ISIA/MedTech guidance

Concerning the health rules and importation from Third Countries into the EU for ABP/ADP

TRAINING – SESSION 2

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Terms and Definitions

- **Appendix 1** Glossary of Terms and Definitions (EU laws, ISIA and industry standards)
- '**animal by-products**' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen (Regulation 1069/2009/EC, Article 3(1))
- '**derived products**' means products obtained from one or more treatments, transformations or steps of processing of animal by-products (Regulation 1069/2009/EC, Article 3(2))
- '**blood**' means fresh whole blood (Regulation 142/2011/EU Annex I Point 2)
- '**whole blood**' is an animal by-product that contains an anticoagulant and has not been depleted of any of its components (Serum industry standard. ISIA approved)
- '**blood products**' means derived products from blood or fractions of blood, excluding blood meal; they include dried/frozen/liquid plasma, dried whole blood, dried/frozen/liquid red cells or fractions thereof and mixtures (Regulation 142/2011/EU Annex I Point 4)

Changes in ‘ Terms and Definitions ’(1)

- Border Inspection Post (BIP) replaced by: ‘**Border Control Post**’ (BCP) means a place, and the facilities belonging to it, designated by a Member State for the performance of official controls (Regulation 2017/625/EU, Article 3(38))
- Common Veterinary Entry Document (CVED) replaced by ‘**CHED**’ (The Common Health Entry Document) shall be issued as a result of the inspection at the border control post by national competent authorities. Customs authorities shall only allow the release for free circulation of a consignment upon presentation of a duly finalised CHED (https://trade.ec.europa.eu/access-to-markets/en/content/health-and-consumer-protection-animal-and-plant-product)
- '**country of origin**' (often abbreviated to COO) could be defined differently depending on the regulatory framework, e.g., on EU health certificates I.7 they ask for country in which the finished products were produced, manufactured or packaged, in II.5 they ask for the country where the blood was collected. Other jurisdictions have different definitions (e.g., country of slaughter, collection, manufacturing).

Changes in ‘ Terms and Definitions ’(2)

- '**end point**' means that the derived products referred to in Article 33 of Regulation (EC) 1069/2009 which have reached the stage of manufacturing regulated by the Community legislation have reached the end point in the manufacturing chain, beyond which they are no longer subject to the requirements of this Regulations (Regulation 1069/2009/EC, Article 5)
- ‘**laboratory reagent**’ means a packaged product, ready for use, containing animal by-products or derived products and intended as such or in combination with substances of non-animal origin for specific laboratory use as a reagent or reagent product, calibrator or control material to detect, measure, examine or produce other substances (Regulation 142/2011/EU Annex I, Point 36)
- GBR (Geographical BSE Risk) replaced by: ‘**OIE**‘ (World Organisation for Animal Health) (https://www.oie.int/en/who-we-are/) (see following slides)
- Added ‘**transit**’ (Regulation 2017/625/EC, Article 3(44)) and ‘**transshipped consignments**’ (Regulation 2124/2019/EU, Article 2(2)) (see following slides)
- **TRACES** (see session 1)

Finished product

- Finished products are regulated under the scope of other EU legislation and do not fall under the ABP regulatory framework (even if they contain ABP material) = derived products referred to in Article 33 of Regulation (EC) 1069/2009: (Article 5(1) of Regulation (EC) 1069/2009)
  - medicinal products
  - veterinary medicinal products
  - medical devices
  - active implantable medical devices
  - in vitro diagnostic medical devices
  - cosmetic products
- A product which still requires packaging or labelling to make it suitable for placing on the market according to EU legislation is NOT considered to be a finished product under the ABP regulatory framework and should be imported as a derived product or as an intermediate product.

End point

- Products that have reached their end point in the manufacturing chain are listed in Article 33 of Regulation (EC) 1069/2009 or Article 3 of Regulation (EU) 142/2011.
    - Example - Article 3(d): hides and skins of ungulates which fulfil the specific requirements for the end point for those products set out in point C of Chapter V of Annex XIII
- Those derived products may subsequently be placed on the market without restrictions and shall no longer be subject to official controls in accordance with ABP regulations.

→ Manufacturers **cannot directly** rely on Article 5, 36-39 (safe sourcing, treatment, end use) to determine the end point in the manufacturing chain.

Article 51a and Article 52

- Article 3 of Regulation (EU) 142/2011: For derived products referred to in Articles 32, 35 and 36 ((EC) 1069/2009) which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined. The Commission is empowered to adopt delegated acts in accordance with Article 51a by determining an end point in the manufacturing chain:
  Exercise of the delegation
  - Delegated acts are legally binding acts that enable the Commission to supplement or amend non-essential parts of EU legislative acts, for example, in order to define detailed measures.
  - The Commission adopts the delegated act and if Parliament and Council have no objections, it enters into force.
- Article 33 of (EC) 1069/2009 shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(6): **Committee procedure**
  - Comitology applies when the Commission has been granted implementing powers in the text of a law. The same law also stipulates that the Commission is to be assisted by a committee when defining the measures contained in the resulting implementing act.
  - The **Standing Committee on Plants, Animals, Food and Feed** (PAFF Committee) plays a key role in ensuring that Union measures on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt.

