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 and repealing Council Directives 79/117/EEC and 91/414/EEC

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 and repealing Council Directives 79/117/EEC and 91/414/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

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

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(4)] provides for rules governing plant protection products and the active substances contained in those products.

(2) Following the progress report presented by the Commission under Directive 91/414/EEC, the European Parliament by its Resolution of 30 May 2002[(5)] and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

(3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.

(4) By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances[(6)].

(5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.

(7) Plant protection products can however also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used.

(8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

(10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

(11) The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use.

(12) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a rapporteur for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority established by 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[7] (the Authority). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active

substance. Provisions should be included to ensure the transparency of the evaluation process.

(13) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.

(14) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.

(15) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. The renewal of the approval should be for a period not exceeding 15 years.

(16) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied, or where compliance with 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[(8)] is compromised, should be provided for under certain conditions.

(17) The evaluation of an active substance may reveal that it presents considerably less of a risk than other substances. In order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to facilitate the placing on the market of plant protection products containing them. Incentives should be given for the placing on the market of low-risk plant protection products.

(18) Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use.

(19) Some active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly examine plant protection products containing such active substances with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods.

(20) In certain Member States non-chemical control or prevention methods, which are significantly safer for human and animal health and for the environment, have been established and generally applied for certain uses. In exceptional cases Member States should also be able to apply the comparative assessment when granting authorisation for plant protection products.

(21) In addition to active substances, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.

(22) Plant protection products may also contain co-formulants. It is appropriate to provide a list of co-formulants which should not be included in plant protection products.

(23) Plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Authorisations for plant protection products should therefore be granted by Member States.

(24) The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

(25) In the interest of predictability, efficiency and consistency, criteria, procedures and conditions for the authorisation of plant protection products should be harmonised, account being taken of the general principles of protection of human and animal health and the environment.

(26) Where the decision on approval cannot be finalised within the period provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for a limited period in order to facilitate the transition to the approval procedure provided for under this Regulation. In the light of the experience gained from the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary.

(27) The active substances contained in a plant protection product can be produced by different manufacturing processes, leading to differences in specifications. Such differences may have safety implications. For efficiency reasons, a harmonised procedure at Community level should be provided for the assessment of those differences.

(28) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure.

(29) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore,

the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of one or more Member States might require that, on application, Member States recognise or amend an authorisation issued by another Member State, or refuse to authorise the plant protection product in their territory, where justified as a result of specific environmental or agricultural circumstances or where the high level of protection of both human and animal health and the environment required by this Regulation cannot be achieved. It should also be possible to impose appropriate conditions having regard to the objectives laid down in the National Action Plan adopted in accordance with Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides[(9)].

(30) The economic incentive for industry to apply for an authorisation is limited for certain uses. In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses.

(31) Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products.

(32) In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level.

(33) Community seeds legislation provides for free movement of seeds within the Community but does not contain a specific provision concerning seeds treated with plant protection products. Such a provision should therefore be included in this Regulation. If treated seeds constitute a serious risk to human or animal health or to the environment, Member States should have the possibility of taking protective measures.

(34) To promote innovation, special rules should be established permitting the use of plant protection products in experiments even where they have not yet been authorised.

(35) To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible. The Council should include in the statutory management requirement referred to in Annex III to Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers[(10)], the principles of integrated pest management, including good plant protection practice and non-chemical methods of plant protection and pest and crop management.

(36) In addition to this Regulation and Directive 2009/128/EC, a thematic strategy on the sustainable use of pesticides was adopted. In order to achieve coherence between these instruments, the user should know from the product label where, when and under what circumstances a plant protection product may be used.

(37) A system of exchange of information should be established. Member States should make available to each other, the Commission and the Authority the particulars and scientific documentation submitted in connection with applications for authorisation of plant protection products.

(38) Adjuvants may be used to increase the efficacy of a plant protection product. Their placing on the market or use should be forbidden where they contain a co-formulant which has been prohibited. The technical rules necessary for the authorisation should be established.

(39) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, tests and studies, other than those involving vertebrate animals, which will be subject to obligatory data sharing, lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary. Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.

(40) The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[11], tests on vertebrate animals must be replaced, restricted or refined. Therefore, rules should be laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. For the purpose of developing new plant protection products, there should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access.

(41) As different rules are applied by Member States, the Commission and the Authority in relation to access to and confidentiality of documents, it is appropriate to clarify the provisions concerning access to information contained in the documents in the possession of these authorities and the confidentiality of these documents.

(42) 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[12] applies to the classification, packaging and labelling of plant protection products. However, to improve further the protection of users of plant protection products, of consumers of plants and plant products and of the environment, further specific rules are appropriate which take account of the specific conditions of use of plant protection products.

(43) To ensure that advertisements do not mislead users of plant protection products or the public, it is appropriate to lay down rules on the advertising of those products.

(44) Provisions on record-keeping and information about the use of plant protection products should be established in order to raise the level of protection of human and animal health and the environment by ensuring the traceability of potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality.

(45) Provisions on control and inspection arrangements with regard to the marketing and use of plant protection products should ensure correct, safe and harmonised implementation of the requirements laid down in this Regulation in order to achieve a high level of protection of both human and animal health and the environment.

(46) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[13] provides for control measures for the use of plant protection products at all stages of the production of food, including record-keeping on the use of plant protection products. Similar rules on monitoring and controls relating to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004 should be adopted by the Commission. The bureaucratic burden on farmers should be as limited as possible.

(47) The measures provided for in this Regulation should apply without prejudice to other Community legislation, in particular Directive 2009/128/EC, Directive 2000/60/EC, 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[14] and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.

(48) It is necessary to establish procedures for the adoption of emergency measures in situations where an approved active substance, a safener, a synergist or a plant protection product is likely to constitute a serious risk to human or animal health or the environment.

(49) Member States should lay down rules on penalties applicable to infringements of this Regulation and should take the measures necessary to ensure that they are implemented.

(50) General civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the plant protection product on the market or using it should remain applicable.

(51) Member States should have the possibility of recovering the costs of the procedures associated with the application of this Regulation from those seeking to place, or

placing, plant protection products or adjuvants on the market and from those applying for the approval of active substances, safeners or synergists.

(52) Member States should designate the necessary national competent authorities.

(53) The Commission should facilitate the application of this Regulation. Therefore, it is appropriate to provide for the necessary financial resources and the possibility of amending certain provisions of this Regulation in the light of experience or of developing technical notes for guidance.

(54) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(15)].

(55) In particular, the Commission should be empowered to adopt harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants, and maximum quantities of plant protection products to be released, and to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(56) On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a Regulation postponing the expiry of the approval period for a period sufficient to examine the application.

(57) Furthermore, it is appropriate to transfer certain current provisions set out in the Annexes to Directive 91/414/EEC into separate legal instruments to be adopted by the Commission within 18 months after the entry into force of this Regulation. Since these current provisions should be, as a first step, transferred into new legal instruments and thus be adopted without any substantial modification, the advisory procedure is the most appropriate.

(58) It is also appropriate to use the advisory procedure to adopt some purely technical measures, in particular technical guidelines in view of their non-binding character.

(59) Certain provisions of Directive 91/414/EEC should remain applicable during the transitional period,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and purpose

1 This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within **[**F1Great Britain**]**.

2 This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.

3 The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the F2... market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

4 The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, **[**F3a competent authority**]** shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their **[**F4constituent**]** territory.

Textual Amendments

F1 Words in Art. 1(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(2)(a)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(a)); 2020 c. 1, Sch. 5 para. 1(1)

F2 Word in Art. 1(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(2)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 1(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(2)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in Art. 1(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(2)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Scope

1 This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

a protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

[[F5]b influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;**]**

c preserving plant products, in so far as such substances or products are not subject to **[**[F6]retained EU law**]** provisions on preservatives;

d destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

e checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

These products are referred to as 'plant protection products'.

2 This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.

3 This Regulation shall apply to the following:

a substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as 'safeners';

b substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as 'synergists';

c substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants';

d substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'.

Textual Amendments

F5 Substituted by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (Text with EEA relevance).

F6 Words in Art. 2(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 3

[[F7]**Definitions: general]**

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

1. 'residues' means one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products;

2. ‘substances’ means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

3. ‘preparations’ means mixtures or solutions composed of two or more substances intended for use as a plant protection product or as an adjuvant;

4. ‘substance of concern’ means any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect.

   Such substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with 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[(16)], and present in the plant protection product at a concentration leading the product to be regarded as **[**[F8]hazardous**]** within the meaning of **[**[F9]that Regulation**]**;

5. ‘plants’ means live plants and live parts of plants, including fresh fruit, vegetables and seeds;

6. ‘plant products’ means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plants;

7. ‘harmful organisms’ means any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products;

8. ‘non-chemical methods’ means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC, or physical, mechanical or biological pest control methods;

9. ‘placing on the market’ means the holding for the purpose of sale within **[**[F10]Great Britain**]**, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation **[**[F11]in Great Britain**]** shall constitute placing on the market for the purposes of this Regulation;

10. ‘authorisation of a plant protection product’ means an administrative act by which **[**[F12]a competent authority**]** authorises the placing on the market of a plant protection product in its **[**[F13]constituent**]** territory;

11. ‘producer’ means a person who manufactures plant protection products, active substances, safeners, synergists, co-formulants or adjuvants on his own, or who contracts this manufacturing to another party, or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;

12. ‘letter of access’ means an original document by which the owner of data protected under this Regulation agrees to the use of such data under the specific terms and conditions by the competent authority for the purpose of granting an authorisation of a plant protection product or an approval of an active substance, synergist or safener for the benefit of another applicant;

13. ‘environment’ means waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms;

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

15. ‘micro-organisms’ means any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;

16. ‘genetically modified organisms’ means organisms in which the genetic material has been altered within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms[17] **[**F14, as last amended by Directive (EU) 2015/412 of the European Parliament and of the Council**]**;

17. F15 . . . . . .

18. ‘good plant protection practice’ means a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;

19. ‘good laboratory practice’ means a practice as defined in point 2.1 of Annex I to 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 applications for tests on chemical substances[18];

20. ‘good experimental practice’ means a practice in accordance with the provisions of European and Mediterranean Plant Protection Organisation (EPPO) Guidelines 181 and 152;

21. ‘data protection’ means the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant;

22. F16 . . . . . .

23. ‘tests and studies’ means investigations or experiments whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products;

24. ‘authorisation holder’ means any natural or legal person holding an authorisation of a plant protection product;

25. ‘professional user’ means a professional user as defined in Article 3(1) of Directive 2009/128/EC **[**F17, and for these purposes, Directive 2009/128/EC is to be read as if Article 3(10)(b) were omitted**]**;

26. ‘minor use’ means use of a plant protection product F18... on plants or plant products which are:

(a) not widely grown in **[**F19Great Britain**]**; or

(b) widely grown, to meet an exceptional plant protection need;

27. 'greenhouse' means a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment.

For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses;

28. 'post-harvest treatment' means treatment of plants or plant products after harvest in an isolated space where no run-off is possible, for example in a warehouse;

29. 'biodiversity' means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;

30. F20. . . . . .

31. 'advertisement' means a means of promoting the sale or use of plant protection products (to anyone other than the authorisation holder, the person placing the plant protection product on the market and their agents) by printed or electronic media;

31B. **[**F21'approvals register' means the register maintained in accordance with Article 27A;

31C. 'unacceptable co-formulants register' means the register maintained in accordance with Article 27B;

31D. 'EU-derived domestic legislation' has the meaning given by section 2(2) of the European Union (Withdrawal) Act 2018;**]**

32. 'metabolite' means any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment.

A metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures;

33. 'impurity' means any component other than the pure active substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage)**[**F5;**]**

34. **[**F22' plant biostimulant ' means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

(a) nutrient use efficiency;

(b) tolerance to abiotic stress;

(c) quality traits;

(d) availability of confined nutrients in soil or rhizosphere.**]**

Textual Amendments

F5 Substituted by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (Text with EEA relevance).

F7 Art. 3 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Word in Art. 3(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in Art. 3(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Art. 3(9) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(c)(i)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(a)); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 3(9) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(c)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(b)(i)); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in Art. 3(10) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F13 Word in Art. 3(10) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Art. 3(16) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F15 Art. 3(17) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(f)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F16 Art. 3(22) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(f)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in Art. 3(25) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(g)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in Art. 3(26) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(h)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in Art. 3(26)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(h)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(b)(i)); 2020 c. 1, Sch. 5 para. 1(1)

F20 Art. 3(30) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F21 Art. 3(31B)-(31D) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(4)(j)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(b)(ii)); 2020 c. 1, Sch. 5 para. 1(1)

F22 Inserted by Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (Text with EEA relevance).

I[F23] Article 3A

Definitions: competent authority, constituent territory and appropriate authority

1 In this Regulation, a reference to a competent authority or a constituent territory is to be interpreted in accordance with the provisions of this Article.

2 The Secretary of State is the competent authority for the constituent territory of England.

3 The Welsh Ministers are the competent authority for the constituent territory of Wales.

4 The Scottish Ministers are the competent authority for the constituent territory of Scotland.

6 In this Regulation, "the appropriate authority" means—

a for regulations applying in relation to England, the Secretary of State;

b for regulations applying in relation to Wales, the Welsh Ministers;

c for regulations applying in relation to Scotland, the Scottish Ministers;

7 But the appropriate authority is the Secretary of State if consent is given by—

a for regulations applying in relation to Wales, the Welsh Ministers;

b for regulations applying in relation to Scotland, the Scottish Ministers;**]**

Textual Amendments

F23 Art. 3A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **3(5)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(3)(c) (which amendment included the omission of para. (5))); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 1

Requirements and conditions for approval

Article 4

Approval criteria for active substances

1 An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2 The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted **[**F24in accordance with paragraph 8**]** to assess such effects are available, or on groundwater;

b they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3 A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a it shall be sufficiently effective;

b it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted **[**F25in accordance with paragraph 8**]** to assess such effects are available; or on groundwater;

c it shall not have any unacceptable effects on plants or plant products;

d it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

e it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted **[**F26in accordance with paragraph 8**]** to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.

4 The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in **[**F27Article 29(6)(a) which apply to each constituent territory to which approval of the active substance relates**]**.

5 For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

6 In relation to human health, no data collected on humans shall be used to lower the safety margins resulting from tests or studies on animals.

7 By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

[F28A competent authority**]** may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in **[**F29its constituent**]** territory.

At the same time, **[**F30the competent authority**]** shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay **[**F31publish that plan in a manner which the competent authority considers appropriate**]**.

[F32**8** For the purposes of paragraphs 2(a) and 3(b) and (e), scientific methods are accepted if they are accepted—

a in relation to England, by the Secretary of State;

b in relation to Wales—

i) by the Secretary of State with the consent of the Welsh Ministers, or

ii) by the Welsh Ministers;

c in relation to Scotland—

i) by the Secretary of State with the consent of the Scottish Ministers, or
ii) by the Scottish Ministers;**]**

Textual Amendments

F24 Words in Art. 4(2)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F25 Words in Art. 4(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F26 Words in Art. 4(3)(e) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F27 Words in Art. 4(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F29 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F30 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F32 Art. 4(8) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(a)); 2020 c. 1, Sch. 5 para. 1(1)

[F33 Article 5

First approval

1 First approval must be for a period not exceeding—
- a 10 years for an active substance, safener or synergist;
- b 15 years for a low-risk active substance (see Article 22);
- c 7 years for a candidate for substitution (see Article 24).

2 Paragraph 1 is subject to Article 17.

3 Approval for a basic substance (see Article 23) is for an unlimited period.**]**

Textual Amendments

F33 Art. 5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Conditions and restrictions

[F34 1.**]** Approval may be subject to conditions and restrictions including:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;

(d) type of preparation;

(e) manner and conditions of application;

(f) submission of further confirmatory information to **[**F35 each specified competent authority within a specified period**]**, where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;

(g) designation of categories of users, such as professional and non-professional;

(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;

(i) the need to impose risk mitigation measures and monitoring after use;

(j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.

