 By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1)

on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in **[**F301the Simplified Active Substance List**]**, may be placed on the market until one of the following dates:

a in the case of a decision adopted **[**F302by the Commission after 1 September 2016 but before IP completion day or issued by the Secretary of State after IP completion day**]** to reject the application for approval of, or not to approve, one of the active substances for the relevant use, the date falling 180 days after such a decision;

b in other cases, the date of approval for the relevant product-type and use of the last active substance to be approved and contained in the biocidal product.

F3032 . . . . . .

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F301 Words in Art. 94(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 135(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F302 Words in Art. 94(1)(a) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 135(2)(b)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 37**); 2020 c. 1, **Sch. 5 para. 1(1)**

F303 Art. 94(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 135(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 95

Transitional measures concerning access to the active substance dossier

1 **[**F304The competent authority**]** shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ('the complete substance dossier') **[**F305is**]** submitted and accepted or validated by **[**F306the competent authority**]** in a procedure provided for by this Regulation or that Directive ('the relevant substances'). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the **[**F307competent authority**]** in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, and the product-type(s) for which they have made a submission, as well as the date of inclusion of the substance in the list.

A person established within the **[**F308United Kingdom**]** who manufactures or imports a relevant substance, on its own or in biocidal products ('the substance supplier') or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ('the product supplier'), may at any time submit to the **[**F309competent authority**]** either a complete substance dossier for that relevant substance, a **[**F310letter of access which provides the competent authority with

access to a complete substance dossier**]**, or a reference to a complete substance dossier for which all data protection periods have expired. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the **[**F309competent authority**]** a letter of access to all the data which was considered by the F311... competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired ('the relevant data').

The **[**F312competent authority**]** shall inform the submitting supplier of the **[**F313appropriate fees**]**. It shall reject the application if the submitting supplier fails to pay those fees within 30 days and shall inform the submitting supplier accordingly.

Upon receipt of the **[**F314appropriate fees**]**, the **[**F315competent authority**]** shall verify whether the submission complies with the second subparagraph of this paragraph and shall inform the submitting supplier accordingly.

2 As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs.

3 For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.

4 A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1) **[**F316, where that letter of access gives the competent authority direct access to the information, and where the competent authority holds the relevant data**]**.

5 By way of derogation from Article 60, all data protection periods for active substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, shall end on 31 December 2025.

6 Paragraphs 1 to 5 shall not apply to substances listed in **[**F317the Simplified Active Substance List**]** in **[**F318categories A and C**]** or to biocidal products containing only such substances.

7 The **[**F319competent authority**]** shall regularly update the list referred to in paragraph 1 of this Article. Following the renewal of the approval of an active substance, the **[**F319competent authority**]** shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data, either in accordance with the second subparagraph of paragraph 1 of this Article or in an application in accordance with Article 13.**]**

[F320**8** The competent authority may refuse to accept a letter of access for the purposes of this Article if they do not hold the relevant data.**]**

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market

and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F304 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F305 Word in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F306 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F307 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F308 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F309 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F310 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F311 Word in Art. 95(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(b)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F312 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F313 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F314 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F315 Words in Art. 95(1) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(2)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F316 Words in Art. 95(4) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F317 Words in Art. 95(6) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F318 Words in Art. 95(6) substituted (31.12.2020 immediately before IP completion day) by S.I. 2019/720, **Sch. 4 para. 4(2)** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

F319 Words in Art. 95(7) substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F320 Art. 95(8) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 136(6)**; 2020 c. 1, Sch. 5 para. 1(1)

I[F321] *Article 95A*

Transitional measures for simplified notification procedure

1 Where, before IP completion day, a product was authorised in a country which was a Member State of the EU other than the United Kingdom in accordance with Article 26 of Regulation (EU) No 528/2012, and was placed on the market in the United Kingdom in accordance with Article 27 of Regulation (EU) No 528/2012—

a it is to be treated as if it were authorised by the competent authority under Article 26 of this Regulation, and

b the competent authority must grant an authorisation under Article 26 of this Regulation.

2 The authorisation must be cancelled and Article 52 of this Regulation will apply where—

a the authorisation holder is not established in the United Kingdom within 12 months from IP completion day, or

b the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

i the date of any application for renewal or the date of any application for amendment of the authorisation under Article 50 of this Regulation, or

ii within 60 days of any request made by the competent authority to the authorisation holder.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95B

Transitional measures for mutual recognition applications

1 This Article applies where—

a an application for mutual recognition of a national authorisation of a biocidal product was made before IP completion day in accordance with Articles 33, 34 or 39 of Regulation (EU) No 528/2012, and

b a decision was not made before IP completion day.

2 Paragraphs 3, 4, 7 and 8 apply where the United Kingdom was the reference Member State, before exit day, for an application for mutual recognition under Article 34 of Regulation (EU) No 528/2012.

3 The application for mutual recognition is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 are suspended until—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

4 On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 29 and 30 of this Regulation apply, less any time which expired between the date of acceptance of the application and data under Article 34 of Regulation (EU) No 528/2012 and exit day.

[F322 4A But paragraph 4 does not apply so as to shorten—

a the deadline in paragraph 1 of Article 29, as it is modified by paragraph 1A of that Article; or

b the deadlines in paragraphs 1A, 2A and 4 of Article 30.**]**

5 Paragraphs 6, 7 and 8 apply where, before IP completion day, the United Kingdom was the Member State concerned in relation to an application for mutual recognition under Articles 33, 34 or 39 of Regulation (EU) No 528/2012.

6 The application is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

7 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

8 Anything done before IP completion day by the United Kingdom competent authority, where the United Kingdom was either the Member State concerned or the reference Member State, is taken as having been done by the competent authority under this Regulation.

9 The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10 The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

F322 Art. 95B(4A) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(6)**

Article 95C

Renewal of authorisations subject to mutual recognition under Regulation 492/2014

1 This Article applies where—

a an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before IP completion day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for renewal of authorisations of biocidal products subject to mutual recognition, and

b a decision on the renewal of the authorisation was not made before IP completion day.

2 Paragraph 3 applies where, before exit day, the United Kingdom was the reference Member State for an application for renewal.

3 The application is to be treated as having been made under Article 31 of this Regulation and the time limits under Article 31 are suspended until—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

4 On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 30 and 31 (where applicable) of this Regulation apply less any time which expired between the date of acceptance of the application and data under Articles 3 and 4 of Regulation (EU) No 492/2014 and exit day.

[F323 But paragraph 4 does not apply so as to shorten the deadlines in paragraphs 1A, 2A and 4A of Article 30.**]**

5 Paragraph 6 applies where, before IP completion day, the United Kingdom was the Member State concerned for an application for renewal.

6 The application is to be treated as having been made under Article 31 of this Regulation, and the time limits under Articles 30 and 31 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

7 Anything done before IP completion day by the United Kingdom, either as the Member State concerned or as the reference Member State, is taken as having been done by the competent authority under this Regulation.

8 The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

9 The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

10 Where the applicant or authorisation holder does not meet the requirements of this Article—

a the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9), and

b the authorisation must be cancelled by the competent authority and Article 52 applies.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

F323 Art. 95C(4A) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(7)**

Article 95D

Transitional measure for national authorisation applications

1 This Article applies where—

a an application was made before IP completion day to the United Kingdom competent authority under Articles 29 or 31 of Regulation (EU) No 528/2012, and

b a decision was not made before IP completion day.

2 The application is to be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 Where the applicant or authorisation holder does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

4 Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

5 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95E

Transitional measures simplified authorisation applications

1 This Article applies where—

a an application was made to the United Kingdom competent authority before IP completion day under Articles 25 or 26 of Regulation (EU) No 528/2012, and

b a decision was not made before IP completion day.

2 Where the application was made to the United Kingdom competent authority as the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 In a case where an application was made but the United Kingdom competent authority was not the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

4 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

5 Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

6 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

7 The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95F

Transitional measures for applications for same biocidal product authorisations

1 This Article applies where—

a an application was made to the United Kingdom competent authority before IP completion day under Articles 3 or 4 of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, and

b a decision was not made before IP completion day.

2 The application is to be treated as having been made under Articles 3 or 4 (as appropriate) of Regulation (EU) No 414/2013 and the time limits under those Articles are apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

4 For the purposes of this Article, data submitted by the applicant or the data owner must include relevant data for the reference product.

5 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

I

[F324]Article 95FA

Transitional measures for applications for same biocidal product authorisations under the simplified procedure

1 This Article applies where—

a an application was made to the United Kingdom competent authority before IP completion day under Article 4a of Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; and

b a decision was not made before IP completion day.

2 The application is to be treated as having been made under Article 4a of Regulation (EU) 414/2013.

3 The applicant must—

a resubmit the application and any supporting data to the competent authority; or

b where the applicant relies on a letter of access—

i resubmit the application; and

ii ensure that the data owner resubmits the data.

4 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

5 For the purposes of this Article, data resubmitted by the applicant or the data owner must include relevant data for the reference product.

6 The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 before 31 January 2023.**]**

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

F324 Art. 95FA inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(8)**

Article 95G

Transitional measures for Regulation (EU) No 528/2012 authorisations

1 This Article applies to authorisations granted by the United Kingdom competent authority before IP completion day under Articles 19, 26, 30, 31, 33, 34, 36, 39 or 44 of Regulation (EU) No 528/2012.

2 The authorisation is to be treated as if it were authorised by the competent authority under the relevant Article of this Regulation.

3 The authorisation must be cancelled and Article 52 of this Regulation will apply where—

a the authorisation holder is not established in the United Kingdom within 12 months after IP completion day, or

b the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

i the date of any application for renewal or for amendment of the authorisation under Article 50 of this Regulation, or

ii within 60 days of any request made by the competent authority to the authorisation holder.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95H

Transitional measures for ongoing applications for Union authorisations

1 This Article applies where—

a an application for Union authorisation was made before IP completion day in accordance with Articles 42, 43 or 45 of Regulation (EU) No 528/2012, and

b a decision was not made before IP completion day.

2 Paragraph 3 applies where, before IP completion day, the United Kingdom competent authority was the evaluating competent authority for applications for Union authorisations made under Regulation (EU) No 528/2012.

3 The application is to be treated as being made under Articles 29 or 31 of this Regulation and the time limits under Articles 29, 30 or 31 are suspended until—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the applicant relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

4 On receipt of the resubmitted application and data to the competent authority, the time limits under Article 29, 30 or 31 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Articles 43, 44, 45 or 46 of Regulation (EU) No 528/2012 and exit day.

[F325 4A But paragraph 4 does not apply so as to shorten—

a the deadline in paragraph 1 of Article 29, as it is modified by paragraph 1A of that Article; or

b the deadlines in paragraphs 1A, 2A and 4 of Article 30.**]**

5 Paragraph 6 applies to those ongoing Union authorisation applications made under Regulation (EU) No 528/2012 where the United Kingdom competent authority was not the evaluating competent authority.

6 The application is to be treated as having been made under Articles 29, 30 or 31 of this Regulation, and the time limits under those Articles apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

7 Where the applicant or authorisation holder does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

8 Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority is taken as having been done by the competent authority under this Regulation.

9 The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10 The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

F325 Art. 95H(4A) inserted (31.12.2022) by The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 (S.I. 2022/1291), regs. 1(2), **2(9)**

Article 95I

Transitional measures for Article 95 List

1 This Article applies to the list prepared pursuant to Article 95 of Regulation (EU) No 528/2012 ("the Article 95 pre-IP completion day List") of active substances and persons having made submissions in relation to those active substances.

