ISIA/MedTech guidance

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

TRAINING – SESSION 1

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Revision of ISIA/MedTech guidance

- Guidance concerning the **health rules and importation from Third Countries** into the EU of animal by-products and derived products not intended for human consumption according to Regulation 1069/2009/EC and the implementing Regulation 142/2011/EU

- Guidance published in 2013 and minor revision in 2019
- Major revision published in September 2021

- Guidance is intended to provide a **step-by-step guidance regarding the European animal by-products regulatory framework for suppliers, manufacturers, importers** and other interested parties

MedTech Europe

- Guidance published in collaboration between the ABP working group at MedTech Europe (formerly EDMA) and the regulatory team at ISIA
- MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health https://www.medtecheurope.org/
- MedTech Europe started as an alliance in October 2012 formed by two organisations – EDMA, representing the European in vitro diagnostic industry; and Eucomed, representing the European medical devices industry.
- Animal By Products Working Group focuses on questions relevant mainly to the import of materials of animal by-products and derived products, which ranges from the import of various serums to a number of purified proteins and antibody preparations.

European Union (EU) and European Economic Area (EEA)

- The European Economic Area, abbreviated as EEA, consists of the **Member States of the European Union (EU)*** and three countries of the European Free Trade Association (EFTA) (**Iceland, Liechtenstein and Norway**; excluding Switzerland).
  - Countries in the EEA are allowed to be part of the EU´s single market.
  - European laws considered EEA-relevant apply in Iceland, Liechtenstein and Norway.
- **Switzerland**: is not an EU or EEA member but is part of the single market; and ABP legal framework applies.
  - Switzerland and Liechtenstein from an economic, customs and monetary area.
- **Northern Ireland** (NI): Under the provisions of the Northern Ireland Protocol from 1 January 2021 movements of animal by products and derived products between EU Member States to NI remains unchanged. Great Britain (England, Scotland, Wales) is currently retaining parts of the EU ABP legislation.
- Other countries with special agreements: **Faroe Islands, Greenland, San Marino**

* Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden

Types of EU law – primary law

- Every action taken by the EU is founded on treaties that have been approved democratically by its members.
- Treaties are binding agreements between EU member countries set out EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its members.
- Treaties are negotiated and agreed by all the EU countries and then ratified by their parliaments, sometimes following a referendum.
- The EU treaties have from time to time been amended to reform the EU institutions and to give it new areas of responsibility.
- They have also been amended to allow new EU countries to join the EU.
- Treaties are the starting point for EU law and are known in the EU as **primary law**.

Types of EU law – secondary law

- The EU can pass laws only in those areas where its members have authorised it to do so, via the EU treaties.
- The body of law that comes from the principles and objectives of the treaties is known as **secondary law**; and includes **regulations, directives, decisions, recommendations and opinions**.

EU secondary law

- **Regulations**: apply automatically and uniformly to all EU countries as soon as they enter into force, without needing to be transposed into national law. They are binding in their entirety on all EU countries.
- **Directives**: require EU countries to achieve a certain result but leave them free to choose how to do so. EU countries must adopt measures to incorporate them into national law (transpose) in order to achieve the objectives, set by the directive. National authorities must communicate these measures to the European Commission.
- **Decisions**: shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them.
- **Recommendations**: allow the EU institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed. They have no binding force.
- **Opinions**: allows the EU institutions to make a statement, without imposing any legal obligation about the opinion. An opinion has no binding force.