[F36 2 A competent authority may request from a specified competent authority a copy of any confirmatory information received in accordance with paragraph 1(f), which the specified competent authority must provide as soon as reasonably practicable.

3 In this Article, "specified" means specified in the condition referred to in paragraph 1(f).**]**

Textual Amendments

F34 Art. 6 renumbered as Art. 6(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F35 Words in Art. 6(1)(f) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F36 Art. 6(2)(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 2

Approval procedure

Article 7

Application

[[F37]1 An application for the approval of an active substance may be submitted by the producer of the active substance to a competent authority.

1A An application for an amendment to the conditions of an approval may be submitted by the producer of the active substance to a competent authority for a constituent territory to which the approval applies.

1B A joint application may be submitted under paragraph 1 or 1A by an association of producers designated by the producers for the purpose of compliance with this Regulation.

1C For the purposes of this Subsection, "the assessing competent authority" in relation to an application is the competent authority referred to in paragraph 1 or 1A respectively, except where a transfer has been agreed under Article 12A(1).

1D An application under paragraph 1 or 1A must be submitted together with a summary and a complete dossier as provided for in Article 8(1) and (2) or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.**]**

[F38]2 . . . . . .

3 When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

[[F39]The assessing competent authority**]** shall assess the confidentiality requests. Upon a request for access to information, the **[**[F40]assessing competent authority**]** shall decide what information is to be kept confidential.

4 When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2) and a list of any claims for data protection pursuant to Article 59.

[[F41]5 When assessing the application the assessing competent authority may obtain independent scientific advice, where the assessing competent authority considers it appropriate to do so.**]**

Textual Amendments

F37 Art. 7(1)-(1D) substituted for Art. 7(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F38 Art. 7(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F39 Words in Art. 7(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F40 Words in Art. 7(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F41 Art. 7(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Dossiers

1 The summary dossier shall include the following:

a information with respect to one or more representative uses on a **[**F42crop grown in the United Kingdom**]** of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met; where the information submitted does not F43... concern a crop F44... , justification for this approach;

b for each point of the data requirements for the active substance **[**F45which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

c for each point of the data requirements for the plant protection product **[**F46which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

d for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

e a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

f the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

g where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

h an assessment of all information submitted.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

F473 . . . . . .

[F484 The appropriate authority may by regulations prescribe the data requirements for—

a one or more active substances, safeners and synergists for the purposes of paragraph 1(b);

b plant protection products for the purposes of paragraph 1(c).**]**

5 Scientific peer-reviewed open literature, as **[**[F49]described in guidance issued under Article 77**]**, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Textual Amendments

F42 Words in Art. 8(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in Art. 8(1)(a) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F44 Words in Art. 8(1)(a) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F45 Words in Art. 8(1)(b) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F46 Words in Art. 8(1)(c) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F47 Art. 8(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F48 Art. 8(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F49 Words in Art. 8(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 9

Admissibility of the application

1 Within 45 days of receiving the application, the **[**[F50]assessing competent authority**]** shall send the applicant a written acknowledgement, stating the date of receipt, and check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in point (e) of Article 8(1). It shall also check the requests for confidentiality referred to in Article 7(3) and the complete lists of tests and studies submitted pursuant to Article 8(2).

2 Where one or more of the elements provided for in Article 8 are missing, the **[**[F51]assessing competent authority**]** shall inform the applicant, setting a period for their submission. Such period shall be a maximum of 3 months.

Where at the end of that period, the applicant has not submitted the missing elements, the **[**F51assessing competent authority**]** shall inform the applicant **[**F52and the other competent authorities**]** that the application is inadmissible.

A new application for the same substance may be submitted at any time.

3 Where the dossiers submitted with the application contain all the elements provided for in Article 8, the **[**F53assessing competent authority**]** shall notify the applicant **[**F54and the other competent authorities**]** of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant **[**F55must on request**]** forward the dossiers as provided for in Article 8 to the other **[**F56competent authorities**]**, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 7(3).

Textual Amendments

F50 Words in Art. 9(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F51 Words in Art. 9(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in Art. 9(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F54 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F55 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F56 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 10

Access to the summary dossier

The **[**F57assessing competent authority**]** shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Textual Amendments

F57 Words in Art. 10 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(8)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 11

Draft assessment report

1 Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the **[**F58assessing competent authority**]** shall prepare and submit to the **[**F59other competent authorities**]** a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2 The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The **[**F60assessing competent authority**]** shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3 Where the **[**F61assessing competent authority**]** needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the **[**F61assessing competent authority**]**. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the **[**F61assessing competent authority**]**. It shall inform the **[**F62other competent authorities**]** accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the **[**F63assessing competent authority**]** shall inform the applicant **[**F64and the other competent authorities,**]** and shall state the missing elements in the assessment included in the draft assessment report.

F65 4 . . . . . .

Textual Amendments

F58 Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F59 Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F60 Words in Art. 11(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F61 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F62 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F63 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F64 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F65 Art. 11(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 12

Conclusion by the [F66assessing competent authority]

1

[F67a) The assessing competent authority must circulate the draft assessment report to the applicant and the other competent authorities at the latest 30 days after its completion. The assessing competent authority may ask the applicant to circulate any updated dossier to the assessing competent authority and the other competent authorities.]

[F68b)] The [F69assessing competent authority] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

[F68c)] The [F70assessing competent authority] shall allow a period of 60 days for the submission of written comments.

2 F71...

Within 120 days of the end of the period provided for the submission of written comments, the [F72assessing competent authority] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant [F73and the other competent authorities,] and shall make it available to the public. [F74In the event that independent scientific advice is obtained by the assessing competent authority in accordance with Article 7(5), the 120-day period must be extended by 90 days.]

Where appropriate, the [F75assessing competent authority] shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3

[F76a)] Where the [F77assessing competent authority] needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the [F78assessing competent authority and the other competent authorities].

[F79b) The assessing competent authority must assess the additional information, and for that purpose the period provided for in paragraph 2 may be extended by a maximum of 60 days.]

[F80c)] The [F81assessing competent authority] may F82... consult a F83... reference laboratory, designated pursuant to [F84Regulation (EU) 2017/625] for the purposes of verifying whether the analytical method for the determination of the residues proposed by

the applicant is satisfactory and meets the requirements in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the [F83]... reference laboratory, provide samples and analytical standards.

4 The conclusion of the **[**[F85]assessing competent authority**]** shall include details concerning the evaluation procedure and the properties of the active substance concerned.

[F86]5 . . . . . .

6 The time **[**[F87]limit**]** for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

[F88]7 . . . . . .

[F88]8 . . . . . .

Textual Amendments

F66 Words in Art. 12 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(11)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F67 Art. 12(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F68 Words in Art. 12(1) renumbered as Art. 12(1)(b)(c) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(b)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F69 Words in Art. 12(1)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F70 Words in Art. 12(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F71 Words in Art. 12(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F72 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F73 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F74 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(ii)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in Art. 12(3) renumbered as Art. 12(3)(a) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F77 Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F78 Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F79 Art. 12(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F80 Words in Art. 12(3) renumbered as Art. 12(3)(c) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(d)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F81 Words in Art. 12(3)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F82 Words in Art. 12(3)(c) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F83 Words in Art. 12(3)(c) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F84 Words in Art. 12(3)(c) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **2(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F85 Words in Art. 12(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(15)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F86 Art. 12(5) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(16)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F87 Word in Art. 12(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(17)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F88 Art. 12(7)(8) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(18)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F89 Article 12A

Application for approval: transfer of assessment functions

1 The assessing competent authority may by agreement transfer the functions listed in paragraph 2 in relation to an application for approval to another competent authority for a constituent territory in relation to which the same application has been made, and upon transfer that competent authority is the assessing competent authority for the purposes of this Subsection.

2 For the purposes of paragraph 1 the functions are the functions of the assessing competent authority under Articles 7(3) and (5), 9, 10, 11 and 12.

3 Following a transfer under paragraph 1, the assessing competent authority must notify the applicant of the transfer.

4 A transfer in accordance with paragraph 1 does not—

a affect anything done by the assessing competent authority prior to transfer;

b affect the timing of any requirements placed on the assessing competent authority under this Subsection.**]**

Textual Amendments

F89 Art. 12A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(19)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F90] Article 13

Approval Decision

1 Within six months of the relevant conclusion date, a competent authority for a constituent territory to which the application relates must decide to do one of the following—

a approve the active substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate;

b amend the conditions of the approval; or

c refuse to approve the active substance.

2 In making a decision under paragraph 1, the competent authority must have regard to—

a the conclusion of the assessing competent authority;

b any comments received by the assessing competent authority in relation to the application, including any environmental monitoring information submitted by an appropriate agency;

c where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained;

d where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 are relevant, the precautionary principle;

e any other matters which the competent authority considers relevant to the competent authority's decision.

3 As soon as reasonably practicable after making a decision under paragraph 1, the competent authority must—

a notify the applicant and the other competent authorities in writing of the decision and the reasons for it, and

b update the approvals register accordingly.

4 The Secretary of State may make a decision under paragraph 1 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers;

5 Where the Secretary of State makes a decision in accordance with paragraph 4—

a a reference in paragraphs 2 and 3 to the competent authority is to be read as a reference to the Secretary of State;

b paragraph 3(a) is to be read as if "other" were omitted.

6 In paragraph 1, the "relevant conclusion date" means—

a where the competent authority is the assessing competent authority, the date on which the competent authority adopts a conclusion under Article 12(2);

b otherwise, the date on which the competent authority receives the conclusion of the assessing competent authority in accordance with Article 12(2).

7 In paragraph 2(b), "appropriate agency" means one of the following—

a the Environment Agency;

b the Natural Resources Body for Wales;

c the Scottish Environment Protection Agency.**]**

Textual Amendments

F90 Art. 13 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(20)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 3

Renewal and review

Article 14

Renewal of approval

1 On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in **[**[F91]Article 6(1)**]**.

[[F92]2 The renewal of the approval must be for a period not exceeding—

a where the active substance is covered by Article 4(7), 5 years;

b for a candidate for substitution (see Article 24), 7 years;

c otherwise, 15 years.

3 Paragraph 2 is subject to Article 17.**]**

Textual Amendments

F91 Words in Art. 14(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(21)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F92 Art. 14(2)(3) substituted for Art. 14(2) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(21)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 15

Application for renewal

1 The application provided for in Article 14 shall be submitted by a producer of the active substance to a **[**F93competent authority for a constituent territory in relation to which the active substance is approved**]**, no later than three years before the expiry of the approval.

[F94 1A For the purposes of this Subsection, "the assessing competent authority" in relation to an application is the competent authority referred to in paragraph 1, except where a transfer has been agreed under Article 15A(1).**]**

2 When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval. The applicant shall at the same time submit a timetable of any new and ongoing studies.

The applicant shall identify, giving reasons, the parts of the information submitted that he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

[F95 3 The assessing competent authority must notify the other competent authorities as soon as reasonably practicable after receipt of an application under paragraph 1.

4 A competent authority which receives a notification under paragraph 3 may request in writing from the applicant a copy of the application and any accompanying information, which the applicant must provide as soon as reasonably practicable.**]**

Textual Amendments

F93 Words in Art. 15(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F94 Art. 15(1A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F95 Art. 15(3)(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

***I**F96 Article 15A*

Applications for renewal: transfer of assessment

1 The assessing competent authority may by agreement transfer the function of assessing an application for renewal to another competent authority for a constituent territory in relation to which the active substance to be renewed is approved, and upon transfer that competent authority is the assessing competent authority for that application for the purposes of the renewal provisions.

2 The application for renewal and any supporting dossiers or information must be transferred at the same time as the transfer under paragraph 1.

3 Following a transfer under paragraph 1, the assessing competent authority must notify the applicant of the transfer.

4 A transfer in accordance with paragraph 1 does not—

a affect anything done by the assessing competent authority prior to transfer;

b affect the timing of any requirements placed on the assessing competent authority under the renewal provisions.

5 In this Article, the "renewal provisions" means the provisions of—

a this Subsection, and

b Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances.**]**

Textual Amendments

F96 Art. 15A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(23)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 16

Access to the information for renewal

The **[**F97assessing competent authority**]** shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Textual Amendments

F97 Words in Art. 16 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(24)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 17

Extension of approval period for the duration of the procedure

[F98 1 Where for reasons beyond the control of the applicant it appears to a competent authority that the approval is likely to expire before a decision has been taken on renewal, the competent authority must extend the approval period by a further period sufficient to examine the application.**]**

F99 . . . . . .

[F100 3**]** The length of that period shall be established on the basis of the following:

(a) the time needed to provide the information requested;

(b) the time needed to complete the procedure;

(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

[F101 4 As soon as reasonably practicable after extending the approval period in accordance with the first paragraph, the competent authority must—

a notify the applicant and the other competent authorities of the extension, and

b update the approvals register accordingly.

5 The Secretary of State may extend approval under paragraph 1 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

6 Where the Secretary of State extends approval in accordance with paragraph 5, paragraph 4 is to be read as if—

a in the words before point (a), the reference to the competent authority were a reference to the Secretary of State;

b in point (a), "other" were omitted.**]**

Textual Amendments

F98 Art. 17(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F99 Words in Art. 17 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F100 Words in Art. 17 renumbered as Art. 17(3) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F101 Art. 17(4)-(6) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(c)); 2020 c. 1, Sch. 5 para. 1(1)

Article 18

Work programme

[F102 1**]** **[**F103 A competent authority**]** may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the **[**F104 competent authority**]** within a period provided for in the programme.

[F105 2**]** The programme shall include the following:

(a) the procedures concerning the submission and assessment of applications for renewal of approvals;

(b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) F106 . . . . . .

[F107 3 The competent authority may vary or withdraw a work programme established by it.

4 The competent authority must publish the work programme and notice of any variation or withdrawal of a work programme in such manner as the competent authority thinks appropriate.

5 The Secretary of State may establish, vary or withdraw a work programme under paragraph 1 or 3 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

6 Where the Secretary of State establishes, varies or withdraws a work programme in accordance with paragraph 5, a reference in paragraph 4 to the competent authority is to be read as a reference to the Secretary of State.

7 Where the Secretary of State establishes, varies or withdraws a work programme in accordance with paragraph 5 in respect of one or more competent authorities, the programme must also include an allocation of evaluation of active substances to the Secretary of State and those competent authorities, taking into account a balance in the responsibilities and work to be done among the Secretary of State and those competent authorities.

8 A competent authority may request in writing from the competent authority which receives data relating to an active substance in accordance with a work programme under this Article a copy of that data, which the competent authority must provide as soon as reasonably practicable.**]**

Textual Amendments

F102 Words in Art. 18 renumbered as Art. 18(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F103 Words in Art. 18(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F104 Words in Art. 18(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F105 Words in Art. 18 renumbered as Art. 18(2) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F106 Art. 18(2)(f) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F107 Art. 18(3)-(8) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(e)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F108 Article 19

Implementing measures

The appropriate authority may, by regulations, make provision necessary for the implementation of the renewal procedure. **]**

Textual Amendments

F108 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F108 Article 20

Renewal decision

1 Within six months of the relevant conclusion date, a competent authority for a constituent territory to which the application relates must decide to either—

a renew the approval of the active substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate; or

b refuse to renew approval of the active substance.

2 In making a decision under paragraph 1, the competent authority must have regard to—

a the conclusion of the assessing competent authority and the opinion of the Agency, if any, referred to in Article 37(4) of Regulation (EC) No 1272/2008;

b any comments received by the assessing competent authority in relation to the application, including any environmental monitoring information submitted by an appropriate agency;

c where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained;

d where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council are relevant, the precautionary principle;

e any other matters which the competent authority considers relevant to the competent authority's decision.

3 Where the reasons for not renewing the approval of an active substance—

a relate to immediate concerns for the protection of human or animal health or the environment, plant protection products containing that active substance must be withdrawn from the market immediately;

b do not fall within point (a), the competent authority must set a grace period in respect of existing stocks of the plant protection products containing that active substance.