2 Subject to paragraph 3, from IP completion day the entries included in the Article 95 pre-IP completion day List are to be included in the list prepared pursuant to Article 95 of this Regulation ("the Article 95 List").

3 An entry on the Article 95 List must be removed if either of the following conditions are not met within 2 years from IP completion day—

a the person must be established in the United Kingdom;

b the person must provide to the competent authority any of the following—

i a complete dossier for the relevant active substance;

ii a reference to a complete active substance dossier for which all data protection periods have expired and the competent authority is able to obtain all the data;

iii a letter of access to a complete active substance dossier, where that dossier has been submitted to the competent authority within 2 years of IP completion day.

4 Where an entry is removed from the Article 95 List for reasons beyond the control of the supplier of a biocidal product containing the relevant active substance, the competent authority may grant a period of grace for the making available on the market of that biocidal product, except in cases where the continued making available on the market of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

5 A period of grace in excess of 180 days may only be granted under paragraph 4 in exceptional circumstances.

6 Where a period of grace is granted in accordance with paragraph 4, and the supplier of a biocidal product does not comply with the second subparagraph of Article 95(1) during that period, the prohibition in Article 95(2) applies.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95J

Transitional measure for active substance applications made to the United Kingdom competent authority before 30 March 2019 and subsequently reallocated

1 This Article applies where—

a an application was made to the United Kingdom competent authority as evaluating competent authority before 30 March 2019 under Article 7 of Regulation (EU) No 528/2012,

b the competent authority had not completed its evaluation of the application before IP completion day due to the evaluation being reallocated at EU level, and

c a decision was not made before IP completion day.

2 An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits in Articles 7 and 8 are suspended until—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 7 and 8 apply, less any time which expired between the date of acceptance of the application and data under Article 7 of Regulation (EU) No 528/2012 and—

a 30 March 2019 for active substances listed in the Annex to Commission Delegated Regulation (EU) 2019/227, or

b exit day for other substances.

4 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.

5 Anything done before exit day by the competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.

6 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95K

Transitional measure for active substance applications made before IP completion day pursuant to Article 93 where the United Kingdom competent authority was not the evaluating competent authority

1 This Article applies where—

a an application to approve an active substance was made before IP completion day under Article 7 of Regulation (EU) No 528/2012 and in compliance with point (a) of Article 93,

b the United Kingdom competent authority was not the evaluating competent authority, and

c a decision was not made before IP completion day.

2 An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits under Articles 7 and 8 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.

4 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95L

Transitional measures for renewal of an approval of an active substance

1 This Article applies where—

a an application for renewal of an approval of an active substance was made before IP completion day in accordance with Article 13 of Regulation (EU) No 528/2012, and

b a decision was not made before IP completion day.

2 Where the United Kingdom competent authority was the evaluating competent authority before exit day, the application is to be treated as if it were made under Article 13 of this Regulation, and the time limits under Articles 13 and 14 are suspended until—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Article 13 and 30 March 2019.

4 Where the United Kingdom competent authority was not the evaluating competent authority before exit day, the application is to be treated as if it were made under Article 13 of this Regulation and the time limits under Articles 13 and 14 apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

5 Where the applicant does not meet the requirements of this Article, the approval must not be renewed by the competent authority and Article 52 applies to any biocidal product containing the active substance.

6 Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.

7 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

8 The resubmission of any application and data referred to in paragraph 4 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95M

Transitional measures for ongoing applications to change or amend authorisations

1 This Article applies where—

a an application was made before IP completion day to the United Kingdom competent authority under Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation EU (No) 528/2012 of the European Parliament and of the Council, and

b a decision was not made before IP completion day.

2 An application referred to in paragraph 1 is to be treated as having been made under Regulation (EU) No 354/2013 and the time limits under that Regulation apply from—

a the date on which the applicant resubmits the application and any supporting data to the competent authority, or

b where the application relies on a letter of access, whichever is the later of the following—

i the applicant resubmits the application, or

ii the data owner resubmits the data.

3 Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority.

4 For the purposes of this Article, data submitted by the applicant or the data owner for changes to authorisations issued under Commission Implementing Regulation (EU) No 414/2013 must include relevant data on the reference product.

5 The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 95N

Interpretation of Articles 95A to 95M

1 For the purposes of Articles 95A to 95M, the following definitions apply—

"evaluating competent authority" has the meaning given in Article 7 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"Member State concerned" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"receiving competent authority" has the meaning given in Article 17 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"reference Member State" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day.**]**

Textual Amendments

F321 Arts. 95A-95N inserted (31.12.2020) by S.I. 2019/720, **Sch. 4 para. 2** (as inserted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**)

Article 96

Repeal

[F11Without prejudice to Articles 86, 89 to 93 and 95 of this Regulation, Directive 98/8/EC is hereby repealed with effect from 1 September 2013.**]**

References to the repealed Directive shall be construed as references to this Regulation and read in accordance with the correlation table in Annex VII.

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Article 97

Entry into force

F326
. . . . . .

Textual Amendments

F326 Art. 97 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 138**; 2020 c. 1, Sch. 5 para. 1(1)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[F327]ANNEX I

Textual Amendments

F327 Annex 1 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 139**; 2020 c. 1, Sch. 5 para. 1(1)

. . . . . .

ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation of the dossier referred to in point (a) of Article 6(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all active substances. However, in some cases the physical or chemical properties of the substance may mean that it is impossible or unnecessary to provide specific data elements belonging to the CDS.

With regard to the ADS, the data elements to be provided for a specific active substance shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the substance, existing data, information which is part of the CDS and the types of products in which the active substance will be used and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex II table. The general considerations regarding adaptation of information requirements as set out in Annex IV shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the Annex II table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates. The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in Article 4(1) are met.

The applicant should consult the detailed technical guidance regarding the application of this Annex and the preparation of the dossier referred to in point (a) of Article 6(1), which is **[**[F328]to be made available online by the competent authority**]**.

Textual Amendments

F328 Words in Annex 2 para. 2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 140(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 62(2), applicants may also consult with the competent authority

[F329]... with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

Textual Amendments

F329 Words in Annex 2 para. 2 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 140(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Additional information may need to be submitted if it is necessary to carry out the evaluation as indicated in Article 8(2).

3. A detailed and full description of the studies conducted or referred to and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements. Evidence should also be provided to demonstrate that the active substance upon which the tests have been carried out is the same as the substance for which the application has been submitted.

[[F330]4. Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.**]**

Textual Amendments

F330 Annex 2 para. 4 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 140(3)**; 2020 c. 1, Sch. 5 para. 1(1)

5. Tests submitted for the purpose of the approval of an active substance shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[(43)]. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes[(44)] and in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances[(45)] or other international standards recognised as being equivalent by the **[**[F331]competent authority**]**. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

Textual Amendments

F331 Words in Annex 2 para. 6 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 140(4)**; 2020 c. 1, Sch. 5 para. 1(1)

7. Where testing is done, a detailed description (specification) of the active substance used and its impurities must be provided. Testing should be performed with the active substance as manufactured or, in the case of some of the physical and chemical properties (see indications given in column I of the table), with a purified form of the active substance.

8. Where test data exist that have been generated before 1 September 2013 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority [F332]..., on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrates.

Textual Amendments

F332 Words in Annex 2 para. 8 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 140(5)**; 2020 c. 1, Sch. 5 para. 1(1)

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In-vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

TITLE 1

CHEMICAL SUBSTANCES

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 and are not repeated in column 3, also apply.

Column 1Information required	Column 2All data is CDS unless indicated as ADS	Column 3Specific rules for adaptation from standard information concerning
a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.	
b	The information provided should be for the purified active substance of stated specification.	
c	OJ L 20, 26.1.1980, p. 43.	
d	OJ L 372, 27.12.2006, p. 19.	
e	OJ L 348, 24.12.2008, p. 84.	

			some of the information requirements that may require recourse to testing of vertebrates
1. APPLICANT			
1.1.	Name and address		
1.2.	Contact person		
1.3.	Active substance manufacturer (name, address and location of manufacturing plant(s))		
2. IDENTITY OF THE ACTIVE SUBSTANCE			
For the active substance, the information given in this Section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated			
2.1.	Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)		
2.2.	Chemical name (IUPAC and CA nomenclature or other international chemical name(s))		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

2.3.	Manufacturer's development code number(s)		
2.4.	CAS number plus EC, INDEX and CIPAC numbers		
2.5.	Molecular and structural formula (including SMILES notation, if available and appropriate)		
2.6.	Information on optical activity and full details of any isomeric composition (if applicable and appropriate)		
2.7.	Molar mass		
2.8.	Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability		
2.9.	Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	v) as appropriate, providing inclusively the upper and lower limit		
2.10.	The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances		
2.11.	Analytical profile of at least five representative batches (g/kg active substance) including information on content of the impurities referred to in 2.10.		
2.12.	The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower		

3. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
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c	OJ L 20, 26.1.1980, p. 43.
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e	OJ L 348, 24.12.2008, p. 84.

3.1. Appearance[a]			
3.1.1.	Aggregate state (at 20 °C and 101,3 kPa)		
3.1.2.	Physical state (i.e. viscous, crystalline, powder) (at 20 °C and 101,3 kPa)		
3.1.3.	Colour (at 20 °C and 101,3 kPa)		
3.1.4.	Odour (at 20 °C and 101,3 kPa)		
3.2.	Melting/freezing point[b]		
3.3.	Acidity, alkalinity		
3.4.	Boiling point[b]		
3.5.	Relative Density[b]		
3.6.	Absorption spectra data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient at relevant wavelengths, where relevant[b]		
3.7. Vapour pressure[b]			
3.7.1.	Henry's law constant must always be stated for solids and liquids if it can be calculated		

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3.8.	Surface tension[b]		
3.9.	Water solubility[b]		
3.10.	Partition coefficient (n-octanol/ water) and its pH dependency[b]		
3.11.	Thermal stability, identity of breakdown products[b]		
3.12.	Reactivity towards container material		
3.13.	Dissociation constant	ADS	
3.14.	Granulometry		
3.15.	Viscosity	ADS	
3.16.	Solubility in organic solvents, including effect of temperature on solubility[b]	ADS	
3.17.	Stability in organic solvents used in biocidal products and identity of relevant breakdown products[a]	ADS	
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			
4.1.	Explosives		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Self-reactive substances and mixtures		
4.9.	Pyrophoric liquids		
4.10.	Pyrophoric solids		
4.11.	Self-heating substances and mixtures		
4.12.	Substances and mixtures which in contact with water emit flammable gases		
4.13.	Oxidising liquids		
4.14.	Oxidising solids		
4.15.	Organic peroxides		
4.16.	Corrosive to metals		

4.17. Additional physical indicators for hazards

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
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e	OJ L 348, 24.12.2008, p. 84.

4.17.1.	Auto-ignition temperature (liquids and gases)		
4.17.2.	Relative self ignition temperature for solids		
4.17.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	Analytical methods including validation parameters for the determination of active substance as manufactured and where appropriate, for relevant residues, isomers and impurities of the active substance and additives (e.g. stabilisers) For impurities other than relevant impurities this only applies if they are present at ≥ 1 g/kg		
5.2. Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in/on the following where relevant			
5.2.1.	Soil		

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
b	The information provided should be for the purified active substance of stated specification.
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5.2.2.	Air		
5.2.3.	Water (surface, drinking etc.) and sediment		
5.2.4.	Animal and human body fluids and tissues		
5.3.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor articles treated with it come into contact with food-producing animals, food of plant or animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISMS			
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g.		

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b The information provided should be for the purified active substance of stated specification.

