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Animal By-Products not for human consumption

Mel Herzog

- New Regulations on imports of Animal By-Products came into force on 4th March 2011
- Regulation (EC) No 1069/2009 and Regulation (EU) 142/2011(as amended)

Covers imports of animal by-products NOT for human consumption only

Recent changes

Commission Regulation (EU) 2015/9



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Was published on 6th January 2015 – Main changes were:

- Ready to sell growing media, including potting soil with less than 5% Cat 3 or Cat 2 material other than processed manure or less than 50% in volume of processed manure is not subject to any animal health conditions (6)
- Changes to definition of “Trade samples” and “intermediate products” (7)
- New processing method for ensilage of fish material (10)
- Changes to allow Cat 3 materials or ABP from aquatic animals (Art 10(i) & (j)) for the production of rendered fats - no animal health grounds to prohibit the mixing of aquatic and terrestrial animal fats (14)
- Changes to use of intermediate products (16)
- Enforcing Reg (EU) No 483/2014 re blood products for feed into 142/2011 (17 to 21)
- Certain bones, horns, hooves and their products can now come in by air (22)

INTERMEDIATE PRODUCTS

- Annex I point 35 of 142/2011 - As from 25th February 2015, definition of intermediate product is now:
- (a) which is intended for uses within the manufacturing of medicinal products, veterinary medicinal products, medical devices **for medical and veterinary purposes**, active implantable medical devices, *in vitro* diagnostic medical devices **for medical and veterinary purposes**, laboratory reagents or **cosmetic products** as follows:
 - **(i) as material in a manufacturing process or in the final production of a finished product;**
 - **(ii) in validation or verification during a manufacturing process; or**
 - **(iii) in quality control of a finished product;**
- (b) whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as a derived product and to qualify the material directly or as a component of a product for the purposes referred to in point (a);
- (c) which however requires some further manufacturing or transformation, such as **mixing, coating, assembling or packaging** to make it suitable for placing on the market or putting into service, as applicable, a medicinal product, veterinary medicinal product, medical device **for medical and veterinary purposes**, active implantable medical device, *in vitro* diagnostic medical devices **for medical and veterinary purposes**, laboratory reagent or **cosmetic products;**

INTERMEDIATE PRODUCTS CONT:

New uses for manufacturing the following products:

- *Medical devices for medical and veterinary purposes*
- *In vitro diagnostic medical devices for medical and veterinary purposes.*
- *Cosmetic products.*

(Also intermediate products may be used, inter alia, for the production of lab reagents or in vitro diagnostic for animal purposes (16)).

- List of premises of final destination have been expanded to take into account additional uses.
- Transitional period until 27th Sept 2015 provided any model declaration/ document was completed and signed before 27th July 2015.

TRADE SAMPLES

Annex I point 39 of 142/2011 -
Definition of “trade samples” is now:

- Animal by-products or derived products intended for particular studies or analyses authorised by a competent authority in accordance with Article 17(1) of Regulation 1069/2009 with a view to carrying out a production process, **including the processing of animal by-products or derived products**, the development of feedingstuff, **pet food** or derived products, or the testing of machinery or equipment.

TRADE SAMPLES CONTINUED

Examples of trade samples

- Tinned pet food intended for examination and development of new pet food lines.
- Bacon for testing machinery which is intended for use in another country.
- Testing a new tinning/ packaging method.

(taste testing for human consumption is dealt with by the FSA)

Health certificate / declaration or authorisation/ TAY licence?

- Copies of model health certificates and declarations to import certain ABP from third countries can be found at Annex XV of 142/2011.
- However, not all animal by-products that are imported are covered under Regulation (EC) No 1069/2009 or (EU) No 142/2011.
- 1069/2009 or 142/2011 may require a CA in the MS to authorise imports of certain products.

Health certificate / declaration or authorisation/ TAY licence? - continued

EXAMPLES WHEN A COMPETENT AUTHORITY NEEDS TO AUTHORISE AN IMPORT

- Art 18 of 1069/2009 – allows feeding of Cat 2 and 3 material to certain animals.
- Art 41.3 of 1069/2009 - allows for competent authorities to lay down National Rules for ABP currently NOT covered in 142/2011.
- Art 48 of 1069/2009 - trade of Cat 1 material & Cat 2 material and meat-and-bone-meal or animal fat derived from Cat 1 or Cat 2 materials between MS to be authorised by the CA of destination BEFORE it can be moved.
- Article 26 of 142/2011 - allows for certain Cat 1 material.
- Article 27 of 142/2011 – allows for research & diagnostic samples.
- Article 28 of 142/2011 – allows for trade samples & display items.
- Annex XIV, Chapter IV, Section 2 – allows for certain materials for purposes other than feeding the farmed land animals.

When do we issue an authorisation for ABP products not for human consumption?

- Issued when no model health certificate/ model declaration is available to use in 142/2011.
- Issued when legislation states a CA can authorise an import.
- Will state under which Article an authorisation has been issued.
- Will lay down specific requirements for import.
- Will need a commercial document/ health cert or other assurances depending on ABP being imported.
- Normally needs vet checks UNLESS stated otherwise.