4 The grace period—

a for the sale and distribution of the plant protection products must take into account the normal period of use of those plant protection products but must not exceed six months;

b for the disposal, storage, and use of the plant protection products must be consecutive to the period described in point (a) and must not exceed one year.

5 As soon as reasonably practicable after making a decision under paragraph 1, the competent authority must—

a notify the applicant and the other competent authorities in writing of the decision under paragraph 1, the reasons for that decision and the details of any grace period set in accordance with paragraphs 3 and 4, and

b update the approvals register accordingly.

6 The Secretary of State may make a decision under paragraph 1 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

7 Where the Secretary of State makes a decision in accordance with paragraph 6, a reference in paragraphs 2, 3 and 5 to the competent authority is to be read as a reference to the Secretary of State.

8 In paragraph 1, the "relevant conclusion date" means—

a where the competent authority is the assessing competent authority, the date on which the competent authority adopts a conclusion under Article 13(1) of Commission Implementing Regulation (EU) No 844/2012;

b otherwise, the date on which the competent authority receives the conclusion of the assessing competent authority in accordance with Article 13(1) of Commission Implementing Regulation (EU) No 844/2012.

9 In paragraph 2(b), "appropriate agency" has the meaning given by Article 13(7).**]**

Textual Amendments

F108 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

I[F108] Article 20A

Review of further information submitted

1 Where an approval is subject to a condition in accordance with Article 6(1)(f), any confirmatory information received within the period specified in the condition must be assessed by the reviewing authority.

2 Within 6 months of receipt of the confirmatory information, the reviewing authority must—

a assess that information, and

b submit its assessment to the other competent authorities.

3 For the purposes of this Article, the "reviewing authority" is—

a the competent authority specified in the condition to which the approval is subject, or

b a competent authority to which the function of reviewing the confirmatory information is transferred in accordance with paragraph 4.

4 The reviewing authority may by agreement transfer the function of reviewing confirmatory information received to another competent authority.

5 Any confirmatory information received must be transferred at the same time as the transfer under paragraph 4.

6 Following a transfer under paragraph 4, the competent authority to which the function is transferred must notify the applicant of the transfer.

7 A transfer in accordance with paragraph 4 does not—

a affect anything done by the reviewing authority prior to transfer;

b affect the timing of the requirement in paragraph 2.**]**

Textual Amendments

F108 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F108 Article 21

Review of approval

1 A competent authority may review the approval of an active substance in relation to its constituent territory at any time.

2 The competent authority must review the approval of an active substance in relation to its constituent territory where—

a the competent authority has assessed confirmatory information as reviewing authority in accordance with Article 20A(1),

b the competent authority receives the assessment of the reviewing competent authority in accordance with Article 20A(2)(b), or

c further information required in accordance with a condition under Article 6(1)(f) has not been provided within the period specified in the condition.

3 Where the competent authority considers that—

a in light of new scientific and technical knowledge or the assessment of the reviewing authority in accordance with Article 20A, there are indications that the active substance no longer satisfies the approval criteria provided for in Article 4, or

b further information required in accordance with a condition under Article 6(1)(f) has not been provided

the competent authority must inform each of the other competent authorities and the producer of the active substance accordingly, setting a period for the submission of comments.

4 The competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

5 Where the competent authority concludes, having considered comments received during the period set in accordance with paragraph 3 and any other information or matters that the competent authority considers relevant to the review, that paragraph 3(a) or (b) apply, the competent authority must decide to either—

a amend the conditions or restrictions of the approval, or

b withdraw the approval.

6 Where the reasons for withdrawing the approval of an active substance—

a relate to immediate concerns for the protection of human or animal health or the environment, plant protection products containing that active substance must be withdrawn from the market immediately;

b do not fall within point (a), the competent authority must set a grace period in respect of existing stocks of the plant protection products containing that active substance.

7 The grace period—

a for the sale and distribution of the plant protection products must take into account the normal period of use of those plant protection products but must not exceed six months;

b for the disposal, storage, and use of the plant protection products must be consecutive to the period described in point (a) and must not exceed one year.

8 As soon as reasonably practicable after making a decision under paragraph 5, the competent authority must—

a notify the producer of the active substance and the other competent authorities in writing of the decision, the reasons for that decision, and the details of any grace period set in accordance with paragraphs 6 and 7, and

b update the approvals register accordingly.

9 The Secretary of State may review an active substance under paragraph 1 or 2 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

10 Where the Secretary of State reviews an active substance in accordance with paragraph 9, a reference in paragraphs 3 to 6 and 8 to the competent authority is to be read as a reference to the Secretary of State.**]**

Textual Amendments

F108 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Subsection 4

Derogations

[*F109**** Article 22***

Low-risk active substances

1 An active substance complying with the criteria provided for in Article 4 must be approved as a low-risk active substance where—

a that substance complies with the criteria in point 5 of Annex 2, and

b it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1).

2 Articles 4 to 21 apply.

3 The appropriate authority may, by regulations, amend point 5 of Annex 2 to specify new criteria for approving an active substance as a low-risk active substance.**]**

Textual Amendments

F109 Art. 22 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(28)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 23

Approval criteria for basic substances

1 Basic substances shall be approved in accordance with **[**F110this Article**]**. F111...

For the purpose of **[**F110this Article**]**, a basic substance is an active substance which:

a is not a substance of concern; and

b does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

c is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

d is not placed on the market as a plant protection product.

For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

2 By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other F112... legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

3 By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted F113... by any interested party to the **[**F114the competent authority for the constituent territory in relation to which approval is sought**]**.

The application shall be accompanied by the following information:

a any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other F115... legislation regulating the use of the substance; and

b other relevant information on its possible effects on human or animal health or the environment.

F116 4 . . . . . .

[F117 5 Article 6 applies to the approval of a basic substance.

5A Within the decision period following receipt of the application and accompanying information, the competent authority must decide to either—

a approve the basic substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate, or

b refuse to approve the basic substance.

5B In paragraph 5A, the "decision period" is—

a where the competent authority obtains independent scientific advice in respect of the application, nine months;

b otherwise, six months.

5C In making a decision under paragraph 5A, the competent authority must have regard to—

a the application and accompanying information,

b where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained,

c where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council are relevant, the precautionary principle, and

d any other matters which the competent authority considers relevant to the competent authority's determination of the application.

5D As soon as reasonably practicable after making a decision under paragraph 5A, the competent authority must—

a notify the applicant and the other competent authorities in writing of that decision and the reasons for it, and

b update the approvals register accordingly.

5E Article 20A applies to an approval of a basic substance which is subject to a condition in accordance with Article 6(1)(f) as it applies to an approval of an active substance.

5F The Secretary of State may make a decision under paragraph 5A instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

5G Where the Secretary of State makes a decision in accordance with paragraph 5F, a reference in paragraphs 5A to 5D to the competent authority is to be read as a reference to the Secretary of State.**]**

F118 6 . . . . . .

Textual Amendments

F110 Words in Art. 23(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F111 Words in Art. 23(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F112 Word in Art. 23(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F113 Words in Art. 23(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F114 Words in Art. 23(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F115 Word in Art. 23(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F116 Art. 23(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F117 Art. 23(5)-(5G) substituted for Art. 23(5) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(e)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(e)); 2020 c. 1, Sch. 5 para. 1(1)

F118 Art. 23(6) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(f)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F119] *Article 23A*

Review of basic substance approval

1 A competent authority may review the approval of a basic substance at any time.

2 A competent authority must review the approval of a basic substance where—

a the competent authority has received and assessed confirmatory information in accordance with Article 20A (as applied by Article 23(5E));

b further information required in accordance with a condition under Article 6(1)(f) has not been provided within the period specified in that condition.

3 Where the competent authority considers that there are indications that the substance no longer satisfies the criteria provided for in Article 23(1) to (3), the competent authority must inform the other competent authorities and the interested party referred to in Article 23(3) accordingly, setting a period for the submission of comments.

4 The competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

5 Where the competent authority concludes that, having considered comments received during the period set in accordance with paragraph 3 and any other information or matters that the competent authority considers important and relevant to the review, the substance no longer satisfies the criteria provided for in Article 23(1), the competent authority must decide to either—

a amend the conditions of the approval, or

b withdraw the approval.

6 As soon as reasonably practicable after making a decision under paragraph 5, the competent authority must—

a notify the other competent authorities and the interested party referred to in Article 23(3) in writing of the decision and the reasons for it, and

b update the approvals register accordingly.

7 The Secretary of State may review an active substance under paragraph 1 or 2 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

8 Where the Secretary of State reviews an active substance in accordance with paragraph 7, a reference in paragraphs 3 to 6 to the competent authority is to be read as a reference to the Secretary of State.**]**

Textual Amendments

F119 Art. 23A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(30)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 24

Candidates for substitution

1 An active substance complying with the criteria provided for in Article 4 shall be approved [F120]... as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. [F121]...

2 Without prejudice to paragraph 1, Articles 4 to 21 shall apply. [F122]...

Textual Amendments

F120 Words in Art. 24(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(31)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F121 Words in Art. 24(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(31)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F122 Words in Art. 24(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(31)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2

Safeners and synergists

Article 25

Approval of safeners and synergists

1 A safener or synergist shall be approved, where it complies with Article 4.

2 Articles 5 to 21 shall apply.

[F123]3 . . . . . .

Textual Amendments

F123 Art. 25(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(32)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F124 Article 25A

Safeners and synergists on the market on or before 14th June 2011

1 A safener or synergist is deemed to be approved for the purposes of this Regulation in each constituent territory if on or before 14th June 2011 it was—

a held for the purpose of sale within the European Union, an EEA state or the United Kingdom, including being offered for sale or other form of transfer, whether free of charge or not;

b sold, distributed or otherwise transferred within the European Union, an EEA state or the United Kingdom, but not including return to the previous seller; or

c released for free circulation into the territory of the European Union, an EEA state or the United Kingdom.

2 For the purposes of paragraph 1, "the European Union" does not include the Republic of Croatia.

3 A safener or synergist is deemed to be approved in accordance with paragraph 1 in a constituent territory until—

a where an application for approval of that safener or synergist is received in accordance with Article 7 (as applied by Article 25(2)), the date on which a decision is made by the competent authority for that constituent territory or the Secretary of State in accordance with Article 13 (as applied by Article 25(2));

b otherwise, the earliest of the following dates—

i) the date on which the competent authority or the Secretary of State decides to withdraw approval of the safener or synergist for that constituent territory in accordance with Article 21 as applied by paragraph 4;

ii) the date on which the first regulations made under Article 8(4)(a) in respect of safeners or synergists (as the case may be) which apply to that constituent territory come into force.

4 Article 21 applies to a safener or synergist deemed to be approved in accordance with paragraph 1 as if—

a a reference to an active substance were a reference to that safener or synergist;

b paragraph 2 were omitted;

c in paragraph 3—

i) in point (a), the words from "or the assessment" to "Article 20A," were omitted;

ii) point (b) (and the "or" immediately preceding it) were omitted;

d in paragraph 5, for "or (b) apply" there were substituted "applies";

e paragraph 8(b) (and the "and" immediately preceding it) were omitted;

f in paragraph 9, in the words before point (a) "or 2" were omitted.**]**

Textual Amendments

F124 Art. 25A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(33)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 26

Safeners and synergists already on the market

By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.

SECTION 3

Unacceptable co-formulants

Article 27

Co-formulants

1 A co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

a its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or

b its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.

2 Co-formulants which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included **[**F125on the unacceptable co-formulants register**]**.

3 **[**F126A competent authority may review co-formulants which are not accepted in the competent authority's constituent territory for inclusion in a plant protection product at any time.**][**F127The competent authority**]** may take into account relevant information provided by **[**F128the other competent authorities**]**.

F1294 . . . . . .

[F1305 The appropriate authority may, by regulations, make provision necessary for the implementation of this Article.**]**

Textual Amendments

F125 Words in Art. 27(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F126 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F127 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F128 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F129 Art. 27(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F130 Art. 27(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F131] *SECTION 4*

Registers

Article 27A

Approvals register

1 The competent authorities must jointly establish and maintain a register of active substances, safeners, synergists, low-risk active substances, basic substances and candidates for substitution approved in accordance with this Regulation.

2 The entry on the register for each substance must contain the following information—

a the common name and identification numbers of the substance;

b the IUPAC name of the substance, where available;

c the minimum purity of the substance;

d in respect of each constituent territory to which the entry relates—

i) whether the substance has been approved as an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution;

ii) the date of the approval decision;

iii) except in relation to approved basic substances, the expiration date of approval;

iv) information on any specific provisions, conditions or requirements in respect of the approved substance.

3 The register must contain a search facility.

4 The competent authorities must jointly make the register available for inspection by the public on a website maintained by one or more of the competent authorities.

Article 27B

Unacceptable co-formulants register

1 The competent authorities must jointly establish and maintain a register of co-formulants which are not acceptable for inclusion in a plant protection product in accordance with Article 27.

2 The entry on the register for each co-formulant must contain the following information—

a the common name of the co-formulant;

b the IUPAC name of the co-formulant (where available);

c the CAS number of the co-formulant (where available);

d the EC number of the co-formulant (where available);

e in respect of each constituent territory to which the entry relates—

i) the date of the decision that the co-formulant was not acceptable for inclusion in a plant protection product;

ii) the sunset date for the co-formulant;

iii) any conditions of restriction relating to the co-formulant;

iv) any other information regarding the co-formulant that the competent authority considers relevant.

3 The register must contain a search facility.

4 The competent authorities must jointly make the register available for inspection by the public on a website maintained by one or more of the competent authorities.**]**

Textual Amendments

F131 Ch. 2 Section 4 inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(35)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER III

PLANT PROTECTION PRODUCTS

F132F133 *SECTION 1*

Authorisation

Subsection 1

Requirements and contents

Article 28

Authorisation for placing on the market and use

1 A plant protection product shall not be placed on the market or used **[**F134in a constituent territory**]** unless it has been authorised **[**F135by the relevant competent authority**]** in accordance with this Regulation.

2 By way of derogation from paragraph 1, no authorisation shall be required in the following cases:

a use of products containing exclusively one or more basic substances;

b placing on the market and use of plant protection products for research or development purposes in accordance with Article 54;

c production, storage or movement of a plant protection product intended for use in **[**F136the constituent territory of another competent authority**]**, provided that the product is authorised **[**F137by that other competent authority for that constituent territory**]**;

d production, storage or movement of a plant protection product intended for use **[**F138outside Great Britain**]** provided that **[**F139there are inspection requirements in place**]** to ensure that the plant protection product is exported from **[**F140the United Kingdom or, where the product is intended for use in Northern Ireland, is transported to Northern Ireland**]**;

e placing on the market and use of plant protection products for which a parallel trade permit **[**F141is in force**]** in accordance with **[**F142Article 52A and, for these purposes, a plant protection product subject to a grace period granted in accordance with Article 46 (as applied by Article 52A) is to be treated as though it were a product for which a parallel trade permit is in force**]**.

Textual Amendments

F134 Words in Art. 28(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F135 Words in Art. 28(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F136 Words in Art. 28(2)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F137 Words in Art. 28(2)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F138 Words in Art. 28(2)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(ii)(aa)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(a)(i)); 2020 c. 1, Sch. 5 para. 1(1)

F139 Words in Art. 28(2)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F140 Words in Art. 28(2)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(ii)(cc)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(a)(ii)); 2020 c. 1, Sch. 5 para. 1(1)

F141 Words in Art. 28(2)(e) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(2)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F142 Words in Art. 28(2)(e) substituted (31.12.2023) by The Plant Protection Products (Miscellaneous Amendments) Regulations 2023 (S.I. 2023/1321), regs. 1(2), **4(2)** (with reg. 5)

Article 29

Requirements for the authorisation for placing on the market

1 Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 **[**[F143]for the constituent territory of authorisation**]** it complies with the following requirements:

a its active substances, safeners and synergists **[**[F144]are approved in the constituent territory of authorisation, and approval is not suspended in accordance with Article 69**]**;

b where its active substance, safener or synergist is produced by a different source, or by the same source with a change in the manufacturing process and/or manufacturing location:

(i) the specification, pursuant to Article 38, does not deviate significantly from the specification **[**[F145]of that substance, safener or synergist as approved in the constituent territory of authorisation**]**; and

(ii) the active substance, safener or synergist has no more harmful effects within the meaning of Article 4(2) and (3) due to its impurities than if it had been produced in accordance with the manufacturing process specified in the dossier that supported the approval;

c its co-formulants are not included **[**[F146]on the unacceptable co-formulants register in relation to the constituent territory of authorisation**]**;

d its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

e in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

f the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;

g its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate

methods in general use in **[**F147Great Britain**]**, with appropriate limits of determination on relevant samples;

h its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

i for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified **[**F148in relation to the constituent territory of authorisation**]** in accordance with Regulation (EC) No 396/2005.

