ANNEX XII

INTERMEDIATE PRODUCTS

In accordance with Article 34(2) of Regulation (EC) No 1069/2009, the following conditions shall apply to the importation and transit through the Union of intermediate products:

1. The import 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 or Article 2(b) of Directive 96/23/EC;

      (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 set out in Chapter 20 of Annex XV, which must be at least in one of the official languages of the Member State in which the inspection at the border inspection post must be carried out and of the Member State of destination; these Member States 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 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 Member State where the inspection at the border inspection post must be carried out and to the Member State of destination.

3. The intermediate products imported into the Union shall be checked at the border inspection post in accordance with Article 4 of Directive 97/78/EC and transported directly from the border inspection post either to:

(a) a registered establishment or plant for the production of 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,

packaged or labelled before they are placed on the market or put into services in accordance with the Union legislation 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 the Union shall be transported in accordance with Article 11 of Directive 97/78/EC.

5. The official veterinarian at the border inspection 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 TRACES 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 Directive 97/78/EC, that the consignments of intermediate products are sent from the Member State where the inspection at the border inspection post must be carried out to the plant of destination, as referred to in point 3 or, in the case of transit, to the border inspection 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 border inspection posts 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.

Status:
Point in time view as at 25/02/2011.

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