ANNEX XII

INTERMEDIATE PRODUCTS

In accordance with Article 34(2) of Regulation (EC) No 1069/2009, the following conditions shall apply to the importation **[**F1from a third country**]** and transit through **[**F2Great Britain**]** of intermediate products:

Textual Amendments

F1 Words in Annex 12 inserted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(a)(i)**

F2 Words in Annex 12 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(a)(ii)**

1. The import **[**F3from a third country**]** and transit of intermediate products shall be authorised, provided that:

   (a) they are derived from the following materials:

      (i) Category 3 material, other than materials referred to in Article 10(c), (n), (o) and (p) of Regulation (EC) No 1069/2009;

      (ii) products generated by the animals referred to in Article 10(i), (l) and (m) of Regulation (EC) No 1069/2009; or

      (iii) mixtures of the materials referred to in points (i) and (ii);

   (b) in the case of intermediate products destined for the production of medical devices, in vitro diagnostic medical devices and laboratory reagents, they are derived from:

      (i) materials which fulfil the criteria referred to in point (a), except that they may have originated from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC **[**F4, reading that Article as if for references to "Community legislation" there were substituted references to "retained EU law**]**;

      (ii) Category 2 material referred to in Article 9(f) and (h) of Regulation (EC) No 1069/2009; or

      (iii) mixtures of the materials referred to in points (i) and (ii);

   (c) in the case of intermediate products destined for the production of active implantable medical devices, medicinal products and veterinary medicinal products, they are derived from the materials referred to in point (b), where the competent authority considers the use of such materials justified for the protection of public or animal health;

   (d) they come from a third country listed as a member of the World Organisation for Animal Health (OIE) in the OIE bulletin;

(e) they come from an establishment or plant registered or approved by the competent authority of a third country referred to in point (d), in accordance with the conditions set out in point 2;

(f) each consignment is accompanied by a declaration of the importer in accordance with the model declaration **[**F5made available or published for the time being by the appropriate authority**]**, which must be at least in **[**F6English; the appropriate authority**]** may allow the use of other languages and request official translations for declarations in such other languages;

(g) in the case of materials referred to in point (b), the importer demonstrates to the competent authority that the materials:

(i) do not carry any risk of transmission of a disease communicable to humans or animals; or

(ii) are transported under conditions which prevent the transmission of any diseases communicable to humans or animals.

2. An establishment or plant may be registered or approved by the competent authority of a third country, as referred to in point 1(e), provided that:

(a) the operator or owner of the plant or his representative:

(i) demonstrates that the plant has adequate facilities for the transformation of the materials referred to in point 1(a), (b) or (c), as applicable, to ensure the completion of the necessary design, transformation and manufacturing stages;

(ii) establishes and implements methods of monitoring and checking the critical control points on the basis of the process used;

(iii) keeps a record of the information obtained pursuant to point (ii) for a period of at least two years for submission to the competent authority;

(iv) informs the competent authority if any available information reveals the existence of a serious animal health or public health risk;

(b) the competent authority of the third country carries out, at regular intervals, inspections of the establishment or plant and supervises the plant in accordance with the following conditions:

(i) the frequency of inspections and supervision shall depend on the size of the plant, the type of products manufactured, risk assessment and guarantees offered, based on a system of checks which has been set up in accordance with the hazard analysis and critical control points (HACCP) principles;

(ii) if the inspection carried out by the competent authority reveals that the provisions of this Regulation are not being complied with, the competent authority shall take appropriate action;

(iii) the competent authority shall draw up a list of establishments or plants approved or registered **[**F7in its constituent nation**]** in

accordance with this Annex and shall assign an official number to each plant, which identifies the establishment or plant with respect to the nature of its activities; that list and subsequent amendments to it shall be submitted to the **[**F8appropriate authority**]**.

3. **[**F9The intermediate products imported into **[**F10Great Britain from a third country**]** shall be checked at the **[**F11border control post**]** in accordance with **[**F12Article 49 of the Official Controls Regulation**]** and transported directly from the **[**F11border control post**]** either to:

(a) a registered establishment or plant for the production of laboratory reagents, medical devices and *in vitro* diagnostic medical devices for veterinary purposes or the derived products referred to in Article 33 of Regulation (EC) No 1069/2009, where the intermediate products must be further mixed, used for coating, assembled or packaged before they are placed on the market or put into services in accordance with the **[**F13retained EU law**]** applicable to the derived product;**]**

(b) an establishment or plant which has been approved for the storage of animal by-products in accordance with Article 24(1)(i) of Regulation (EC) No 1069/2009, from where they must only be dispatched to an establishment or plant referred to in (a) of this point for the uses referred to in (a).

4. Intermediate products in transit through **[**F14Great Britain from a third country outside the European Union**]** shall be transported in accordance with **[**F15Article 51(1)(d) of the Official Controls Regulation**]**.

5. The official veterinarian at the **[**F11border control post**]** concerned shall inform the authority in charge of the establishment or plant at the place of destination of the consignment by means of the **[**F16appropriate computerised information management system**]**.

6. The operator or owner of the establishment or plant of destination or his representative shall keep records in accordance with Article 22 of Regulation (EC) No 1069/2009 and shall provide the competent authority on request with the necessary details of purchases, sales, uses, stocks and disposals of surplus of the intermediate products for the purposes of checking compliance with this Regulation.

7. The competent authority shall ensure, in accordance with **[**F17the Official Controls Regulation**]**, that the consignments of intermediate products are sent from the **[**F18constituent nation**]** where the inspection at the **[**F11border control post**]** must be carried out to the plant of destination, as referred to in point 3 or, in the case of transit, to the **[**F11border control post**]** of exit.

8. The competent authority shall carry out documentary checks at regular intervals for the purpose of reconciliation of the quantities of intermediate products imported on the one hand, and stocked, used, dispatched or disposed of on the other, in order to check compliance with this Regulation.

9. For consignments of intermediate products in transit, the competent authorities responsible for the **[**F11border control post**]**s of entry and of exit respectively shall cooperate as necessary to ensure that effective checks are carried out and to ensure the traceability of such consignments.

Textual Amendments

F3 Words in Annex 12 point 1 inserted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(b)(i)**

F4 Words in Annex 12 point 1(b)(i) substituted (E.W.S.) (31.12.2020) by virtue of The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(b)(ii)**

F5 Words in Annex 12 point 1(f) substituted (31.12.2020) by The Animals (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/588), regs. 1, **10(7)** (with reg. 12); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Words in Annex 12 point 1(f) substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(b)(iii)**

F7 Words in Annex 12 point 2(b)(iii) inserted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(c)(i)**

F8 Words in Annex 12 point 2(b)(iii) substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(c)(ii)**

F9 Substituted by Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance).

F10 Words in Annex 12 point 3 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(d)(i)**

F11 Words in Regulation substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(2)(b)**

F12 Words in Annex 12 point 3 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(d)(ii)**

F13 Words in Regulation substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(2)(a)**

F14 Words in Annex 12 point 4 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(e)(i)**

F15 Words in Annex 12 point 4 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(e)(ii)**

F16 Words in Annex 12 point 5 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(f)**

F17 Words in Annex 12 point 7 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(g)(i)**

F18 Words in Annex 12 point 7 substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), regs. 1(2)(c), **13(64)(g)(ii)**

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 142/2011, ANNEX XII.