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organism(s)		
6.4.	Likely concentration at which the active substance will be used in products and, where appropriate, in treated articles		
6.5.	Mode of action (including time delay)		
6.6.	Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate		

6.7. Any known limitations on efficacy

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
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6.7.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.7.2.	Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms		
7. INTENDED USES AND EXPOSURE			
7.1.	Field of use(s) envisaged for biocidal products and, where appropriate, treated articles		
7.2.	Product-type(s)		
7.3.	Detailed description of the intended use pattern(s) including in treated articles		
7.4.	Users e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Likely tonnage to be placed on the market per		

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e OJ L 348, 24.12.2008, p. 84.

	year and, where relevant, for the envisaged major use categories		
7.6. Exposure data in conformity with Annex VI to this Regulation			
7.6.1.	Information on human exposure associated with the intended uses and disposal of the active substance		
7.6.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance		
7.6.3.	Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.6.4.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
8. TOXICOLOGICAL PROFILE FOR HUMAN AND ANIMAL INCLUDING METABOLISM			

a	The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.
b	The information provided should be for the purified active substance of stated specification.
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e	OJ L 348, 24.12.2008, p. 84.

8.1. Skin irritation or skin corrosion The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/ Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		
8.2. Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/ Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		
8.3. Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing.		Step 2 does not need to be conducted if: — the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)

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	If another skin sensitisation test is used justification shall be provided		
8.4.	Respiratory sensitisation	ADS	
8.5. Mutagenicity			
The assessment of this endpoint shall comprise the following consecutive steps: — an assessment of the available in vivo genotoxicity data — an in vitro test for gene mutations in bacteria, an in vitro cytogenicity test in mammalian cells and an in vitro gene mutation test in mammalian cells are required — appropriate in vivo genotoxicity studies shall be considered in case of a positive result in any of the in vitro genotoxicity studies			
8.5.1.	In vitro gene mutation study in bacteria		
8.5.2.	In vitro cytogenicity study in mammalian cells		
8.5.3.	In vitro gene mutation study in mammalian cells		

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b	The information provided should be for the purified active substance of stated specification.
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d	OJ L 372, 27.12.2006, p. 19.
e	OJ L 348, 24.12.2008, p. 84.

8.6. In vivo genotoxicity study The assessment of this endpoint shall comprise the following consecutive steps: — If there is a positive result in any of the in vitro genotoxicity studies and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed/ conducted by the applicant — If either of the in vitro gene mutation tests is positive, an in vivo test to investigate unscheduled DNA synthesis shall be conducted — A second in vivo somatic cell test may be necessary, depending on the results, quality and relevance of all the available data — If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic	ADS	The study/ies do(es) not generally need to be conducted if: — the results are negative for the three in vitro tests and if no metabolites of concern are formed in mammals or — valid in vivo micronucleus data is generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement — the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.

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b	The information provided should be for the purified active substance of stated specification.
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evidence to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered		
8.7. Acute toxicity In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 shall be provided for at least one other route of administration — The choice for the second route will depend on the nature of the substance and the likely route of human exposure — Gases and volatile liquids should be administered by the inhalation route — If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered. Before a new dermal acute toxicity study is		The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin

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e OJ L 348, 24.12.2008, p. 84.

carried out, an in vitro dermal penetration study (OECD 428) should be conducted to assess the likely magnitude and rate of dermal bioavailability — There may be exceptional circumstances where all routes of administration are deemed necessary		
8.7.1. By oral route The Acute Toxic Class Method is the preferred method for the determination of this endpoint		The study need not be conducted if: — the substance is a gas or a highly volatile substance
8.7.2. By inhalation Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account: — the vapour pressure of the substance (a volatile substance has vapour pressure > 1×10^{-2} Pa at 20 °C) and/or — the active substance is a powder containing a significant proportion (e.g. 1 % on a weight basis) of particles with particle size MMAD < 50 micrometers or		

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b The information provided should be for the purified active substance of stated specification.

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e OJ L 348, 24.12.2008, p. 84.

— the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD < 50 micrometers) — the Acute Toxic Class Method is the preferred method for the determination of this endpoint		
8.7.3. By dermal route Testing by the dermal route is necessary only if: — inhalation of the substance is unlikely, or — skin contact in production and/or use is likely, and either — the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin, or — the results of an in vitro dermal penetration study (OECD 428) demonstrate high dermal absorption and bioavailability		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

8.8. Toxicokinetics and metabolism studies in mammals		
The toxicokinetics and metabolism studies should provide basic data about the rate and extent of absorption, the tissue distribution and the relevant metabolic pathway including the degree of metabolism, the routes and rate of excretion and the relevant metabolites		
8.8.1. Further toxicokinetic and metabolism studies in mammals Additional studies might be required based on the outcome of the toxicokinetic and metabolism study conducted in rat. These further studies shall be required if: — there is evidence that metabolism in the rat is not relevant for human exposure — route-to-route extrapolation from oral to dermal/ inhalation exposure is not feasible Where it is considered appropriate to obtain information on dermal absorption, the assessment of this endpoint shall proceed using a tiered approach for assessment of dermal absorption	ADS	

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8.9. Repeated dose toxicity In general, only one route of administration is necessary and the oral route is the preferred route. However, in some cases it may be necessary to evaluate more than one route of exposure. For the evaluation of the safety of consumers in relation to active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route Testing by the dermal route shall be considered if: — skin contact in production and/or use is likely, and — inhalation of the substance is unlikely, and — one of the following conditions is met: (i) toxicity is observed in an acute dermal toxicity test at lower doses than in the oral toxicity test, or (ii) information or test data indicate dermal absorption is comparable		The repeated dose toxicity study (28 or 90 days) does not need to be conducted if: — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products for systemic and local effects and no synergistic effects are expected, or — relevant human exposure can be excluded in accordance with Section 3 of Annex IV In order to reduce testing carried out on vertebrates and in particular the need for free-standing single-endpoint studies, the design of the repeated dose toxicity studies shall take account of the possibility to explore several endpoints within the framework of one study

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(iii) or higher than oral absorption, or dermal toxicity is recognised for structurally related substances and for example is observed at lower doses than in the oral toxicity test or dermal absorption is comparable or higher than oral absorption Testing by the inhalation route shall be considered if: — exposure of humans via inhalation is likely taking into account the vapour pressure of the substance (volatile substances and gases have vapour pressure > 1×10^{-2} Pa at 20 °C), and/or — there is the possibility of exposure to aerosols, particles or droplets of an inhalable size		

a The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

b The information provided should be for the purified active substance of stated specification.

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	(MMAD < 50 micrometers)		
8.9.1.	Short-term repeated dose toxicity study (28 days), preferred species is rat		The short-term toxicity study (28 days) does not need to be conducted if: (i) a reliable sub-chronic (90 day) study is available, provided that the most appropriate species, dosage, solvent and route of administration were used, (ii) the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: — other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or — appropriately designed toxicokinetic studies reveal accumulation

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b The information provided should be for the purified active substance of stated specification.

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e OJ L 348, 24.12.2008, p. 84.

			of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short term toxicity study but which are liable to result in adverse effects after prolonged exposure
8.9.2.	Sub-chronic repeated dose toxicity study (90 days), preferred species is rat		The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as H372 and H373 (Regulation (EC) No 1272/2008), for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor allows the

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e OJ L 348, 24.12.2008, p. 84.

			extrapolation towards the NOAEL-90 days for the same route of exposure, and — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — the substance is unreactive, insoluble, not bioaccumulative and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure
8.9.3.	Long-term repeated dose toxicity (≥ 12 months)		The long-term toxicity study (≥ 12 months) does not need to be conducted if: — Long-term exposure can be excluded and no effects have been seen at the limit dose in the 90-day study or — a combined long-term repeated dose/ carcinogenicity study (8.11.1) is undertaken
8.9.4.	Further repeat dose studies	ADS	

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b The information provided should be for the purified active substance of stated specification.

c OJ L 20, 26.1.1980, p. 43.

d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of administration shall be undertaken in case of: — no other information on toxicity for a second non-rodent species is provided for, or — failure to identify a no observed adverse effect level (NOAEL) in the 28- or the 90-day study, unless the reason is that no effects have been observed at the limit dose, or — substances bearing positive structural alerts for effects for which the rat or mouse is an inappropriate or insensitive model, or — toxicity of particular concern (e.g. serious/severe effects), or — indications of an effect for which the available data is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that		

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b The information provided should be for the purified active substance of stated specification.

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d OJ L 372, 27.12.2006, p. 19.

e OJ L 348, 24.12.2008, p. 84.

	are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity, hormonal activity), or — concern regarding local effects for which a risk characterisation cannot be performed by route-to route extrapolation, or — particular concern regarding exposure (e.g. use in biocidal products leading to exposure levels which are close to the toxicologically relevant dose levels), or — effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28- or the 90-day study, or — the route of administration used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made.		

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8.10. Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		The studies need not be conducted if: — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection

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		limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and the pattern of use indicates there is no or no significant human exposure — If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for developmental toxicity must be considered — If a substance is known to cause developmental toxicity, meeting the criteria for classification as Reproductive toxicity Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to

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		support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered
8.10.1. Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route. The study shall be initially performed on one species		
8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route. If another reproductive toxicity test is used justification shall be provided. The extended one-generation reproductive toxicity study adopted at OECD level shall be considered as an alternative approach to the multi-generation study		
8.10.3. Further pre-natal developmental toxicity study. A decision on the need to perform additional studies on a second species or mechanistic	ADS	

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studies should be based on the outcome of the first test (8.10.1) and all other relevant available data (in particular rodent reprotox studies). Preferred species is rat, oral route of administration		
8.11. Carcinogenicity See 8.11.1 for new study requirements		A carcinogenicity study does not need to be conducted if: — the substance is classified as mutagen category 1A or 1B. The default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required
8.11.1. Combined carcinogenicity study and long-term repeated dose toxicity Rat, oral route of administration is the preferred route. If an alternative route is proposed a justification must be provided. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		

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8.11.2. Carcinogenicity testing in a second species — A second carcinogenicity study should normally be conducted using the mouse as test species — For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.12. Relevant health data, observations and treatments		
Justification should be provided if data is not available		
8.12.1. Medical surveillance data on manufacturing plant personnel		
8.12.2. Direct observation, e.g. clinical cases, poisoning incidents		
8.12.3. Health records, both from industry and any other available sources		
8.12.4. Epidemiological studies on the general population		

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8.12.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests		
8.12.6. Sensitisation/ allergenicity observations		
8.12.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
8.12.8. Prognosis following poisoning		
8.13. Additional studies Additional data which may be required depending on the characteristics and intended use of the active substance Other available data: Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic' (genomic, proteomic, metabolomic, etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel	ADS	
8.13.1. Phototoxicity	ADS	

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8.13.2. Neurotoxicity including developmental neurotoxicity — The preferred test species is the rat unless another test species is justified to be more appropriate — For delayed neurotoxicity tests the preferred species will be the adult hen — If anticholinesterase activity is detected a test for response to reactivating agents should be considered If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties then additional information or specific studies will be required. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route	ADS	
8.13.3. Endocrine disruption If there is any evidence from in vitro, repeat dose or	ADS	

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reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required to: — elucidate the mode/ mechanism of action — provide sufficient evidence for relevant adverse effects For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route		
8.13.4. Immunotoxicity including developmental immunotoxicity If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required to: — elucidate the mode/ mechanism of action — provide sufficient evidence for relevant adverse effects in humans For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to	ADS	