2 The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3 Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the **[**F149areas of Great Britain**]** where the product is intended to be used.

F150 4 . . . . . .

F150 5 . . . . . .

6

[F151a) The appropriate authority may, by regulations, prescribe uniform principles for the evaluation and authorisation of plant protection products.**]**

[F152b)**]** Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.

Textual Amendments

F143 Words in Art. 29(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F144 Words in Art. 29(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F145 Words in Art. 29(1)(b)(i) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F146 Words in Art. 29(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F147 Words in Art. 29(1)(g) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(v)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(b)); 2020 c. 1, Sch. 5 para. 1(1)

F148 Words in Art. 29(1)(i) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(vi)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F149 Words in Art. 29(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(b)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(b)); 2020 c. 1, Sch. 5 para. 1(1)

F150 Art. 29(4)(5) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F151 Art. 29(6)(a) substituted for words in Art. 29(6) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(d)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F152 Words in Art. 29(6) renumbered as Art. 29(6)(b) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(d)(ii)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 30

Provisional authorisations

1 By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:

a the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and

b pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and

c the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and

d maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2 In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3 The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 31

Contents of authorisations

1 The authorisation shall define plants or plant products and non-agricultural areas (for example railways, public areas, storage rooms) on which and the purposes for which the plant protection product may be used.

2 The authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall as a minimum include the conditions of use necessary to comply with the conditions and requirements provided for in the **[**[F153]approval of**]** the active substances, safeners and synergists **[**[F154]in the constituent territory of authorisation**]**.

The authorisation shall include a classification of the plant protection product for the purpose of **[**[F155]Regulation (EC) No 1272/2008 of the European Parliament and

of the Council**]**. **[**[F156]A competent authority**]** may provide that authorisation holders shall classify or update the label without undue delay following any change to the classification and labelling of the plant protection product in accordance with **[**[F157]Regulation (EC) No 1272/2008 of the European Parliament and of the Council**]**. In such cases, they shall immediately inform the competent authority thereof.

3 The requirements referred to in paragraph 2 shall also include where applicable:

a the maximum dose per hectare in each application;

b the period between the last application and harvest;

c the maximum number of applications per year.

4 The requirements referred to in paragraph 2 may include the following:

a a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, residents, consumers or workers concerned or the environment, taking into consideration requirements imposed by other **[**[F158]retained EU law**]**; such restriction shall be indicated on the label;

b the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed;

c indications for proper use according to the principles of Integrated Pest Management referred to in Article 14 of and Annex III to Directive 2009/128/EC;

d designation of categories of users, such as professional and non-professional;

e the approved label;

f the interval between applications;

g the period between the last application and consumption of the plant product where applicable;

h the re-entry interval;

i the packaging size and material.

[[F159]5 For the purposes of paragraph 4(c), Directive 2009/128/EC is to be read as if—

a Article 3(10)(b) were omitted;

b in Article 14—

i) obligations on Member States were obligations on the competent authorities;

ii) paragraph 3 were omitted.**]**

Textual Amendments

F153 Words in Art. 31(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(5)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F154 Words in Art. 31(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(5)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F155 Words in Art. 31(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(5)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F156 Words in Art. 31(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(5)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F157 Words in Art. 31(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(5)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F158 Words in Art. 31(4)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(6)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F159 Art. 31(5) inserted by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(7)** (with Sch 1) (as substituted by S.I. 2019/1410, regs. 1(2), **6(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 32

Duration

1 The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval **[**[F160]in the constituent territory of authorisation**]** of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved **[**[F161]in the constituent territory of authorisation**]**.

This period shall allow the examination as provided for in Article 43 to be carried out.

2 Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.

Textual Amendments

F160 Words in Art. 32(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(8)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F161 Words in Art. 32(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(8)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

[[F162]1 An applicant or a representative of the applicant may apply to the competent authority for authorisation to place a plant protection product on the market in a constituent territory.

1A An applicant or a representative of the applicant may apply to the competent authority which granted an authorisation to amend that authorisation.**]**

2 The application shall include the following:

a a list of intended uses **[**F163and the competent authorities to whom**]** the applicant has made or intends to make an application;

F164b . . . . . .

c where relevant, a copy of any authorisations already granted for that plant protection product **[**F165by a competent authority**]**;

d where relevant, a copy of any conclusion of the **[**F166competent authority**]** assessing equivalence as referred to in Article 38(2).

3 The application shall be accompanied by the following:

a for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

b for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

c for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

d the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

e where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

f where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

g a draft label.

4 When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the **[**F167competent authority**]** examining the application **[**F168(see Article 35)**]** shall decide what information is to be kept confidential.

[F1695 Where permitted by the competent authority, the applicant may submit an application in a language other than English.**]**

6 On request, the applicant shall provide the **[**F170competent authority**]** with samples of the plant protection product and analytical standards of its ingredients.

Textual Amendments

F162 Art. 33(1)(1A) substituted for Art. 33(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(a)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F163 Words in Art. 33(2)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(b)(i)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F164 Art. 33(2)(b) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(b)(ii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F165 Words in Art. 33(2)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(b)(iii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F166 Words in Art. 33(2)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(b)(iv)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F167 Words in Art. 33(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(c)(i)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F168 Words in Art. 33(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(c)(ii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F169 Art. 33(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(d)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

F170 Words in Art. 33(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(9)(e)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 34

Exemption from the submission of studies

1 Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the **[**F171competent authority examining the application**]** has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired **[**F172, or where paragraph 3 applies**]**.

2 However, applicants to whom paragraph 1 applies shall provide the following information:

a all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that **[**F173, in respect of each constituent territory to which the application relates,**]** no unacceptable co-formulants are used;

b the information needed to identify the active substance, safener or synergist, where they have been approved **[**F174in respect of each constituent territory to which the application relates**]**, and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;

c on the request of the **[**F175competent authority examining the application**]**, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

[F176 3 This paragraph applies where another competent authority has the test and study reports concerned.

4 Where paragraph 3 applies—

a the competent authority examining the application must request those reports from the competent authority which has those reports, and

b the competent authority which has those reports must send them to the competent authority examining the application as soon as reasonably practicable.**]**

Textual Amendments

F171 Words in Art. 34(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F172 Words in Art. 34(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F173 Words in Art. 34(2)(a) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F174 Words in Art. 34(2)(b) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F175 Words in Art. 34(2)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F176 Art. 34(3)(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

*[*F177 *Article 35*

Competent authority examining the application

1 For the purposes of this Subsection "the competent authority examining the application" is the competent authority which receives the application under Article 33.

2 But a competent authority may examine an application on behalf of one or more of the other competent authorities (and consequently for the purposes of this Subsection is "the competent authority examining the application") where—

a each competent authority receives the same application;

b each competent authority agrees which competent authority is to examine the application;

c each active substance, safener or synergist in the plant protection product to which the application relates—

i) is approved in relation to the constituent territory of each competent authority, and the conditions of each approval are compatible with the proposed authorisation, and

ii) has an equivalent technical specification in relation to each constituent territory, where necessary as determined in accordance with Article 38;

d any co-formulant in the plant protection product to which the application relates is not included on the unacceptable co-formulants register in relation to the constituent territory of each competent authority; and

e any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) and any guidance relating to those requirements or principles are the same in relation to the constituent territory of each competent authority.

3 Where paragraph 2 applies in relation to an application—

a the competent authority examining the application must inform the applicant that it is to examine the application;

b the other competent authorities must —

i) not proceed to determine the application pending assessment by the competent authority examining the application;

ii) at the request of the competent authority examining the application, cooperate to ensure a fair division of the workload.**]**

Textual Amendments

F177 Art. 35 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(11)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 36

Examination for authorisation

1 The **[**F178competent authority**]** examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. **[**F179Where Article 35(2) applies in relation to an application, the competent authority examining the application must give the other competent authorities**]** the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in **[**F180Article 29(6)(a)**]**, to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 F181... , where used in accordance with Article 55, and under realistic conditions of use.

[F182Where Article 35(2) applies in relation to an application, the competent authority examining the application must make available its assessment to the other competent authorities.**]**

2 **[**F183Where Article 35(2) applies in relation to an application, the competent authorities which received that application**]** shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the **[**F184competent authority**]** examining the application as provided for in Articles 31 and 32.

3 By way of derogation from paragraph 2 and subject to **[**F185retained EU**]** law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a **[**F186competent authority**]** relating to human or animal health or the environment cannot be controlled by the establishment of the F187... risk mitigation measures referred to in the first subparagraph, **[**F188that competent authority**]** may refuse authorisation of the plant protection product in its **[**F189constituent**]** territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That **[**F190competent authority**]** shall immediately inform the applicant and the **[**F191other competent authorities**]** of its decision and provide a technical or scientific justification therefor.

F192 …

Textual Amendments

F178 Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F179 Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F180 Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F181 Words in Art. 36(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F182 Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F183 Words in Art. 36(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F184 Words in Art. 36(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F185 Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F186 Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F187 Word in Art. 36(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F188 Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F189 Word in Art. 36(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F190 Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(iii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F191 Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(iii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F192 Words in Art. 36(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 37

Period for examination

1 The **[**F193competent authority**]** examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the **[**F193competent authority**]** needs additional information, it shall set a period for the applicant to supply it. In that case, the 12-month period shall be extended by the additional period granted by the **[**F193competent authority**]**. That additional period shall be a maximum of 6 months and shall cease at the moment when the additional information is received by the **[**F193competent authority**]**. Where at the end of that period the applicant has not submitted the missing elements, the **[**F193competent authority**]** shall inform the applicant that the application is inadmissible.

2 The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3 For an application for authorisation of a plant protection product containing an active substance not yet approved, the **[**F194competent authority**]** examining the application shall start the evaluation as soon as **[**F195the draft assessment report for that active substance is circulated in accordance with Article 12(1)(a)**]**. In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the **[**F194competent authority**]** shall decide on the application at the latest within six months of the active substance being approved.

[F196**3A** Where Article 35(2) applies in relation to an application, the requirement in paragraph 3 to decide on the application within 6 months of the active substance being approved is to be read as a requirement to decide on the application within 6 months of the earliest date on which the active substance is approved by one of the competent authorities which received the application for authorisation.**]**

4 **[**F197Where Article 35(2) applies in relation to an application, the competent authorities which received the application for authorisation**]** shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the **[**F198competent authority**]** examining the application decide on the application as referred to in Article 36(2) and (3).

Textual Amendments

F193 Words in Art. 37(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F194 Words in Art. 37(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F195 Words in Art. 37(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F196 Art. 37(3A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F197 Words in Art. 37(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F198 Words in Art. 37(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F199] Article 38

Assessment of equivalence under Article 29(1)(b)

1 This Article applies where it is necessary in relation to an application to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process or location complies with Article 29(1)(b).

1A Where this Article applies, equivalence—

a may be assessed by a competent authority examining the application, where—

i) each of the other competent authorities examining the application consents to that competent authority assessing equivalence, and

ii) in relation to the active substance, safener or synergist for which equivalence is to be assessed, any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority examining the application;

b otherwise, must be assessed by each competent authority examining the application.

1B The applicant must submit all necessary data to each competent authority assessing equivalence.

2 A competent authority assessing equivalence must—

a give the applicant the opportunity to submit comments,

b prepare a report on the competent authority's conclusion on equivalence within 60 days from receiving the application, and

c provide a copy of that report to—

i) the applicant, and

ii) where the assessment is undertaken in accordance with paragraph 1A(a), the other competent authorities examining the application.

3 Where an assessment is undertaken in accordance with paragraph 1A(a), a competent authority examining the application which does not agree with the conclusion in the report provided in accordance with paragraph 2(c)(ii) must notify the competent authority which

assessed equivalence, the other competent authorities examining the application and the applicant, stating its reasons for not agreeing.

3A Following a notification under paragraph 3, the competent authorities concerned must—

a give the applicant the opportunity to submit comments, and

b try to reach agreement on whether Article 29(1)(b) is complied with.

4 Article 29(1)(b) is deemed not to be complied with where the competent authorities concerned under paragraph 3A do not reach agreement within 45 days of the latest date on which a notification from a competent authority is communicated in accordance with paragraph 3.**]**

Textual Amendments

F199 Art. 38 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(14)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 39

Reporting and exchange of information on applications for authorisation

1 **[**F200A competent authority**]** shall compile a file on each application **[**F201it receives**]**. Each file shall contain the following:

a a copy of the application;

b a report containing information on the evaluation of and decision on the plant protection product; F202...

c a record of the administrative decisions taken by the **[**F203competent authority**]** concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;

d the approved label, where applicable.

2 On request, **[**F204a competent authority**]** shall, without delay, make available to the other **[**F205competent authorities**]** a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3 On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to **[**F206the competent authorities**]**.

F207 4 . . . . . .

Textual Amendments

F200 Words in Art. 39(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F201 Words in Art. 39(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F202 Words in Art. 39(1)(b) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F203 Words in Art. 39(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F204 Words in Art. 39(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F205 Words in Art. 39(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F206 Words in Art. 39(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F207 Art. 39(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(15)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 3

[F132Ongoing applications for] mutual recognition of authorisations

F208Article 40

Mutual recognition

. . . . . .

Textual Amendments

F208 Art. 40 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F209Article 40A

Application and interpretation

1 This Subsection applies where—

a before IP completion day the holder of an authorisation of a plant protection product granted by a member State or EEA state in accordance with Article 29 as it had effect immediately before IP completion day had applied for—

i) authorisation of the same product in the United Kingdom in accordance with Article 40 as it had effect immediately before IP completion day, or

ii) authorisation of the same product for minor uses in accordance with Articles 40 and 51(7) as those Articles had effect immediately before IP completion day, and

b immediately before IP completion day that application had not been determined.

2 In this Subsection—

a a reference to an Article as it had effect immediately before IP completion day in relation to an EEA state is a reference to that Article as adapted by the EEA Agreement as it had effect immediately before IP completion day;

b "reference state" means the member State or EEA state referred to in paragraph 1(a).**]**

Textual Amendments

F209 Art. 40A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(c)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(c)); 2020 c. 1, Sch. 5 para. 1(1)

Article 41

Authorisation

1 The **[**[F210]competent authority**]** to which an application under Article 40 **[**[F211]as it had effect immediately before IP completion day**]** is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the **[**[F212]reference state**]**, except where Article 36(3) applies.

[[F213]1A But where the application was for authorisation of minor uses in accordance with Article 51(7) as it had effect immediately before IP completion day, the competent authority must authorise such uses, except where—

a Article 36(3) applies, or

b the competent authority considers that those uses are not minor.**]**

2 By way of derogation from **[**[F214]paragraphs 1 and 1A, the competent authority**]** may authorise the plant protection product where:

a an authorisation under point (b) of Article 40(1) **[**[F215]as it had effect immediately before IP completion day**]** was applied for;

b it contains a candidate of substitution; **[**[F216]or**]**

c Article 30 has been applied; or

[F217]d . . . . . .

Textual Amendments

F210 Words in Art. 41(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F211 Words in Art. 41(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(bb)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)

F212 Words in Art. 41(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F213 Art. 41(1A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)

F214 Words in Art. 41(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F215 Words in Art. 41(2)(a) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(bb)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)

F216 Word in Art. 41(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F217 Art. 41(2)(c) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 42

Procedure

1 The application shall be accompanied by the following:

a a copy of the authorisation granted by the reference **[**F218state**]** as well as a translation of the authorisation into **[**F219English or another language permitted by the competent authority**]**;

b a formal statement that the plant protection product is identical to that authorised by the reference **[**F220state**]**;

c a complete or summary dossier as required in Article 33(3) **[**F221as it had effect immediately before IP completion day, when requested by the competent authority**]**;

d an assessment report of the reference **[**F222state**]** containing information on the evaluation and decision on the plant protection product.

