

ANNEX: KEELING SCHEDULE

Technical Consultation on the Alternative Transitional Registration model (ATRm) for UK REACH

This Annex reproduces selected provisions of UK REACH, with proposed amendments to implement the ATRm indicated. Where they are not relevant to the proposals, some provisions, including recitals and footnotes, have been omitted in order to limit the material.

This document shows provisions as they would be amended by the proposed legislation. It is intended to assist the consideration of these proposed amendments and should not be taken as a definitive statement of the law as it would have effect on the coming into force of the legislation.

Deletions are shown ~~striketrough~~ and additions in underline.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

(Text with EEA relevance)

TITLE I

GENERAL ISSUES

CHAPTER 1

Aim, scope and application

Article 1

Aim and scope

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances while enhancing competitiveness and innovation.
2. This Regulation lays down provisions on substances and mixtures within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.
3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

Article 2

Application

1. This Regulation shall not apply to:
 - (a) radioactive substances within the scope of assimilated law that transposed Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation;
 - (b) substances, on their own, in a mixture or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
 - (c) non-isolated intermediates;
 - (d) the carriage of dangerous substances and dangerous substances in dangerous
 - (e) mixtures by rail, road, inland waterway, sea or air.
2. Waste as defined in Article 3(1) of Directive 2008/98/EC of the European Parliament and of the Council is not a substance, mixture or article within the meaning of Article 3 of this Regulation.
- 2A. For the purposes of this Regulation, “Directive 2008/98/EC” means that Directive as last amended by Directive (EU) 2018/851, and read in accordance with paragraphs 2B and 2C.
- 2B. Article 5 is to be read as if—
 - (a) in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
 - (b) after paragraph 1 there were inserted—
 - “1A. Any decision as to whether a substance or object is a by-product must be made—
 - (a) in accordance with any regulations setting out detailed criteria on the application of the conditions in paragraph 1 to specific substances or objects; and

- (b) having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.”;
 - (c) paragraphs 2 and 3 were omitted.
 - 2C. Article 6 is to be read as if—
 - (a) in paragraph 1, “Member States shall take appropriate measures to ensure that” were omitted;
 - (b) after paragraph 1 there were inserted—
 - “1A. Any decision as to whether a substance or object has ceased to be waste must be made—
 - (a) in accordance with any regulations or assimilated direct legislation setting out detailed criteria on the application of the conditions in paragraph 1 to specific types of waste; and
 - (b) having regard to any guidance published by the appropriate authority or the appropriate agency for the purposes of this Article.”;
 - (c) in paragraph 2—
 - (i) the first subparagraph were omitted;
 - (ii) in the second subparagraph, for “Those detailed criteria” there were substituted “Any detailed criteria set out in guidance as referred to in paragraph 1A”;
 - (iii) the third and fourth subparagraphs were omitted;
 - (d) paragraph 3 were omitted;
 - (e) in paragraph 4—
 - (i) in the first subparagraph—
 - (aa) in the first sentence, for the words from the beginning to “Member State”, there were substituted “Where criteria have not been set out as referred to in paragraph 1A(a), the appropriate agency”;
 - (bb) the second sentence were omitted;
 - (ii) in the second subparagraph—
 - (aa) for “Member States” there were substituted “The appropriate agency”;
 - (bb) “by competent authorities” were omitted.
- 2D. In paragraphs 2B and 2C, “appropriate agency” means—
 - (a) the Environment Agency, in relation to England;
 - (b) the Natural Resources Body for Wales, in relation to Wales;
 - (c) the Scottish Environment Protection Agency, in relation to Scotland.
- 3. The Secretary of State may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence.
- 4.

5. The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:
 - (a) in medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;
 - (b) in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
 - (i) as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;
 - (ii) as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods;
 - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition;
 - (iv) in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.
6. The provisions of Title IV shall not apply to the following mixtures in the finished state, intended for the final user:
 - (a) medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;
 - (b) cosmetic products as defined in Regulation (EC) No 1223/2009 on cosmetic products;
 - (c) medical devices which are invasive or used in direct physical contact with the human body in so far as legislation relating to the classification and labelling of dangerous substances and mixtures applies to them which ensures the same level of information provision and protection as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;
 - (d) food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
 - (i) as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;
 - (ii) as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods;
 - (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;

(iv) in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.

7. The following shall be exempted from Titles II, V and VI:
 - (a) substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
 - (b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
 - (c) substances on their own or in mixtures, registered in accordance with Title II, exported from Great Britain by an actor in the supply chain and re-imported into Great Britain by the same or another actor in the same supply chain who shows that:
 - (i) the substance being re-imported is the same as the exported substance;
 - (ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;
 - (d) substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in Great Britain if:
 - (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
 - (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
8. On-site isolated intermediates and transported isolated intermediates shall be exempted from:
 - (a) Chapter 1 of Title II, with the exception of Articles 8 and 9; and
 - (b) Title VII.
9. The provisions of Titles II and VI shall not apply to polymers.

CHAPTER 2

Definitions and general provision

Article 2A

The Agency

1. The functions and powers of the Agency under the REACH legislation are to be functions and powers of the HSE.

Accordingly, any reference to the Agency in the REACH legislation must be read as meaning the HSE.

2. The general incidental powers of the HSE are to be exercisable for the purpose of carrying out the functions of the Agency under the REACH legislation.

But that does not limit the powers which the HSE has under the REACH legislation.

3. The non-REACH functions of the HSE are not limited by the functions of the Agency under the REACH legislation.

Accordingly, the HSE is not prevented from carrying out non-REACH functions in relation to a matter just because any of the functions of the Agency under the REACH legislation is also exercisable, or has been exercised, in relation to that matter.

4. The power of the Secretary of State under section 12(2)(a) of HASWA 1974 to give directions (as read with section 12(4) of HASWA 1974) is to be exercisable with respect to the functions of the Agency under the REACH legislation.

The Secretary of State may not give any such directions with regard to the enforcement of the REACH legislation in any particular case.

The Secretary of State must consider any request made by any of the other appropriate authorities for the Secretary of State to give a direction by virtue of this paragraph.

The function of giving directions by virtue of this section is subject to the consent requirement in Article 4A (whether or not there has been a request under the previous subparagraph).

5. In this Article—

“general incidental powers” means the powers which the HSE has under—

- (a) section 13 of HASWA 1974, and
- (b) Schedule 2 to HASWA 1974;

“HASWA 1974” means the Health and Safety at Work etc. Act 1974;

“HSE” means the Health and Safety Executive;

“non-REACH function” means any function which arises otherwise than under the REACH legislation;

“REACH legislation” means—

- (a) this Regulation,
- (b) any instrument made under this Regulation, and
- (c) any assimilated direct legislation that was originally made under EU REACH.

Article 2B

Advice from Environment Agency or other environmental regulators to Agency

1. The Agency must comply with paragraph 2 when exercising—
 - (a) its functions under—
 - i Article 7(5),

- ii Article 9(4), (7) and (8),
- iii Article 21,
- iv Articles 40(1) and (3), 41(1), (3) and (5), 42(1), 43, 44, 45, 46(1) and (3), 48, 49, 51 and 52,
- v Articles 58(3) and (4) and 59(1), (2), (3), (6) and (7),
- vi Article 64(1), (3), (4), (5) and (6),
- ~~vii~~ Articles 69, 70 and 71, ~~and~~
- ~~viii~~ Articles 127Q(1) and (4), 127R(2) and 127T(3), and

(b) any of its other functions under this Regulation,

if, and to the extent that, the exercise of the function involves consideration of any relevant environmental issues.

2. The Agency must—
 - (a) obtain the advice of the Environment Agency before exercising the function concerned, and
 - (b) use the advice obtained when exercising the function concerned.
3. Whenever the advice of the Environment Agency is sought by the Agency under this Article, the Environment Agency must collaborate with the other environmental regulators when formulating the advice.
4. If, as part of a collaboration under paragraph 3, one of the other environmental regulators gives advice to the Environment Agency, the Environment Agency must pass that advice on to the Agency if that other environmental regulator requires it to do so.
5. In this Article—

“other environmental regulator” means—

 - (a) in relation to Wales, the Natural Resources Body for Wales;
 - (b) in relation to Scotland, the Scottish Environment Protection Agency;

“relevant environmental issue” means—

 - (a) exposure of the environment to chemicals;
 - (b) exposure of humans to chemicals in the environment;
 - (c) assessment of the potential effect of chemicals on the environment;
 - (d) measures aimed at controlling the release of chemicals into the environment.

Article 3

Definitions

For the purposes of this Regulation:

- A1. EU REACH: means Regulation (EC) No 1907/2006 of the European Parliament and of the Council as it has effect in EU law;
- A2. appropriate authority: means—
 - (a) the Secretary of State, in relation to England;

(b) the Scottish Ministers, in relation to Scotland;

(c) the Welsh Ministers, in relation to Wales;

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2. mixture: means a mixture or solution composed of two or more substances;
3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
4. producer of an article: means any natural or legal person who makes or assembles an article within Great Britain;
5. polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
 - (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
 - (b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;
6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;
7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
8. manufacturing: means production or extraction of substances in the natural state;
9. manufacturer: means any natural or legal person established within Great Britain who manufactures a substance within Great Britain;
10. import: means the physical introduction into Great Britain;
- 10A. protected NI import: has the meaning given by Article 139A(2);
- 10B. qualifying Northern Ireland good: has the meaning given to it from time to time in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

11. importer: means any natural or legal person established within Great Britain who is responsible for import;
12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
13. downstream user: means any natural or legal person established within Great Britain, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;
14. distributor: means any natural or legal person established within Great Britain, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties;
15. intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):
 - (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
 - (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
 - (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
16. site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
17. actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;
18. Agency: see Article 2A;
- 18A. ECHA: means the European Chemicals Agency established under EU REACH;
19.

20. phase-in substance: means a substance which meets at least one of the following criteria:
- (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
 - (b) it was manufactured in the European Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before 1 June 2007, provided the manufacturer or importer has documentary evidence of this;
 - (c) it was placed on the market in the European Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before 1 June 2007 and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive;
21. notified substance: means a substance for which a notification was submitted and which could be placed on the market in accordance with Directive 67/548/EEC;
22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;
24. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
25. registrant's own use: means an industrial or professional use by the registrant;
26. identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
27. full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;
30. per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
31. restriction: means any condition for or prohibition of the manufacture, use or placing on the market;
32. supplier of a substance or a mixture: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;
33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
34. recipient of a substance or a mixture: means a downstream user or a distributor being supplied with a substance or a mixture;
35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
36. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises and, in its application for the purposes of this paragraph, the Annex to that Recommendation has effect with the following modifications—

(a) in Article 2(1)—

- (i) the reference to EUR 50 million has effect as a reference to £43.650 million;
- (ii) the reference to EUR 43 million has effect as a reference to £37.539 million;

(b) in Article 2(2) the reference to EUR 10 million has effect as a reference to £8.730 million;

(c) in Article 2(3) the reference to EUR 2 million has effect as a reference to £1.746 million;

(d) in Article 3(2)—

- (i) in point (a), the reference to EUR 1,250,000 has effect as a reference to £1,091,250;

(ii) in point (d), the reference to EUR 10 million has effect as a reference to £8.730 million;

37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
39. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
41. alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.
42. GB mandatory classification and labelling list: the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.
43.
44. relevant medical device: means a medical device within the scope of—
 - (a) the Medical Devices Regulations 2002;
 - (b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law; or
 - (c) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as it has effect in EU law;
45. relevant accessory to a medical device: means an accessory to a medical device within the scope of—
 - (a) the Medical Devices Regulations 2002;
 - (b) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as it has effect in EU law; or
 - (c) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as it has effect in EU law.

46. substance group: means a forum of registrants and potential registrants who manufacture or import, or intend to manufacture or import, the same substance, established with the aim of agreeing the classification and labelling of the substance and facilitating the exchange of information between registrants for any of the purposes mentioned in Article 25A(3).

Article 4

General provision

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

Article 4A

The consent requirement

1. Where any provision of this Regulation states that a function is subject to the consent requirement in this Article, the function may be exercised in a particular instance only if the person exercising it has obtained the consent or consents (if any) required by paragraphs 2 to 4.
2. The consent of the Scottish Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998), whether or not the exercise of the function also relates to a part of Great Britain other than Scotland.
3. The consent of the Welsh Ministers is required if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006) whether or not the exercise of the function also relates to a part of Great Britain other than Wales.

TITLE II

REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

Article 5

No data, no market

Subject to Articles 6, 7 and 21, substances on their own, in mixtures or in articles shall not be manufactured in Great Britain or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Article 6

General obligation to register substances on their own or in mixtures

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency.
2. For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.
3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:
 - (a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
 - (b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.
4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 7

Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
 - (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
 - (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.
2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:
 - (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
 - (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).
3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:
 - (a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
 - (b) the registration number(s) referred to in Article 20(1), if available;
 - (c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
 - (d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
 - (e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
 - (f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.
 5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
 - (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
 - (b) the Agency has grounds for suspecting that:
 - (i) the substance is released from the articles, and
 - (ii) the release of the substance from the articles presents a risk to human health or the environment;
 - (c) the substance is not subject to paragraph 1.
- A submission for registration shall be accompanied by the fee required in accordance with Title IX.
6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.
 7. Paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).
 8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.

Article 8

Only representative of a non-Great British manufacturer

1. A natural or legal person established outside Great Britain who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into Great Britain may by mutual agreement appoint a natural

or legal person established in Great Britain to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Great British manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

Article 9

Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a five-year exemption period to a substance manufactured in Great Britain or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.
- 1A. In paragraph 1 “five-year exemption period” means a period of five years beginning when Articles 5, 6, 7, 17, 18 and 21 would otherwise apply to the substance (if it were not manufactured or imported as mentioned in paragraph 1).
2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:
 - (a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;
 - (b) the identity of the substance, as specified in section 2 of Annex VI;
 - (c) the classification of the substance as specified in section 4 of Annex VI, if any;
 - (d) the estimated quantity as specified in section 3.1 of Annex VI;
 - (e) the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to

the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the appropriate authorities that request it.

4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the mixture or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a mixture or article and that remaining quantities will be re-collected for disposal after the exemption period.

In such cases, the Agency may ask the notifier to provide additional necessary information.

5. In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.
6. The manufacturer or importer or producer of articles shall comply with any conditions imposed by the Agency in accordance with paragraph 4.
7. The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development programme.
8. The Agency shall forthwith communicate any draft decisions to the appropriate authorities that request them.

When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by the appropriate authorities.

9. The Agency and the appropriate authorities shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.
10. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 4 and 7 of this Article.