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conduct toxicity studies by the oral route		
8.13.5. Mechanistic data — any studies necessary to clarify effects reported in toxicity studies	ADS	
8.14. Studies related to the exposure of humans to the active substance	ADS	
8.15. Toxic effects on livestock and pets	ADS	
8.16. Food and feeding stuffs studies including for food-producing animals and their products (milk, eggs and honey) Additional information related to the exposure of humans to the active substance contained in biocidal products	ADS	
8.16.1. Proposed acceptable residue levels i.e. maximum residue limits (MRL) and the justification of their acceptability	ADS	
8.16.2. Behaviour of the residue of the active substance on the treated or contaminated food or feeding stuffs including	ADS	

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the kinetics of disappearance Residue definitions should be provided where relevant. It is also important to compare residues found in toxicity studies with residues formed in food-producing animals and their products, as well as food and feed		
8.16.3. Overall material balance for the active substance Sufficient residue data from supervised trials on food-producing animals and their products, as well as food and feed, to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	ADS	
8.16.4. Estimation of potential or actual exposure of humans to the active substance and residues through diet and other means	ADS	
8.16.5. If residues of the active substance occur in or on feeding stuffs for a significant period of time or are found in food of animal origin after treatment on or around food-producing animals (e.g.	ADS	

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direct treatment on animals or indirect treatment of animal houses or surroundings) then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin		
8.16.6. Effects of industrial processing and/ or domestic preparation on the nature and magnitude of residues of the active substance	ADS	
8.16.7. Any other available information that is relevant It may be appropriate to include information on migration into food, especially in the case of treatment of food contact materials	ADS	
8.16.8. Summary and evaluation of data submitted under 8.16.1 to 8.16.8 It is important to establish whether the metabolites found in food (from animals or plants) are the same as those tested in toxicity studies. Otherwise values for risk assessment (e.g. ADI) are not valid for the residues found	ADS	

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8.17. If the active substance is to be used in products for action against plants including algae then tests shall be required to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals	ADS	
8.18. Summary of mammalian toxicology Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL		
9. ECOTOXICOLOGICAL STUDIES		
9.1. Toxicity to Aquatic Organisms		
9.1.1. Short-term toxicity testing on fish When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied		The study does not need to be conducted if: — a valid long-term aquatic toxicity study on fish is available
9.1.2. Short-term toxicity testing on aquatic invertebrates		
9.1.2.1. Daphnia magna		
9.1.2.2. Other species	ADS	

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9.1.3. Growth inhibition study on algae		
9.1.3.1. Effects on growth rate of green algae		
9.1.3.2. Effects on growth rate of cyanobacteria or diatoms		
9.1.4. Bioconcentration		The experimental determination may not need to be carried out if: — it can be demonstrated on the basis of physico-chemical properties (e.g. log Kow < 3) or other evidence that the substance has a low potential for bioconcentration
9.1.4.1. Estimation methods		
9.1.4.2. Experimental determination		
9.1.5. Inhibition of microbial activity The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria		
9.1.6. Further Toxicity Studies on Aquatic Organisms If the results of the ecotoxicological studies, studies on fate and behaviour and/or the intended use(s) of the active substance indicate a risk for the aquatic environment, or if long-term exposure is expected,	ADS	

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then one or more of the tests described in this Section shall be conducted		
9.1.6.1. Long term toxicity testing on Fish (a) Fish Early Life Stage (FELS) Test (b) Fish short term toxicity test on embryo and sack fry stages (c) Fish juvenile growth test (d) Fish full life cycle test	ADS	
9.1.6.2. Long term toxicity testing on invertebrates (a) Daphnia growth and reproduction study (b) Other species reproduction and growth (e.g. Mysid) (c) Other species development and emergence (e.g. Chironomus)	ADS	
9.1.7. Bioaccumulation in an appropriate aquatic species	ADS	
9.1.8. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	
9.1.9. Studies on sediment- dwelling organisms	ADS	

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9.1.10.	Effects on aquatic macrophytes	ADS	
9.2.	Terrestrial toxicity, initial tests	ADS	
9.2.1.	Effects on soil micro-organisms		
9.2.2.	Effects on earthworms or other soil- dwelling non-target invertebrates		
9.2.3.	Acute toxicity to plants		
9.3.	Terrestrial tests, long term	ADS	
9.3.1.	Reproduction study with earthworms or other soil-dwelling non-target invertebrates		
9.4.	Effects on birds	ADS	For endpoint 9.4.3 the study does not need to be conducted if: — the dietary toxicity study shows that the LC_{50} is above 2 000 mg/kg
9.4.1.	Acute oral toxicity		
9.4.2.	Short-term toxicity — eight-day dietary study in at least one species (other than chickens, ducks and geese)		
9.4.3.	Effects on reproduction		

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9.5.	Effects on arthropods	ADS	
9.5.1.	Effects on honeybees		
9.5.2.	Other non-target terrestrial arthropods, e.g. predators		
9.6.	Bioconcentration, terrestrial	ADS	
9.7.	Bioaccumulation, terrestrial	ADS	
9.8.	Effects on other non-target, non-aquatic organisms	ADS	
9.9.	Effects on mammals	ADS	Data are derived from the mammalian toxicological assessment. The most sensitive relevant mammalian long-term toxicological endpoint (NOAEL) expressed as mg test compound/kg bw/day shall be reported
9.9.1.	Acute oral toxicity		
9.9.2.	Short term toxicity		
9.9.3.	Long term toxicity		
9.9.4.	Effects on reproduction		
9.10.	Identification of endocrine activity	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR			
10.1. Fate and behaviour in water and sediment			
10.1.1. Degradation, initial studies			

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If the assessment performed indicates the need to investigate further the degradation of the substance and its degradation products or the active substance has an overall low or absent abiotic degradation, then the tests described in 10.1.3 and 10.3.2 and where appropriate — in 10.4 shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed		
10.1.1.1. Abiotic		
(a) Hydrolysis as a function of pH and identification of breakdown products — The identification of breakdown products is required when the breakdown products at any sampling time are present at ≥ 10 %		
(b) Phototransformation in water, including identification of transformation products		
10.1.1.2. Biotic		
(a) Ready biodegradability		

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(b)	Inherent biodegradability (where appropriate)		
10.1.2.	Adsorption/ desorption		
10.1.3. Rate and route of degradation including identification of metabolites and degradation products			
10.1.3.1.	Biological sewage treatment		
(a)	Aerobic biodegradation	ADS	
(b)	Anaerobic biodegradation	ADS	
(c)	STP simulation test	ADS	
10.1.3.2.	Biodegradation in freshwater		
(a)	Aerobic aquatic degradation study	ADS	
(b)	Water/sediment degradation test	ADS	
10.1.3.3.	Biodegradation in sea water	ADS	
10.1.3.4.	Biodegradation during manure storage	ADS	
10.1.4.	Adsorption and desorption in water/ aquatic sediment	ADS	

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	systems and, where relevant, adsorption and desorption of metabolites and degradation products		
10.1.5.	Field study on accumulation in sediment	ADS	
10.1.6.	Inorganic substances: information on fate and behaviour in water	ADS	
10.2.	Fate and behaviour in soil	ADS	
10.2.1.	Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions Laboratory studies on rate of degradation in three additional soil types	ADS	
10.2.2.	Field studies, two soil types	ADS	
10.2.3.	Soil accumulation studies	ADS	

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10.2.4. Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.2.5. Further studies on sorption		
10.2.6. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	ADS	
10.2.6.1. Column leaching studies		
10.2.6.2. Lysimeter studies		
10.2.6.3. Field leaching studies		
10.2.7. Extent and nature of bound residues The determination and characteristics of bound residues is recommended to be combined with a soil simulation study	ADS	
10.2.8. Other soil degradation studies	ADS	
10.2.9. Inorganic substances: information on fate		

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	and behaviour in soil		
10.3. Fate and behaviour in air			
10.3.1.	Phototransformation in air (estimation method) Identification of transformation products		
10.3.2.	Fate and behaviour in air, further studies	ADS	
10.4.	Additional studies on fate and behaviour in the environment	ADS	
10.5.	Definition of the residue	ADS	
10.5.1.	Definition of the residue for risk assessment		
10.5.2.	Definition of the residue for monitoring		
10.6.	Monitoring data	ADS	
10.6.1.	Identification of all degradation products (> 10 %) must be included in the studies on degradation in soil, water and sediments		
11. MEASURES NECESSARY TO PROTECT HUMANS,			

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ANIMALS AND THE ENVIRONMENT

11.1.	Recommended methods and precautions concerning handling, use, storage, transport or fire		
11.2.	In case of fire, nature of reaction products, combustion gases etc.		
11.3.	Emergency measures in case of accident		
11.4.	Possibility of destruction or decontamination following release in or on the following:		
(a)	air		
(b)	water, including drinking water		
(c)	soil		
11.5.	Procedures for waste management of the active substance for industry or professional users		
11.6.	Possibility of reuse or recycling		
11.7.	Possibility of neutralisation of effects		

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11.8.	Conditions for controlled discharge including leachate qualities on disposal		
11.9.	Conditions for controlled incineration		
11.10.	Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances[c], of Annexes I and II to Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration[d], of Annex I to Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy[e], of Part B of Annex I to Directive 98/83/EC		

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	or Annexes VIII and X to Directive 2000/60/EC		
12. CLASSIFICATION, LABELLING AND PACKAGING			
12.1.	State any existing classification and labelling		
12.2. The hazard classification of the substance resulting from the application of Regulation (EC) No 1272/2008			
In addition, for each entry, the reasons why no classification is given for an endpoint should be provided			
12.2.1.	Hazard classification		
12.2.2.	Hazard pictogram		
12.2.3.	Signal word		
12.2.4.	Hazard statements		
12.2.5.	Precautionary statements including prevention, response, storage and disposal		
12.3.	Specific concentration limits, where applicable, resulting from the application		

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of Regulation (EC) No 1272/2008		
13. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

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TITLE 2

MICRO-ORGANISMS

Core data set and additional data set for active substances

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in Regulation (EC) No 440/2008 that are not repeated in column 3, also apply.