2 The **[**F223competent authority**]** to which **[**F224the application**]** is submitted shall decide on the application within 120 days.

[F225**]**3 Where permitted by the competent authority, the applicant may submit an application in a language other than English.**]**

Textual Amendments

F218 Word in Art. 42(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(18)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F219 Words in Art. 42(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(18)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F220 Word in Art. 42(1)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(18)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F221 Words in Art. 42(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(18)(c)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(e)); 2020 c. 1, Sch. 5 para. 1(1)

F222 Word in Art. 42(1)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(18)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F223 Words in Art. 42(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(19)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F224 Words in Art. 42(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(19)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F225 Art. 42(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(20)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F133Subsection 3A

Mutual recognition of authorisations within Great Britain

Article 42A

Mutual recognition

1 This Subsection applies where a plant protection product has been authorised by a competent authority in accordance with Article 29 (the "reference competent authority").

2 The following persons may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices within the constituent territory of another competent authority—

a the holder of the authorisation granted by the reference competent authority;

b an official or scientific body involved in agricultural activities or a professional agricultural organisation—

i) with the consent of the authorisation holder, or

ii) where consent is refused, with the consent of the competent authority to which the application is made on the grounds of public interest.

3 An applicant under paragraph 2(b) must demonstrate that the use of such a plant protection product is of general interest within the constituent territory of the competent authority.

4 An application may not be made under paragraph 2 where—

a the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is not approved in relation to the constituent territory of the other competent authority;

b the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is approved in relation to the constituent territory of the other competent authority, but—

i) the conditions of that approval are incompatible with the product to which the application relates, or

ii) the technical specification relating to that approval is not equivalent to the technical specification of the approval of the same substance, safener, synergist or candidate in relation to the constituent territory of the reference competent authority, where necessary as determined in accordance with Article 38;

b the plant protection product contains a co-formulant which is entered on the unacceptable co-formulants register in relation to the constituent territory of the other competent authority; or

c the relevant data requirements specified in regulations made under Article 8(4)(a) and (b), the relevant uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) or any guidance issued under Article 77 relating to those requirements or principles are not the same in relation to the constituent territory of each competent authority.

Article 42B

Authorisation

1 The competent authority to which an application under Article 42A(2) is submitted, having examined the application and the accompanying documents referred to in Article 42C(1), and as appropriate with regards to the circumstances in its constituent territory, must authorise the plant protection product concerned under the same conditions as the reference competent authority, except in accordance with paragraph 2 or 3.

2 The competent authority may authorise the plant protection product where it contains a candidate for substitution or a substance approved in accordance with Article 4(7).

3 Paragraphs 1 and 2 do not apply where Article 36(3) applies.

Article 42C

Procedure

1 An application under Article 42A must be accompanied by the following—

a a copy of the authorisation granted by the reference competent authority;

b a formal statement that the plant protection product is identical to that authorised by the reference competent authority;

c a complete or summary dossier as required in Article 33(3) when requested by the competent authority;

d an assessment report of the reference competent authority containing information on the evaluation and decision on the plant protection product.

2 The competent authority to which an application under Article 42A is submitted must decide on the application within 120 days.**]**

Subsection 4

Renewal, withdrawal and amendment

Article 43

Renewal of authorisation

1 An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2 Within 3 months from the renewal of the approval **[**F226in relation to a constituent territory**]** of an active substance, safener or synergist contained in the plant protection product

[F227authorised in that constituent territory**]**, the applicant shall submit the following information **[**F228to the competent authority for that constituent territory**]**:

a a copy of the authorisation of the plant protection product;

b any new information required as a result of amendments in data requirements or criteria;

c evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;

d any information required to demonstrate that the plant protection product meets the requirements set **[**F229by the competent authority**]** on the renewal of the approval of the active substance, safener or synergist contained therein;

e a report on the monitoring information, where the authorisation was subject to monitoring.

3

[F230a**]** **[**F231The competent authority examining the application**]** shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for **[**F232on renewal of the approval of the active substance, safener or synergist**]**.

[F233b The competent authority which examined the plant protection product application in accordance with Article 35(2) may coordinate the compliance check and assessment of the information submitted for all competent authorities which receive an application for renewal of authorisation for the same product, provided that the conditions in Article 35(2) apply in relation to the renewal application.**]**

F2344 . . . . . .

5 **[**F235The competent authority examining the application**]** shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6 Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the **[**F236competent authority examining the application**]** shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

Textual Amendments

F226 Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F227 Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F228 Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F229 Words in Art. 43(2)(d) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F230 Words in Art. 43(3) renumbered as Art. 43(3)(a) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F231 Words in Art. 43(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F232 Words in Art. 43(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F233 Art. 43(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F234 Art. 43(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F235 Words in Art. 43(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F236 Words in Art. 43(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 44

Withdrawal or amendment of an authorisation

1 **[**F237A competent authority**]** may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

A **[**F238competent authority**]** shall review an authorisation where it concludes that the **[**F239environmental objectives of a river basin district**]** may not be achieved.

2 Where a **[**F240competent authority**]** intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3 The **[**F241competent authority**]** shall withdraw or amend the authorisation, as appropriate, where:

a the requirements referred to in Article 29 are not or are no longer satisfied;

b false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

c a condition included in the authorisation has not been met;

d on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or

e the authorisation holder fails to comply with the obligations resulting from this Regulation.

4 Where a **[**F242competent authority**]** withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation **[**F243and the other competent authorities**]**. The other **[**F244competent authorities may**]** withdraw or amend the authorisation accordingly taking into account **[**F245conditions in its constituent territory**]** and risk mitigation measures except for cases where the second **[**F246or third**]** subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

[F2475 In paragraph 1, "environmental objectives"—

a in relation to the Northumbria River Basin District, means the objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003;

b in relation to the Solway Tweed River Basin District, means the objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004;

c in relation to any other river basin district, within the meaning of the WFD Regulations, has the same meaning as in those regulations;

d in relation to a river basin district in Scotland, means the objectives set under section 9(1)(a)(i) of the Water Environment and Water Services (Scotland) Act 2003.

6 In paragraph 4, the "conditions" in the constituent territory of a competent authority include—

a any data requirements specified in regulations made under Article 8(4)(a) or (b) in relation to that constituent territory;

b any uniform principles prescribed by regulations made under Article 29(6)(a) in relation to that constituent territory;

c any guidance issued under Article 77 in relation to that constituent territory.

7 In this Article—

a "river basin district" means any of the following—

i) the Northumbria River Basin District;

ii) the Solway Tweed River Basin District;

iii) a river basin district within the meaning of the WFD Regulations;

iv) in relation to Scotland, an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;

b "the WFD Regulations" means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017.**]**

Textual Amendments

F237 Words in Art. 44(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F238 Words in Art. 44(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F239 Words in Art. 44(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F240 Words in Art. 44(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F241 Words in Art. 44(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F242 Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F243 Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F244 Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F245 Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F246 Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F247 Art. 44(5)-(7) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 45

Withdrawal or amendment of an authorisation at the request of the authorisation holder

1 An authorisation may be withdrawn or amended at the request of the holder of the authorisation, who shall state the reasons for his request.

2 Amendments may only be granted where it is established that the requirements referred to in Article 29 continue to be met.

3 Article 46 shall apply where appropriate.

Article 46

Grace period

Where a **[**[F248]competent authority**]** withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Textual Amendments

F248 Words in Art. 46 substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **9**; 2020 c. 1, Sch. 5 para. 1(1)

Subsection 5

Special cases

Article 47

Placing on the market of low-risk plant protection products

1 Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

a the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II **[**F249in relation to the constituent territory of application**]**;

b it does not contain a substance of concern;

c it is sufficiently effective;

d it does not cause unnecessary pain and suffering to vertebrates to be controlled;

e it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as ‘low-risk plant protection products’.

2 An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product.

3 **[**F250A competent authority**]** shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product.

Where the **[**F251competent authority**]** needs additional information, it shall set a time limit for the applicant to supply it. In that case, the period specified shall be extended by the additional time limit granted by the **[**F251competent authority**]**.

The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the **[**F251competent authority**]**. Where at the end of that period the applicant has not submitted the missing elements, the **[**F251competent authority**]** shall inform the applicant that the application is inadmissible.

4 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Textual Amendments

F249 Words in Art. 47(1)(a) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(25)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F250 Words in Art. 47(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(25)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F251 Words in Art. 47(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(25)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 48

Placing on the market and use of plant protection products containing a genetically modified organism

1 A plant protection product which contains **[**[F252]a genetically modified organism**]** shall be examined in respect of the genetic modification in accordance with **[**[F253]the examination legislation**]**, in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent **[**[F254]to market the genetically modified organism under section 111(1) of the Environmental Protection Act 1990**]** has been granted for it.

2 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

[[F255]3 In paragraph 1, "the examination legislation" means—

a in relation to England, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;

b in relation to Wales, regulation 24(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;

c in relation to Scotland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002.**]**

Textual Amendments

F252 Words in Art. 48(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(26)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F253 Words in Art. 48(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(26)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F254 Words in Art. 48(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(26)(a)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(h)(i)); 2020 c. 1, Sch. 5 para. 1(1)

F255 Art. 48(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(26)(b)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(h)(ii)); 2020 c. 1, Sch. 5 para. 1(1)

Article 49

Placing on the market of treated seeds

1 **[**[F256]A competent authority**]** shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use **[**[F257]by at least one competent authority**]**.

[[F258]2 The appropriate authority may, by regulations, implement measures to restrict or prohibit the use or sale of treated seeds as referred to in paragraph 1 where the appropriate authority has substantial concerns that—

a the treated seeds are likely to constitute a serious risk to human or animal health or to the environment, and

b such risk cannot be contained satisfactorily by measures taken by the competent authorities concerned.

2A Before making regulations in accordance with paragraph 2, the appropriate authority may obtain independent scientific advice where the appropriate authority considers it appropriate to do so.**]**

[F2593 . . . . . .

4 Without prejudice to other **[**[F260]retained EU law**]** concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in **[**[F261]Regulation (EC) No 1272/2008 of the European Parliament and of the Council**]** and risk mitigation measures set out in the authorisation for that product where appropriate.

Textual Amendments

F256 Words in Art. 49(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F257 Words in Art. 49(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F258 Art. 49(2)(2A) substituted for Art. 49(2) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F259 Art. 49(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F260 Words in Art. 49(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F261 Words in Art. 49(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(27)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 50

Comparative assessment of plant protection products containing candidates for substitution

1 A comparative assessment shall be performed by **[**[F262]a competent authority**]** when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution **[**[F263]in relation to its constituent territory**]**. **[**[F264]A competent authority**]** shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

a for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;

b the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;

c the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and

d the consequences on minor use authorisations are taken into account.

2 By way of derogation from Article 36(2) **[**F265a competent authority**]** may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in **[**F266Great Britain**]**.

3 By way of derogation from paragraph 1, a plant protection product containing a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.

Such authorisations shall be granted once for a period not exceeding five years.

4 For plant protection products containing a candidate for substitution **[**F267a competent authority**]** shall perform the comparative assessment provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, **[**F268the competent authority**]** shall maintain, withdraw or amend the authorisation.

5 Where a **[**F269competent authority**]** decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect 3 years after the decision of the **[**F269competent authority**]** or at the end of the approval period of the candidate for substitution **[**F270in relation to its constituent territory**]** where that period ends earlier.

6 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Textual Amendments

F262 Words in Art. 50(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F263 Words in Art. 50(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F264 Words in Art. 50(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F265 Words in Art. 50(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F266 Words in Art. 50(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(b)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(i)); 2020 c. 1, Sch. 5 para. 1(1)

F267 Words in Art. 50(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F268 Words in Art. 50(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F269 Words in Art. 50(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F270 Words in Art. 50(5) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(28)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 51

Extension of authorisations for minor uses

1 The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised **[**F271by a competent authority**]** to be extended to minor uses not yet covered by that authorisation.

2 **[**F272The competent authority**]** shall extend the authorisation provided that:

a the intended use is minor in nature;

b the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;

c the extension is in the public interest; and

d the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3 **[**F273A competent authority**]** may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4 The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation F274...

5 When **[**F275the competent authority grants**]** an extension of authorisation for a minor use, **[**F276the competent authority**]** shall inform if necessary the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the **[**F277competent authority**]** shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures

concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6 Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7 The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with **[**F278Article 42A, except where one or more of the conditions in Article 42A(4) are met**]**. **[**F279The competent authority which receives such an application**]** shall authorise such uses in accordance with the provisions of **[**F280Article 42B**]** provided that those uses are also considered minor **[**F281by that competent authority**]**.

8 **[**F282Each competent authority**]** shall establish and regularly update a list of minor uses.

9 By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

10 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Textual Amendments

F271 Words in Art. 51(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F272 Words in Art. 51(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F273 Words in Art. 51(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F274 Words in Art. 51(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F275 Words in Art. 51(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(e)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F276 Words in Art. 51(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(e)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F277 Words in Art. 51(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(e)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F278 Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F279 Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F280 Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F281 Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F282 Words in Art. 51(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(g)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F283 Article 52

Parallel trade

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Textual Amendments

F283 Art. 52 omitted (31.12.2023) by virtue of The Plant Protection Products (Miscellaneous Amendments) Regulations 2023 (S.I. 2023/1321), regs. 1(2), **4(3)** (with reg. 5)

I F284 Article 52A

Parallel trade

1. This Article applies in respect of a parallel trade permit which—
   a immediately before IP completion day was a permit of a description referred to in Article 52(4A), and
   b by virtue of Article 52(6)(b), ceased to be valid on 1st January 2023 (an "original parallel trade permit").

2. The person to which an original parallel trade permit was issued may submit an application to the competent authority for the reinstatement of that permit as it had effect in relation to a constituent territory immediately before it ceased to be valid.

3. An application for the reinstatement of the original parallel trade permit must be made no later than 1st April 2024.

4. The application must be accompanied by—
   a a duplicate of the information that was submitted in connection with—
      i the initial application for the original parallel trade permit, and
      ii any subsequent application to amend that permit before it ceased to be valid;
   b where applicable, notification of any changes to the contact details supplied in connection with applications concerning the original parallel trade permit;
   c as regards the plant protection product authorised in the Member State of origin at the time of application for the original parallel trade permit—
      i confirmation that the product remains authorised and available for sale in the Member State of origin at the time of application for the reinstatement of the permit,
      ii confirmation that the label for the product as submitted with the application for the original parallel trade product remains unchanged as regards the identification of the product in the Member State of origin at the time of application for the reinstatement of the permit, and

iii photographs of the plant protection product container (including all sides of the container) with visible and readable label, showing the product as it is being marketed in the Member State of origin at the time of application for the reinstatement of the permit;

d as regards the label for the plant protection product as it is to be marketed in the constituent territory concerned—

i confirmation that the label for the product as submitted with the initial application for the original parallel trade product remains unchanged, or

ii notification of any change to the label for the plant protection product, together with the draft label which is to be attached to the product as it is to be marketed in the constituent territory concerned;

e a declaration by the applicant that, to the best of that person's knowledge—

i all information supplied in accordance with this paragraph is accurate, as it applies to the manufacture and placing on the market of the plant protection product in respect of which the application for reinstatement of the original parallel trade permit is made, and

ii for the purposes of paragraph (i), that the duplicate information supplied in accordance with subparagraph (a) continues to apply in respect of that product, subject to any changes required to be notified in accordance with this paragraph.

5. At any time after receiving an application and before determining it the competent authority may require the applicant to provide it with such further information as it reasonably considers necessary to determine the application.