Article 10

Information to be submitted for general registration purposes

Subject to Articles 127B and 127NA, Aa registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

- (a) a technical dossier including:
 - (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

- (ii) the identity of the substance as specified in section 2 of Annex VI;
- (iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
- (iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
- (v) guidance on safe use of the substance as specified in Section 5 of Annex VI;
- (vi) study summaries of the information derived from the application of Annexes VII to XI;
- (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
- (viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
- (ix) proposals for testing where listed in Annexes IX and X;
- (x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;
- (xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3) or Article 27(6), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

- (b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 11

Joint submission of data by multiple registrants

1. When a substance is intended to be manufactured in Great Britain by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2. Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.
3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:
 - (a) it would be disproportionately costly for him to submit this information jointly; or
 - (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
 - (c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 12

Information to be submitted depending on tonnage

1. Subject to Articles 127B and 127NA, Tthe technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:
 - (a) the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;
 - (b) the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;

- (c) the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;
 - (d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;
 - (e) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.
- 2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.
- 3. This Article shall apply to producers of articles adapted as necessary.

Article 13

General requirements for generation of information on intrinsic properties of substances

- 1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.
- 2. These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Secretary of State, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Test Methods Regulation, and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Amendments to the Test Methods Regulation may be made by regulations made by the Secretary of State. Amendments to the Annexes of this Regulation may be made by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament. The functions of making regulations under this paragraph are subject to the consent requirement in Article 4A.
- 3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down

in the Test Methods Regulation or in accordance with other international test methods recognised by the Agency as being appropriate.

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

4. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in the Good Laboratory Practice Regulations 1999 or other international standards recognised as being equivalent by the Agency and with the provisions of the Animals (Scientific Procedures) Act 1986, if applicable.
5. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

6. In this Article “Test Methods Regulation” means Commission Regulation (EU) No 440/2008.

Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1. A chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

Subject to Articles 127B(5A) and 127NA(7), ~~The~~ the chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:
 - (a) the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;
 - (b) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.
3. A chemical safety assessment of a substance shall include the following steps:
 - (a) human health hazard assessment;
 - (b) physicochemical hazard assessment;
 - (c) environmental hazard assessment;

- (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.
4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
 - (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
 - (c) hazard class 4.1;
 - (d) hazard class 5.1,
- or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:
- (a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;
 - (b) risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

5. The chemical safety report need not include consideration of the risks to human health from the following end uses:
- (a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food;
 - (b) in cosmetic products within the scope of Regulation (EC) No 1223/2009 on cosmetic products.
6. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.
7. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

CHAPTER 2

Substances regarded as being registered

Article 15

Substances in plant protection and biocidal products

1. The following are regarded as being registered, and the registration as completed, for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title—

- (a) active substances manufactured or imported for use in plant protection products only and included in the approvals register in relation to at least one constituent territory;
 - (b) co-formulants manufactured or imported for use in plant protection products only and not included in the unacceptable co-formulants register in relation to the whole of the UK;
 - (c) any substance in relation to which the applicant has been notified in accordance with Article 9(3) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.
- 1A. In paragraph 1—
- (a) in point (a)—
 - (i) “approvals register” means the register maintained in accordance with Article 27A of Regulation (EC) No 1107/2009;
 - (ii) “constituent territory” has the meaning given by Article 3A of Regulation (EC) No 1107/2009;
 - (b) in point (b), “unacceptable co-formulants register” means the register maintained in accordance with Article 27B of Regulation (EC) No 1107/2009.
2. Active substances manufactured or imported for use in biocidal products only and included either in the GB List or the Simplified Active Substance List defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products or Annex II of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, subject to the transitional measures detailed in Article 89 of Regulation (EU) No 528/2012, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

Article 16

Duties of registrants of substances regarded as being registered

1.
2. Articles 21, 22 and 25 to 27 shall not apply to uses of substances regarded as registered according to Article 15.

CHAPTER 3

Obligation to register and information requirements for certain types of isolated intermediates

Article 17

Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.
2. Subject to Articles 127L and 127NB, Aa registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:
 - (a) the identity of the manufacturer as specified in Section 1 of Annex VI;
 - (b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
 - (c) the classification of the intermediate as specified in Section 4 of Annex VI;
 - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
 - (e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
 - (f) details of the risk management measures applied.

Except in cases covered under Article 25(3) or Article 27(6), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

Article 18

Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.
2. Subject to Articles 127M and 127NB, Aa registration for a transported isolated intermediate shall include all the following information:
 - (a) the identity of the manufacturer or importer as specified in Section 1 of Annex VI;
 - (b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
 - (c) the classification of the intermediate as specified in Section 4 of Annex VI;
 - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

- (e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
- (f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3) or Article 27(6), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.

For the generation of this information, Article 13 shall apply.

4. Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an) other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:
 - (a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
 - (b) procedural and control technologies shall be used that minimise emission and any resulting exposure;
 - (c) only properly trained and authorised personnel handle the substance;
 - (d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
 - (e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
 - (f) substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

Article 19

Joint submission of data on isolated intermediates by multiple registrants

1. When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in Great Britain by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (d) and Article 18(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as ‘the lead registrant’).

Each registrant shall subsequently submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18(2)(a), (b), (e) and (f).

2. A manufacturer or importer may submit the information referred to in Article 17(2) (c) or (d) and Article 18(2)(c) or (d) separately if:
 - (a) it would be disproportionately costly for him to submit this jointly; or
 - (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or
 - (c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

CHAPTER 4

Common provisions for all registrations

Article 20

Duties of the Agency

1. The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.
2. The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date.

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three-week period referred to in the second subparagraph, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

3. Once the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Agency shall without delay communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.
4. The Agency shall notify the appropriate authorities that request the notification within 30 days of the submission date, that the following information is available in the Agency database:
 - (a) the registration dossier together with the submission or registration number;
 - (b) the submission or registration date;
 - (c) the result of the completeness check; and
 - (d) any request for further information and deadline set in accordance with the third subparagraph of paragraph 2.

The Agency shall forthwith notify the appropriate authorities that request the notification when any further information submitted by the registrant is available on the Agency database.
5. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 2 of this Article.
6. Where additional information for a particular substance is submitted to the Agency by a new registrant, the Agency shall notify the existing registrants that this information is available on the database for the purposes of Article 22.

Article 21

Manufacturing and import of substances

1. A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the submission date, without prejudice to Article 27(8).

In the case of an update of a registration according to Article 22 a registrant may continue the manufacture or import of the substance, or the production or import of the article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the update date, without prejudice to Article 27(8).
2. If the Agency has informed the registrant that he is to submit further information in accordance with the third subparagraph of Article 20(2), the registrant may start the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from the Agency within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to Article 27(8).
3. If a lead registrant submits parts of the registration on behalf of one or more other registrants, as provided for in Articles 11 or 19, any of the other registrants may

manufacture or import the substance or produce or import the articles only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary from the Agency in respect of the registration of the lead registrant acting on behalf of the others and his own registration.

Article 22

Further duties of registrants

1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:
 - (a) any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;
 - (b) any change in the composition of the substance as given in Section 2 of Annex VI;
 - (c) changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
 - (d) new identified uses and new uses advised against as in Section 3.7 of Annex VI for which the substance is manufactured or imported;
 - (e) new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
 - (f) any change in the classification and labelling of the substance;
 - (g) any update or amendment of the chemical safety report or Section 5 of Annex VI;
 - (h) the registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed;
 - (i) any change in the access granted to information in the registration.

The Agency shall communicate this information to the appropriate authorities that request it.

2. A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the appropriate authorities that request it that the information is available on its database.
3. The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with Article 12(2) and with paragraph 1(c) of this Article then the Agency shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.

4. In cases covered by Articles 11 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.
5. An update shall be accompanied by the relevant part of the fee required in accordance with Title IX.

CHAPTER 5

Transitional provisions applicable to phase-in substances and notified substances

Article 23

Specific provisions for phase-in substances

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Article 24

Notified substances

1.
2. If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 12, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 10 and 12, unless it has already been submitted in accordance with those Articles.

TITLE III

DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

CHAPTER 1

Objectives and general rules

Article 25

Objectives and general rules

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.
2. The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.
3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation, or owned by a registrant and submitted under EU REACH before IP completion day, at least 12 years previously can be used by

another manufacturer or importer for the purposes of registration, or for the purposes of responding to a decision by the Agency under Articles 127S or 127T by another manufacturer or importer.

Article 25A

Substance Groups

1. The following registrants must participate in a substance group if they are manufacturing or importing, or intending to manufacture or import, the same substance—
 - a. potential registrants who have submitted an inquiry to the Agency under Article 26, and
 - b. registrants who have been assigned a registration number by the Agency under Article 20(3).
2. The aim of each substance group is to—
 - a. facilitate, for the purposes specified in paragraph 3, the exchange of information listed in paragraph 4 between its participants, and
 - b. agree classification and labelling, where there are differences in the classification and labelling of the substance between its participants.
3. The purposes referred to in paragraph 2(a) are—
 - a. registration under Title 2 (registration of substances), including where Articles 127NA and 127NB apply,
 - b. submitting information to the Agency for registrations under Title 14A (EU withdrawal: transitional provision),
 - c. updating registrations under Article 12(2) (information to be submitted depending on tonnage) and Article 22(1)(b) and (e) to (i) (further duties of registrants), and
 - d. responding to Agency decisions under Title 6 (evaluation) and Articles 127S and 127T (transitional evaluation).
4. The information referred to in paragraph 2(a) is—
 - a. for substances, other than intermediates—
 - (i) the information specified in Article 10(a)(iv) and, where applicable, Article 10(a)(vi), (vii), (ix);
 - (ii) the information specified in Article 10(a)(v) and, where applicable, Article 10(b), if registrants have agreed under Article 11(1) that one registrant will submit this information on behalf of the others;
 - (iii) any relevant indication under Article 10(a)(viii);
 - b. for on-site isolated intermediates, the information specified in Article 17(2)(c) and, where applicable, Article 17(2)(d);

- c. for transported isolated intermediates, the information specified in Article 18(2)(c), and, where applicable, Article 18(2)(d) and (3);
- a-d. for all substances, any additional items of information required to respond to an Agency decision under Title 6 (evaluation).

CHAPTER 2

Rules for registrants of substances

Article 26

Duty to inquire prior to registration

1. Every potential registrant shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:
 - (a) his identity as specified in Section 1 of Annex VI, with the exception of the use sites;
 - (b) the identity of the substance, as specified in Section 2 of Annex VI;
 - (c) which information requirements would require new studies involving vertebrate animals to be carried out by him;
 - (d) which information requirements would require other new studies to be carried out by him.
2. If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.
3. If there is a previous registration of the same substance that is less than 12 years old, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them.

A registration of a substance is less than 12 years old if—

- (a) in a case where the registration came into existence under Article 127A, the existing EU registration (as defined in Article 127~~ZAD~~) began less than 12 years before the potential registrant's enquiry to the Agency;
- (b) in any other case, the registration under this Regulation began less than 12 years before the potential registrant's enquiry to the Agency.

Studies involving vertebrate animals shall not be repeated.

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 27.

4. If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

Article 27

Sharing of existing data in the case of registered substances

1. Where there is a previous registration of a substance that is less than 12 years old as referred to in Article 26(3), the potential registrant:
 - (a) shall, in the case of information involving tests on vertebrate animals; and
 - (b) may, in the case of information not involving tests on vertebrate animals, request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.
2. Within one month of a request for information being made according to paragraph 1, the owner of the study shall provide proof of the cost of the information to the potential registrant(s) requesting it. The potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.
3. The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost sharing guidance based on those principles which is adopted by the Agency in accordance with Article 77(2)(g). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.
4. On agreement on the sharing of the information, the previous registrant shall, within two weeks of receipt of payment, make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.
5. If the previous registrant as referred to in paragraph 1 refuses to provide either proof of the cost of that study or the study itself to a potential registrant, or there is failure to reach an agreement referred to in paragraph 4, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).
6. Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that

information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77(2)(g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

7. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 6 of this Article.
8. The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests.

CHAPTER 3

Rules for phase-in substances

[Articles 28-30 omitted]

TITLE IV

INFORMATION IN THE SUPPLY CHAIN

Article 31

Requirements for safety data sheets

1. The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:
 - (a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or
 - (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or
 - (c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).
2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety report for each substance in the mixture.

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:
 - (a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and $\geq 0,2$ % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or
 - (b) in an individual concentration of $\geq 0,1$ % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or
 - (c) a substance in relation to which the law of any part of Great Britain provides workplace exposure limits.
4. The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.
5. The safety data sheet shall be supplied in English and may also be supplied in any other language.
6. The safety data sheet shall be dated and shall contain the following headings:
 1. identification of the substance/ mixture and of the company/undertaking;
 2. hazards identification;
 3. composition/information on ingredients;
 4. first-aid measures;
 5. fire-fighting measures;
 6. accidental release measures;
 7. handling and storage;
 8. exposure controls/personal protection;
 9. physical and chemical properties;
 10. stability and reactivity;
 11. toxicological information;
 12. ecological information;
 13. disposal considerations;
 14. transport information;
 15. regulatory information;
 16. other information.
7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

8. A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.
9. Suppliers shall update the safety data sheet without delay on the following occasions:
 - (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
 - (b) once an authorisation has been granted or refused;
 - (c) once a restriction has been imposed.

The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.

10.

Article 32

Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a mixture who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:
 - (a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;
 - (b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
 - (c) details of any restriction imposed under Title VIII;
 - (d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.
2. The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a mixture.

3. Suppliers shall update this information without delay on the following occasions:
 - (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
 - (b) once an authorisation has been granted or refused;
 - (c) once a restriction has been imposed.

In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.

Article 33

Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Article 34

Duty to communicate information on substances and mixtures up the supply chain

Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:

- (a) new information on hazardous properties, regardless of the uses concerned;
- (b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 35

Access to information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or mixtures that they use or may be exposed to in the course of their work.

Article 36

Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to the Agency or to any appropriate authority, without prejudice to Titles II and VI.
2. In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

TITLE V

DOWNSTREAM USERS

Article 37

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

1. A downstream user or distributor may provide information to assist in the preparation of a registration.
2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a mixture to the downstream user making the request referred to in

paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.

Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).

4. A downstream user of a substance on its own or in a mixture shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.

A downstream user need not prepare such a chemical safety report in any of the following cases:

- (a) a safety data sheet is not required to be communicated with the substance or mixture in accordance with Article 31;
 - (b) a chemical safety report is not required to be completed by his supplier in accordance with Article 14;
 - (c) the downstream user uses the substance or mixture in a total quantity of less than one tonne per year;
 - (d) the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;
 - (e) the substance is present in a mixture in a concentration lower than any of the concentrations set out in Article 14(2);
 - (f) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.
5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:
 - (a) the safety data sheet(s) supplied to him;
 - (b) his own chemical safety assessment;
 - (c) any information on risk management measures supplied to him in accordance with Article 32.

6. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.
7. Downstream users shall keep their chemical safety report up to date and available.
8. A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 14(5).