Column 1Information required	**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Manufacturer (name, address and location of manufacturing plant)		
2. IDENTITY OF THE MICRO-ORGANISM		

2.1.	Common name of the micro-organism (including alternative and superseded names)		
2.2.	Taxonomic name and strain		
2.3.	Collection and culture reference number where the culture is deposited		
2.4.	Methods, procedures and criteria used to establish the presence and identity of the micro-organism		
2.5.	Specification of the technical grade active ingredient		
2.6.	Method of production and quality control		
2.7.	Content of the micro-organism		
2.8.	Identity and content of impurities, additives, contaminating micro-organisms		
2.9.	Analytical profile of batches		
3. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM			
3.1. General information on the micro-organism			
3.1.1.	Historical background		

3.1.2.	Historical uses		
3.1.3.	Origin, natural occurrence and geographical distribution		
3.2.	Development stages/life cycle of the micro-organism		
3.3.	Relationships to known plant or animal or human pathogens		
3.4.	Genetic stability and factors affecting it		
3.5.	Information on the production of metabolites (especially toxins)		
3.6.	Production and resistance to antibiotics and other anti-microbial agents		
3.7.	Robustness to environmental factors		
3.8.	Further information on the micro-organism		
4. METHODS OF DETECTION AND IDENTIFICATION			
4.1.	Analytical methods for the analysis of the micro-organism as manufactured		
4.2.	Methods used for monitoring purposes to		

	determine and quantify residues (viable or non-viable)		
5. EFFECTIVENESS AGAINST TARGET ORGANISM			
5.1.	Function and mode of control e.g. attracting, killing, inhibiting		
5.2.	Infectiveness, dispersal and colonisation ability		
5.3.	Representative organism(s) controlled and products, organisms or objects to be protected		
5.4.	Effects on representative target organism(s) Effects on materials, substances and products		
5.5.	Likely concentration at which the micro-organism will be used		
5.6.	Mode of action (including time delay)		
5.7.	Efficacy data		
5.8. Any known limitations on efficacy			
5.8.1.	Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and appropriate		

	management strategies		
5.8.2.	Observations on undesirable or unintended side effects		
5.8.3.	Host specificity, range and effects on species other than the target organism		
5.9.	Methods to prevent loss of virulence of seed stock of the micro-organism		
6. INTENDED USES AND EXPOSURE			
6.1.	Field of use(s) envisaged		
6.2.	Product-type(s)		
6.3.	Detailed description of the use pattern(s)		
6.4.	Category of users for which the micro-organism should be approved		
6.5. Exposure data applying, as appropriate, the methodologies described in Section 5 of Annex I to Regulation (EC) No 1907/2006			
6.5.1.	Information on human exposure associated with the intended uses and disposal of the active substance		
6.5.2.	Information on environmental exposure associated with the intended		

	uses and disposal of the active substance		
6.5.3.	Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.	EFFECT ON HUMAN AND ANIMAL HEALTH		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
7.1. Basic information			
7.1.1.	Medical data		
7.1.2.	Medical surveillance on manufacturing plant personnel		
7.1.3.	Sensitisation/ allergenicity observations		
7.1.4.	Direct observation, e.g. clinical cases Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression		
7.2. Basic studies			
7.2.1.	Sensitisation		
7.2.2. Acute toxicity, pathogenicity, and infectiveness			
7.2.2.1.	Acute oral toxicity, pathogenicity and infectiveness		
7.2.2.2.	Acute inhalatory toxicity,	ADS	

	pathogenicity and infectiveness		
7.2.2.3.	Intraperitoneal/ subcutaneous single dose	ADS	
7.2.3.	In vitro genotoxicity testing		
7.2.4.	Cell culture study		
7.2.5.	Information on short-term toxicity and pathogenicity	ADS	
7.2.5.1.	Health effects after repeated inhalatory exposure	ADS	
7.2.6.	Proposed treatment: first aid measures, medical treatment		
7.3.	Specific toxicity, pathogenicity and infectiveness studies	ADS	
7.4.	Genotoxicity — in vivo studies in somatic cells	ADS	
7.5.	Genotoxicity — in vivo studies in germ cells	ADS	
7.6.	Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation		
7.7.	Residues in or on treated articles, food and feedingstuffs	ADS	
7.7.1.	Persistence and likelihood of	ADS	

	multiplication in or on treated articles, feedingstuffs or foodstuffs		
7.7.2.	Further information required	ADS	
7.7.2.1.	Non-viable residues	ADS	
7.7.2.2.	Viable residues	ADS	
7.8.	Summary and evaluation of residues in or on treated articles, food and feedingstuffs	ADS	
8.	EFFECTS ON NON-TARGET ORGANISMS		Information requirements in this Section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.
8.1. Effects on aquatic organisms			
8.1.1.	Effects on fish		
8.1.2.	Effects on freshwater invertebrates		
8.1.3.	Effects on algae growth		
8.1.4.	Effects on plants other than algae	ADS	
8.2.	Effects on earthworms		
8.3.	Effects on soil micro-organisms		
8.4.	Effects on birds		
8.5.	Effects on bees		

8.6.	Effects on arthropods other than bees		
8.7.	Further studies	ADS	
8.7.1.	Terrestrial plants	ADS	
8.7.2.	Mammals	ADS	
8.7.3.	Other relevant species and processes	ADS	
8.8.	Summary and evaluation of effects on non-target organisms		
9. ENVIRONMENTAL FATE AND BEHAVIOUR			
9.1. Persistence and multiplication			
9.1.1.	Soil		
9.1.2.	Water		
9.1.3.	Air		
9.1.4.	Mobility		
9.1.5.	Summary and evaluation of fate and behaviour in the environment		
10. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
10.1.	Recommended methods and precautions concerning handling, storage, transport or fire		

10.2.	Emergency measures in case of an accident		
10.3.	Procedures for destruction or decontamination		
10.4.	Procedures for waste management		
10.5.	Monitoring plan to be used for the active micro-organism including handling, storage, transport and use		
11. CLASSIFICATION, LABELLING AND PACKAGING OF THE MICRO-ORGANISM			
11.1.	Relevant risk group specified in Article 2 of Directive 2000/54/EC		
12.	SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with point (b) of Article 6(1) and the dossier accompanying an application for the authorisation of a biocidal product in accordance with point (a) of Article 20(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex III table. The general considerations regarding adaptation of information requirements as set out in Annex IV to this Regulation shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates.

For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the **[**F333competent authority**]** in accordance with point (e) of Article 77(2) of that Regulation.

Textual Amendments

F333 Words in Annex 3 para. 2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

The relevant calculation methods used for the classification of mixtures as laid down in Regulation (EC) No 1272/2008 shall, where appropriate, be applied in the hazard assessment of the biocidal product. Such calculation methods shall not be used if, in relation to a particular hazard, synergistic and antagonistic effects between the different substances contained in the product are considered likely.

Detailed technical guidance regarding the application of this Annex and the preparation of the dossier is **[**F334to be made available online by the competent authority**]**.

Textual Amendments

F334 Words in Annex 3 para. 2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority F335... with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

Textual Amendments

F335 Words in Annex 3 para. 2 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Additional information may need to be submitted if necessary to carry out the evaluation as indicated in Article 29(3) [F336]....

Textual Amendments

F336 Words in Annex 3 para. 2 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(2)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria in Article 19(1)(b) are met.

3. A detailed and full description of studies conducted and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements.

[[F337]4 Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.**]**

Textual Amendments

F337 Annex 3 para. 4 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(3)**; 2020 c. 1, Sch. 5 para. 1(1)

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate, whenever possible internationally recognised, and their appropriateness must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC or other international standards recognised as being equivalent by the **[**[F338]competent authority**]**. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

Textual Amendments

F338 Words in Annex 3 para. 6 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(4)**; 2020 c. 1, Sch. 5 para. 1(1)

7. Where testing is done, a detailed quantitative and qualitative description (specification) of the product used for each test and its impurities must be provided.

8. Where test data exist that have been generated before 17 July 2012 by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data

for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority [F339]..., on a case-by-case basis, taking into account, among other factors, the need to avoid unnecessary testing.

Textual Amendments

F339 Words in Annex 3 para. 8 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 141(5)**; 2020 c. 1, Sch. 5 para. 1(1)

9. New tests involving vertebrates shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

TITLE 1

CHEMICAL PRODUCTS

Core data set and additional data set for chemical products

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1Information required:		**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT			
1.1.	Name and address, etc.		
1.2.	Contact person		
1.3.	Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

2. IDENTITY OF THE BIOCIDAL PRODUCT			
2.1.	Trade name or proposed trade name		
2.2.	Manufacturer's development code and number of the product, if appropriate		
2.3.	Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and non-active substances (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained in the biocidal product. For non-active substances, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in the case of a		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

reaction mixture, the final composition of the biocidal product shall be given			
2.4.	Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution		
[F340 2.5.	Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC		]
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES			
3.1. Appearance (at 20 °C and 101,3 kPa)			

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

3.1.1. Physical state (at 20 °C and 101,3 kPa)		
3.1.2. Colour (at 20 °C and 101,3 kPa)		
3.1.3. Odour (at 20 °C and 101,3 kPa)		
3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1 %) is outside the pH range 4-10		
3.3. Relative density (liquids) and bulk, tap density (solids)		
3.4. Storage stability, stability and shelf-life		
3.4.1. Storage stability tests		
3.4.1.1. Accelerated storage test		
3.4.1.2. Long term storage test at ambient temperature		
3.4.1.3. Low temperature stability test (liquids)		
3.4.2. Effects on content of the active substance and technical characteristics of the biocidal product		
3.4.2.1. Light		
3.4.2.2. Temperature and humidity		
3.4.2.3. Reactivity towards container material		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

3.5. Technical characteristics of the biocidal product			
3.5.1.	Wettability		
3.5.2.	Suspensibility, spontaneity and dispersion stability		
3.5.3.	Wet sieve analysis and dry sieve test		
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability		
3.5.5.	Disintegration time		
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability		
3.5.7.	Persistent foaming		
3.5.8.	Flowability/ Pourability/ Dustability		
3.5.9.	Burning rate — smoke generators		
3.5.10.	Burning completeness — smoke generators		
3.5.11.	Composition of smoke — smoke generators		
3.5.12.	Spraying pattern — aerosols		
3.5.13.	Other technical characteristics		
3.6. Physical and chemical compatibility with other products including other			

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

biocidal products with which its use is to be authorised			
3.6.1.	Physical compatibility		
3.6.2.	Chemical compatibility		
3.7.	Degree of dissolution and dilution stability		
3.8.	Surface tension		
3.9.	Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS			
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Self-reactive substances and mixtures		
4.9.	Pyrophoric liquids		
4.10.	Pyrophoric solids		
4.11.	Self-heating substances and mixtures		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

4.12.	Substances and mixtures which in contact with water emit flammable gases		
4.13.	Oxidising liquids		
4.14.	Oxidising solids		
4.15.	Organic peroxides		
4.16.	Corrosive to metals		
4.17. Additional physical indications of hazard			
4.17.1.	Auto-ignition temperatures of products (liquids and gases)		
4.17.2.	Relative self-ignition temperature for solids		
4.17.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product		
5.2.	In so far as not covered by Annex II 5.2 and 5.3, analytical methods for monitoring	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	purposes including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:		
5.2.1.	Soil	ADS	
5.2.2.	Air	ADS	
5.2.3.	Water (including drinking water) and sediment	ADS	
5.2.4.	Animal and human body fluids and tissues	ADS	
5.3.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs)	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

6. EFFECTIVENESS AGAINST TARGET ORGANISMS			
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which the active substance will be used		
6.5.	Mode of action (including time delay)		
6.6.	The proposed label claims for the product and, where label claims are made, for treated articles		
6.7.	Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	appropriate and relevant		
6.8. Any known limitations on efficacy			
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2.	Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms		
6.9.	Summary and evaluation		
7. INTENDED USES AND EXPOSURE			
7.1.	Field(s) of use envisaged for biocidal products and, where appropriate, treated articles		
7.2.	Product-type		
7.3.	Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles		
7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

7.5.	Likely tonnage to be placed on the market per year and, where relevant, for different use categories		
7.6.	Method of application and a description of this method		
7.7.	Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes		
7.8.	Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal health and the environment		
7.9.	Proposed instructions for use		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

7.10. Exposure data in conformity with Annex VI to this Regulation			
7.10.1.	Information on human exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.2.	Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.3.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
7.10.4.	Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS			
8.1.	Skin corrosion or skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/ Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.2. Eye irritation[a] The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/ Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ECand Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.3. Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: 1. an assessment of the available human, animal and alternative data 2. in vivo testing The Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for in vivo testing. If another skin sensitisation test is		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected — the available information

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	used justification shall be provided		indicates that the product should be classified for skin sensitisation or corrosivity; or — the substance is a strong acid (pH < 2,0) or base (pH > 11,5)
8.4.	Respiratory sensitisation	ADS	Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.5. —	Acute toxicity Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.5.1.	By oral route		
8.5.2.	By inhalation		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