6. The competent authority must grant the application for the reinstatement of the original parallel trade permit where—

a at the time of application for that permit, the authorisation of the reference product granted prior to the application for the original parallel trade permit has not been withdrawn by that authority in relation to the constituent territory concerned;

b the authority is satisfied that—

i the application complies with the requirements of paragraphs 2 and 3;

ii all information and documentation required to accompany the application in accordance with paragraphs 4 and 5 is complete;

iii where the applicant has notified a change to the label for the plant protection product in accordance with paragraph 4(d), that change—

aa is consistent with the proposition that the product must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product, or

bb is a minor change (such as a change of address) that is not material to the identicality of that label with the label for the reference product;

iv the declaration made by the applicant in accordance with paragraph 4(e) is valid on the basis of all relevant information available to the authority concerning the plant protection product.

7. Where the reinstatement of a parallel trade permit is granted in accordance with this Article—

a the competent authority must issue the parallel trade permit and must specify the date on which the permit has effect, and

b the parallel trade permit is valid in relation to a constituent territory until the earlier of—

i the date on which the authorisation of the reference product expires in relation to that constituent territory;

ii the date two years after the day on which the permit was specified to have effect under this Article.

8. A plant protection product for which a parallel trade permit has been issued in accordance with this Article must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product.

9. The plant protection product for which the parallel trade permit has been issued may be the subject of a grace period granted in accordance with Article 46 as though the permit for the product concerned were an authorisation and, for these purposes, Article 46 applies—

a where a parallel trade permit ceases to be valid in accordance with paragraph 7(b), or

b where a parallel trade permit is withdrawn under paragraph 10(a).

10. A parallel trade permit that has been issued in accordance with this Article is to be treated as an authorisation for the purposes of Articles 44 and 45 and—

a may be withdrawn—

i in accordance with either Article, or

ii without prejudice to Article 44, where the authorisation of the plant protection product in respect of which the original parallel trade permit was issued is withdrawn in the Member State of origin for safety or efficacy reasons;

b may be amended in accordance with either Article, but only to the extent necessary to enable the product to be placed on the market and used in accordance with the provisions of the authorisation of the reference product.

11. The holder of a parallel trade permit must report any available information to the competent authority in accordance with Article 56(4) as though the authority had authorised the plant protection product concerned.

12. Chapters 6 to 10 apply in respect of any plant protection product for which a parallel trade permit has been granted in accordance with this Article, as if references in those Chapters to an authorisation were references to the parallel trade permit.

13. Subject to Chapter 6, each competent authority must take steps to make publicly available information which it holds about parallel trade permits.

14. In this Article—

"Member State of origin" means the Member State or EEA state which was the Member State of origin in accordance with paragraph 1 of Article 52 as it had effect immediately before IP completion day, as adapted by the EEA agreement as it had effect immediately before IP completion day;

"reference product" means the plant protection product which was already authorised in the United Kingdom prior to the application for the original parallel trade permit, and to which the product to which that permit relates (including that permit in its reinstated form), is identical in composition.**]**

Textual Amendments

F284 Art. 52A inserted (31.12.2023) by The Plant Protection Products (Miscellaneous Amendments) Regulations 2023 (S.I. 2023/1321), regs. 1(2), **4(4)** (with reg. 5)

Subsection 6

Derogations

Article 53

Emergency situations in plant protection

1 By way of derogation from Article 28, in special circumstances a **[**[F285]competent authority**]** may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use **[**[F286]in its constituent territory**]**, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The **[**[F287]competent authority**]** concerned shall immediately inform the other **[**[F288]competent authorities**]** of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

[F289]2 . . . . . .

[F289]3 . . . . . .

4 **[**[F290]Paragraph 1**]** shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with **[**[F291]section 111(1) of the Environmental Protection Act 1990**]**.

Textual Amendments

F285 Words in Art. 53(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F286 Words in Art. 53(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F287 Words in Art. 53(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F288 Words in Art. 53(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(a)(ii)(bb)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), 6(2)(c)); 2020 c. 1, Sch. 5 para. 1(1)

F289 Art. 53(2)(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(b)** (with Sch. 1) ; 2020 c. 1, Sch. 5 para. 1(1)

F290 Words in Art. 53(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F291 Words in Art. 53(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(c)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(k)); 2020 c. 1, Sch. 5 para. 1(1)

Article 54

Research and development

1 By way of derogation from Article 28, experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product or involving unauthorised use of a plant protection product may be carried out if the **[**[F292]competent authority**]** in whose **[**[F293]constituent**]** territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes. The permit may limit the quantities to be used and the areas to be treated and may impose further conditions to prevent any harmful effects on human or animal health or any unacceptable adverse effect on the environment, such as the need to prevent entry into the food chain of feed and food containing residues unless a relevant provision has already been established under Regulation (EC) No 396/2005 **[**[F294]in relation to that constituent territory**]**.

The **[**[F292]competent authority**]** may authorise a programme of experiments or tests in advance or require a permit for each experiment or test.

2 An application shall be submitted to the **[**[F295]competent authority**]** in whose **[**[F296]constituent**]** territory the experiment or test is to be conducted, together with a dossier containing all the available data to permit an assessment of possible effects on human or animal health or the possible impact on the environment.

3 A permit for trial purposes shall not be granted for experiments or tests involving the release into the environment of a genetically modified organism unless such release has been accepted under **[**[F297]section 111(1) of the Environmental Protection Act 1990**]**.

4 Paragraph 2 shall not apply if the **[**[F298]competent authority**]** has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

[F299]5 . . . . . .

Textual Amendments

F292 Words in Art. 54(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F293 Words in Art. 54(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F294 Words in Art. 54(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F295 Words in Art. 54(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F296 Words in Art. 54(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F297 Words in Art. 54(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(c)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(k)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F298 Words in Art. 54(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F299 Art. 54(5) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

F132 Words in Ch. 3 Section 1 Subsection 3 heading inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F133 Ch. 3 Section 1 Subsection 3A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(21)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

SECTION 2

Use and information

Article 55

Use of plant protection products

[[F300]1**]** Plant protection products shall be used properly.

[[F300]2**]** Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive [F301]...

[[F302]3 For the purposes of this Article, Article 14 of Directive 2009/128/EC is to be read as if—

a obligations on Member States were obligations on the competent authorities;

b paragraph 3 were omitted.**]**

Textual Amendments

F300 Words in Art. 55 renumbered as Art. 55(1)(2) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(33)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F301 Words in Art. 55(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(33)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F302 Art. 55(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(33)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 56

Information on potentially harmful or unacceptable effects

1 The holder of an authorisation for a plant protection product shall immediately notify **[**F303each competent authority**]** that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in **[**F304other**]** countries.

2 The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3 Without prejudice to the right of **[**F305competent authorities**]** to adopt interim protective measures, **[**F306where paragraph 3A applies, the competent authority**]** which first granted an authorisation F307... shall evaluate the information received and inform the other **[**F308competent authorities which granted authorisation for the plant protection product**]**, where it decides to withdraw or amend the authorisation under Article 44.

That **[**F309competent authority**]** shall inform the other **[**F310competent authorities**]** where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled or whether in the case of a co-formulant it has been considered unacceptable and propose that the approval be withdrawn or the conditions amended.

[F311 3A This paragraph applies where—

a each competent authority which granted authorisation agrees which competent authority is to evaluate the information;

b each active substance, safener or synergist in the plant protection product to which the information relates has the same conditions of approval in relation to the constituent territory of each competent authority concerned;

c any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed by regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority concerned.**]**

4 The holder of an authorisation for a plant protection product shall report annually to the competent authorities [F312]... which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Textual Amendments

F303 Words in Art. 56(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F304 Word in Art. 56(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F305 Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F306 Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F307 Words in Art. 56(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F308 Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F309 Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F310 Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F311 Art. 56(3A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F312 Words in Art. 56(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 57

Obligation to keep information available

1 **[**[F313]A competent authority**]** shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

a the name or business name of the holder of the authorisation and the authorisation number;

b the trade name of the product;

c the type of preparation;

d the name and amount of each active substance, safener or synergist which it contains;

e the classification, risk and safety phrases in accordance **[**F314with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and any regulations made under Article 65(1A)**]**;

f the use or uses for which it is authorised;

g the reasons for withdrawal of an authorisation if they are related to safety concerns;

h the list of minor uses referred to in Article 51(8).

2 The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

F3153 . . . . . .

Textual Amendments

F313 Words in Art. 57(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(35)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F314 Words in Art. 57(1)(e) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(35)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F315 Art. 57(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(35)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER IV

ADJUVANTS

[F316Article 58

Placing on the market and use of adjuvants

1 An adjuvant must not be placed on the market or used in a constituent territory unless it has been authorised in that territory in accordance with Schedule 2 to the Plant Protection Products Regulations 2011.

2 The appropriate authority may, by regulations, make provision regarding the authorisation of adjuvants including (but not limited to) data requirements, notification, evaluation, assessment and decision making procedures.**]**

Textual Amendments

F316 Art. 58 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **6(2)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

CHAPTER V

DATA PROTECTION AND DATA SHARING

Article 59

Data protection

1 Test and study reports shall benefit from data protection under the conditions laid down in this Article.

The protection shall apply to test and study reports concerning the active substance, safener or synergist F317... and the plant protection product as referred to in Article 8(2) when they are submitted to a **[**F318competent authority**]** by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were:

a necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and

b certified as compliant with the principles of good laboratory practice or of good experimental practice.

Where a report is protected, it may not be used by **[**F319any competent authority**]** for the benefit of other applicants for authorisation of plant protection products, safeners or synergists F320... , except as provided in paragraph 2 of this Article, in Article 62 or in Article 80.

The period of data protection is 10 years starting at the date of **[**F321the first authorisation by a competent authority in Great Britain in relation to which the report is submitted**]**, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47.

Those periods shall be extended by 3 months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation **[**F322described in the fourth subparagraph**]**. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years.

The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).

A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*.

2 Paragraph 1 shall not apply:

a to test and study reports for which the applicant has submitted a letter of access; or

b where any period of data protection granted for the test and study reports concerned in relation to another plant protection product has expired.

3 Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or

synergist [F323]... and the plant protection product at the time of submitting the dossier and has provided to the **[**[F324]competent authority**]** concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired.

Textual Amendments

F317 Word in Art. 59(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F318 Words in Art. 59(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F319 Words in Art. 59(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F320 Words in Art. 59(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F321 Words in Art. 59(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(iii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F322 Words in Art. 59(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(a)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F323 Words in Art. 59(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F324 Words in Art. 59(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(2)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 60

List of test and study reports

1 For each active substance, safener and synergist **[**[F325], the assessing competent authority**]** shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the **[**[F326]other competent authorities**]**.

2 For each plant protection product which they authorise, **[**[F327]a competent authority**]** shall keep and make available to any interested party upon request:

a a list of the test and study reports concerning the active substance, safener or synergist [F328]... and the plant protection product necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation; and

b a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.

3 The lists provided for in paragraphs 1 and 2 shall include information on whether those test and study reports were certified as compliant with the principles of good laboratory practice or of good experimental practice.

[F329 4 In paragraph 1, "assessing competent authority" has the same meaning as in Subsection 2 of Section 1 of Chapter 2.**]**

Textual Amendments

F325 Words in Art. 60(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(3)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F326 Words in Art. 60(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(3)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F327 Words in Art. 60(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(3)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F328 Word in Art. 60(2)(a) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(3)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F329 Art. 60(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(3)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 61

General rules on avoidance of duplicative testing

1 In order to avoid duplicative testing, any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, consult the information referred to in Article 57 to ascertain if and to whom an authorisation has already been granted for a plant protection product containing the same active substance, safener or synergist **F330**... . **[**F331 A competent authority**]** shall on request from the prospective applicant provide him with the list of test and study reports prepared in accordance with Article 60 for that product.

The prospective applicant shall submit all data regarding the identity and impurities of the active substance he proposes to use. The enquiry shall be supported by evidence that the prospective applicant intends to apply for an authorisation.

2 **[**F332 A competent authority**]**, where satisfied that the prospective applicant intends to apply for an authorisation, or the renewal or review thereof, shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.

3 The prospective applicant for the authorisation, or the renewal or review thereof, and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 59, in a fair, transparent and non-discriminatory way.

Textual Amendments

F330 Words in Art. 61(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(4)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F331 Words in Art. 61(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(4)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F332 Words in Art. 61(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(4)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 62

Sharing of tests and studies involving vertebrate animals

1 Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.

2 **[**[F333]A competent authority**]** shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods described in **[**[F334]Part 3 of Annex 1 to Regulation (EC) No 1272/2008 of the European Parliament and of the Council**]** could reasonably have been used, in support of applications for authorisations. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

3 The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

4 Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist [F335]... cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the prospective applicant shall inform the competent authority [F336]... referred to in Article 61(1).

The failure to reach agreement, as provided in paragraph 3, shall not prevent the competent authority [F337]... from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.

5 By 14 December 2016, the Commission shall report on the effects of the provisions in this Regulation concerning data protection of tests and studies involving vertebrate animals. The Commission shall submit this report to the European Parliament and the Council accompanied, if necessary, by an appropriate legislative proposal.

6 The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The competent authority [F338]... may direct the parties involved to resolve the matter by formal and binding arbitration [F339]... . Otherwise the parties may resolve the matter through litigation in the courts [F340]... . Awards from

arbitration or litigation shall have regard to the principles determined in paragraph 3 and shall be enforceable **[**[F341]as a civil debt**]**.

Textual Amendments

F333 Words in Art. 62(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F334 Words in Art. 62(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F335 Words in Art. 62(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F336 Words in Art. 62(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F337 Words in Art. 62(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F338 Words in Art. 62(6) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F339 Words in Art. 62(6) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F340 Words in Art. 62(6) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F341 Words in Art. 62(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **7(5)(c)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VI

PUBLIC ACCESS TO INFORMATION

Article 63

Confidentiality

1 A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

2 Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

a the method of manufacture;

b the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

c results of production batches of the active substance including impurities;

d methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

e links between a producer or importer and the applicant or the authorisation holder;

f information on the complete composition of a plant protection product;

g names and addresses of persons involved in testing on vertebrate animals.

3 This Article is without prejudice to **[**[F342]the Environmental Information Regulations 2004 or the Environmental Information (Scotland) Regulations 2004**]**.

Textual Amendments

F342 Words in Art. 63(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **8(2)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VII

PACKAGING, LABELLING AND ADVERTISING OF PLANT PROTECTION PRODUCTS AND ADJUVANTS

Article 64

Packaging and presentation

1 Plant protection products and adjuvants that may be mistaken for food, drink or feed shall be packaged in such a way as to minimise the likelihood of such a mistake being made.

2 Plant protection products and adjuvants available to the general public that may be mistaken for food, drink or feed shall contain components to discourage or prevent their consumption.

3 **[**[F343]Article 35 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council**]** shall also apply to plant protection products and adjuvants not covered by that **[**[F344]Regulation**]**.

Textual Amendments

F343 Words in Art. 64(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F344 Word in Art. 64(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(2)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 65

Labelling

[F345 1 The labelling of plant protection products must include—

a the classification, labelling and packaging requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council, and

b any requirements contained in regulations made under paragraph 1A which apply in relation to the constituent territory in which the product is to be placed on the market or used.

1A The appropriate authority may, by regulations, specify additional requirements for the labelling of plant protection products, including (but not limited to) standard phrases for special risks and safety precautions which supplement the phrases provided for in Regulation (EC) No 1272/2008 of the European Parliament and of the Council.**]**

2 **[**F346 A competent authority**]** may require samples or mock-ups of the packaging and drafts of labels and leaflets to be submitted before the authorisation is granted.

F347 3 . . . . . .

Textual Amendments

F345 Art. 65(1)(1A) substituted for Art. 65(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(3)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F346 Words in Art. 65(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(3)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F347 Art. 65(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(3)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 66

Advertising

1 Plant protection products which are not authorised shall not be advertised. Every advertisement for a plant protection product shall be accompanied by the sentences ‘Use plant protection products safely. Always read the label and product information before use’. These sentences shall be easily legible and clearly distinguishable in relation to the whole advertisement. The words ‘plant protection products’ may be replaced by a more precise description of the product-type, such as fungicide, insecticide or herbicide.