Article 38

Obligation for downstream users to report information

1. Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 6 or 18, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases:
 - (a) the downstream user has to prepare a chemical safety report in accordance with Article 37(4); or
 - (b) the downstream user is relying on the exemptions in Article 37(4)(c) or (f).
2. The information reported by the downstream user shall include the following:
 - (a) his identity and contact details as specified in Section 1.1 of Annex VI;
 - (b) the registration number(s) referred to in Article 20(3), if available;
 - (c) the identity of the substance(s) as specified in Section 2.1 to 2.3.4 of Annex VI;
 - (d) the identity of the manufacturer(s) or the importer(s) or other supplier as specified in Section 1.1 of Annex VI;
 - (e) a brief general description of the use(s), as specified in Section 3.5 of Annex VI, and of the conditions of use(s);
 - (f) except where the downstream user is relying on the exemption in Article 37(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.
3. The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.
4. A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.
5. Except where a downstream user is relying on the exemption in Article 37(4)(c), reporting in accordance with paragraphs 1 to 4 of this Article shall not be required in

respect of a substance, on its own or in a mixture, used by the downstream user in quantities of less than one tonne per year for that particular use.

Article 39

Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.
2. Downstream users shall be required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

TITLE VI

EVALUATION

CHAPTER 1

Dossier evaluation

Article 40

Examination of testing proposals

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008:
 - (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
 - (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
 - (c) hazard class 4.1;
 - (d) hazard class 5.1.
2. Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and

studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.

3. On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:
 - (a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;
 - (b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;
 - (c) a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;
 - (d) a decision rejecting the testing proposal;
 - (e) a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.
4. The registrant or downstream user shall submit the information required to the Agency by the deadline set.

Article 41

Compliance check of registrations

1. The Agency may examine any registration in order to verify any of the following:
 - (a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
 - (b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;
 - (c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;
 - (d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.
2. The list of dossiers being checked for compliance by the Agency shall be made available to the appropriate authorities that request it.

3. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.
4. The registrant shall submit the information required to the Agency by the deadline set.
5. The registration dossiers selected by the Agency for compliance checking must include—
 - (a) until 27 October 2030, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(a);
 - (b) until 27 October 2032, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(b);
 - (c) until 27 October 2036, not less than 20% of the registration dossiers received by the Agency for substances referred to in Article 127P(4B)(c).

In this paragraph, references to registration dossiers do not include the dossiers referred to in Article 127B(9).

6.
7. The Secretary of State may, by regulations, make provision to modify the effect of paragraph 5 by—
 - (a) modifying the percentage of dossiers to be selected;
 - (b) modifying the criteria which determine the dossiers to which priority is to be given.

Regulations under this paragraph may amend paragraph 5.

The Secretary of State must consult the Agency before making regulations under this paragraph.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.

Article 42

Check of information submitted and follow-up to dossier evaluation

1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.
2. Once the dossier evaluation is completed, the Agency shall notify the appropriate authorities that request the notification of the information obtained and any conclusions

made. The Agency shall use the information obtained from this evaluation for the purposes of Article 44.

Article 43

Procedure and time periods for examination of testing proposals

1. In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 40(3) within 180 days of receiving a registration or downstream user report containing a testing proposal.
2. In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 40(3):
 - (a)
 - (b)
 - (c) by 1 June 2023 for any registrations containing testing proposals received by ECHA by 1 June 2018.
3. The list of registration dossiers being evaluated under Article 40 shall be made available to appropriate authorities that request it.

CHAPTER 2

Substance evaluation

Article 44

Criteria for substance evaluation

1. The Agency shall in cooperation with the appropriate authorities develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider:
 - (a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bioaccumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
 - (b) exposure information;
 - (c) tonnage, including aggregated tonnage from the registrations submitted by several registrants.
2. The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. The Agency must submit its draft rolling action plan to the appropriate authorities within 12 months of IP completion day and give the appropriate authorities the opportunity to comment on it. The Agency must submit a draft annual update to its

rolling action plan by 31 May in each subsequent year and give the appropriate authorities the opportunity to comment on it. The Agency must adopt a final rolling annual action plan for each year (after taking account of any comments made on the draft by the appropriate authorities) and must publish it on its website.

Article 45

Evaluation of substances on the rolling action plan

1. The Agency shall be responsible for ensuring that substances on the rolling action plan are evaluated.
2.
3.
4.
5.

Article 46

Requests for further information and check of information submitted

1. If the Agency considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.
2. The registrant shall submit the information required to the Agency by the deadline set.
3. The Agency shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.
4. The Agency shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Article 47

Coherence with other activities

1. An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52, any draft decision requiring further

information under Article 46 may be justified only by a change of circumstances or acquired knowledge.

2.

Article 48

Follow-up to substance evaluation

Once the substance evaluation has been completed, the Agency must consider how to use the information obtained from this evaluation for the purposes of Article 59(3) and Article 69(4). The Agency must inform the appropriate authorities and the registrant of its conclusions as to whether or how to use the information obtained.

CHAPTER 3

Evaluation of intermediates

Article 49

Further information on on-site isolated intermediates

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where the Agency considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

- (a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;
- (b) examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

Where the appropriate authority in relation to the part of Great Britain where the site is located considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, that appropriate authority may request the Agency to take the steps set out in points (a) and (b) of the first paragraph.

The Agency must inform the appropriate authorities that request them of the results of an assessment under this Article.

CHAPTER 4

Common provisions

Article 50

Registrants' and downstream users' rights

1. The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency.
2. If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. The Agency shall inform the appropriate authorities that request it, when a registrant has informed the Agency in accordance with this paragraph.
3. The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform the Agency of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report. The Agency shall inform the appropriate authorities that request it, when a registrant has informed the Agency in accordance with this paragraph.
4. Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 46 in either or both of the following cases:
 - (a) where the Agency prepares a dossier in accordance with Annex XV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;
 - (b) where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

The procedure in Articles 69 to 73 shall apply *mutatis mutandis*.

Article 51

Adoption of decisions under dossier evaluation

1. This Article applies where the Agency has notified its draft decision in accordance with Article 40 or 41.
2. If the Agency receives no comments from the registrant or downstream user, the Agency must make its decision in the version notified under paragraph 1.

3. If the Agency receives any comments from the registrant or downstream user, the Agency must—
 - (a) take the comments into account, and
 - (b) make its decision (whether that is to make the decision in the version notified or vary the decision notified).
4. The Agency must notify the registrant or downstream user and the appropriate authorities of the decision made under paragraph 2 or 3.
5. An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.

Article 52

Adoption of decisions under substance evaluation

1. This Article applies where the Agency has circulated its draft decision in accordance with Article 46.
2. If the Agency receives no comments from the registrant or the downstream user, the Agency must make its decision in the version circulated under paragraph 1.
3. If the Agency receives any comments from the registrant or the downstream user, the Agency must—
 - (a) take the comments into account, and
 - (b) make its decision (whether that is to make the decision in the version circulated or vary the decision circulated).
4. The Agency must notify the registrant or the downstream user, and the appropriate authorities, of the decision made under paragraph 2 or 3.
5. An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.

Article 53

Cost sharing for tests without an agreement between registrants and/or downstream users

1. Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.
2. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

3. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.
4. The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 54

Publication of information on evaluation

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

TITLE VII

AUTHORISATION

[Title VII omitted]

TITLE VIII

RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES

[Title VIII omitted]

TITLE IX

FEES AND CHARGES

Article 74

Fees and charges

1. The Secretary of State may, by regulations, specify the fees that are required according to Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2), Article 18(2), Article 19(3), Article 22(5) and Article 62(7).

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.

2. A fee need not be paid for a registration of a substance in a quantity of between 1 and 10 tonnes where the registration dossier contains the full information in Annex VII.
3. In the case of Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2) and Article 18(2), the structure and amount of fees shall take account of the tonnage range of the substance being registered.

In all cases, a reduced fee shall be set for SMEs.

In the case of Article 11(4), the structure and amount of fees shall take into account whether information has been submitted jointly or separately.

In the case of a request made under Article 10(a)(xi), the structure and amount of fees shall take into account the work required by the Agency in assessing the justification.

4.
5. The Agency may collect charges for other services it provides.

TITLE X

AGENCY

[Articles 75-76 omitted]

Article 77

Tasks

- A1. When forming opinions the Agency must take relevant scientific knowledge and advice into account (including any relevant knowledge and advice relating to socio-economic matters).
- A2. The Agency may take any such knowledge or advice into account when forming an opinion only if—
 - (a) the knowledge or advice has been commissioned by the Agency, from one or more suitably qualified or experienced persons who are independent of the Agency, for the purposes of forming the opinion concerned, or
 - (b) the knowledge or advice—
 - (i) is already in existence (whether within the Agency or externally),
 - (ii) is produced within the Agency for the purposes of forming the opinion concerned, or
 - (iii) is, in accordance with Article 2B, produced by the Environment Agency or one of the other environmental regulators in connection with the

Agency forming the opinion concerned and then passed on to the Agency, and the Agency considers that it is appropriate to take it into account, rather than to commission knowledge or advice in compliance with point (a).

The knowledge or advice that the Agency may take into account in compliance with point (b)(i) includes knowledge or advice which has previously been commissioned by the Agency from one or more suitably qualified or experienced persons who are independent of the Agency for the purposes of forming a previous opinion on any matter.

- A3. The Agency must comply with this paragraph if —
- (a) it is forming—
 - (i) an opinion in connection with deciding whether to grant an authorisation under Article 60,
 - (ii) an opinion under Article 70 as to whether suggested restrictions are appropriate in reducing the risk to human health or the environment, or
 - (iii) an opinion under Article 71 on suggested restrictions and on the related socioeconomic impact, and
 - (b) it only takes into account knowledge or advice that is not commissioned in compliance with paragraph A2(a) for the purposes of forming that opinion.
- The Agency must—
- (a) produce an explanation of why it considered that it was appropriate to take only that knowledge or advice into account,
 - (b) publish the explanation, and
 - (c) send a copy of the explanation to the appropriate authorities.
- A4. When exercising its functions, the Agency must act in a way that ensures a high degree of transparency.
- A5. The Agency must produce and publish a statement of how it will comply with paragraphs A1, A2 and A4.
- The Agency must produce and publish the first statement within the period of 3 months beginning with the day after IP completion day.
- The Agency must consult such persons as it considers appropriate before producing the first, or any subsequent, statement.
- A6. The statement must include—
- (a) information about the qualifications or relevant experience that are suitable in order for persons to be commissioned to provide knowledge or advice to the Agency,
 - (b) examples of situations in which the Agency envisages that it might be appropriate to take existing knowledge or advice (rather than knowledge or advice commissioned as mentioned in paragraph A2(a)) into account.
- A7. Paragraphs A1 to A6 do not limit the Agency's duties under Article 2B.

1. The Agency shall provide the appropriate authorities with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.
2. The Agency shall undertake the following tasks:
 - (a)
 - (b)
 - (c)
 - (d)
 - (e) establishing and maintaining database(s) with information on all registered substances. It shall make the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified;
 - (f) making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 119(1);
 - (g) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;
 - (h)
 - (i) providing guidance to stakeholders on communication to the public of information on the risks and safe use of substances, on their own, in mixtures or in articles;
 - (j) providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);
 - (k) preparing explanatory information on this Regulation for other stakeholders;
 - (l) at the request of any appropriate authority, providing technical and scientific support for steps to improve cooperation with international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
 - (m) keeping a Manual of Decisions and Opinions regarding interpretation and implementation of this Regulation;
 - (n) notification of decisions taken by the Agency;
 - (o) provision of formats for submission of information to the Agency.
3.
4.

[Articles 78-82 omitted]

Article 83

Annual report by the Agency to the appropriate authorities

1.

2.
3. Each year, the Agency shall submit the following to the Secretary of State for approval:
 - (a) a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction prepared by the Agency, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; the Agency's compliance with Article 77(A1) by taking into account scientific knowledge and advice (including knowledge and advice relating to socio-economic matters); complaints received and the action taken;
 - (b) a draft work-programme for the coming year;
 - (c) the draft annual accounts;
 - (d) the draft forecast budget for the coming year;
 - (e) a draft multiannual work programme.

The Agency must provide any draft submitted to the Secretary of State under points (a) to (e) to the other appropriate authorities at the same time it is submitted to the Secretary of State.

The Secretary of State must consult the other appropriate authorities before giving approval to any draft submitted under points (a) to (e).

[Articles 84-87 omitted]

Article 88

Qualification and interests

1. The details of the suitably qualified or experienced persons that provide advice to the Agency under Article 77(A2)(a) must be made public. Individuals may request that their names not be made public if they believe that such publication could place them at risk. The Agency must decide whether to agree to such requests. When details are published, the professional qualifications of each suitably qualified or experienced person must be specified.
2. Suitably qualified or experienced persons that provide advice to the Agency pursuant to Article 77(A2)(a) shall make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing and, without prejudice to paragraph 1, be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.
3.

[Articles 89-90 omitted]

Article 91

Decisions subject to appeal

1. An appeal may be brought against decisions of the Agency taken pursuant to Articles 9, ~~Article 20~~, ~~Article 27(6)~~, ~~Article 51~~, and ~~Article 52~~, 127OA(8) and 127S.
- 1A. An appeal pursuant to paragraph 1 lies to the First-tier Tribunal.
2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.
3. On an appeal pursuant to paragraph 1, the First-tier Tribunal—
 - (a) may dismiss the appeal, or
 - (b) if it allows the appeal may—
 - (i) quash the decision and (if appropriate) remit the matter to the Agency, or
 - (ii) substitute for the decision any other decision which could have been made by the Agency.

Article 92

Persons entitled to appeal

1. Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.
2.
3.

Article 93

Change of decision where appeal made

1. If—
 - (a) an appeal against a decision is brought pursuant to Article 91, and
 - (b) the Agency considers the appeal to be admissible and well founded,
 the Agency may rectify the decision within the period of 30 days beginning with the day when the appeal is brought.
2.
3.
4.

Article 94

Actions before the Court of First Instance and the Court of Justice

.....

Article 95

Conflicts of opinion with other bodies

1. The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other public bodies carrying out a similar task in relation to issues of common concern.
2. Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.
3. Where there is a fundamental conflict over scientific or technical points, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the appropriate authorities clarifying the scientific and/or technical points of conflict.

[Articles 96 - 107 omitted]

Article 108

Contacts with stakeholder organisations

The Agency must develop appropriate contacts with relevant stakeholder organisations.

Article 109

Rules on transparency

To ensure transparency, the Agency must adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in mixtures or in articles which is not of a confidential nature.

Article 110

Relations with relevant public bodies

1. The Agency shall cooperate with other public bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.
2. The Agency, having consulted the Food Standards Agency and Food Standards Scotland shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context.

This Title shall not otherwise affect the competences vested in the Food Standards Agency and Food Standards Scotland.

3. This Title shall not affect the competences vested in the Medicines and Healthcare products Regulatory Agency.

4.