Examples of authorisations

- Honey for *cosmetic/ technical use (*where it needs further processing in the UK)
- ABP for the manufacture of pet supplements/ pet treats
- Blood, tissues and organs from animals NOT slaughtered for human consumption (i.e. lab bred animals including livestock species)
- Bodily fluids other than blood
- Diets for lab animals/ zoo animals
- Cat 1 salted bovine serosa from the EU for manufacturing musical/ sport strings

When do we issue a TAY licence for ABP products not for human consumption?



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- Normally issued for very low risk products (i.e. finished pet food supplements)
- Issued under IAPPPO (Importation of Animal Products and Poultry Products Order 1980 (as amended))
- Only issued for mammal and bird products
- Can be unconditional
- Does not need vet checks

Examples of TAY licences

- Dead road kill to be imported for scientific study
- Finished pet supplements/ supplements for racing or pet equines containing less than 50% whey
- Bone charcoal for water filtration for re-export

What else do we issue?

- If a finished product contains an ABP not covered under IAPPPO (i.e. fish/ honey/ venom provided it is less than 50%) and we view it as low risk we can issue a facilitation letter to permit import with no restrictions or requirements.
- Done on a case by case basis

Examples

- Parrot fruit and honey treats containing pollen and honey
 - Supplements for racing/ pet equines containing fish oil

General licences and General authorisations

- General licences and authorisations are available for certain ABP imports
- Means specific licences do not need to be issued on a case by case basis
- Generally produced for low risk products
- Conditions for import will vary based on product being imported
- Looking to create more as we go on

Products outside the scope but containing ABP that is in scope

Some products considered outside the scope of the ABP Regulations can contain additional ABP products that still fall under ABP legislation.

e.g. Antibodies/ cell lines containing an ABP as a carrier/ stabiliser (i.e. FBS)

Current Commission advice is that any ABP used as a carrier/ stabiliser agent will still require documentation, even if the other ABP product does not.

However there are exceptions:

- Where the ABP carrier/ stabiliser is 3% or less – General licence available for landing in England – IMP/GEN/14/02
- Where the ABP carrier/ stabiliser is 10% or less and only for in vitro use - General licence available for landing in England – IMP/GEN/15/06
- Where the finished product complies with the legislation listed in Article 33 of 1069/2009 – deemed outside the ABP Regs (see next slide)

Article 33 of 1069/2009

Some finished ABP products can be deemed outside the ABP Regs.

Article 33 of 1069/2009 states where certain derived products are regulated by other Community legislation namely:

- *cosmetic products as defined in Article 1(1) of Directive 76/768/EEC;*
- *active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;*
- *medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;*
- *in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;*
- *veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;*
- *medicinal products as defined in Article 1(2) of Directive 2001/83/EC.*

Article 33 of 1069/2009 cont

HOWEVER! – To be deemed outside the ABP Regs under Article 33:

- The finished product **MUST** comply with one of the legislation listed in Article 33. (Product may not be defined as per the VMD or MHRA definitions)
- It must be, processed, packaged, imported (with any documentation if required) and labelled according with that legislation.
- If the product cannot comply with one of the legislation laid down in Article 33 then it's classed as an ABP– It has to comply with something.

Article 33 of 1069/2009

cont

Examples of Article 33 products

- Finished lab reagent containing ABP cells and over 10% FBS – Needs to comply with medical device or in-vitro medical device legislation under Article 33 **OR** will need a blood product model health cert for the over 10% FBS.
- 100% radiated honey, pre-packaged in tubes for use on wounds – Needs to comply with medical device or cosmetic legislation under Article 33.
- Pre-packaged hand cream containing honey and lanolin – Needs to comply with cosmetic legislation under Article 33.

NOTE – If the ABP is not pre-packaged for final sale (i.e. in drums) or needs further manufacturing in the EU (i.e. putting in final tube/ jar) it does not comply with Article 33 and is an ABP.

FISH MAWS, ISINGLASS AND OTHER PRODUCTS USED IN THE CLARIFICATION OF BEVERAGES



- Commission is amending Regulation (EC) No 853/2004 on hygiene rules for foods of animal origin. Introduces import conditions for highly refined products such as chondroitin, glucosamine, chitosan and isinglass and raw materials for the production of such materials.
- Therefore current conditions for fish maws, isinglass and other products previously imported under the ABP Regulations will no longer apply.
- APHA been advised to send all queries to FSA.
- ABP IINs for fish maws and isinglass have been withdrawn
- Waiting for FSA to issue instructions to importers to advise them of the changes.

What's coming up

- Review of all Research and Diagnostic sample General licences
- Procedures for PAP requiring re-processing
- Procedures for the re-classification of imported ABP as Cat 2 material
- Re-labelling at BIPs
- New IIN for Ornamental aquatic animals, aquatic invertebrates, amphibians and reptile pet food
- New General licence for hides and skins from Channel Islands and Isle of Man



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Thank you for listening

Any questions?