2 The advertisement shall not include information in text or graphic form which could be misleading as regards possible risks to human or animal health or to the environment, such as the terms ‘low risk’, ‘non-toxic’ or ‘harmless’.

Only in the case of low-risk plant protection products shall the term ‘authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009’ be

allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product.

3 **[**F348A competent authority**]** may prohibit or restrict the advertising of plant protection products in certain media, subject to **[**F349retained EU**]** law.

4 All statements used in advertising shall be technically justifiable.

5 Advertisements shall not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, nor any use near food or use by or in the vicinity of children.

6 Advertising or promotional material shall draw attention to the appropriate warning phrases and symbols as laid down in the labelling.

Textual Amendments

F348 Words in Art. 66(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(4)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F349 Words in Art. 66(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **9(4)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VIII

CONTROLS

Article 67

Record-keeping

1 Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.

They shall make the relevant information contained in these records available to **[**F350a competent authority**]** on request. Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the **[**F351relevant**]** competent authority.

The competent authorities shall provide access to such information in accordance with applicable national F352... law.

By 14 December 2012, the Commission shall present a report to the European Parliament and the Council on the costs and benefits of the traceability of information from users to retailers concerning the applications of plant protection products on agricultural products, accompanied, if necessary, by appropriate legislative proposals.

2 Producers of plant protection products shall undertake post-authorisation monitoring on the request of **[**F353a competent authority**]**. They shall notify the competent **[**F354authority**]** of the relevant results.

3 Authorisation holders shall provide the competent authorities F355... with all data relating to the volume of sales of plant protection products **[**F356for the purposes of establishing and maintaining risk indicators in accordance with Annex 4 to Directive 2009/128/EC**]**.

F3574 . . . . . .

Textual Amendments

F350 Words in Art. 67(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F351 Word in Art. 67(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F352 Words in Art. 67(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F353 Words in Art. 67(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F354 Word in Art. 67(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F355 Words in Art. 67(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F356 Words in Art. 67(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F357 Art. 67(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(2)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F358 Article 68

Monitoring and controls

A competent authority shall publish by 31 August each year a report, for the previous year, on the scope and the outcome of the official controls performed in order to verify compliance with this Regulation.**]**

Textual Amendments

F358 Art. 68 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **10(3)** (with Sch. 1) (as substituted by S.I. 2020/1376, regs. 1(4), **3(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

CHAPTER IX

EMERGENCIES

I[F359] Article 69

Emergency measures

1 Where a competent authority is satisfied that the conditions in paragraph 2 are met, the competent authority may—

a in the case of an active substance, safener or synergist approved in relation to its constituent territory—

i) amend the conditions of approval, or

ii) suspend approval;

b in the case of a co-formulant, add that co-formulant to the unacceptable co-formulants register in relation to its constituent territory;

c in the case of a plant protection product authorised in its constituent territory—

i) amend the authorisation for that product;

ii) suspend the authorisation for that product.

2 The conditions referred to in paragraph 1 are—

a the approved active substance, safener, synergist, co-formulant or plant protection product is likely to constitute a serious risk to human or animal health or the environment, and

b that risk cannot be contained satisfactorily by means of other measures taken by the competent authority.

3 In performing a function under paragraph 1, the competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

4 As soon as reasonably practicable after acting in accordance with paragraph 1(a), (b) or (c), the competent authority must—

a update the approvals register or unacceptable co-formulants register accordingly;

b in relation to an amendment or suspension under paragraph 1(a), begin a review of the active substance, safener or synergist in accordance with Article 21 or that Article as applied by Article 25A(4);

c in relation to a register addition under paragraph 1(b), begin a review of the co-formulant under Article 27(3);

d in relation to an amendment or suspension under paragraph 1(c), begin a review of the plant protection product authorisation under Article 44.

5 An amendment or suspension under paragraph 1(a) expires upon the completion of the review described in paragraph 4(b).

6 A register addition under paragraph 1(b) expires upon the completion of the review described in paragraph 4(c).

7 An amendment or suspension under paragraph 1(c) expires upon the completion of the review described in paragraph 4(d).

8 Following the expiry of an amendment or suspension under paragraph 1(a), or a register addition under paragraph 1(b), the competent authority must update the approvals register or unacceptable co-formulants register accordingly.

9 The Secretary of State may perform a function under paragraph 1 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

10 Where the Secretary of State performs a function in accordance with paragraph 9, a reference to the competent authority in paragraphs 3, 4 and 8 is to be read as a reference to the Secretary of State.**]**

Textual Amendments

F359 Art. 69 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **11(2)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), 6(3); S.I. 2020/1376, regs. 1(4), 3(9)); 2020 c. 1, Sch. 5 para. 1(1)

F360 Article 70

Emergency measures in cases of extreme urgency

. . . . . .

Textual Amendments

F360 Art. 70 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **11(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F361 Article 71

Other emergency measures

. . . . . .

Textual Amendments

F361 Art. 71 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **11(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER X

ADMINISTRATIVE AND FINANCIAL PROVISIONS

[F362]*Article 72*

Penalties

. . . . . .

Textual Amendments

F362 Art. 72 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(2)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 73

Civil and criminal liability

The granting of authorisation and any other measures in conformity with this Regulation shall be without prejudice to general civil and criminal liability in **[**[F363]Great Britain**]** of the producer and, where applicable, of the person responsible for placing the plant protection product on the market or using it.

Textual Amendments

F363 Words in Art. 73 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(3)** (with Sch. 1) (as substituted by S.I. 2020/1376, regs. 1(4), **3(10)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F364]*Article 74*

Fees and charges

. . . . . .

Textual Amendments

F364 Art. 74 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(4)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 75

Competent authority

[F365]1 . . . . . .

[F365]2 . . . . . .

3 **[**[F366]A competent authority must ensure that it has**]** a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively.

[F367]4 . . . . . .

[F367]5 . . . . . .

Textual Amendments

F365 Art. 75(1)(2) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(5)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F366 Words in Art. 75(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(5)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F367 Art. 75(4)(5) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(5)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F368]*Article 76*

[[F368]**Expenditure by the Commission]**

. . . . . .

Textual Amendments

F368 Deleted by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC.

[[F369]*Article 77*

Guidance documents

1 A competent authority may issue, amend or withdraw technical and other guidance documents relating to the implementation of this Regulation, including (but not limited to)—

a guidance relating to the format of the summary or complete dossiers to be used for the purposes of Article 8;

b guidance relating to the format of the draft assessment report for the purposes of Article 11;

c guidance relating to the format of the assessment for the purposes of Article 36;

d guidance regarding the rules and procedure for the assessment of equivalence under Article 38;

e guidelines on the coordination of compliance checks to be undertaken in accordance with Article 43(3);

f guidance on the application of Article 54, including on—

i) the maximum quantities of plant protection products that may be released during experiments or tests;

ii) the minimum data to be submitted in accordance with Article 54(2);

g guidance concerning the content of the application concerning micro-organisms, pheromones and biological products.

2 A competent authority must publish any guidance document issued or amended, or a notice specifying any guidance document withdrawn, under paragraph 1 in a manner which that competent authority considers appropriate.

3 Before issuing, amending or withdrawing a guidance document under paragraph 1 a competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

4 The Secretary of State may issue, amend or withdraw a guidance document under paragraph 1 instead of a competent authority—

a in relation to Wales, with the consent of the Welsh Ministers;

b in relation to Scotland, with the consent of the Scottish Ministers.

5 Where the Secretary of State issues, amends or withdraws a guidance document in accordance with paragraph 4, a reference in paragraphs 2 and 3 to the competent authority is to be read as a reference to the Secretary of State.

6 In complying with any obligation under this Regulation, a person or competent authority must have regard to any guidance issued in accordance with paragraph 1.**]**

Textual Amendments

F369 Arts. 77-78A substituted for Arts. 77, 78 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(6)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(10)(b) (which amendment includes the omission of Art. 78A(3)(7))); 2020 c. 1, Sch. 5 para. 1(1)

[F369 Article 78

Amendments and implementing measures

The appropriate authority may by regulations—

a) amend the Annexes to take account of current scientific and technical knowledge;

b) make further provision as necessary for the implementation of this Regulation.**]**

Textual Amendments

F369 Arts. 77-78A substituted for Arts. 77, 78 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(6)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(10)(b) (which amendment includes the omission of Art. 78A(3)(7))); 2020 c. 1, Sch. 5 para. 1(1)

I[F369] Article 78A

Regulations

1 Regulations made by the Secretary of State or Welsh Ministers under this Regulation are to be made by statutory instrument.

2 For regulations made under this Regulation by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

4 A statutory instrument containing regulations made by the Secretary of State under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

5 A statutory instrument containing regulations made by the Welsh Ministers under this Regulation is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

6 Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

8 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.**]**

Textual Amendments

F369 Arts. 77-78A substituted for Arts. 77, 78 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(6)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(10)(b) (which amendment includes the omission of Art. 78A(3)(7))); 2020 c. 1, Sch. 5 para. 1(1)

F370 Article 79

Committee procedure

. . . . . .

Textual Amendments

F370 Art. 79 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **12(7)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER XI

TRANSITIONAL AND FINAL PROVISIONS

I[F371] Article 80

Existing transitional measures

1 The following application is taken to have been made under Article 7(1) on the date it was made—

Common Name, CIPAC Identification Number	***Applicant***	***Date of application***
Ethametsulfuron CIPAC-No: 834	DuPont de Nemours GmbH	29th June 2010

1A For the determination of the application described in paragraph 1, this Regulation is to be read subject to the modifications in paragraphs 1B to 1F.

1B Article 4(1) is to be read as if—

a in the first subparagraph—

i) "in accordance with Annex II" were omitted;

ii) the words from ", taking into account" to "that Annex," were omitted;

b the second subparagraph were omitted.

1C Article 4(2)(a) is to be read as if the words from ", taking into account" to "available," were omitted.

1D Article 4(3) is to be read as if—

a point (a) were omitted;

b in point (b), the words from "or consequences" to "effects are available;" were omitted;

c points (c), (d) and (e)(iii) were omitted;

1E Article 4(7) is to be ignored.

1F Article 11(2) is to be read as if the third subparagraph were omitted.

1G Anything done before IP completion day in relation to the application described in paragraph 1—

a by the United Kingdom —

i) under Directive 91/414/EEC, as the member State described in Article 6 of that Directive;

ii) as the rapporteur Member State under Regulation 188/2011;

b by the European Food Safety Authority under Directive 91/414/EEC or Regulation 188/2011,

is taken to have been done by the relevant competent authority as the assessing competent authority.

1H If the application described in paragraph 1 is approved in accordance with Article 13—

a Article 13(1) to (4) of Directive 91/414/EEC applies in relation to that approval for a period of 10 years beginning with the date of approval;

b Regulation 544/2011 and Regulation 545/2011 apply in relation to that approval as if, in Article A1(1)(a) of each Regulation, for the words from "as it has effect" in the first place it occurs to the end there were substituted " as read with Article 80(1) of that Regulation ".

1I In paragraph 1G—

a "rapporteur Member State" has the meaning given by Article 2(1) of Regulation 188/2011;

b the "relevant competent authority" is the Secretary of State.

2 Paragraphs 2A to 2E apply to an active substance—

a included in Annex 1 to Directive 91/414/EEC;

b approved in accordance with paragraph 1 of this Article as it had effect immediately before IP completion day.

2A Article 13(1) to (4) of Directive 91/414/EEC applies—

a for active substances covered by Article 8(2) of Directive 91/414/EEC, for a period of five years beginning with the date of the inclusion or approval of the active substance;

b for active substances which were not on the market in the European Union, an EEA state or the United Kingdom on 26th July 1993, for a period of 10 years from the date of the inclusion or approval of the active substance.

2B In paragraph 2A(b), "on the market" means any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the European Union, an EEA state or the United Kingdom or disposal.

2C In paragraphs 2A(b) and 2B, the "European Union" does not include the Republic of Croatia.

2D Regulation 544/2011 applies to the active substance, and is to be read as if, in Article A1(1) of that Regulation—

a point (a) were omitted;

b for point (c)(i) there were substituted—

i) described in Article 80(2) of Regulation (EC) No 1107/2009, and.

2E Regulation 545/2011 applies to the active substance, and is to be read as if, in Article A1(1) of that Regulation—

a point (a) were omitted;

b in point (c)(ii), for "to which point (a) applies" there were substituted "described in Article 80(2) of Regulation (EC) No 1107/2009".

2F In this Article—

a "assessing competent authority" has the same meaning as in Subsection 2 of Section 1 of Chapter 2;

b "Directive 91/414/EEC" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market, as it had effect by virtue of paragraph 1 and 2 of this Article as those paragraphs had effect immediately before IP completion day, read in accordance with paragraph 2G;

c "Regulation 188/2011" means Commission Regulation (EU) No 188/2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years

after the date of notification of that Directive as it had effect immediately before IP completion day;

d "Regulation 544/2011" means Commission Regulation (EU) No 544/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances;

e "Regulation 545/2011" means Commission Regulation (EU) No 545/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

2G For the purposes of this Article, Article 13(1) to (4) of Directive 91/414/EEC is to be read as if—

a a term used in those paragraphs which is defined in this Regulation has the meaning given in this Regulation;

b in paragraph 1—

i) in the words before point (a), for "Without prejudice to Article 10, Member States" there were substituted " A competent authority ";

ii) in point (a), for "Annex III" there were substituted " Regulation 545/2011 ";

iii) in point (b), for "Annex II" there were substituted " Regulation 544/2011 ";

c in paragraph 3—

i) for "Member States" there were substituted " a competent authority ";

ii) for "Annex II" there were substituted " Regulation 544/2011 ";

iii) in point (b), for the words from "two years" to the end there were substituted " by 26th July 1993 ";

iv) point (c) (and the "or" immediately preceding it) were omitted;

v) in point (d), for "paragraphs 3(b) and (c)" there were substituted " paragraph 3(b) ";

d in paragraph 4—

i) for "Member States" there were substituted " a competent authority ";

ii) for "Annex III" there were substituted " Regulation 545/2011 ";

iii) point (c) (and the "or" immediately preceding it) were omitted.**]**

Textual Amendments

F371 Art. 80 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(2)** (with Sch. 1) (as amended by S.I. 2019/559, regs. 1(2), 7(3); S.I. 2020/1376, regs. 1(4), 3(11)); 2020 c. 1, Sch. 5 para. 1(1)

F372 Article 81

Derogation for safeners and synergists, co-formulants and adjuvants

. . . . . .

Textual Amendments

F372 Art. 81 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 82

Review clause

By 14 December 2014, the Commission shall present a report to the European Parliament and the Council on the functioning of mutual recognition of authorisations and in particular on the application by the Member States of the provisions referred to in Article 36(3) and Article 50(2), the division of the Community into three zones and on the application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

Article 83

Repeal

Without prejudice to Article 80, Directives 79/117/EEC and 91/414/EEC, as amended [F373]... , are repealed with effect from 14 June 2011 [F374]...

References to the repealed Directives shall be construed as references to this Regulation. In particular, references [F375]... to Article 3 of Directive 91/414/EEC shall be construed as references to Article 55 of this Regulation.

Textual Amendments

F373 Words in Art. 83 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(4)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F374 Words in Art. 83 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(4)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F375 Words in Art. 83 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(4)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F376]Article 84

Entry into force and application

. . . . . .

Textual Amendments

F376 Art. 84 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(5)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F377 . . . . . .

Textual Amendments

F377 Words in Signature omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **13(6)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F378] ANNEX I

. . . . . .

Textual Amendments

F378 Annex 1 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(2)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

ANNEX II

Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II

1. Evaluation

1.1. During the process of evaluation and decision-making provided for in Articles 4 to 21, the **[**[F379]assessing competent authority**]** shall cooperate with applicants to resolve any questions on the dossier quickly or to identify at an early stage any further explanations or additional studies necessary for the evaluation of the dossier, including information to eliminate the need for a restriction of the approval, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Regulation.