Article 111

Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Manufacturers, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

**TITLE XI
CLASSIFICATION AND LABELLING INVENTORY**

[Title XI omitted]

**TITLE XII
INFORMATION**

Article 117

Reporting

1.
2. Every five years, the Agency shall submit to the appropriate authorities a report on the operation of this Regulation. The Agency shall include in its report sections on evaluation and enforcement, information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 April 2022.
3. Every three years the Agency, in accordance with the objective of promoting nonanimal testing methods, shall submit to the appropriate authorities a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by 1 April 2022.
4. Every five years, the Secretary of State, in cooperation with the other appropriate authorities, must publish a general report on:
 - (a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and;

- (b) the amount and distribution of funding made available by the appropriate authorities for the development and evaluation of alternative test methods.

The first report shall be published by 1 April 2023.

Article 118

Access to information

1.
2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:
 - (a) details of the full composition of a mixture;
 - (b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or mixture, including information about its precise use as an intermediate;
 - (c) the precise tonnage of the substance or mixture manufactured or placed on the market;
 - (d) links between a manufacturer or importer and his distributors or downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.
3. The Agency shall adopt the practical arrangements for appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request.
4.

Article 119

Electronic public access

1. The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):
 - (a) without prejudice to paragraph 2(f) and (g) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:
 - hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
 - hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
 - hazard class 4.1;
 - hazard class 5.1;
 - (b) if applicable, the name of the substance as given in EINECS;
 - (c) the classification and labelling of the substance;

- (d) physicochemical data concerning the substance and on pathways and environmental fate;
 - (e) the result of each toxicological and ecotoxicological study;
ea the result of each persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment undertaken in accordance with Annex I;
 - (f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
 - (g) the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;
 - (h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.
2. The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:
- (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
 - (b) the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
 - (c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
 - (d) information, other than that listed in paragraph 1, contained in the safety data sheet;
 - (e) the trade name(s) of the substance;
 - (f) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years;
 - (g) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:
 - (i) as an intermediate;
 - (ii) in scientific research and development;
 - (iii) in product and process orientated research and development.

Article 120

Cooperation with other countries and international organisations

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of another country or an

international organisation in accordance with an agreement concluded between the United Kingdom and the other country or international organisation, provided that both the following conditions are met:

- (a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;
- (b) the other country or international organisation concerned protects the confidential information as mutually agreed.

TITLE XIII PROVISION OF INFORMATION

[Articles 121-122 omitted]

Article 123

Communication to the public of information on risks of substances

The Agency shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency, in consultation with the appropriate authorities and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in mixtures or in articles.

Article 124

Other responsibilities

The Agency must establish a national helpdesk to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the registration of substances in accordance with Article 12(1), in addition to the operational guidance documents provided by the Agency under Article 77(2)(g).

TITLE XIV ENFORCEMENT

[Articles 125-126 omitted]

Article 127

Report

The report referred to in Article 117(2) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken during the previous reporting period.

TITLE 14A

EU WITHDRAWAL: TRANSITIONAL PROVISIONArticle 127ZA.**Interpretation**In this Title—

“Article 10 information” means the information which a registration is required to include by virtue of Article 10, excluding the following information if that information has previously been submitted to ECHA under EU REACH—

- (a) study summaries,
- (b) robust study summaries, and
- (c) any physicochemical, toxicological and ecotoxicological information required under Article 12 (where applicable);

“EU CLP” means 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, as it has effect in EU law;

“existing EU registration” means a registration of a substance with ECHA which is subsisting immediately before IP completion day;

“GB registration” means a registration of a substance with the Agency;

“lead registrant” has the meaning given in Article 11(1) or 19(1), as modified by Articles 127B(4F), 127L(4), 127M(4), 127NA(8) or 127NB(6);

“transferred GB registration” has the meaning given in Article 127A(1).

*Article 127A***Existing EU registrations which have effect as GB registrations**

1. An existing EU registration under Articles 6, 7(1), 7(5) or 24(1) of EU REACH has effect on and after IP completion day as a GB registration (the “transferred GB registration”) if the registration—
 - (a) has a current connection with Great Britain, or
 - (b) has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).
2. A registration has a current connection with Great Britain if—
 - (a) the registrant immediately before IP completion day is a person established in Great Britain (a “current GB registrant”), and

- (b) a registration of the substance concerned by the current GB registrant is a registration of a kind that could be submitted on IP completion day under Article 6 or 7(1) or (5) of this Regulation.
3. A registration has a relevant past connection with Great Britain if—
 - (a) the registrant at any time in the period beginning with 29 March 2017 and ending immediately before IP completion day was a person established in Great Britain (a “former GB registrant”), and
 - (b) a registration of the substance concerned by the former GB registrant is a registration of a kind that could be submitted on IP completion day under Article 6 or 7(1) or (5) of this Regulation.
 4. Where an existing EU registration has effect by virtue of this Article as a transferred GB registration, it has effect—
 - (a) if it is an existing EU registration under Article 6 of EU REACH, as a transferred GB registration under Article 6 of this Regulation;
 - (b) if it is an existing EU registration under Article 7(1) of EU REACH, as a transferred GB registration under Article 7(1) of this Regulation;
 - (c) if it is an existing EU registration under Article 7(5) of EU REACH, as a transferred GB registration under Article 7(5) of this Regulation;
 - (d) if it is an existing EU registration that existed by virtue of Article 24(1) of EU REACH, as a transferred GB registration that exists by virtue of Article 6 of this Regulation.
 5. Where a registration that has a current connection with Great Britain has effect as a transferred GB registration by virtue of this Article, the current GB registrant becomes the registrant in relation to the transferred GB registration on IP completion day.
 6. Where a registration that has a relevant past connection with Great Britain has effect as a transferred GB registration by virtue of this Article, the former GB registrant becomes the registrant in relation to the transferred GB registration on IP completion day.
- If two or more persons have been former GB registrants at different times in the period beginning with 29 March 2017 and ending immediately before IP completion day, only the person who was the former GB registrant most recently before IP completion day is to become registrant in relation to the transferred GB registration by virtue of this paragraph.

Article 127B

Application of this Regulation to transferred GB registrations

1. The other Titles of this Regulation apply to a transferred GB registration as they would apply to the registration—
 - (a) if it had been submitted on IP completion day to the Agency under Article 6 or 7(1) or (5) (as the case may be);
 - (b) in a case where the existing EU registration came into existence by virtue of Article 24(1) of EU REACH, if it had been submitted on IP completion day to the Agency under Article 6.

Accordingly, no registration under that Article needs to be submitted.

2. But, in their application to the transferred GB registration, the other Titles of this Regulation have effect with the modifications set out in the following provisions of this Article.
3. In the case of—
 - (a) a transferred GB registration under Article 6, no fee is payable under Article 6(4);
 - (b) a transferred GB registration under Article 7, no fee is payable under Article 7(1) or (5).
4. The registrant must submit—
 - (a) the Article 10 information referred to in Article 10(a)(i), (ii), and (iii), and any relevant indication under Article 10(a)(viii), to the Agency within the 120 day post-IP completion period;
 - (b) the other Article 10 information to the Agency within the relevant post-IP completion period, unless paragraph 4A applies.

Where the existing EU registration existed by virtue of Article 24(1) of EU REACH, the duty under this paragraph does not apply in relation to a transferred GB registration unless Article 24(2) applied in relation to the notified substance concerned before IP completion day.

4A Where condition 1 or 2 in paragraph 4B is satisfied, the registrant must submit the information specified in paragraph 4C to the Agency within the relevant post-IP completion period, subject to Article 127Q (transitional evaluation).

4B The conditions are—

- a. that the substance being manufactured or imported under the transferred GB registration is registered under EU REACH, other than as an intermediate, at the same or a higher tonnage band (condition 1), or
- b. that—
 - i. the tonnage band of the substance being manufactured or imported under the transferred GB registration is 1 tonne or more, but less than 10 tonnes, per year, and
 - ii. that substance is registered under EU REACH as a transported isolated intermediate in quantities of 1000 tonnes or more per year (condition 2).

4C The information required to be submitted under paragraph 4A is—

- a. the information referred to in Article 10(a)(iv), any relevant indication under Article 10(a)(viii) relating to the information in Article 10(a)(iv) and a statement—
 - i. confirming that, for each hazard class or differentiation of the substance which is not on the GB mandatory classification and labelling list, the registrant's classification is consistent with the

- harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
- ii. where the registrant's classification is not consistent under point (i), providing reasons for any inconsistencies or, where it is not possible for the registrant to give a classification, providing reasons why no classification is given, in accordance with subsection 4.1 of Annex 6 (information requirements referred to in Article 10);
- b. the information referred to in Article 10(a)(v) and, where relevant, (x);
- c. where Article 14(1) applies, and a chemical safety report is required under Article 10(b), the information referred to in paragraph 4D.

4D The information required under paragraph 4C(c) is—

- a. the information referred to in the following provisions of Annex 1 (general provisions for assessing substances and preparing chemical safety reports)—
 - i. subsection 1.3 (human health hazard assessment: classification);
 - ii. subsection 1.4 (human health hazard assessment: identification of DNELs), excluding the justification required under point 1.4.1 specifying the choice of information used, the route of exposure and the duration and frequency of exposure to the substance for which the DNEL is valid;
 - iii. subsection 2.5 (physicochemical hazard assessment: classification);
 - iv. subsection 3.2 (environmental hazard assessment: classification);
 - v. subsection 3.3 (environmental hazard assessment: identification of PNECs);
 - vi. the first sentence of subsection 4.1 (PBT and vPvB assessment: classification);
- b. a statement confirming that—
 - i. the results of the registrant's PBT and vPvB assessment are consistent with the results of a PBT and vPvB assessment submitted by the lead registrant under EU REACH, as published by ECHA or, where the registrant's results are not consistent, providing reasons for any inconsistencies, and
 - ii. for each DNEL, DMEL or PNEC derived by the registrant, the registrant's results are consistent with the results of a DNEL, DMEL or PNEC derivation submitted by the lead registrant under EU REACH, as published by ECHA, or—

- aa. where the results are not consistent, providing reasons for any inconsistencies, or
 - bb. where it is not possible for the registrant to derive a DNEL, DMEL or PNEC, providing reasons why no DNEL, DMEL or PNEC derivation is given, in accordance with points 1.4.2 and 3.3.2 of Annex 1;
 - c. where Article 14(4) applies, the information referred to in sections 5 and 6 of Annex 1 (exposure assessment and risk characterisation) and the following provisions of Annex 7 (standard information requirements for substances manufactured or imported in quantities of one tonne or more)—
 - i. in column 1 of the table in section 7 (information on the physicochemical properties of the substance)—
 - aa. subsection 7.1 (state of the substance at 20°C and 101,3 kPa);
 - bb. subsection 7.2 (melting/freezing point);
 - cc. subsection 7.3 (boiling point);
 - dd. subsection 7.5 (vapour pressure);
 - ee. subsection 7.7 (water solubility);
 - ff. subsection 7.8 (partition coefficient n-octanol/water);
 - ii. in column 1 of the table in section 9 (ecotoxicological information), point 9.2.1.1 (ready biodegradability); and
 - d. any relevant indication under Article 10(a)(viii) relating to information submitted under points (a) and (c) of this paragraph.

4E Where the information in paragraph 4D is required—

- (a) the chemical safety assessment requirements in Annex 1 listed in the Table apply for the purpose of providing that information, and
- (b) the registrant is not required to document in the chemical safety report, the steps of the chemical safety assessment conducted under Annex 1.

Table

<u>Chemical safety assessment requirements in Annex 1 that apply for the purpose of providing the information specified in paragraph 4D</u>						
<u>0. Introduction</u>	<u>1. Human Health Assessment</u>	<u>2. Physicochemical Hazard Assessment</u>	<u>3. Environmental Hazard Assessment</u>	<u>4. PBT and vPvB Assessment</u>	<u>5. Exposure Assessment</u>	<u>6. Risk Characterisation</u>
<u>Subsections 0.1 – 0.4</u>	<u>Point 1.0.1</u>	<u>Subsection 2.1</u>	<u>Point 3.0.1</u>	<u>Point 4.0.1</u>	<u>All of section 5 if any of the hazard criteria listed in point 0.6.3 is met or the substance is assessed to be a PBT or vPvB.</u>	<u>All of section 6 if any of the hazard criteria listed in point 0.6.3 is met or the substance is assessed to be a PBT or vPvB.</u>
<u>First sentence of subsection 0.5</u>	<u>Point 1.0.2</u>	<u>First sentence of subsection 2.2</u>	<u>Point 3.0.4 (steps 2 and 3 only)</u>	<u>Point 4.0.2</u>		
<u>Points 0.6.1 – 0.6.3</u>	<u>Point 1.0.3 (steps 3 and 4 only)</u>	<u>Subsection 2.5</u>	<u>Point 3.2.1</u>	<u>First sentence of subsection 4.1</u>		
<u>Subsections 0.7 and 0.8 if any of the hazard criteria listed in point 0.6.3 is met or the substance is assessed to be a PBT or vPvB.</u>	<u>Point 1.0.4 (step 3 only)</u>		<u>Point 3.3.1</u>	<u>Subsection 4.2</u>		
<u>Subsection 0.10, excluding the requirement for the manufacturer or importer to include a full description and justification of the assessments in the chemical safety report and summaries in the safety data sheet.</u>	<u>Point 1.0.6 (based on results available to the registrant from step 3 and other sources)</u>		<u>Point 3.3.2</u>			
<u>Subsection 0.11</u>	<u>Point 1.3.1</u>					

<u>Subsection 0.11bis, excluding the requirement for the manufacturer or importer to provide a justification in the chemical safety report and a summary in the safety data sheet).</u>	<u>Point 1.4.1 (based on the information available to the registrant from step 3 and other sources), excluding the requirements to provide a full justification specifying the choice of information used, route of exposure and the duration and frequency of exposure to the substance for which the DNEL is valid and to take into account the factors listed in points (a) to (c).</u>					
<u>Subsection 0.13</u>	<u>Point 1.4.2</u>					

4F. Article 11 applies to the submission of information under paragraphs 4(b) or 4A, with the following provision substituted for paragraphs 1 to 3—

“1. Where a substance is manufactured in, or imported into, Great Britain by one or more registrants under a transferred GB registration, the following provisions apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii), (ix), any relevant indication under Article 10(a)(viii) and the statement referred to in Article 127B(4C)(a) must be submitted by one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Where applicable, each registrant must submit separately the information specified in Article 10(a)(x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b), any relevant indication under Article 10(a)(viii) and the statements referred to in Article 127B(4D)(b) separately, or whether one registrant is to submit this information on behalf of the others.

2. Each registrant is only required to comply with paragraph 1 for items of information they are required to submit to satisfy their registration requirements under Article 127B(4)(b) or (4A), as applicable.

3. A registrant may submit the information specified in Article 10(a)(iv), (vi), (vii) or (ix), or the statements referred to in Article 127B(4C)(a) and (4D)(b) separately if—

a. it would be disproportionately costly for the registrant to submit this information jointly,

b. submitting the information jointly would lead to disclosure of information which the registrant considers to be commercially sensitive and is likely to cause the registrant substantial commercial detriment, or

c. the registrant disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant must submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4. No fee is payable under this Article for the submission of information to the Agency under Article 127B(4)(b) or (4A)."