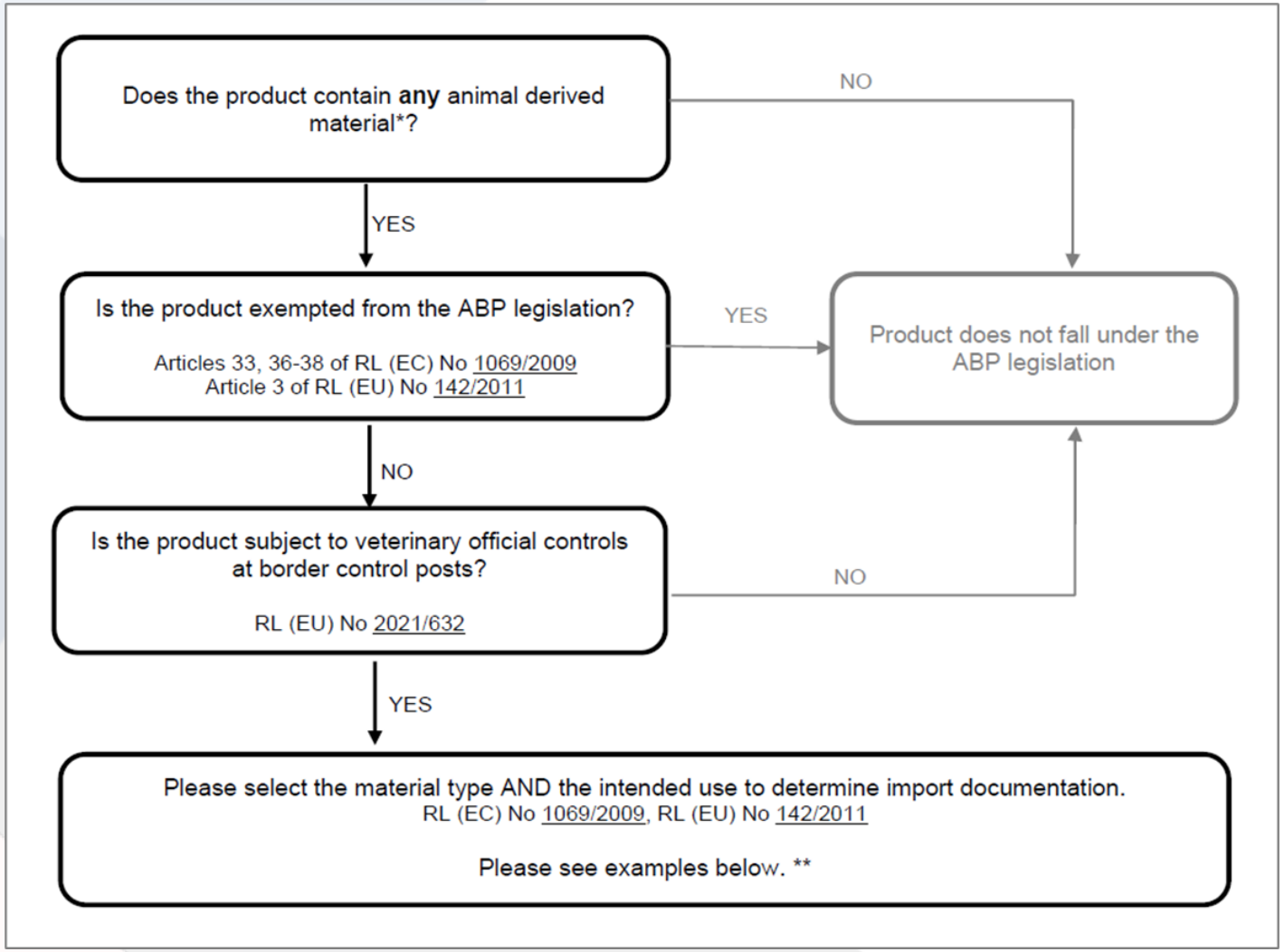
Non-legislative acts

- **Implementing acts** are legally binding acts that enable the Commission – under the supervision of committees consisting of EU countries' representatives – to set conditions that ensure that EU laws are applied uniformly.
- **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.

Consolidation / Codification

- **Consolidation** is the unofficial simplification of a legal act incorporating its amendments. This document shows the legal rules that are applicable at a certain point in time.
  - Consolidated texts have no legal effect. They are intended for use as documentation only, although they do serve as a basis of codification.
  - Consolidated texts help you to identify amendments within the legal act.
- **Codification** is the process of bringing together a legal act (or several related acts) and all its amendments into a single new act through the full legislative process.
  - vertical: where an original act and its amendments are incorporated in a single new act; or
  - horizontal: where 2 or more original acts covering related subjects, and any amendments to them, are merged in a single new act.

Decision Tree



* Even material containing trace amounts of animal by-products falls under the ABP regulatory framework. This includes stabilizers and carriers.

** If requirements for the product are not clearly defined in the legislation, please check with the local authority and/or the designated border control post.

Examples

MATERIAL TYPE		INTENDED USE			
		Technical use, not otherwise specified *(at time of importation)*	**Use in manufacturing finished products**[2]	**Research**	**QC or validation**
	Derived product	Blood products: Chapter 4 A, C or D Selected material: Chapter 2, 11, 12 or import permit from EU Competent Authority Other: Chapter 8	Chapter 20 *(intermediate product)*	Import permit from EU Competent Authority	Blood products: Chapter 4 A, C or D Selected material: Chapter 2, 11, 12 or import permit from EU Competent Authority Other: Chapter 8, Chapter 20
	Research and diagnostic sample	N/A	N/A	Import permit	Import permit
	Trade sample[3]	N/A	N/A	Import permit and Chapter 8	Import permit and Chapter 8
	Animal by- product	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority	Raw blood and non-blood ABPs: Chapter 8 (or import permit), except: – Equine raw blood: Chapter 4 A – Selected ABPs: Chapter 2 or import permit from EU Competent Authority

TRACES

- **TRA**de **C**ontrol and **E**xpert **S**ystem launched on 04 March 2011
- In early 2020, new electronic database TRACES NT (New Technology) was implemented.
- TRACES is the European Commission's multilingual online sanitary and phytosanitary certification platform supporting the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products.
  - **Traceability** (monitoring movements of consignments, both within the EU and from non-EU countries)
  - **Information exchange** (enabling trade partners and competent authorities to easily exchange information on the movements of their consignments, and by significantly speeding up administrative procedures)
  - **Risk management** (reacting rapidly to health threats by tracing the movements of consignments and facilitating the risk management of rejected consignments).

Sections

Third country facilities handling animal derived products are listed in TRACES under one or more of the following 10 sections:

I. Slaughterhouses

II. Dairy plants

III. Other facility for the collection or handling of animal by-products (i.e., unprocessed/untreated materials)

IV. Processing plants

V. Pet food plants (including plants manufacturing dogchews and flavouring innards)

VI. Game trophies plants

VII. Plants or establishments manufacturing Intermediate Products

VIII. Fertilizer and soil improvers

IX. Storage of derived products

X. Blood and blood products, excluding of equidae, for technical purposes other than feed for animals

Approved establishment

- The EU requires both EU Member States and third countries to list facilities approved or registered for the handling and manufacture of ABPs and derived products.
- Information listed within TRACES includes information concerning category or activity of material handled and types of approval of plants and facilities.
- In the case of third countries, facilities exporting animal by-products and derived products must also be listed in TRACES.
- Consignments may only enter the EU if they have originated from Third Country plants and establishments listed on the approved establishment lists published on the Commission website.
    - For third country establishments: https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en
    - For establishments in the EU: https://ec.europa.eu/food/safety/animal-by-products/approved-establishments_en

More to come …

- Terms and Definitions
- Finished products and Article 52
- GBR vs OIE BSE risk classification and virus risks
- Transit and Transshipment
- EU legislation changes

THANK YOU FOR YOUR ATTENTION!

Q&A

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