OIE

- The World Organisation for Animal Health (OIE) is the intergovernmental organisation responsible for improving animal health worldwide.
  - Founded in 1924 as the Office International des Epizooties (OIE), in May 2003 we adopted the common name World Organisation for Animal Health. An intergovernmental organisation, we focus on transparently disseminating information on animal diseases, improving animal health globally and thus build a safer, healthier and more sustainable world.
- Serious transmissible diseases = diseases listed by the OIE in Article 1.2.3 of the Terrestrial Animal Health Code, 2010 edition (Article 4 in Regulation (EU) 142/2011)
- Terrestrial Code Online Access: https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/
- 117 OIE-Listed diseases (criteria for including diseases in the OIE-list are detailed in the OIE Terrestrial and Aquatic Codes)

Terrestrial Animal Health Code, Article 1.3.2

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine viral diarrhoea
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infection with lumpy skin disease virus
- Infection with Mycoplasmamycoides subsp. mycoides SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Theileriosis
- Trichomonosis

BSE

- The European Commission used to establish a scientific platform for the evaluation process for the allocation of a GBR (Geographical BSE Risk) in respect of BSE to countries wishing to export to EU Member Countries.
- The European Commission stopped evaluation of countries according to the GBR and recognizes the OIE categorization system for its own recognition of countries in respect to BSE risks in animals and animal products.
- 2007/453/EC: Commission Decision establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk

- The BSE status of Member States or third countries or regions thereof shall be determined by classification into one of the following three categories: (Regulation (EU) 999/2001)
  - **negligible** BSE risk
  - **controlled** BSE risk
  - **undetermined** BSE risk

Transit and Transshipment

- New chapter 6 in revised guidance document
- Commission Delegated Regulation (EU) 2019/2124 supplements Regulation (EU) 2017/625 as regards rules for official controls of consignments in transit, transshipment and onward transportation through the Union.
- Health certificates models in Annex XV to Regulation (EU) 142/2011 issued for transit through the European Union
- Document, identity and physical checks for goods subject to the animal health requirements where the transshipment period:

  (a) at the airport exceeds 3 days or at the port exceeds 30 days; or

  (b) for all other goods where the transshipment period exceeds 90 days.

Changes to legislation

- Regulation **(EU) 2016/429** on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’)
- Implementing Regulation (EU) 2019/2007 and Decision 2007/275/EC repealed by Implementing Regulation **(EU) 2021/632** laying down the lists of animal by-products and derived product subject to official controls at border control posts
- Commission Implementing Regulation **(EU) 2019/1084** amending Regulation (EU) No 142/2011 as regards the harmonisation of the list of approved or registered establishments, plants and operators and the traceability of certain animal by-products and derived products

Changes on official controls

- Regulation **(EU) 2017/625** on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 1069/2009, etc.
- Commission Delegated Regulation **(EU) 2019/2124** supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transhipment and onward transportation through the Union
- Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products repealed and replaced by Regulation **(EU) 2017/625**

  → Reference in health certificates did not change
- Commission Implementing Regulation **(EU) 2019/1715** laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)

Fresh meat list

- Commission Regulation **(EU) 206/2010** laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements repealed by Commission Delegated Regulation (EU) 2020/692
- Commission Regulation **(EU) 2022/384** of 4 March 2022 amending Annex XIV to Regulation (EU) No 142/2011 as regards adaptation of the lists of third countries, territories or zones thereof from which the entry into the Union of animal by-products and derived products is permitted
- Commission Implementing Regulation **(EU) 2021/404** of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council

2	Blood products, excluding from equidae, for the manufacture of derived products for uses outside the feed chain for farmed animals	Category 1 material referred to in Article 8, points (c) and (d), and Category 3 material referred to in Article 10, points (a), (b), (d) and (h).	The blood products must have been produced in accordance with Section 2.	The following third countries: (a) in the case of untreated blood products of ungulates: Third countries or parts of third countries listed in Part 1 of Annex XIII to Implementing Regulation (EU) 2021/404 from which imports of fresh meat of any domestic ungulate species is authorised and only for the period indicated in columns 7 and 8 of that Part. (b) in the case of untreated blood products of poultry and other avian species: Third countries or parts of third countries listed in Part 1 of Annex XIV to Implementing Regulation (EU) 2021/404.	(a) In the case of untreated blood products: Annex XV, Chapter 4 (C). (b) In the case of treated blood products: Annex XV, Chapter 4 (D).

ISIA position on offal

- Commission Regulation **(EU) 206/2010**
  - Annex 2 Part 1 ”1” Category restrictions: No offal is authorized for introduction into the Union (except, in the case of bovine species, diaphragm and masseter muscles).
- Regulation **(EU) 2021/404** replaces Commission Regulation (EU) 206/2010.
  - Article 2, Definitions states that “For the purpose of this Regulation, the definitions laid down in Article 2 of Delegated Regulation (EU) 2020/692 apply.”
- Commission Delegated Regulation **(EU) 2020/692**,
  - Article 2, Definitions states “(40) ‘meat’ means all parts of ungulates, poultry and game birds which are suitable for human consumption, including blood”
  - whereas “(43) ‘**offal**’ means fresh meat other than that of a carcass of an ungulate even if it remains naturally connected to the carcass.”

THANK YOU FOR YOUR ATTENTION!

Q&A

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