5. Where paragraph 4A does not apply, The technical dossier that is submitted in accordance with point (a) in Article 10 does not need to include the proposals for testing mentioned in paragraph (ix) if, before IP completion day, ECHA has made a decision under Article 40(3) of EU REACH in relation to the testing proposals included in the technical dossier that was included in the existing EU registration.

For further provision about certain cases where there is an existing EU decision on a testing proposal, see Article 127I.

6. The registrant must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.
7. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—
 - “1. The Agency must assign a submission date to each transferred GB registration, which must be the date on which the registrant complies with paragraph 4(a) or (b), or where relevant paragraph 4A, of Article 127B.
 2. The Agency may undertake a completeness check of each registration in order to ascertain that all ~~the applicable~~ elements required under Articles 10 and 12 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3. Once the registrant has complied with paragraph 4(a) of Article 127B, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”.
8. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—
 - “1. A registrant of a transferred GB registration may continue the manufacture or import of a substance or production or import of an article from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”

8A Article 26 has effect with the following provision substituted for the final sentence of paragraph 3—

“The available studies shall be shared with the potential registrant in accordance with Article 127OA (obligation to share data and costs).”

8B Article 27 does not apply to any registrant who submits information to the Agency under paragraph 4(b) or 4A.

9. The Agency is not required by Article 41(5) to carry out compliance checking of dossiers relating to transferred GB registrations in the tonnage bands of over 100 to 1,000 tonnes or over 1,000 tonnes.
10. The reference in Article 43(1) to the preparation of a draft decision within 180 days of receiving a registration has effect as a reference to the preparation of a draft decision within 180 days of receipt of the information required by Article 10(a)(ix) under paragraph 4.

Article 127C

Decisions of ECHA relating to existing EU registrations

1. This Article applies in relation to an existing EU registration which has effect as a transferred GB registration under Article 127A.
2. Any existing ECHA decision which relates to the registration has effect on and after IP completion day as a decision of the Agency which relates to the transferred GB registration.
3. The registrant must—
 - (a) notify the Agency, within the 120 day post-IP completion period, of any existing ECHA decision which relates to the registration, and
 - (b) if required to do so by the Agency, supply the Agency, within the period specified by the Agency, with copies of any existing ECHA decision which relates to the registration.
4. The Agency may extend any period of time specified in an existing ECHA decision.
5. The other Titles of this Regulation apply to the decision as they would apply to it if it had been made by the Agency on IP completion day.
6. In this Article “existing ECHA decision” means a decision which has been made by ECHA under any provision of EU REACH and which is valid immediately before IP completion day.

~~*Article 127D*~~

~~**Interpretation of Articles 127A to 127C**~~

~~**1 — In Articles 127A to 127C —**~~

~~“Article 10 information” means the information which a registration is required to include by virtue of Article 10;~~

~~“existing EU registration” means a registration of a substance with ECHA which is subsisting immediately before IP completion day;~~

~~“transferred GB registration” has the meaning given in Article 127A(1); “GB registration” means a registration of a substance with the Agency.~~

Article 127E

Pre-IP completion downstream users and distributors that are to continue to be regarded as downstream users

1. This Article applies in a case where—
 - (a) a person is—
 - (i) an existing GB downstream user under EU REACH, or
 - (ii) an existing GB distributor under EU REACH,
 in relation to a substance (the “GB user or distributor”), and
 - (b) there is a protected transitional import of the substance by the GB user or distributor.
2. There is a protected transitional import of the substance by the GB user or distributor if—
 - (a) the substance is imported to Great Britain on its own, in a mixture or in an article,
 - (b) the GB user or distributor is the importer in relation to the import,
 - (c) the import occurs during the relevant post-IP completion period, and
 - (d) either—
 - (i) the person who supplies the substance, mixture or article to the GB user or distributor for the import is a registrant or a downstream user under EU REACH as respects the substance as it is imported (the “relevant supplier”), or
 - (ii) an only representative appointed under Article 8(1) of EU REACH by the manufacturer, formulator or producer of the substance, mixture or article is a registrant under EU REACH as respects the substance as it is imported.
3. The GB user or distributor is to be treated for the purposes of this Regulation—
 - (a) as a downstream user as respects any protected transitional imports of the substance by them (if they are an existing GB downstream user under EU REACH), or
 - (b) as a distributor as respects any protected transitional imports of the substance by them (if they are an existing GB distributor under EU REACH).
4. For the purposes of deciding whether the requirement in paragraph 2(d)(i) is met in relation to a particular import, it does not matter whether the relevant supplier is—
 - (a) the person from which the GB user or distributor obtained supplies of the substance, mixture or article before IP completion day (and therefore the person in relation to which the GB user was a downstream user or distributor under EU REACH), or
 - (b) a different person.
5. For the purposes of deciding whether the requirement in paragraph 2(d)(ii) is met in relation to a particular import, it does not matter whether the manufacturer, formulator or producer who has appointed the only representative is—

- (a) the person who was the manufacturer, formulator or producer of supplies of the substance, mixture or article which the GB user or distributor obtained before IP completion day, or
 - (b) a different person.
- 6. The provisions of this Regulation that apply to importers, including in respect of protected NI imports, do not apply to the GB user or distributor in relation to the protected transitional import of the substance by the GB user or distributor.
- 7. If the GB user or distributor imports the substance into Great Britain in quantities of 1 to 10 tonnes per year, they must within the 300 day post-IP completion period—
 - (a) supply the Agency with the information referred to in point (a)(i) of Article 10;
 - (b) supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB user or distributor;
 - (c) supply the Agency with the information referred to in points (a) to (d) of Article 32(1) and otherwise comply with Article 32;
 - (d) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB user or distributor;
 - (e) supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (c) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB user or distributor imports into Great Britain by protected transitional imports);
 - (f) if any part of the import is a protected NI import, notify the Agency of the quantity of the import that is a protected NI import.
- 8. If the GB user or distributor imports the substance into Great Britain in quantities of 10 tonnes or more per year, they must within the 300 day post-IP completion period—
 - (a) supply the Agency with the information referred to in point (a)(i) of Article 10;
 - (b) supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB user or distributor;
 - (c) supply the Agency with the information referred to in—
 - (i) Article 14(6) to the extent that information is available to the GB user or distributor,
 - (ii) Article 31, and
 - (iii) Article 32(1)(a) to (d);
 - (d) otherwise comply with Articles 14(6), 31 and 32;
 - (e) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB user or distributor;
 - (f) supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph

- (c) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB user or distributor imports into Great Britain by protected transitional imports);
 - (g) if any part of the import is a protected NI import, notify the Agency of the quantity of the import that is a protected NI import.
- 9. The GB user or distributor must provide the Agency with updated information of the kind required by paragraph 7 or 8, in particular where the GB user or distributor begins to import the substance—
 - (a) from a different relevant supplier, or
 - (b) from a different manufacturer, formulator or producer who (as described in paragraph 2(d)(ii)) has appointed an only representative that is a registrant under EU REACH.
- 10. This Article ceases to apply to the GB user or distributor as respects a protected transitional import of the substance by them if they become a registrant or downstream user under this Regulation, or a notification is made under Article 139A, in relation to the substance as so imported by them.

 For that purpose, a person is not to be treated as having become a downstream user because they are treated as one in accordance with paragraph 3(a).
- 11. Paragraphs 7, 8 and 9 are subject to paragraph 3 of Article 127EA and paragraph 6 of Article 127EB.
- 12. In this Article—
 - “existing GB distributor under EU REACH” means a person who was, at any time in the 2 year period before IP completion day, a distributor under EU REACH established in Great Britain in relation to a substance on its own, in a mixture or in an article;
 - “existing GB downstream user under EU REACH” means a person who was, at any time in the 2 year period before IP completion day, a downstream user under EU REACH established in Great Britain in relation to a substance on its own, in a mixture or in an article;
 - “relevant supplier” has the meaning given in paragraph 2(d)(i);
 - “GB user or distributor” has the meaning given in paragraph 1(a).

Article 127EA

Appointment of only representative where Article 127E applies

1. This Article applies in relation to a protected transitional import of a substance by a GB user or distributor (within the meaning of Article 127E) that is not a protected NI import.

2. If, or to the extent that, the appointment of an only representative by the manufacturer, formulator or producer relates to the substance as imported, Article 8 has effect as if the following provision were substituted for paragraphs 1 to 3 of that Article—
 - “1. A person established outside Great Britain who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into Great Britain may by mutual agreement appoint a person established in Great Britain to fulfil, as his only representative, the obligations on the GB user or distributor under Article 127E.
 - 1A. Article 36 applies to the representative.
 2. The representative must have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, must keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
 3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Great British manufacturer shall inform the GB user or distributor of the appointment.”.
3. If the GB user or distributor is informed of the appointment of the only representative in accordance with paragraph 3 of Article 8 (as set out above), paragraphs 7, 8 and 9 of Article 127E cease to apply to the GB user or distributor as respects any protected transitional import where the manufacturer, formulator or producer is the person who appointed the representative.

Article 127EB

Import from Northern Ireland where Article 127E applies

1. This Article applies in relation to a protected transitional import of a substance by a GB user or distributor (within the meaning of Article 127E) that is also a protected NI import.
2. A person established in Northern Ireland who manufactures a substance on its own, in mixtures or in articles, formulates a mixture, or produces an article that is imported into Great Britain may fulfil the obligations on the GB user or distributor under Article 127E (the “NI notifier”).
3. Article 36 applies to the NI notifier.
4. The NI notifier must, without prejudice to Article 36, keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
5. A person who intends to act in accordance with paragraph 2 must inform the GB user or distributor that they intend to do so.

6. If the GB user or distributor is informed of the intention in accordance with paragraph 5, paragraphs 7 to 9 of Article 127E apply to the NI notifier instead of the GB user or distributor as respects any protected transitional import from the NI notifier.

Article 127F

Existing EU authorisations

1. The holder of an existing EU authorisation which has the relevant connection with Great Britain must, before the end of the 60 day post-IP completion period, supply the Agency with the required technical information relating to the authorisation.
2. An existing EU authorisation which does not have the relevant connection with Great Britain ceases to have effect (as assimilated law) on IP completion day.
3. An existing EU authorisation has the relevant connection with Great Britain if the holder of the authorisation is established in Great Britain.
4. In this Article—

“existing EU authorisation” means an authorisation granted in accordance with Articles 60 to 64 of EU REACH which is subsisting immediately before IP completion day;

“holder”, in relation to an existing EU authorisation, means the person to whom the authorisation has been granted;

“required technical information”, in relation to an existing EU authorisation, means—

- (a) the information included in the application for the authorisation in accordance with Article 62(4) and (5) of EU REACH,
- (b) any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion in relation to the application for the authorisation, and
- (c) any information required to be submitted or recorded before IP completion day under any condition under which the authorisation is granted.

Article 127G

Existing applications for EU authorisations

1. The Secretary of State must decide an existing application for an EU authorisation (as mentioned in Article 64(8)) if—
 - (a) the application—
 - (i) is at the final decision stage on IP completion day,
 - (ii) has the relevant connection with Great Britain; and
 - (b) the person who made the application—
 - (i) notifies the Secretary of State of the existence of the application,

- (ii) provides the Secretary of State with copies of the application, the information included in it under Article 62(4) and (5) of EU REACH, and any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA's opinion in relation to the application for the authorisation, and
 - (iii) provides the Secretary of State with copies of the final opinions of ECHA referred to in Article 64(5) of EU REACH.
- 2. An application for an EU authorisation is at the final decision stage if—
 - (a) ECHA has adopted the final opinions referred to in Article 64(5) of EU REACH, but
 - (b) the Commission has not made a final decision granting or refusing the application.
- 3. An application for an EU authorisation has the relevant connection with Great Britain if the person making the application is established in Great Britain.
- 4. The period of six months for the Secretary of State to make an authorisation decision in accordance with Article 64(8) of this Regulation begins with the day on which paragraph 1(b) is complied with.
- 5. Where, immediately before IP completion day, a person may place a substance on the market for a use or use it himself in reliance on Article 56(1)(d) of EU REACH, the person may continue to do so on and after IP completion day in reliance on Article 56(1)(d) of this Regulation.

 But this paragraph ceases to apply at the end of the 180 day post-IP completion period if the person does not comply with paragraph 1(b) of this Article before the end of that period.
- 6. In this Article “existing application for an EU authorisation” means an application made before IP completion day for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH.

Article 127GA

Substances of very high concern: sunset dates and latest application dates

- 1. Paragraphs 2 and 3 apply where—
 - (a) immediately before IP completion day, a substance is included in Annex 14 to EU REACH;
 - (b) the EU latest application date fell before or during the relevant pre-IP completion period;
 - (c) the EU sunset date fell during the relevant pre-IP completion period;
 - (d) before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
 - (e) immediately before IP completion day, the authorisation application was still under consideration (see paragraph 11).

2. Where, immediately before IP completion day, a person established in Great Britain may place the substance on the market or use it himself in reliance on Article 56(1)(d) of EU REACH by virtue of the authorisation application having been made, this Regulation has effect subject to the modifications set out in paragraph 3.
3. As respects that person placing the substance on the market or using it himself on and after IP completion day—
 - (a) the GB latest application date, and
 - (b) the GB sunset date,
 both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).
4. Paragraphs 5 and 6 apply where—
 - (a) immediately before IP completion day, a substance is included in Annex 14 to EU REACH;
 - (b) the EU latest application date fell during the relevant pre-IP completion period;
 - (c) the EU sunset date falls after the end of that period;
 - (d) before the EU latest application date, an application had been made for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH in relation to the substance (the “authorisation application”); and
 - (e) immediately before IP completion day, the authorisation application was still under consideration (see paragraph 11).
5. Where, on and after the GB sunset date, a person established in Great Britain would be able to place the substance on the market or use it himself in reliance on Article 56(1)(d) of this Regulation had the authorisation application been made under this Regulation, this Regulation has effect subject to the modifications set out in paragraph 6.
6. As respects that person placing the substance on the market or using it himself on and after IP completion day—
 - (a) the GB latest application date, and
 - (b) the GB sunset date,
 both fall on the transitional cut-off date (rather than on the dates specified in Annex 14 for that substance).

 The effect of this paragraph is to be ignored in reading the reference to the GB sunset date in paragraph 5.
7. Paragraph 8 applies where—
 - (a) immediately before IP completion day, a substance is included in Annex 14 to EU REACH; and
 - (b) the GB latest application date falls during the 18 month post-IP completion period.
8. As respects a person established in Great Britain placing the substance on the market or using it himself on and after IP completion day, the GB latest application date falls on the transitional cut-off date (rather than on the date specified in Annex 14 for that substance).