8.5.3.	By dermal route		
8.5.4.	For biocidal products that are intended to be authorised for use with other biocidal products, the risks to human health, animal health and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried out using combinations of the products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.6.	Information on dermal absorption Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach		
8.7.	Available toxicological data relating to: — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s)		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

of concern is a component of If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of		1999/45/EC and Regulation (EC) No 1272/2008 (CLP)
8.8. Food and feedingstuffs studies	ADS	
8.8.1. If residues of the biocidal product remain in or on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	ADS	
8.9. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product	ADS	
8.10. Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required for the biocidal product In addition, for certain biocides which are applied directly or around livestock	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

(including horses) residue studies might be needed			
9. ECOTOXICOLOGICAL STUDIES			
9.1.	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/ or the biocidal product itself may be necessary		
9.2.	Further Ecotoxicological studies		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

Further studies chosen from among the endpoints referred to in Section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4. If the biocidal product is in the form of bait or granules the following studies may be required:		
9.4.1. Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk		
9.5. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR		
The test requirements below are applicable only to the relevant components of the biocidal product		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

10.1.	Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2.	Further studies on fate and behaviour in the environment Further studies chosen from among the endpoints referred to in Section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required. For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3.	Leaching behaviour	ADS	
10.4.	Testing for distribution and dissipation in the following:	ADS	
10.4.1.	Soil	ADS	
10.4.2.	Water and sediment	ADS	
10.4.3.	Air	ADS	
10.5.	If the biocidal product is to be sprayed near to surface waters then an overspray study	ADS	

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

	may be required to assess risks to aquatic organisms or plants under field conditions		
10.6.	If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
11.1.	Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire		
11.2.	Identity of relevant combustion products in cases of fire		
11.3.	Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment		
11.4. Possibility of destruction or			

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

decontamination following release in or on the following:			
11.4.1.	Air		
11.4.2.	Water, including drinking water		
11.4.3.	Soil		
11.5.	Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)		
11.6.	Procedures for cleaning application equipment where relevant		
11.7.	Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms		
12. CLASSIFICATION, LABELLING, AND PACKAGING			
As established in point (b) of Article 20(1), proposals including justification for the hazard and precautionary			

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted. Example labels, instructions for use and safety data sheets shall be provided		
12.1. Hazard classification		
12.2. Hazard pictogram		
12.3. Signal word		
12.4. Hazard statements		
12.5. Precautionary statements including prevention, response, storage and disposal		
12.6. Proposals for safety-data sheets should be provided, where appropriate		
12.7. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. EVALUATION AND SUMMARY The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

a Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

Textual Amendments

F340 Inserted by Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products (Text with EEA relevance).

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1Information required:		**Column 2All data is CDS unless indicated as ADS**	**Column 3Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrates**
1. APPLICANT			
1.1.	Name and address		
1.2.	Contact person		
1.3.	Manufacturer and formulator of the biocidal product and the micro-organism(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCTS			
2.1.	Trade name or proposed trade name		
2.2.	Manufacturer's development code and number of the biocidal product, if appropriate		

2.3.	Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product non-active substances and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given		
2.4.	Formulation type and nature of the biocidal product		
[F340 2.5.	Where the biocidal product contains an active substance that has been manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9 of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an		]

	evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC		
3. BIOLOGICAL, PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT			
3.1.	Biological properties of the micro-organism in the biocidal product		
3.2. Appearance (at 20 °C and 101,3 kPa)			
3.2.1.	Colour (at 20 °C and 101,3 kPa)		
3.2.2.	Odour (at 20 °C and 101,3 kPa)		
3.3.	Acidity, alkalinity and pH value		
3.4.	Relative density		
3.5. Storage stability, stability and shelf-life			
3.5.1.	Effects of light		
3.5.2.	Effects of temperature and humidity		
3.5.3.	Reactivity towards the container		
3.5.4.	Other factors affecting stability		
3.6. Technical characteristics of the biocidal product			
3.6.1.	Wettability		

3.6.2.	Suspensibility and suspension stability		
3.6.3.	Wet sieve analysis and dry sieve test		
3.6.4.	Emulsifiability, re-emulsifiability, emulsion stability		
3.6.5.	Particle size distribution content of dust/fines, attrition and friability		
3.6.6.	Persistent foaming		
3.6.7.	Flowability/ Pourability/ Dustability		
3.6.8.	Burning rate — smoke generators		
3.6.9.	Burning completeness — smoke generators		
3.6.10.	Composition of smoke — smoke generators		
3.6.11.	Spraying patterns — aerosols		
3.6.12.	Other technical characteristics		
3.7. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered			
3.7.1.	Physical compatibility		

3.7.2.	Chemical compatibility		
3.7.3.	Biological compatibility		
3.8.	Surface tension		
3.9.	Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS			
4.1.	Explosives		
4.2.	Flammable gases		
4.3.	Flammable aerosols		
4.4.	Oxidising gases		
4.5.	Gases under pressure		
4.6.	Flammable liquids		
4.7.	Flammable solids		
4.8.	Oxidising liquids		
4.9.	Oxidising solids		
4.10.	Organic peroxides		
4.11.	Corrosive to metals		
4.12. Other physical indications of hazard			
4.12.1.	Auto-ignition temperatures of products (liquids and gases)		
4.12.2.	Relative self-ignition temperature for solids		

4.12.3.	Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION			
5.1.	Analytical method for determining the concentration of the micro-organism(s) and substances of concern in the biocidal product		
5.2.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the article treated with it does not come into contact with food-producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISM			
6.1.	Function and mode of control		
6.2.	Representative pest organism(s) to be controlled and products, organisms		

	or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which micro-organism will be used		
6.5.	Mode of action		
6.6.	The proposed label claims for the product		
6.7.	Efficacy data to support these claims, including any available standard protocols, laboratory tests, or field trials used including performance standards, where appropriate and relevant		
6.8. Any other known limitations on efficacy including resistance			
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2.	Observations on undesirable or unintended side effects		
7. INTENDED USES AND EXPOSURE			

7.1.	Field of use envisaged		
7.2.	Product-type		
7.3.	Detailed description of intended use		
7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Method of application and a description of this method		
7.6.	Application rate and if appropriate the final concentration of the biocidal product or the micro-organism active substance in a treated article or the system in which the product is to be used (e.g. in the application device or bait)		
7.7.	Number and timing of applications and duration of protection Any particular information relating to the geographical location or climatic variations including necessary waiting periods for re-entry or necessary withdrawal period or other precautions to protect human health, animal health and the environment		
7.8.	Proposed instructions for use		

7.9. Exposure data

7.9.1.	Information on human exposure associated with the proposed/expected uses and disposal		
7.9.2.	Information on environmental exposure associated with the proposed/ expected uses and disposal		
8.	TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected
8.1.	Skin corrosion or irritation		
8.2.	Eye irritation		
8.3.	Skin sensitisation		
8.4.	Respiratory sensitisation	ADS	
8.5. —	Acute toxicity Classification using the tiered approach to classification of mixtures for acute toxicity in		

	Regulation (EC) No 1272/2008 is the default approach		
8.5.1.	Oral		
8.5.2.	Inhalation		
8.5.3.	Dermal		
8.5.4.	Additional acute toxicity studies		
8.6.	Information on dermal absorption if required		
8.7. — non-active substance(s) (i.e. substance(s) of concern), or — a mixture that a substance(s) of concern is a component of If insufficient data are available for a non-active substance(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of	Available toxicological data relating to:		Testing on the product/ mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.8.	Supplementary studies for combinations of biocidal products		Testing on the mixture of products does not need to be conducted if: — there are valid data available on each

For biocidal products that are intended to be authorised for use with other biocidal products, the risks to humans, animals and the environment arising from the use of these product combinations shall be assessed. As an alternative to acute toxicity studies, calculations can be used. In some cases, for example where there are no valid data available of the kind set out in column 3, this may require a limited number of acute toxicity studies to be carried using combinations of the products			of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
8.9.	Residues in or on treated articles, food and feedingstuffs	ADS	
9. ECOTOXICOLOGICAL STUDIES			
9.1.	Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required — Where there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006		

	(REACH) and Regulation (EC) No 1272/2008 (CLP) — Where valid data on the components are not available or where synergistic effects may be expected then testing of components and/ or the biocidal product itself may be necessary		
9.2.	Further ecotoxicological studies Further studies chosen from among the endpoints referred to in Section 8 of Annex II 'Micro-organisms' for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3.	Effects on any other specific non-target organisms (flora and fauna) believed to be at risk	ADS	Data for the assessment of hazards to wild mammals are derived from the mammalian toxicological assessment
9.4.	If the biocidal product is in the form of bait or granules	ADS	
9.4.1.	Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2.	Studies on acceptance by ingestion of the		

	biocidal product by any non-target organisms thought to be at risk		
9.5.	Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR			
10.1.	Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2.	Further studies on fate and behaviour in the environment Where relevant, all the information required in Section 9 of Annex II 'Micro-organisms' may be required for the product For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3.	Leaching behaviour	ADS	
10.4.	If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray	ADS	

	behaviour may be required to assess risks to bees under field conditions		
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT			
11.1.	Recommended methods and precautions concerning: handling, storage, transport or fire		
11.2.	Measures in the case of an accident		
11.3. Procedures for destruction or decontamination of the biocidal product and its packaging			
11.3.1.	Controlled incineration		
11.3.2.	Others		
11.4.	Packaging and compatibility of the biocidal product with proposed packaging materials		
11.5.	Procedures for cleaning application equipment where relevant		
11.6.	Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use		

12. CLASSIFICATION, LABELLING AND PACKAGING		
Example labels, instructions for use and safety data sheets shall be provided		
12.1. Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC		
12.2. Precautionary statements including prevention, response, storage and disposal		
12.3. Proposals for safety-data sheets should be provided, where appropriate		
12.4. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed		

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This Annex sets out rules to be followed when the applicant proposes to adapt the data requirements set out in Annexes II and III in accordance with Article 6(2) and (3) or Article 21(1) and (2), without prejudice to the specific rules set out in Annex III on the use of the calculation methods for classification of mixtures to avoid testing on vertebrates.

The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) sufficient adequate and reliable documentation is provided to assess the equivalency of the study; and

(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy of the data for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters/endpoints foreseen to be investigated in the corresponding test methods;

(3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter;

(4) adequate and reliable documentation of the study is provided; and

(5) the study is performed using a system of quality assurance.

1.1.3. Historical human data

As a general rule, in accordance with Article 7(3) of Regulation (EC) No 1272/2008, tests on humans shall not be performed for the purposes of this Regulation. However, existing historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered.

Data collected on humans shall not be used to lower the safety margins resulting from tests or studies on animals.

The strength of the data for a specific human health effect depends, among other things, on the type of analysis and the parameters covered, and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups;

(2) adequate characterisation of exposure;

(3) sufficient length of follow-up for disease occurrence;

(4) valid method for observing an effect;

(5) proper consideration of bias and confounding factors; and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or does not have a particular dangerous property, while the information from each single source alone is considered insufficient to support this notion. There may be sufficient weight of evidence from the use of positive results of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the **[**F341competent authority**]** as being equivalent, leading to the conclusion that a substance has a particular dangerous property. However, if the newly developed test method has been approved by the **[**F341competent authority**]**, but has not yet been published, its results may be taken into account even where this leads to the conclusion that a substance does not have a particular dangerous property.

Textual Amendments

F341 Words in Annex 4 para. 1.2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 142(a)**; 2020 c. 1, Sch. 5 para. 1(1)

Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property:

— further testing on vertebrates for that property shall not be undertaken,

— further testing not involving vertebrates may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence, but not the absence of a given dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

— the results are derived from a (Q)SAR model whose scientific validity has been established,

— the substance falls within the applicability domain of the (Q)SAR model,

— the results are adequate for the purpose of classification and labelling and risk assessment, and

— adequate and reliable documentation of the applied method is provided.