Textual Amendments

F379 Words in Annex 2 point 1.1 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

1.2. The evaluation by the **[**[F380]assessing competent authority**]** must be based on scientific principles and be made with the benefit of expert advice.

Textual Amendments

F380 Words in Annex 2 point 1.2 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[[F381]1.2A In this Annex, "the assessing competent authority" has the meaning given by Article 7(1C) or 15(1A) as the case may be.**]**

Textual Amendments

F381 Annex 2 point 1.2A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

1.3. [F382] . . . . . .

Textual Amendments

F382 Annex 2 point 1.3 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

2. General decision-making criteria

2.1. Article 4 shall only be considered as complied with, where, on the basis of the dossier submitted, authorisation **[**[F383]by at least one competent authority**]** is expected to be possible for at least one plant protection product containing that active substance for at least one of the representative uses.

Textual Amendments

F383 Words in Annex 2 point 2.1 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

2.2. Submission of further information

In principle an active substance, safener or synergist shall only be approved where a complete dossier is submitted.

In exceptional cases an active substance, safener or synergist may be approved even though certain information is still to be submitted where:

(a) the data requirements have been amended or refined after the submission of the dossier; or

(b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.

2.3. Restrictions on approval

Where necessary, the approval may be subject to conditions and restrictions as referred to in **[**[F384]Article 6(1)**]**.

Where the **[**[F385]assessing competent authority**]** considers that the dossier provided lacks certain information, to the effect that the active substance could only be approved subject to restrictions, it shall contact the applicant at an early stage to obtain more information which may possibly enable these restrictions to be removed.

Textual Amendments

F384 Words in Annex 2 point 2.3 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(f)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F385 Words in Annex 2 point 2.3 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(f)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3. Criteria for the approval of an active substance

3.1. Dossier

The dossiers submitted pursuant to **[**[F386]Article 7(1D)**]** shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).

In the case of an active substance, safener or synergist for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed, the dossier submitted pursuant to **[**[F386]Article 7(1D)**]** shall contain the information necessary to carry out a risk assessment and for enforcement purposes.

The dossier shall in particular:

(a) permit any residue of concern to be defined;

(b) reliably predict the residues in food and feed, including succeeding crops;

(c) reliably predict, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;

(d) permit a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;

(e) permit, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.

The dossier submitted pursuant to **[**[F386]Article 7(1D)**]** shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

Textual Amendments

F386 Words in Annex 2 point 3.1 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(g)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.2. Efficacy

An active substance alone or associated with a safener or synergist shall only be approved where it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in **[**[F387]Article 29(6)(a) in relation to the relevant constituent territory**]**.

Textual Amendments

F387 Words in Annex 2 point 3.2 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(h)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.4. Composition of the active substance, safener or synergist

3.4.1. The specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.

3.4.2. The specification shall be in compliance with the relevant Food and Agriculture Organisation specification as appropriate, where such specification exists. However, where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

3.5. Methods of analysis

3.5.1. The methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in **[**[F388]Article 29(6)(a) in relation to the relevant constituent territory**]**.

Textual Amendments

F388 Words in Annex 2 point 3.5.3 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(h)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.6. Impact on human health

3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population. When the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.

3.6.2. An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature [F389]... , it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B.

Textual Amendments

F389 Words in Annex 2 point 3.6.2 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist **[**F390in relation to the relevant constituent territory**]** and other available data and information, including a review of the scientific literature F391... , it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with **[**F392Article 18A of Regulation (EC) No 396/2005 in relation to the relevant constituent territory**]**.

Textual Amendments

F390 Words in Annex 2 point 3.6.3 inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(j)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F391 Words in Annex 2 point 3.6.3 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(j)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F392 Words in Annex 2 point 3.6.3 substituted (31.12.2020) by The Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/557), regs. 1(1), **13(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists **[**F393in relation to the relevant constituent territory**]** and other available data and information, including a review of the scientific literature F394... , it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with **[**F395Article 18A of Regulation (EC) No 396/2005 in relation to the relevant constituent territory**]**.

Textual Amendments

F393 Words in Annex 2 point 3.6.4 inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(k)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F394 Words in Annex 2 point 3.6.4 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(k)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F395 Words in Annex 2 point 3.6.4 substituted (31.12.2020) by The Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/557), regs. 1(1), **13(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of **[**[F396]nationally**]** or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the **[**[F397]competent authority**]**, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

Textual Amendments

F396 Word in Annex 2 point 3.6.5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(l)(i)(aa)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), **6(4)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F397 Words in Annex 2 point 3.6.5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(l)(i)(bb)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), **6(4)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

F398 . . . . . .

Textual Amendments

F398 Words in Annex 2 point 3.6.5 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(l)(ia)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), **6(4)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F398 . . . . . .

[[F399]From **[**[X1]10 November 2018**]**, an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effect in humans if, based on points (1) to (4) of the sixth paragraph, it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant to humans:

(1) it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(3) the adverse effect is a consequence of the endocrine mode of action.

Editorial Information

X1 Substituted by Corrigendum to Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (Official Journal of the European Union L 101 of 20 April 2018).

Textual Amendments

F399 Inserted by Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (Text with EEA relevance).

The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with the fifth paragraph shall be based on all of the following points:

(1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action):

  (a) scientific data generated in accordance with internationally agreed study protocols, in particular those listed in **[**[F400]guidance issued**]** in accordance with this Regulation;

  (b) other scientific data selected applying a systematic review methodology, in particular following guidance on literature data **[**[F401]issued**]**, in accordance with this Regulation;

(2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the fifth paragraph are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall, in particular, consider all of the following factors:

  (a) both positive and negative results;

  (b) the relevance of the study designs, for the assessment of adverse effects and of the endocrine mode of action;

(c) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;

(d) the route of exposure, toxicokinetic and metabolism studies;

(e) the concept of the limit dose, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;

(3) using a weight of evidence approach, the link between the adverse effect(s) and the endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge and under consideration of internationally agreed guidelines;

(4) adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor.**]**

Textual Amendments

F400 Words in Annex 2 point 3.6.5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(l)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F401 Words in Annex 2 point 3.6.5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(l)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.7. Fate and behaviour in the environment

3.7.1. An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP).

A substance that fulfils all three of the criteria of the points below is a POP.

3.7.1.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where there is evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than 2 months, or that its DT50 in soil is greater than 6 months, or that its DT50 in sediment is greater than 6 months.

3.7.1.2. Bioaccumulation

An active substance, safener or synergist fulfils the bioaccumulation criterion where there is:

— evidence that its bio-concentration factor or bioaccumulation factor in aquatic species is greater than 5 000 or, in the absence of such data, that the partition coefficient n-octanol/water (log Ko/w) is greater than 5, or

— evidence that the active substance, safener or synergist present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity.

3.7.1.3. Potential for long-range environmental transport:

An active substance, safener or synergist fulfils the potential for long-range environmental transport criterion where:

— measured levels of the active substance, safener or synergist in locations distant from the sources of its release are of potential concern,
— monitoring data show that long-range environmental transport of the active substance, safener or synergist, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species, or
— environmental fate properties and/or model results demonstrate that the active substance, safener or synergist has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For an active substance safener or synergist that migrates significantly through the air, its DT50 in air is to be greater than 2 days.

3.7.2. An active substance, safener or synergist shall only be approved if it is not considered to be a persistent, bioaccumulative and toxic (PBT) substance.

A substance that fulfils all three of the criteria of the points below is a PBT substance.

3.7.2.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where:
— the half-life in marine water is higher than 60 days,
— the half-life in fresh or estuarine water is higher than 40 days,
— the half-life in marine sediment is higher than 180 days,
— the half-life in fresh or estuarine water sediment is higher than 120 days, or
— the half-life in soil is higher than 120 days.

Assessment of persistency in the environment shall be based on available half-life data collected under appropriate conditions, which shall be described by the applicant.

3.7.2.2. Bioaccumulation

An active substance, safener or synergist fulfils the bioaccumulation criterion where the bioconcentration factor is higher than 2 000.

Assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from both freshwater and marine water species can be used.

3.7.2.3. Toxicity

An active substance, safener or synergist fulfils the toxicity criterion where:
— the long-term no-observed effect concentration for marine or freshwater organisms is less than 0,01 mg/l,
— the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) pursuant to Regulation (EC) No 1272/2008, or
— there is other evidence of chronic toxicity, as identified by the classifications STOT RE 1 or STOT RE 2 pursuant to Regulation (EC) No 1272/2008.

3.7.3. An active substance, safener or synergist shall only be approved if it is not considered to be a very persistent and very bioaccumulative substance (vPvB).

A substance that fulfils both of the criteria of the points below is a vPvB substance.

3.7.3.1. Persistence

An active substance, safener or synergist fulfils the ‘very persistent’ criterion where:

— the half-life in marine, fresh- or estuarine water is higher than 60 days,
— the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
— the half-life in soil is higher than 180 days.

3.7.3.2. Bioaccumulation

An active substance, safener or synergist fulfils the 'very bioaccumulative' criterion where the bioconcentration factor is greater than 5 000.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in **[**F402Article 29(6)(a) in relation to the relevant constituent territory**]** under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

Textual Amendments

F402 Words in Annex 2 point 3.8.1 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(m)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of **[**F403nationally**]** or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

Textual Amendments

F403 Words in Annex 2 point 3.8.2 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(n)(i)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), **6(4)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F399From **[**X1 10 November 2018**]**, an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effects on non-target organisms if, based on points (1) to (4) of the third paragraph, it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant at the (sub)population level for non-target organisms:

(1) it shows an adverse effect in non-target organisms, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(3) the adverse effect is a consequence of the endocrine mode of action.

The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effects on non-target organisms in accordance with the second paragraph shall be based on all of the following points:

(1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action):

  (a) scientific data generated in accordance with internationally agreed study protocols, in particular, those listed in **[**[F404]guidance issued**]** in accordance with this Regulation;

  (b) other scientific data selected applying a systematic review methodology, in particular following guidance on literature data listed in **[**[F405]guidance issued**]** in accordance with this Regulation;

(2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the second paragraph are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall consider all of the following factors:

  (a) both positive and negative results, discriminating between taxonomic groups (e.g. mammals, birds, fish, amphibians) where relevant;

  (b) the relevance of the study design for the assessment of the adverse effects and its relevance at the (sub)population level, and for the assessment of the endocrine mode of action;

  (c) the adverse effects on reproduction, growth/development, and other relevant adverse effects which are likely to impact on (sub)populations. Adequate, reliable and representative field or monitoring data and/or results from population models shall as well be considered where available;

  (d) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different taxonomic groups;

  (e) the concept of the limit dose and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;

(3) using a weight of evidence approach, the link between the adverse effect(s) and the endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge and under consideration of internationally agreed guidelines;

(4) Adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms.**]**

Textual Amendments

F404 Words in Annex 2 point 3.8.2 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(n)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F405 Words in Annex 2 point 3.8.2 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(n)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of **[**F406nationally**]** or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:

— will result in a negligible exposure of honeybees, or

— has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Textual Amendments

F406 Word in Annex 2 point 3.8.3 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(o)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

3.9. Residue definition

An active substance, safener or synergist shall only be approved if, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.

3.10. Fate and behaviour concerning groundwater

An active substance shall only be approved where it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in **[**F407Article 29(6)(a) in relation to the relevant constituent territory**]**.

Textual Amendments

F407 Words in Annex 2 point 3.10 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(p)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

4. Candidate for substitution

An active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met:

— its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories,

— it meets two of the criteria to be considered as a PBT substance,

— there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones),

— it contains a significant proportion of non-active isomers,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,

— if, on the basis of the assessment of **[**F408nationally**]** or internationally agreed test guidelines or other available data and information F409... , it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.

Textual Amendments

F408 Word in Annex 2 point 4 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(q)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F409 Words in Annex 2 point 4 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(q)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F410**5.** Low-risk active substances

5.1. Active substances other than micro-organisms

5.1.1. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it corresponds to any of the following:

(a) it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as any of the following:

— carcinogenic category 1A, 1B or 2,

— mutagenic category 1A, 1B or 2,

— toxic to reproduction category 1A, 1B or 2,

— skin sensitiser category 1,

— serious damage to eye category 1,

— respiratory sensitiser category 1,

— acute toxicity category 1, 2 or 3,

— specific Target Organ Toxicant, category 1 or 2,

— toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests,

— explosive,

— skin corrosive, category 1A, 1B or 1C;

(b) it has been identified as priority substance **[**[F411]and is listed in Annex 10 to**]** Directive 2000/60/EC;

(c) it is deemed to be an endocrine disruptor;

(d) it has neurotoxic or immunotoxic effects.

Textual Amendments

F411 Words in Annex 2 point 5.1.1(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(3)(r)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

5.1.2. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

However, a naturally occurring active substance which does not correspond to any of points (a) to (d) of point 5.1.1 may be considered as being of low-risk, even if it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

5.1.3. An active substance, other than a micro-organism, emitted and used by plants, animals and other organisms for communication, shall be considered as being of low- risk where it does not correspond to any of points (a) to (d) of point 5.1.1.

5.2. Micro-organisms

5.2.1. An active substance which is a micro-organism may be considered as being of low-risk unless at strain level it has demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.

5.2.2. Baculoviruses shall be considered as being of low-risk unless at strain level they have demonstrated adverse effects on non-target insects.**]**

Textual Amendments

F410 Substituted by Commission Regulation (EU) 2017/1432 of 7 August 2017 amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances (Text with EEA relevance).

[F412]ANNEX III

List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27

Textual Amendments

F412 Annex 3 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(4)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

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ANNEX IV

Comparative assessment pursuant to Article 50

1. Conditions for comparative assessment

Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered, referred to as 'substitution', the alternative must, in the light of scientific and technical knowledge, show significantly lower risk to health or the environment. An assessment of the alternative shall be performed to demonstrate whether it can be used with similar effect on the target organism and without significant economic and practical disadvantages to the user or not.

Further conditions for refusal or withdrawal of an authorisation are as follows:

(a) substitution shall be applied only where other methods or the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism;

(b) substitution shall be applied only to plant protection products where their use presents a significantly higher level of risk to human health or the environment; and

(c) substitution shall be applied only after allowing for the possibility, where necessary, of acquiring experience from use in practice, where not already available.

2. Significant difference in risk

A significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment shall also be considered.

For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk.

3. Significant practical or economic disadvantages

Significant practical or economic disadvantage to the user is defined as a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism. Such a major impairment might be, for example, where no technical facilities for the use of the alternative are available or economically feasible.

Where a comparative assessment indicates that restrictions on and/or prohibitions of use of a plant protection product could cause such disadvantage, then this shall be taken into account in the decision-making process. This situation shall be substantiated.

The comparative assessment shall take authorised minor uses into account.

[F413]ANNEX V

Repealed Directives and their successive amendments as referred to in Article 83

Textual Amendments

F413 Annex 5 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **14(4)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

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(**1**) OJ C 175, 27.7.2007, p. 44.

(**2**) OJ C 146, 30.6.2007, p. 48.

(**3**) Opinion of the European Parliament of 23 October 2007 (OJ C 263 E, 16.10.2008, p. 181), Council Common Position of 15 September 2008 (OJ C 266 E, 21.10.2008, p. 1) and European Parliament Position of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.

(**4**) OJ L 230, 19.8.1991, p. 1.

(**5**) OJ C 187 E, 7.8.2003, p. 173.

(**6**) OJ L 33, 8.2.1979, p. 36.

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

(**8**) OJ L 327, 22.12.2000, p. 1.

(**9**) See page 71 of this Official Journal.

(**10**) OJ L 270, 21.10.2003, p. 1.

(**11**) OJ L 358, 18.12.1986, p. 1.

(**12**) OJ L 200, 30.7.1999, p. 1.

(**13**) OJ L 165, 30.4.2004, p. 1.

(**14**) OJ L 70, 16.3.2005, p. 1.

(**15**) OJ L 184, 17.7.1999, p. 23.

(**16**) OJ L 353, 31.12.2008, p. 1.

(**17**) OJ L 106, 17.4.2001, p. 1.

(**18**) OJ L 50, 20.2.2004, p. 44.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council.