9. Where paragraph 3, 6 or 8 modifies this Regulation, Article 56(1) has effect with the following provision substituted for point (d)—
 - “(d) the GB sunset date (within the meaning of Article 127GA) has been reached and he made an application before the GB latest application date (within the meaning of Article 127GA) but a decision on the application for authorisation has not yet been taken; or”.
10. Where paragraph 3 or 6 modifies the date that is the GB sunset date, any reference in this Regulation to the date of the kind referred to in Article 58(1)(c)(i) has effect subject to the modification made by paragraph 3 or 6.
11. For the purposes of paragraph 1(e) or 4(e), the authorisation application is “still under consideration” unless—
 - (a) the Commission has made a final decision granting or refusing the authorisation application, or
 - (b) the authorisation application—
 - (i) has the relevant connection with Great Britain (within the meaning of Article 127G), and
 - (ii) is at the final decision stage (within the meaning of Article 127G).
12. In this Article—

“EU latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“EU sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of EU REACH that is specified in Annex 14 to EU REACH in relation to the substance;

“relevant pre-IP completion period” means the period that—

 - (a) begins with 29 March 2017, and
 - (b) ends immediately before IP completion day;

“transitional cut-off date” means the last day of the 18 month post-IP completion period;

“GB latest application date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(ii) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“GB sunset date”, in relation to a substance, means the date of the kind referred to in Article 58(1)(c)(i) of this Regulation that is specified in Annex 14 to this Regulation in relation to the substance;

“18 month post-IP completion period” means the period of 18 months beginning with the day after that on which IP completion day falls.

Article 127H

Existing authorised downstream users under EU law

1. On and after IP completion day, a person who—
 - (a) is established in Great Britain, and
 - (b) is an existing authorised downstream user under EU law in relation to a substance,
 is authorised to use that substance in accordance with Article 56(2).
2. Where Article 56(2) applies to the use of a substance by virtue of paragraph 1, a reference in Article 56(2) to an authorisation granted to a person up a supply chain is a reference to an existing EU authorisation relating to that use of the substance.
3. Accordingly, paragraph 1 ceases to apply to a person if the existing EU authorisation relating to that use of the substance ceases to have effect.
4. A person to whom paragraph 1 applies must, before the end of the 60 day post-IP completion period—
 - (a) confirm to the Agency that they are an existing authorised downstream user under EU law in relation to the substance, and
 - (b) notify the Agency of—
 - (i) the existing EU authorisation;
 - (ii) any conditions set out in the existing EU authorisation (as referred to in Article 56(2) of EU REACH);
 - (iii) the identity of the supplier of the substance to the person.
5. Article 66(1) does not apply to the use of a substance in accordance with Article 56(2) by virtue of this Article.
6. In this Article—

“existing authorised downstream user under EU law” means a person who, immediately before IP completion day, is authorised to use a substance in accordance with Article 56(2) of EU REACH;

“existing EU authorisation” means an authorisation granted to a person up a supply chain (as referred to in Article 56(2) of EU REACH) which is subsisting immediately before IP completion day, as it has effect in EU law;

Article 127I

Existing examinations of testing proposals

1. On and after IP completion day, an existing EU decision on a testing proposal which has the relevant connection with Great Britain has effect as a decision by the Agency under Article 40(3) of this Regulation.
2. An existing EU decision on a testing proposal has the relevant connection with Great Britain if the registrant, or downstream user, concerned is established in Great Britain.
3. The Agency may extend any deadline specified in an existing EU decision on a testing proposal.

4. In this Article, “existing EU decision on a testing proposal” means a decision taken by ECHA—
 - (a) in accordance with Article 40(3)(a), (b), (c) or (e) of EU REACH, if the requirements of the decision have not been fulfilled, or
 - (b) in accordance with Article 40(3)(d) of EU REACH.

Article 127J

Existing Article 7(2) notifications

1. This Article applies if—
 - (a) before IP completion day, a producer of articles established in Great Britain, or an importer of articles established in Great Britain, has given ECHA a notification under Article 7(2) of EU REACH in relation to a substance, and
 - (b) immediately before IP completion day, that person is not a registrant in relation to the substance concerned.
2. The person that gave the notification to ECHA must submit to the Agency, within the 60 day post-IP completion period, the information notified to ECHA in accordance with Article 7(2) and (4) of EU REACH.

Article 127K

Existing Article 9 exemptions

1. This Article applies if—
 - (a) a five year exemption under Article 9(1) of EU REACH, or
 - (b) an extended exemption under Article 9(7) of EU REACH,
 applies in relation to a substance immediately before IP completion day where the research and development concerned takes place in Great Britain.
2. On and after IP completion day—
 - (a) a five year exemption under Article 9(1) of this Regulation, or,
 - (b) an extended exemption under Article 9(7) of this Regulation, (as the case may be) applies in relation to the substance, subject to the same conditions (if any) imposed by ECHA under Article 9(4) in relation to the corresponding exemption under EU REACH.
3. That exemption under Article 9(1) or (7) of this Regulation is to end on the same date that the corresponding exemption under EU REACH would have ended.
4. Where an exemption under Article 9(1) or (7) of this Regulation applies to a substance by virtue of this Article, the following duties must be complied with in relation to the exemption of the substance within the 120 day post-IP completion period—
 - (a) Article 9(2) must be complied with by the manufacturer or importer or producer, as the case may be (the “notifier”);
 - (b) the notifier must also notify the Agency of the number and notification date assigned by ECHA under Article 9(3) of EU REACH;

- (c) the notifier must give the Agency copies of any additional necessary information given to ECHA under Article 9(4) of EU REACH.

Where the notifier complies with Article 9(2) in accordance with this paragraph, no fee is payable under Article 9(2).

Article 127L

Existing Article 17 registrations

1. This Article applies if a registration with ECHA under Article 17 of EU REACH which relates to an on-site isolated intermediate that is manufactured in Great Britain is—
 - (a) subsisting immediately before IP completion day, and
 - (b) either—
 - (i) has a current connection with Great Britain, or
 - (ii) has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).
2. On and after IP completion day, the registration has effect as a registration with the Agency under Article 17 of this Regulation.
3. Where paragraph 2 operates on a registration the manufacturer concerned must give the Agency—
 - a within the 120 day post-IP completion period, the information referred to in Article 17(2)(a), (b), (e) and (f) and the confirmation referred to in Article 17(3), ~~within the 120 day post-IP completion period,~~ and
 - b within the relevant post-IP completion period, the information referred to in Article 17(2)(c) and a statement— ~~and (d) within the relevant post-IP completion period~~
 - i. confirming that, for each hazard class or differentiation of the intermediate which is not on the GB mandatory classification and labelling list, the manufacturer's classification is consistent with the harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
 - ii. where the manufacturer's classification is not consistent under point (i), providing reasons for any inconsistencies or, where it is not possible to give a classification, providing reasons why no classification is given, in accordance with subsection 4.1 of Annex 6 (information requirements referred to in Article 10).
4. ~~Article 19(1) does not apply to the giving of information in accordance with paragraph 3 of this Article. Article 19 applies to the submission of information under paragraph 3(b), with the following provision substituted for paragraphs 1 to 3—~~

“1. Where an on-site isolated intermediate is manufactured in Great Britain by one or more registrants under a registration which has effect under Article 127L(2), the following provisions apply to the submission of information under Article 127L(3)(b).

Subject to paragraph 2, the information referred to in Article 17(2)(c) and the statement referred to in Article 127L(3)(b) must be submitted by one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as ‘the lead registrant’).

2. A registrant may submit the information referred to in Article 17(2)(c) and the statement referred to in Article 127L(3)(b) separately if—

- a. it would be disproportionately costly for the registrant to submit this jointly,
- b. submitting the information jointly would lead to disclosure of information which the registrant considers to be commercially sensitive and is likely to cause the registrant substantial commercial detriment, or
- c. the registrant disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant must submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3. No fee is payable under this Article for the submission of information under Article 127L(3)(b).”

5. The manufacturer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.
6. Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 17 on IP completion day, but with the modifications set out in the following provisions of this Article.
7. No fee is payable under Article 17(2).
8. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—
 - “1. The Agency must assign a submission date to each registration which has effect under Article 127L, which must be the date on which the registrant complies with paragraph 3(a) or (b) of Article 127L.
 2. The Agency may undertake a completeness check of each registration in order to ascertain that ~~all~~ the applicable elements required under Article 17

have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3. Once the registrant has complied with paragraph 3(a) of Article 127L, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”.

9. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

“A registrant may continue the manufacture of a substance from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”

- 10 Article 26 has effect with the following provision substituted for the final sentence of paragraph 3—

“The available studies shall be shared with the potential registrant in accordance with Article 127OA (obligation to share data and costs).”

- 11 Article 27 does not apply to any manufacturer who submits information to the Agency under paragraph 3(b).

Article 127M

Existing Article 18 registrations

1. This Article applies if a registration with ECHA under Article 18 of EU REACH which relates to a transported isolated intermediate that is manufactured in or imported into Great Britain is—
 - (a) subsisting immediately before IP completion day, and
 - (b) either—
 - (i) has a current connection with Great Britain, or
 - (ii) has a relevant past connection with Great Britain (but does not have a current connection with Great Britain).
2. On and after IP completion day, the registration has effect as a registration with the Agency under Article 18 of this Regulation.
3. Where paragraph 2 operates on a registration, the manufacturer or importer concerned must give the Agency—

- (a) the information referred to in Article 18(2)(a), (b), (e) and (f) and the confirmation referred to in Article 18(4), within the 120 day post-IP completion period, and
- (b) the information referred to in Article 18(2)(c) ~~and (d)~~ and 18(3) within the relevant post-IP completion period, ~~unless paragraph 3A applies.~~

3A Where the condition in paragraph 3B is satisfied, the manufacturer or importer must submit the information specified in paragraph 3C to the Agency within the relevant post-IP completion period, subject to Article 127Q (transitional evaluation).

3B The condition is that the transported isolated intermediate being manufactured or imported is registered under EU REACH—

- a. as a transported isolated intermediate in quantities of 1000 tonnes or more per year, or
- b. as a substance, other than an intermediate, in any tonnage band.

3C The information required to be submitted under paragraph 3A is the information referred to in Article 18(2)(c) and a statement—

- a. confirming that, for each hazard class or differentiation of the intermediate which is not on the GB mandatory classification and labelling list, the manufacturer or importer's classification is consistent with the harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
- b. where the manufacturer or importer's classification is not consistent under point (i), providing reasons for any inconsistencies or, where it is not possible for the manufacturer or importer to give a classification, providing reasons why no classification is given, in accordance with subsection 4.1 of Annex 6 (information requirements referred to in Article 10).

4. Article 19~~(1)~~ does not apply applies to the submission giving of information under in accordance with paragraphs 3(b) or 3A of this Article, with the following provision substituted for paragraphs 1 to 3—

“1. Where a transported isolated intermediate is manufactured in, or imported into Great Britain by one or more registrants under a registration which has effect under Article 127M(2), the following provisions apply.

Subject to paragraph 2, the information specified in Article 18(2)(c) and (3) and the statement referred to in Article 127M(3C) must be submitted by one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as ‘the lead registrant’).

2. A registrant may submit the information specified in Article 18(2)(c) or (3), or the statement referred to in Article 127M(3C) separately if—
- a. it would be disproportionately costly for the registrant to submit this jointly,
 - b. submitting the information jointly would lead to disclosure of information which the registrant considers to be commercially sensitive and is likely to cause the registrant substantial commercial detriment, or
 - c. the registrant disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant must submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3. No fee is payable under this Article for the submission of information under Article 127M(3)(b) or (3A)."

- 5. The manufacturer or importer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-IP completion period.
- 6. Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 18 on IP completion day, but with the modifications set out in the following provisions of this Article.
- 7. No fee is payable under Article 18(2).
- 8. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—

"1 The Agency must assign a submission date to each registration which has effect under Article 127M, which must be the date on which the registrant complies with paragraph 3(a) or (b), or where relevant paragraph 3A, of Article 127M.

2 The Agency may undertake a completeness check of each registration in order to ascertain that all ~~the~~applicable elements required under Article 18 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant.

The Agency must perform a further completeness check, considering the further information submitted.

3 Once the registrant has complied with paragraph 3(a) of Article 127M, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”.

9. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

“A registrant may continue the manufacture or import of a substance from IP completion day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”

- 10 Article 26 has effect with the following provision substituted for the final sentence of paragraph 3—

“The available studies shall be shared with the potential registrant in accordance with Article 127OA (obligation to share data and costs).”

- 11 Article 27 does not apply to any manufacturer or importer who submits information to the Agency under paragraph 3(b) or 3A.

Article 127N

Registrations under Article 127L and Article 127M

1. Articles 127L and 127M are to be read in accordance with paragraphs 2 to 5.
2. A registration under Article 17 or 18 of EU REACH (as the case may be) has a current connection with Great Britain if—
 - (a) the registrant immediately before IP completion day is a person established in Great Britain (a “current GB registrant”), and
 - (b) a registration of the substance concerned by the current GB registrant is a registration of a kind that could be submitted on IP completion day under Article 17 or 18 (as the case may be) of this Regulation.
3. A registration under Article 17 or 18 of EU REACH (as the case may be) has a relevant past connection with Great Britain if—
 - (a) the registrant at any time in the period beginning with 29 March 2017 and ending immediately before IP completion day was a person established in Great Britain (a “former GB registrant”), and
 - (b) a registration of the substance concerned by the former GB registrant is a registration of a kind that could be submitted on IP completion day—

- (i) under Article 17 of this Regulation if the former GB registrant was the manufacturer of the on-site intermediate concerned on IP completion day, or
 - (ii) under Article 18 of this Regulation if the former GB registrant was the manufacturer or importer of the transported isolated intermediate concerned on IP completion day.
- 4. Where a registration that has a current connection with Great Britain has effect as a registration with the Agency by virtue of Article 127L or 127M, the current GB registrant becomes the registrant in relation to the registration with the Agency on IP completion day.
- 5. Where a registration that has a relevant past connection with Great Britain has effect as a registration with the Agency by virtue of Article 127L or 127M, the former GB registrant becomes the registrant in relation to the registration with the Agency on IP completion day.

If two or more persons have been former GB registrants at different times in the period beginning with 29 March 2017 and ending immediately before IP completion day, only the person who was the former GB registrant most recently before IP completion day is to become the registrant in relation to the registration with the Agency by virtue of this paragraph.