F342 ...

Textual Amendments

F342 Words in Annex 4 para. 1.3 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 142(b)**; 2020 c. 1, Sch. 5 para. 1(1)

1.4. In vitro methods

Results obtained from suitable in vitro methods may indicate the presence of a given dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, 'suitable' means sufficiently well-developed according to internationally agreed test development criteria.

Where such in vitro tests are positive, it is necessary to confirm the dangerous property by adequate *in vivo* tests. However, such confirmation may be waived if the following conditions are met:

(1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;

(2) results are adequate for the purpose of classification and labelling and risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

In the case of negative results, these exemptions do not apply. A confirmation test may be requested on a case-by-case basis.

1.5. Grouping of substances and read-across approach

Substances whose physico-chemical, toxicological and ecotoxicological properties are similar or follow a regular pattern as a result of structural similarity may be considered as a group or 'category' of substances. Application of the group concept requires that physico-chemical properties, human and animal health effects, and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based on:

(1) a common functional group indicating the presence of dangerous properties;

(2) common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results shall:

— be adequate for the purpose of classification and labelling and risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method, and

— cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter.

In all cases, adequate and reliable documentation of the applied method shall be provided.

F343 …

Textual Amendments

F343 Words in Annex 4 para. 1.5 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 142(c)**; 2020 c. 1, Sch. 5 para. 1(1)

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion, or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with some endpoints in Sections 8 and 9 of Annexes II and III, notwithstanding Article 6(2), may be omitted based on exposure considerations, where exposure data in accordance with Annex II or III are available.

In that case, the following conditions shall be met:

— An exposure assessment shall be performed, covering primary and secondary exposure under realistic worst case for all intended uses of the biocidal product that contains the active substance for which approval is applied, or of the biocidal product for which the authorisation is sought.

— If a new exposure scenario is introduced at a later stage, during the product authorisation process, additional data shall be submitted to assess whether the justification for data adaptation still applies.

— The reasons why the outcome of the exposure assessment justifies waiving of data requirements shall be clearly and transparently explained.

However, testing cannot be omitted for non-threshold effects. As a consequence, certain core data shall always be obligatory, e.g. genotoxicity testing.

F344 …

Textual Amendments

F344 Words in Annex 4 para. 3.1 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 142(d)**; 2020 c. 1, Sch. 5 para. 1(1)

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment, in accordance with the relevant Technical Notes for Guidance where available.

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1:Disinfectants

These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 3: Veterinary hygiene

Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

[[F11]Products used to be incorporated into materials which may enter into contact with food.**]**

Product-type 5: Drinking water

Products used for the disinfection of drinking water for both humans and animals.

MAIN GROUP 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

Product-type 6: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects.

This product-type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.

Product-type 10: Construction material preservatives

Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product-type 15: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.

Product-type 17: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.

Product-type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.

MAIN GROUP 4: **Other biocidal products**

Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

TERMS AND DEFINITIONS

Correspondence with the criteria set out in Article 19(1)(b)

The subheadings ‘Effects on human and animal health’, ‘Effects on the Environment’, ‘Effects on Target Organisms’ and ‘Efficacy’ used in the Sections ‘Assessment’ and ‘Conclusions’ correspond to the four criteria set out in Article 19(1)(b) as follows:

‘Efficacy’ corresponds to criterion (i): ‘is sufficiently effective’.

‘Effects on target organisms’ corresponds to criterion (ii): ‘has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross resistance or unnecessary suffering and pain for vertebrates’.

‘Effects on human and animal health’ corresponds to criterion (iii): ‘has no immediate or delayed unacceptable effects itself, or as a result of its residues, on human health, including that of vulnerable groups[46], or animal health, directly or through drinking water, food, feed, air, or through other indirect effects’.

‘Effects on the environment’ corresponds to criterion iv: ‘has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— its impact on non-target organisms,

— its impact on biodiversity and the ecosystem’.

Technical definitions

(a) Hazard identification

The identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) Dose (concentration) — response (effect) assessment

The estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) Exposure assessment

The determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) Risk characterisation

The estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation', i.e. the quantification of that likelihood.

(e) Environment

Water, including sediment, air, soil, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex sets out the common principles for the evaluation of dossiers for biocidal products referred to in Article 19(1)(b). A decision by **[**F345the competent authority**]** to authorise a biocidal product shall be taken on the basis of the conditions set down in Article 19, taking account of the evaluation carried out according to this Annex. Detailed technical guidance regarding the application of this Annex is **[**F346to be made available online by the competent authority**]**.

Textual Amendments

F345 Words in Annex 6 para. 1 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F346 Words in Annex 6 para. 1 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials, the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.

3. In order to ensure a high and harmonised level of protection of human health, animal health and the environment, any risks arising from the use of a biocidal product shall

be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product, taking into account any cumulative and synergistic effects.

4. A risk assessment on the active substance(s) present in the biocidal product is always required. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

5. Additional risk assessments shall be carried out, in the same manner as described above, on any substance of concern present in the biocidal product. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

6. In order to carry out a risk assessment, data are required. These data are detailed in Annexes II and III and take account of the fact that there are a wide variety of applications as well as different product-types and that this has an impact on the associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. The **[**[F347]competent authority**]** shall take due consideration of the requirements of Articles 6, 21 and 62 in order to avoid duplication of data submissions. Data may also be required on a substance of concern present in a biocidal product. For in-situ generated active substances, the risk assessment includes also the possible risks from the precursor(s).

Textual Amendments

F347 Words in Annex 6 para. 6 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(3)**; 2020 c. 1, Sch. 5 para. 1(1)

7. The results of the risk assessments carried out on the active substance and on the substances of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

8.

When making evaluations of a biocidal product the **[**[F348]competent authority**]** shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

Textual Amendments

F348 Words in Annex 6 para. 8 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(4)**; 2020 c. 1, Sch. 5 para. 1(1)

9. The application of these common principles shall, when taken together with the other conditions set out in Article 19, lead to the **[**[F349]competent authority or the Secretary of State**]** deciding whether or not a biocidal product can be authorised. Such authorisation may include restrictions on use or other conditions. In certain cases the **[**[F350]competent authority**]** may conclude that more data are required before an authorisation decision can be made.

Textual Amendments

F349 Words in Annex 6 para. 9 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F350 Words in Annex 6 para. 9 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

10. In the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent **[**[F351]authority**]** shall also evaluate whether the conditions of Article 5(2) can be satisfied.

Textual Amendments

F351 Word in Annex 6 para. 10 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(6)**; 2020 c. 1, Sch. 5 para. 1(1)

11. During the process of evaluation, applicants and the **[**[F352]competent authority**]** shall cooperate in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

Textual Amendments

F352 Words in Annex 6 para. 11 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(7)**; 2020 c. 1, Sch. 5 para. 1(1)

12. The judgments made by the **[**[F353]competent authority**]** during the evaluation must be based on scientific principles, preferably recognised at international level, and must be made with the benefit of expert advice.

Textual Amendments

F353 Words in Annex 6 para. 12 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(8)**; 2020 c. 1, Sch. 5 para. 1(1)

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be validated by the [F354]... competent authority in accordance with the relevant articles of the Regulation. After validation of these data the **[**[F355]competent authority**]** shall utilise them by carrying out a risk assessment based on the proposed use. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

Textual Amendments

F354 Words in Annex 6 para. 13 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F355 Words in Annex 6 para. 13 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.

15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. [F356]...

Textual Amendments

F356 Words in Annex 6 para. 15 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(10)**; 2020 c. 1, Sch. 5 para. 1(1)

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail hazard identification and the establishment of appropriate reference values for dose or effect concentrations such as NOAEL or Predicted No Effect Concentrations (PNEC), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the appropriate reference values for each of the active substances and for any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

(a) the hazards due to the physico-chemical properties,

(b) the risk to humans and animals,

(c) the risk to the environment,

(d) the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

20. The information provided on the biocidal product family shall permit the **[**[F357]competent authority**]** to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 19(1)(b).

Textual Amendments

F357 Words in Annex 6 para. 20 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

21. Where relevant the technical equivalence for every active substance contained in the biocidal product shall be established with reference to active substances already included in the list of approved active substances.

Effects on human and animal health

Effects on human health

22. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

23. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute toxicity,
— irritation,
— corrosivity,
— sensitisation,
— repeated dose toxicity,
— mutagenicity,
— carcinogenicity,
— reproductive toxicity,
— neurotoxicity,
— immunotoxicity,
— disruption of the endocrine system,

— any other special properties of the active substance or substance of concern,
— other effects due to physico-chemical properties.

24. The populations previously mentioned are:
— professional users,
— non-professional users,
— humans exposed directly or indirectly via the environment.

In considering these populations, particular attention should be given to the need to protect vulnerable groups within these populations.

25. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

26. The **[**[F358]competent authority**]** shall apply points 27 to 30 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

Textual Amendments

F358 Words in Annex 6 para. 26 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

27. For repeated dose toxicity and reproductive toxicity the dose-response relationship shall be assessed for each active substance or substance of concern and, where possible, a NOAEL identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

28. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or another appropriate dose-effect descriptor shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

29. For mutagenicity and carcinogenicity, a non-threshold assessment should be carried out if the active substance or substance of concern is genotoxic and carcinogenic. If the active substance or a substance of concern is not genotoxic a threshold assessment shall be carried out.

30. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur, particularly in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects as a result of the use of the biocidal product.

31. When carrying out the risk assessment special consideration shall be given to toxicity data derived from observations of human exposure where such data are available, e.g. information gained from manufacture, from poison centres or epidemiology surveys.

32. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed directly or indirectly via the environment), for which exposure to a biocidal product occurs or can reasonably be foreseen, with particular attention paid to the pathways of exposure relevant for vulnerable groups. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern, including relevant metabolites and degradation products to which a population is, or may be exposed during use of the biocidal product and articles treated with that product.

33. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Articles 6 and 21 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,
— the form in which the biocidal product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties of the biocidal product,
— the likely routes of exposure and potential for absorption,
— the frequency and duration of exposure,
— maximum residue levels,
— the type and size of specific exposed populations, where such information is available.

34. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
— be subjected to an analysis taking into account possible elements of uncertainty,
— be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

35. Where, for any of the effects set out in point 23 a reference value has been identified, the risk characterisation shall entail comparison of the reference value with the evaluation of the dose/concentration to which the population will be exposed. Where a reference value cannot be established a qualitative approach shall be used.

Assessment factors account for the extrapolation from animal toxicity to the exposed human population. The setting of an overall assessment factor considers the degree of uncertainty in inter-species and intra-species extrapolation. In the absence of suitable chemical-specific data, a default assessment factor of 100 is applied to the relevant reference value. Additional elements can also be considered for assessment factors, including toxicokinetics and toxicodynamics, the nature and severity of the effect, human (sub-)populations, exposure deviations between study results and human exposure with regard to frequency and duration, study duration extrapolation

(e.g. sub-chronic to chronic), dose-response relationship and the overall quality of the toxicity data package.

Effects on animal health

36. Using the same relevant principles as described in the section dealing with effects on humans, the **[**[F359]competent authority**]** shall consider the risks posed to animals from the biocidal product.

Textual Amendments

F359 Words in Annex 6 para. 36 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Effects on the environment

37. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota, following the use of the biocidal product.

38. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as PNEC. However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Articles 6 and 20. It shall be calculated by applying an assessment factor to the reference values resulting from tests on organisms, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)). Where appropriate, other dose-effect descriptors may be used as reference values.

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller the degree of uncertainty and the size of the assessment factor.