Article 127NA

New registrations for substances subject to existing EU registrations or protected transitional imports

1. This Article applies in a case where either of the following persons submits a registration to the Agency under Articles 6 or 7(1) or (5)—
 - a. a person established in Great Britain who commences or recommences the manufacture or import of a substance (on its own, in a mixture or in an article) after IP completion day, where that substance has an existing EU registration within the meaning of Article 127ZA, or
 - b. a GB user or distributor within the meaning of Article 127E(1)(a) who imports a substance in accordance with Article 127E.
2. Title 2 applies to the registration of a substance by a person mentioned in paragraph 1 (“P”), with the modifications set out in the following provisions of this Article.
3. Subject to Article 127Q (transitional evaluation), P must submit to the Agency—
 - a. the information referred to in Article 10(a)(i), (ii) and (iii), and any relevant indication under Article 10(a)(viii) at the time of registration, and
 - b. the following information within the relevant post-IP completion period or, if later, at the time P submits the information in point (a) to the Agency—

- i. where condition 1 or 2 in paragraph 4 is satisfied, the information specified in paragraph 5, or
- ii. where condition 1 or 2 is not satisfied, the other Article 10 information.

4. The conditions are—

- a. that the substance being manufactured or imported by P is registered under EU REACH, other than as an intermediate, at the same or a higher tonnage band (condition 1), or
- b. that—
 - i. the tonnage band of the substance being manufactured or imported by P is 1 tonne or more, but less than 10 tonnes, per year, and
 - ii. that substance is registered under EU REACH as a transported isolated intermediate in quantities of 1000 tonnes or more per year (condition 2).

5. The information required to be submitted under paragraph 3(b)(i) is—

- a. the information referred to in Article 10(a)(iv), any relevant indication under Article 10(a)(viii) relating to the information in Article 10(a)(iv) and a statement—
 - i. confirming that, for each hazard class or differentiation of the substance which is not on the GB mandatory classification and labelling list, P's classification is consistent with the harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
 - ii. where P's classification is not consistent under point (i), providing reasons for any inconsistencies, or, where it is not possible for P to give a classification, providing reasons why no classification is given, in accordance with subsection 4.1 of Annex 6 (information requirements referred to in Article 10);
- b. the information referred to in Article 10(a)(v) and, where relevant, (x);
- c. where Article 14(1) applies, and a chemical safety report is required under Article 10(b), the information referred to in paragraph 6.

6. The information required under paragraph 5(c) is—

- a. the information referred to in the following provisions of Annex 1 (general provisions for assessing substances and preparing chemical safety reports)—

- i. subsection 1.3 (human health hazard assessment: classification);
 - ii. subsection 1.4 (human health hazard assessment: identification of DNELs), excluding the justification required under point 1.4.1 specifying the choice of information used, the route of exposure and the duration and frequency of exposure to the substance for which the DNEL is valid;
 - iii. subsection 2.5 (physicochemical hazard assessment: classification);
 - iv. subsection 3.2 (environmental hazard assessment: classification);
 - v. subsection 3.3 (environmental hazard assessment: identification of PNECs);
 - vi. the first sentence of subsection 4.1 (PBT and vPvB assessment: classification);
- b. a statement confirming that—
 - i. the results of P's PBT and vPvB assessment are consistent with the results of a PBT and vPvB assessment submitted by the lead registrant under EU REACH, as published by ECHA or, where P's results are not consistent, providing reasons for any inconsistencies, and
 - ii. for each DNEL, DMEL or PNEC derived by P, P's results are consistent with the results of a DNEL, DMEL or PNEC derivation submitted by the lead registrant under EU REACH, as published by ECHA, or—
 - aa. where P's results are not consistent, providing reasons for any inconsistencies, or
 - bb. where it is not possible for P to derive a DNEL, DMEL or PNEC, providing reasons why no DNEL, DMEL or PNEC derivation is given, in accordance with points 1.4.2 and 3.3.2 of Annex 1;
- c. where Article 14(4) applies, the information referred to in sections 5 and 6 of Annex 1 (exposure assessment and risk characterisation) and the following provisions of Annex 7 (standard information requirements for substances manufactured or imported in quantities of one tonne or more)—
 - i. in column 1 of the table in section 7 (information on the physicochemical properties of the substance)—
 - aa. subsection 7.1 (state of the substance at 20°C and 101.3 kPa);
 - bb. subsection 7.2 (melting/freezing point);
 - cc. subsection 7.3 (boiling point);
 - dd. subsection 7.5 (vapour pressure);
 - ee. subsection 7.7 (water solubility);
 - ff. subsection 7.8 (partition coefficient n-octanol/water);
 - ii. in column 1 of the table in section 9 (ecotoxicological information), point 9.2.1.1 (ready biodegradability); and
- d. any relevant indication under Article 10(a)(viii) regarding the information submitted under points (a) and (c) of this paragraph.

7. Where the information in paragraph 6 is required—
 - a. the chemical safety assessment requirements in Annex 1 listed in the Table in Article 127B(4E) apply for the purpose of providing that information, and
 - b. P is not required to document in the chemical safety report, the steps of the chemical safety assessment conducted under Annex 1.
8. Article 11 applies to the submission of information by P under Article 10, as modified in accordance with paragraph 3(b) of this Article, with the following provision substituted for paragraphs 1 to 3—
 - “1. Where a substance is manufactured in or imported into, or intended to be manufactured in or imported into Great Britain by one or more persons mentioned in paragraph Article 127NA(1), the following provisions apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii), (ix), any relevant indication under Article 10(a)(viii) and the statement referred to in Article 127NA(5)(a) must be submitted by one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant must submit separately the information specified in Article 10(a)(i), (ii), (iii), (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b), any relevant indication under Article 10(a)(viii) and the statements referred to in Article 127NA(6)(b) separately, or whether one registrant is to submit this information on behalf of the others.
 2. Each registrant is only required to comply with paragraph 1 for items of information they are required to submit to satisfy their registration requirements under Article 127NA(3)(b)(i) or (ii).
 3. A registrant may submit the information specified in Article 10(a)(iv), (vi), (vii) or (ix) and Article 127NA(5)(a) or (6)(b) separately if —
 - a. it would be disproportionately costly for the registrant to submit this information jointly, or
 - b. submitting the information jointly would lead to disclosure of information which the registrant considers to be commercially sensitive and is likely to cause the registrant substantial commercial detriment, or
 - c. the registrant disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant must submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.”

9 Article 26 has effect with the following provision substituted for the final sentence of paragraph 3—

“The available studies shall be shared with the potential registrant in accordance with Article 127OA (obligation to share data and costs).”

10 Article 27 does not apply to any registrant who submits information to the Agency under paragraph 3.

Article 127NB

New registrations for isolated intermediates subject to existing EU registrations or protected transitional imports

1. This Article applies in a case where any of the following persons submit a registration to the Agency under Articles 17 or 18—
 - a. a person established in Great Britain who commences or recommences—
 - i. the manufacture of an on-site isolated intermediate under Article 17, or
 - ii. the manufacture or import of a transported isolated intermediate under Article 18,

after IP completion day, where that intermediate has an existing EU registration within the meaning of Article 127ZA, or
 - b. a GB user or distributor within the meaning of Article 127E(1)(a) who imports a transported isolated intermediate in accordance with Article 127E.
2. Articles 17 and 18 apply to the registration of an intermediate by a person mentioned in paragraph 1 (“P”), with the modifications set out in paragraphs 3 or 4, as the case may be.
3. In the case of a registration under Article 17, P must submit the following information to the Agency, subject to Article 127Q (transitional evaluation)—
 - a. at the time of registration, the information referred to in Article 17(2)(a), (b), (e) and (f), and the confirmation referred to in Article 17(3);
 - b. within the relevant post-IP completion period or, if later, at the time P submits the information specified in point (a) to the Agency, the information referred to in Article 17(2)(c) and a statement—

- i. confirming that, for each hazard class or differentiation of the intermediate which is not on the GB mandatory classification and labelling list, P's classification is consistent with the harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
 - ii. where P's classification is not consistent under point (i), providing reasons for any inconsistencies, or, where it is not possible to give a classification, providing reasons why no classification is given, in accordance with section 4.1 of Annex 6 (information requirements referred to in Article 10).
- 4. In the case of a registration under Article 18, P must submit the following information to the Agency, subject to Article 127Q (transitional evaluation)—
 - a. at the time of registration, the information referred to in Article 18(2)(a), (b), (e) and (f), and the confirmation referred to in Article 18(4);
 - b. within the relevant post-IP completion period or, if later, at the time P submits the information specified in point (a) to the Agency, the following information—
 - i. where the condition in paragraph 5 is satisfied, the information referred to in Article 18(2)(c) and a statement—
 - aa. confirming that, for each hazard class or differentiation of the intermediate which is not on the GB mandatory classification and labelling list, P's classification is consistent with the harmonised classification in Annex 6 of EU CLP (harmonised classification and labelling for certain hazardous substances) or, where there is no harmonised classification in EU CLP, a classification submitted by the lead registrant under EU REACH, as published by ECHA, or
 - bb. where P's classification is not consistent under point (aa), providing reasons for any inconsistencies or, where it is not possible for P to give a classification, providing reasons why no classification is given in accordance with subsection 4.1 of Annex 6 (information requirements referred to in Article 10);
 - ii. where the condition in paragraph 5 is not satisfied, the information referred to in point (i) and Article 18(3).
- 5. The condition is that the transported isolated intermediate being manufactured or imported is registered under EU REACH—

- a. as a transported isolated intermediate in quantities of 1000 tonnes or more per year, or
- b. as a substance, other than an intermediate, in any tonnage band.

6. Article 19 applies to the submission of information by P under Articles 17 and 18, as modified in accordance with paragraph 2 of this Article, with the following provision substituted for paragraphs 1 to 3—

“1. Where an intermediate is manufactured in or imported into, or intended to be manufactured in or imported into, Great Britain by one or more persons mentioned in paragraph Article 127NB(1), the following provisions apply.

Subject to paragraph 2, the information specified in Articles 17(2)(c), 18(2)(c) and 18(3) and the statements referred to in Articles 127NB(3)(b) and 127NB(4)(b)(i) must be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as ‘the lead registrant’).

Each manufacturer or importer must submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18(2)(a), (b), (e) and (f).

2. A manufacturer or importer may submit the information specified in Articles 17(2)(c), 18(2)(c) or 18(3), or the statements referred to in Articles 127NB(3)(b) or 127NB(4)(b)(i) separately if—

- a. it would be disproportionately costly for the registrant to submit this jointly,
- b. submitting the information jointly would lead to disclosure of information which the registrant considers to be commercially sensitive and is likely to cause the registrant substantial commercial detriment, or
- c. the registrant disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer must submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.”

7 Article 26 has effect with the following provision substituted for the final sentence of paragraph 3—

“The available studies shall be shared with the potential registrant in accordance with Article 127OA (obligation to share data and costs).”

8 Article 27 does not apply to any person who submits information to the Agency under paragraphs 3 or 4.

Article 127O

Obligation to keep information

1. This Article applies to a person established in Great Britain who, immediately before IP completion day, is, as respects any information, bound by the obligation imposed by Article 36(1) of EU REACH.
2. On and after IP completion day, the person is, as respects the information concerned, bound by the obligation imposed by Article 36(1) of this Regulation.
3. Where paragraph 2 applies to a person, the person is not bound by the obligation imposed by Article 36(1) of this Regulation after the end of a 10 year period under Article 36(1) of EU REACH that was running at IP completion day (and the reference to the 10 year period in Article 36(1) of this Regulation is accordingly to be read as a reference to the remainder of the 10 year period under EU REACH that falls after IP completion day).

Article 127OA

Obligation to share information and costs

1. This Article applies to registrants who are required to submit information to the Agency for the purposes of—
 - a. meeting the requirements of Articles 127B(4)(b) or (4A), 127L(3) or 127M(3)(b) or (3A);
 - b. registering substances under Title 2, where Articles 127NA(2) or 127NB(2) apply;
 - c. responding to an Agency decision under Article 127T(1).
2. Before submitting information for a purpose specified in paragraph 1, a registrant must make enquiries with other participants in their substance group to determine if the relevant information is available.
3. Where the information is owned by a participant in the registrant's substance group, the registrant must request the information and the requirements in paragraph 4 apply, unless that participant has opted to submit the information separately to the Agency under Articles 11(3) or 19(2), as modified by Articles 127B(4F), 127L(4), 127M(4), 127NA(8) or 127NB(6);
4. The requirements mentioned in paragraph 3 are that—
 - a. the participant who owns the information (“the owner”) must provide proof of the cost of providing the information to the registrant, and any other participant of the substance group who is required to submit that information to the Agency (“the relevant registrant(s)”, within one month, beginning with the day on which the request for information is made;

- b. the relevant registrant(s) and the owner must make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way, and may facilitate this by following, where appropriate, any cost sharing guidance adopted by the Agency under Article 77(2)(g);
 - c. if the relevant registrant(s) and the owner cannot reach agreement, the costs of providing the information must be shared equally;
 - d. the owner must give permission to the relevant registrant(s) to refer to the information within two weeks, beginning with the day on which payment is received by the owner;
 - e. if the owner refuses to provide proof of the cost of that information, or the information itself to the relevant registrant(s), the relevant registrant(s) must determine whether the information is available from another source outside the substance group.
- 5. Where the information requested is available, but not owned by a participant in the substance group, the requirements in paragraph 6 apply.
- 6. The requirements mentioned in paragraph 5 are that—
 - a. the registrant requesting the information must make every effort to agree access to the information with the owner, on terms acceptable to all other relevant registrants;
 - b. the relevant registrant(s) and the owner must make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way, and may facilitate this by following, where appropriate, any cost sharing guidance adopted by the Agency under Article 77(2)(g);
 - c. if the relevant registrant(s) cannot reach agreement under point (b), the costs of obtaining the information must be shared equally;
 - d. the registrant in receipt of information from the owner must provide that information to any other relevant registrant within two weeks, beginning with the date on which payment from the other relevant registrants is received.
- 7. Where the information is not known to exist, or the owner refuses to provide proof of the cost of the information, or give the relevant registrant(s) access to the information, the relevant registrant(s) must—
 - a. produce that information; and
 - b. comply with the requirements of paragraph 8, if the information required is a study summary under Article 10(a)(vi) or a robust study summary under Article 10(a)(vii).
- 8. The requirements mentioned in paragraph 7(b) are that—
 - a. only one study per item of information may be performed by a registrant acting on behalf of the other relevant registrants;

- b. the relevant registrants must make every effort to reach an agreement within a deadline set by the Agency as to who is to perform the study, and who is to submit the study summary or robust study summary to the Agency, on behalf of the others;
 - c. if no agreement is reached, the Agency must specify who will perform the study and who will submit the study summary and robust study summary to the Agency;
 - d. all relevant registrants who require a study must contribute to the costs for the study, with a share corresponding to the number of participating registrants;
 - e. the registrant who performs the study must provide the information to the other relevant registrants within two weeks, beginning with the date on which payment from the other relevant registrants is received.
9. A registrant is only required to share in the costs of obtaining information under this Article which they are required to submit—
- a. to satisfy their registration requirements under this Title; or
 - b. to respond to an Agency decision under Article 127Q, insofar as the decision relates to the registration requirements for their tonnage band under Title 2.
10. An appeal may be brought against a decision by the Agency under paragraph 8(c) in accordance with Articles 91, 92 and 93.