42. For each environmental compartment, an exposure assessment shall be carried out in order to predict the likely concentration of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However, in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions (including any relevant contribution from articles treated with biocidal products) are known or are reasonably foreseeable.

44. The PEC, or the qualitative estimation of exposure, shall be determined taking account of, in particular and where appropriate:

— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties,
— breakdown/transformation products,
— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
— the frequency and duration of exposure,
— long range environmental transportation.

45. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 34. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

48. The **[**F360competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) if it contains any substance of concern or relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006, or if it has endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Textual Amendments

F360 Words in Annex 6 para. 48 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Effects on target organisms

49. An assessment shall be made to demonstrate that the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate, the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

50. The **[**[F361]competent authority**]** shall, where relevant, evaluate the possibility of the development by the target organism of resistance or cross-resistance to an active substance in the biocidal product.

Textual Amendments

F361 Words in Annex 6 para. 50 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Efficacy

51. Data submitted by the applicant shall be sufficient to substantiate the efficacy claims for the product. Data submitted by the applicant or held by the **[**[F362]competent authority**]** must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

Textual Amendments

F362 Words in Annex 6 para. 51 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

52. Testing should be carried out according to **[**[F363]Great Britain**]** guidelines where these are available and applicable. Where appropriate, other methods from the list below can be used. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method

— national standard method

— industry standard method (if accepted by the **[**[F364]competent authority**]**)

— individual producer standard method (if accepted by the **[**[F364]competent authority**]**)

— data from the actual development of the biocidal product (if accepted by the **[**[F364]competent authority**]**).

Textual Amendments

F364 Words in Annex 6 para. 52 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F363 Words in Annex 6 para. 52 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(12)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 2 para. 39(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Summary

53. In each of the areas where risk assessments have been carried out, the **[**[F365]competent authority**]** shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects.

Textual Amendments

F365 Words in Annex 6 para. 53 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

54. For biocidal product containing more than one active substance, any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

CONCLUSIONS

General principles

55. The purpose of the evaluation is to establish whether or not the product complies with the criteria set down in point (b) of Article 19(1). The **[**[F366]competent authority**]** shall reach its conclusion as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product, based on the assessment carried out in accordance with points 13 to 54 of this Annex.

Textual Amendments

F366 Words in Annex 6 para. 55 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

56.

In establishing compliance with the criteria set out in point (b) of Article 19(1), the **[**[F367]competent authority**]** shall arrive at one of the following conclusions for each product-type and each area of use of the biocidal product for which application has been made:

(1) that the biocidal product complies with the criteria;

(2) that, subject to specific conditions/restrictions, the biocidal product can comply with the criteria;

(3) that it is not possible, without additional data, to establish if the biocidal product complies with the criteria;

(4) that the biocidal product does not comply with the criteria.

Textual Amendments

F367 Words in Annex 6 para. 56 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

57. The **[**[F368]competent authority**]** shall, when seeking to establish whether a biocidal product complies with the criteria in point (b) of Article 19(1), take into account uncertainty arising from the variability in the data used in the evaluation process.

Textual Amendments

F368 Words in Annex 6 para. 57 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

58. If the conclusion arrived at by the **[**[F369]competent authority**]** is that additional information or data are required, then the **[**[F369]competent authority**]** shall justify the need for any such information or data. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

Textual Amendments

F369 Words in Annex 6 para. 58 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Effects on human and animal health

Effects on human health

59. The **[**[F370]competent authority**]** shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment. In reaching these conclusions, particular attention shall be paid to vulnerable groups among the different populations.

Textual Amendments

F370 Words in Annex 6 para. 59 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

60. The **[**[F371]competent authority**]** shall examine the relationship between exposure and effect. A number of factors need to be considered when examining this relationship. One of the most important factors is the nature of the adverse effect of the substance under consideration. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, immunotoxicity, reproductive toxicity, disruption of the endocrine system together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern, or of their relevant metabolites or degradation products.

Textual Amendments

F371 Words in Annex 6 para. 60 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

61. Typically, the margin of exposure (MOE_{ref}) — the ratio between the dose descriptor and the exposure concentration — is in the region of 100, but a MOE_{ref} that is higher or lower than this may also be appropriate depending on, among other things, the nature of the critical effects and the sensitivity of the population.

62. The **[**F372competent authority**]** shall, where appropriate, conclude that criterion (iii) under point (b) of Article 19(1) can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.

Textual Amendments

F372 Words in Annex 6 para. 62 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

63. If, for non-professional users, the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population, the product shall not normally be considered as complying with criterion (iii) under point (b) of Article 19(1) for this population.

Effects on animal health

64. Using the same relevant criteria as described in the section dealing with effects on human health, the **[**F373competent authority**]** shall consider whether criterion (iii) under point (b) of Article 19(1) is complied with for animal health.

Textual Amendments

F373 Words in Annex 6 para. 64 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Effects on the environment

65. The basic tool used in the decision-making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC, the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

66. For any given environmental compartment, if the PEC/PNEC ratio is equal to or less than 1, the risk characterisation shall be that no further information and/or testing is necessary. If the PEC/PNEC ratio is greater than 1, the **[**F374competent authority**]** shall judge, on the basis of the size of that ratio and on other relevant factors, whether further information and/or testing is required to clarify the concern or appropriate risk reduction measures are necessary, or whether the biocidal product cannot comply with criterion (iv) under point (b) of Article 19(1).

Textual Amendments

F374 Words in Annex 6 para. 66 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Water

67.

The **[**[F375]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target organisms in the aquatic, marine or estuarine environment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect. In particular, the **[**[F375]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1), where under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in water (or its sediments), would undermine the achievement of compliance with the standards laid down in:

— Directive 2000/60/EC,

— Directive 2006/118/EC,

— Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy[(47)],

— Directive 2008/105/EC, or

— international agreements on the protection of river systems or marine waters from pollution.

Textual Amendments

F375 Words in Annex 6 para. 67 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

68.

The **[**[F376]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in groundwater, exceeds the lower of the following concentrations:

— the maximum permissible concentration laid down by Directive 98/83/EC, or

— the maximum concentration as laid down following the procedure for approving the active substance under this Regulation, on the basis of appropriate data, in particular toxicological data,

Textual Amendments

F376 Words in Annex 6 para. 68 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

69.

The **[**F377competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where the foreseeable concentration of the active substance or a substance of concern, or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by:
  — Directive 2000/60/EC,
  — Directive 98/83/EC, or
— has an impact deemed unacceptable on non-target organisms,

Textual Amendments

F377 Words in Annex 6 para. 69 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

70. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that, if followed, they minimise the likelihood of accidental contamination of water or its sediments.

Soil

71. The **[**F378competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where, under the proposed conditions of use, the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products in soil, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Textual Amendments

F378 Words in Annex 6 para. 71 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Air

72. The **[**[F379]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) of point (b) of Article 19(1) where there is a reasonably foreseeable possibility of unacceptable effect on the air compartment, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Textual Amendments

F379 Words in Annex 6 para. 72 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Non-target organisms

73.

The **[**[F380]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product, if for any active substance or substance of concern:

— the PEC/PNEC is above 1, or

— the concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products, has an unacceptable impact on non-target species, unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Textual Amendments

F380 Words in Annex 6 para. 73 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

74. The **[**[F381]competent authority**]** shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product, if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1, unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Textual Amendments

F381 Words in Annex 6 para. 74 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Effects on target organisms

75. Where the development of resistance or cross-resistance to the active substance in the biocidal product is likely, the **[**[F382]competent authority**]** shall consider actions to minimise the consequences of this resistance. This may involve modification of the conditions under which an authorisation is given. However, where the development of resistance or cross-resistance cannot be reduced sufficiently, the **[**[F383]competent

authority**]** shall conclude that the biocidal product does not satisfy criterion (ii) under point (b) of Article 19(1).

Textual Amendments

F382 Words in Annex 6 para. 75 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

F383 Words in Annex 6 para. 75 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(13)**; 2020 c. 1, Sch. 5 para. 1(1)

76. A biocidal product intended to control vertebrates shall not normally be regarded as satisfying criterion (ii) under point (b) of Article 19(1) unless:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

77. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in **[**F384Great Britain**]**, except where the biocidal product is intended for use in specific circumstances. The **[**F385competent authority**]** shall evaluate dose-response data generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Textual Amendments

F384 Words in Annex 6 para. 77 substituted (31.12.2020) by S.I. 2019/720, **Sch. 2 para. 143(14)** (as substituted by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 39(b)**)

F385 Words in Annex 6 para. 77 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

Summary

78. In relation to the criteria set out in points (iii) and (iv) of Article 19(1)(b), the **[**F386competent authority**]** shall combine the conclusions arrived at for the active substance(s) and the substances of concern to produce overall summary conclusions for the biocidal product itself. A summary of the conclusions in relation to the criteria set out in points (i) and (ii) of Article 19(1)(b) shall also be made.

Textual Amendments

F386 Words in Annex 6 para. 78 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

OVERALL INTEGRATION OF CONCLUSIONS

The **[**[F387]competent authority**]** shall, on the basis of the evaluation carried out in accordance with the principles set down in this Annex, come to a conclusion as to whether or not it is established that the biocidal product complies with the criteria laid down under point (b) of Article 19(1).

Textual Amendments

F387 Words in Annex 6 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 2 para. 143(11)**; 2020 c. 1, Sch. 5 para. 1(1)

ANNEX VII

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(**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.

(**14**) OJ L 92, 7.4.1990, p. 42.

(**15**) OJ L 139, 30.4.2004, p. 1.

(**16**) OJ L 139, 30.4.2004, p. 55.

(**17**) OJ L 354, 31.12.2008, p. 34.

(**18**) OJ L 229, 1.9.2009, p. 1.

(**19**) OJ L 309, 24.11.2009, p. 1.

(**20**) OJ 196, 16.8.1967, p. 1.

(**21**) OJ L 183, 29.6.1989, p. 1.

(**22**) OJ L 131, 5.5.1998, p. 11.

(**23**) OJ L 330, 5.12.1998, p. 32.

(**24**) OJ L 200, 30.7.1999, p. 1.

(**25**) OJ L 262, 17.10.2000, p. 21.

(**26**) OJ L 327, 22.12.2000, p. 1.

(**27**) OJ L 158, 30.4.2004, p. 50.

(**28**) OJ L 158, 30.4.2004, p. 7.

(**29**) OJ L 376, 27.12.2006, p. 21.

(**30**) OJ L 204, 31.7.2008, p. 1.

(**31**) OJ L 353, 31.12.2008, p. 1.

(**32**) OJ L 309, 24.11.2009, p. 71.

(**33**) OJ L 286, 31.10.2009, p. 1.

(**34**) OJ L 276, 20.10.2010, p. 33.

(**35**) OJ L 334, 17.12.2010, p. 17.

(**36**) OJ L 124, 20.5.2003, p. 36.

(**37**) **[**[F11]Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).**]**

(**38**) **[**[F11]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).**]**

(**39**) **[**[F11]Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).**]**

(**40**) **[**[F11]Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).**]**

(**41**) **[**[F11]Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).**]**

(**42**) OJ L 218, 13.8.2008, p. 30.

(**43**) OJ L 142, 31.5.2008, p. 1.

(**44**) OJ L 276, 20.10.2010, p. 33.

(**45**) OJ L 50, 20.2.2004, p. 44.

(**46**) See definition of vulnerable groups in Article 3.

(**47**) OJ L 164, 25.6.2008, p. 19.

Textual Amendments

F11 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Status:
Point in time view as at 01/10/2023.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 528/2012 of the European Parliament and of the Council.