Article 127P

Post-IP completion periods used in this Title

In this Title—

- 1. “60 day post-IP completion period” means the period of 60 days beginning with the day after that on which IP completion day falls;
- 2. “90 day post-IP completion period” means the period of 90 days beginning with the day after that on which IP completion day falls;
- 3. “120 day post-IP completion period” means the period of 120 days beginning with the day after that on which IP completion day falls;
- 4. “180 day post-IP completion period” means the period of 180 days beginning with the day after that on which IP completion day falls;
- 4A. “300 day post-IP completion period” means the period of 300 days beginning with the day after that on which IP completion day falls;
- 4B. “relevant post-IP completion period” means the period beginning with the day after that on which IP completion day falls and ending with—
 - (a) 27 October 2029 in respect of—
 - (i) substances included on the candidate list by virtue of Article 59(1A) or added to the candidate list referred to in Article 59(1) on or before 27 October 2027,

- (ii) substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in quantities reaching one tonne or more per year per manufacturer or importer, at least once after IP completion day,
 - (iii) substances classified as aquatic chronic category 1 (very toxic to aquatic life with long lasting effects) or aquatic acute category 1 (very toxic to aquatic life) in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day,
 - (iv) substances manufactured in Great Britain or imported, in quantities reaching 1,000 tonnes or more per year per manufacturer or importer, at least once after IP completion day,
- (b) 27 October 2030 in respect of—
- (i) substances added to the candidate list referred to in Article 59(1), other than by virtue of Article 59(1A), during the period beginning with 28 October 2027 and ending with 27 October 2028,
 - (ii) substances manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day,
- (c) 27 October 2031 in respect of substances manufactured in Great Britain or imported, in quantities reaching 1 tonne or more per year per manufacturer or importer, at least once after IP completion day.

Article 127Q

Transitional evaluation: request for further information

1. Where Articles 127B(4A), 127L(3)(b), 127M(3A), 127NA(3) or 127NB(3) apply, but the Agency considers that further information is needed to evaluate the potential hazards and risks of the substance concerned, the Agency may request a registrant or registrants to submit the information specified in paragraph 2.
2. The information that may be requested under paragraph 1 is any item of information referred to in Articles 10, 12, 17 or 18, which has not previously been submitted to the Agency under Articles 127B(4A), 127L(3)(b), 127M(3A), 127NA(3) or 127NB(3), as the case may be (whether or not that information has been submitted to ECHA under EU REACH).
3. If the items of information requested under paragraph 1 are those referred to in Article 10(a)(vi), (vii) or (ix), the Agency may require the registrant(s) to—
 - a. conduct a further chemical safety assessment under Annex 1, to the extent the Agency considers this necessary for the registrant(s) to provide that additional information, and

- b. document the steps of that chemical safety assessment in the chemical safety report.
- 4. When selecting dossiers for further evaluation under paragraph 1, the Agency should give priority, but not exclusively, to dossiers meeting at least one of the following criteria—
 - a. the dossier contains information in Article 10(a)(iv), submitted separately pursuant to Article 11(3);
 - b. the dossier contains information in Articles 17(2)(c) or 18(2)(c), submitted separately pursuant to Article 19(2);
 - c. the dossier is for a substance which, in the Agency’s opinion, meets, or is likely to meet, the criteria for substance evaluation applied under Article 44(1).
- 5. The list of dossiers subject to evaluation by the Agency under this Article must be made available to the appropriate authorities, where requested.

Article 127R

Transitional evaluation: preparation and notification of draft decision

- 1. Where Article 127Q applies, the Agency must prepare a draft decision requiring the registrant or registrants to submit the additional items of information requested and specifying reasonable time limits for the submission of that information.
- 2. A draft decision under paragraph 1 may—
 - a. be limited to individual items of information, and
 - b. extend to more than one technical dossier for a substance.
- 3. The Agency must notify the draft decision to the registrant(s) concerned, informing them of their right to provide comments to the Agency within 30 days, beginning with the date on which the decision is notified.
- 4. If a registrant—
 - a. has ceased the manufacture or import of the substance, or the production or import of the article, at the date the draft decision is notified, the registrant must inform the Agency of that fact within the 30-day period referred to in paragraph 3;
 - b. ceases the manufacture or import of the substance, or the production or import of the article, after the date the draft decision is notified, the registrant must inform the Agency of that fact as soon as reasonably practicable.
- 5. Where the Agency is notified under paragraph 4 that the registrant no longer manufactures or imports the substance, or produces or imports the article, the Agency—

- a. must record the registered volume of the registration as zero, and
 - b. must not request information from the registrant under paragraph 1 relating to that substance or article, unless the registrant notifies the Agency that the registrant has recommenced the manufacture or import of the substance, or the production or import of the article.
6. The Agency must inform the appropriate authorities, if requested, when a registrant has informed the Agency under paragraphs 4(a) or 5(a).

Article 127S

Transitional evaluation: notification of final decision

- 1. If the Agency receives no comments from registrants on the draft decision prepared under Article 127R(1), the Agency must make its final decision in the version notified under Article 127R(3).
- 2. If the Agency receives comments from registrants on the draft decision, the Agency must—
 - a. take the comments into account, and
 - b. make its final decision, either confirming or varying the draft decision notified under Article 127R(1).
- 3. The Agency must notify the registrant and the appropriate authorities of the final decision made under paragraphs 1 or 2(b).

Article 127T

Transitional evaluation: review of information requested

- 1. Following notification of the Agency's decision under Article 127S(3), the registrant must submit the information requested to the Agency by the deadline(s) set.
- 2. The Agency—
 - a. must examine any items of information submitted under paragraph 1;
 - b. may issue further decisions, if necessary, within 12 months of the information being submitted under paragraph 1, in accordance with the procedure in Articles 127R and 127S.
- 3. The Agency must finish its evaluation under paragraph 2(a) within 12 months of the information being submitted under paragraph 1.
- 4. If the deadline in paragraph 3 is exceeded, the evaluation must be deemed to be finished.

5. Article 54 (publication of information on evaluation) applies to any request for information by the Agency under Article 127Q(1) and decisions issued under Article 127S.

Article 127U

Transitional evaluation: appeals

An appeal may be brought against a decision by the Agency under Article 127S(3) in accordance with Articles 91, 92 and 93.

TITLE XV

FINAL PROVISIONS

[Article 128 omitted]

Article 129

Safeguard clause

1. An appropriate authority may impose an appropriate provisional restriction in respect of a substance if that authority—
 - (a) has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of the substance, on its own, in a mixture or in an article, even if satisfying the requirements of this Regulation, and
 - (b) has competence to impose the provisional restriction.
2. If an appropriate authority imposes a provisional restriction in accordance with paragraph 1, it must—
 - (a) immediately inform the Agency and the other appropriate authorities, giving reasons for its decision and submitting the scientific or technical information on which the provisional restriction is based, and
 - (b) within three months of its decision, request the Agency to initiate the procedure under Article 69.
3. When a decision has been reached under Article 73 (as part of the procedure under Article 69) the appropriate authority must revoke the provisional measure.
4. In this Article “restriction” means a restriction on the placing on the market or use of a substance.
5. The Secretary of State has competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction—
 - (a) relates to England;
 - (b) relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);

- (c) relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).
- 6. The Scottish Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).
- 7. The Welsh Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

Article 130

Statement of reasons for decisions

The appropriate authorities and the Agency shall state the reasons for all decisions they take under this Regulation.

Article 131

Amendments to the Annexes

- 1. The Secretary of State may, by regulations, make such amendments of the Annexes as the Secretary of State considers appropriate.
The Secretary of State must consider any request made by any of the other appropriate authorities for amendments of the Annexes to be made.
- 2. Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.
The function of making regulations under this Article is subject to the consent requirement in Article 4A.

Article 132

Implementing legislation

- 1. The Secretary of State may, by regulations, make such provision as the Secretary of State considers appropriate for putting the provisions of this Regulation efficiently into effect.
The Secretary of State must consider any request made by any of the other appropriate authorities for such provision to be made.
- 2. Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.
The function of making regulations under this Article is subject to the consent requirement in Article 4A.

Article 132A

Regulations under this Regulation

Any power to make regulations under this Regulation includes power to make supplementary, incidental, consequential, transitional, transitory or saving provision.

[Articles 133-137 omitted]

Article 138

Review

1. Within 18 months of IP completion day, the Secretary of State shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. When carrying out the review the Secretary of State shall take into account all relevant factors, including:
 - (a) the costs for manufacturers and importers of drawing up the chemical safety reports;
 - (b) the distribution of costs between actors in the supply chain and the downstream user;
 - (c) the benefits for human health and the environment;
 - (d) the views of any appropriate authority.

On the basis of these reviews, the Secretary of State may, if appropriate, formulate proposals to extend this obligation.
2. The Secretary of State may formulate proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:
 - (a) the risks posed by polymers in comparison with other substances;
 - (b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.
3. The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at one tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Secretary of State may formulate proposals to modify the information requirements for substances manufactured or imported in quantities of one tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).
4.
5.

6.
7.
8. Within 18 months of IP completion day, the Secretary of State shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the Secretary of State may, if appropriate, formulate proposals to extend that obligation.
9. In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation, the Secretary of State shall review the testing requirements of Section 8.7 of Annex VIII by within 18 months of IP completion day.

The Secretary of State may, by regulations, amend Annex 8 if the Secretary of State considers that it is appropriate to do so on the basis of this review, while ensuring a high level of protection of health and the environment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.

Article 139

Repeals

Directive 91/155/EEC shall be repealed.

Directives 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 shall be repealed with effect from 1 June 2008 .

Directive 93/67/EEC shall be repealed with effect from 1 August 2008 .

Directive 76/769/EEC shall be repealed with effect from 1 June 2009 .

References to the repealed acts shall be construed as references to this Regulation.

[Articles 140-141 omitted]

TITLE 15A

IMPORTS FROM NORTHERN IRELAND

Article 139A

Protected NI imports

1. This Article applies in a case where there is a protected NI import of a substance.
2. There is a protected NI import of a substance if—

- (a) a substance—
 - (i) has a relevant connection to Northern Ireland, and
 - (ii) is imported on its own, in a mixture or in an article,
 - (b) the substance, mixture or article is a qualifying Northern Ireland good, and
 - (c) the person who supplies the substance, mixture or article for the import is a registrant or a downstream user under EU REACH as respects the substance as it is imported.
- 3. A substance has a relevant connection to Northern Ireland if—
 - (a) it is—
 - (i) manufactured in Northern Ireland,
 - (ii) in a mixture that is manufactured or formulated in Northern Ireland, or
 - (iii) in an article that is manufactured or produced in Northern Ireland, and
 - (b) it is imported from a supplier established in Northern Ireland.
- 4. The importer of the substance (the “GB importer”) is to be treated for the purposes of this Regulation as a downstream user as respects any protected NI imports of the substance by them.
- 5. The provisions of this Regulation that apply to importers do not apply to the GB importer in relation to the protected NI import of the substance by the GB importer.
- 6. If the GB importer imports the substance in quantities of 1 to 10 tonnes per year they must, before they make a protected NI import—
 - (a) notify the Agency of their intention to make the protected NI import,
 - (b) supply the Agency with the information referred to in point (a)(i) of Article 10,
 - (c) supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB importer,
 - (d) supply the Agency with the information referred to in points (a) to (d) of Article 32(1) and otherwise comply with Article 32,
 - (e) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB importer,
 - (f) supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (d) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB importer imports into Great Britain by protected NI imports).
- 7. If the GB importer imports the substance in quantities of 10 tonnes or more per year they must, before they make a protected NI import—
 - (a) notify the Agency of their intention to make the protected NI import,
 - (b) supply the Agency with the information referred to in point (a)(i) of Article 10,
 - (c) supply the Agency with the information referred to in points (a)(ii) and (iv) of Article 10 to the extent that information is available to the GB importer,
 - (d) supply the Agency with the information referred to in—

- (i) Article 14(6) to the extent that information is available to the GB importer,
 - (ii) Article 31, and
 - (iii) Article 32(1)(a) to (d),
 - (e) otherwise comply with Articles 14(6), 31 and 32,
 - (f) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the GB importer,
 - (g) supply the Agency with such other evidence as the Agency may require demonstrating that the information supplied in accordance with subparagraph (d) complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the GB importer imports into Great Britain by protected NI imports).
8. The GB importer must update the information provided to the Agency under paragraph 6 or 7 with any relevant new information and submit it to the Agency.
 9. Paragraphs 6, 7 and 8 are subject to paragraph 6 of Article 139B.

Article 139B

Notification by Northern Irish supplier where Article 139A applies

1. This Article applies in relation to a protected NI import of a substance.
2. A person established in Northern Ireland who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into Great Britain may fulfil the obligations on the GB importer under Article 139A (the “NI notifier”).
3. Article 36 applies to the NI notifier.
4. The NI notifier must, without prejudice to Article 36, keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.
5. A person who intends to act in accordance with paragraph 2 must inform the GB importer that they intend to do so.
6. If the GB importer is informed of the intention in accordance with paragraph 5, then paragraphs 6 to 8 of Article 139A apply to the NI notifier instead of the GB importer as respects any protected NI import from the NI notifier.

Article 139C

Authorisations and imports from Northern Ireland

Subject to Articles 139D and 139E, Title 7 applies to and in respect of substances imported from Northern Ireland as it applies to and in respect of other substances.

Article 139D

Authorisations and qualifying Northern Ireland goods

1. This Article applies to a person (“P”) that is established in Northern Ireland that is a manufacturer, importer or downstream user of a substance under EU REACH.
2. P may apply for an authorisation in respect of that substance under Article 62 if the substance is a qualifying Northern Ireland good (“QNIG”).
3. A substance is a QNIG if it is a QNIG on its own, or contained in a mixture or article that is a QNIG.
4. This Regulation applies to P in respect of the application, and to the authorisation if it is granted, as if P was an only representative of P appointed in accordance with Article 8.

Article 139E

Application of Article 127G to qualifying Northern Ireland goods

1. This Article applies to a person established in Northern Ireland that made an existing application for an EU authorisation within the meaning of Article 127G(6) (the “existing NI applicant”) that satisfies the condition in paragraph 2.
2. The condition is that the substance in respect of which the application was made is a qualifying Northern Ireland good (“QNIG”).
3. The condition in paragraph (2) is satisfied if the application was in respect of a substance that is a QNIG on its own, or a substance contained in a mixture or article that is a QNIG.
4. Paragraphs 1 to 4 and 6 of Article 127G apply to the existing NI applicant as if the references to “Great Britain” were to “the United Kingdom”.
5. If the authorisation is granted—
 - (a) it has no effect in Northern Ireland,
 - (b) this Regulation applies to the existing NI applicant in respect of the authorisation as if the existing NI applicant was an only representative of the existing NI applicant appointed in accordance with Article 8.

This Regulation shall be binding in its entirety and directly applicable in all Member States