

Approval of third country establishments explained

Published by AGRINFO on 21 Dec 2022

Rules for approval of establishments allowed to export animals and animal products to the EU

Animal Health Law, Regulation (EU) [2016/429](#) and Delegated Regulation (EU) [2020/692](#)

Official Control Regulation (EU) [2017/625](#) and Delegated Regulation (EU) [2022/2292](#)

Update

Overview of the rules governing the approval of establishments to allow the export of animals and animal products to the EU.

Background

Approval of establishments is one of the tools allowing the EU to ensure that only food and feed in compliance with EU legislation is imported. It is alongside the obligation for third countries to be listed by the EU; and the signature of health certificates by third country authorities (see AGRINFO explainers on [Third country lists for animal health](#); [Third country lists for public health](#); [EU official health certificates for exports to the EU](#)).

The legal basis for the approval of establishments is:

- Official Control Regulation (EU) 2017/625 (Art. 127.3(e)), and its
- Delegated Regulation (EU) 2022/2292 for exports from third countries to the EU (Arts. 1, 13)
- Animal Health Law, Regulation (EU) 2016/429 (Arts. 94–100; Art. 56 and Annex XIX for captive birds), and its

Delegated Regulation (EU) [2020/692](#) for exports from third countries to the EU (Art. 8).

Impacted products

animals, animal products, animal by-products

What is changing?

Registration of establishments

All operators exporting food to the EU must at least be registered (Regulation [2020/692](#) Art. 8; Regulation [2017/625](#) Art. 10). To do so, operators must complete the procedures of the competent authority in the country where they are established. Once registration is completed, the authority assigns the operator a unique registration number.

Approval of establishments

Establishments exporting risky products must be approved and assigned a unique approval number. These are animals and animal products falling under combined nomenclature (CN) Chapters 2–5, 15, 16; specific headings 1702, 2101, 2105, 2106, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 4101, 4102, 4103; and sprouts (0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 1214 90) (see Council Regulation (EEC) No [2658/87](#)).

Table 1 lists the categories of establishments that require approval. In principle, approval covers all steps in the food supply from the farm onwards, including assembly operations of live animals, when the establishment is doing more than just logistics. (Establishments performing logistics that require temperature control for animal products must also be approved.)

To secure approval, **before** an establishment can start activities, the competent authority must control its compliance with the legislation on-site. This differs significantly from establishments supplying non-risk foods, which may commence activity as soon as they are registered, and only undergo controls at a later stage.

For live animals, detailed requirements to be fulfilled by the establishment are foreseen in Delegated Regulation (EU) [2019/2035](#).

Competent authorities of third countries guarantee that establishments are in compliance with the EU legislation by signing health certificates (see [EU official health certificates for exports to the EU – explained](#)).

The requirements apply in principle not only to the establishment actually exporting to the EU, but to the whole chain in the third country (slaughterhouse, cutting plant, etc.), including establishments supplying raw material from another third country [Regulation (EU) [2022/2292](#), Art. 13 (2)].

Regulation (EU) [2022/2292](#) sets out a few exemptions (Art. 14), and specific rules are foreseen for fishery products (Arts. 18, 19).

Procedure for approval

Since 1 December 2021, a new module, [Establishment Lists](#), is available in TRACES-NT. This replaces the email procedure for establishment listing.

National contact point(s) in the third country are responsible for updating the establishment list. The Commission will then check if all details are correct before publishing the list. Where mistakes are noted, the competent authority will be asked to review its whole list.

Also see [Non-EU countries authorised establishments](#).

What are the major implications for exporting countries?

It is up to third country authorities to approve and control the establishments allowed to export to the EU. Every change in approved establishments must be communicated to the European Commission services.

Resources

Online resources from the European Commission:


- Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin
- IMSOC Establishment Lists
- Non-EU countries authorised establishments

PAFF Committee (2021) [Technical Specifications](#) for the Format for the Lists of approved or registered Establishments, Plants or Operators handling Animal By-Products inside the European Union and in Third Countries.

Sources

- Animal Health Law, Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692
- Official Control Regulation (EU) 2017/625 and Delegated Regulation (EU) 2022/2292

Table & Figures

Table 1 Examples of establishments that need to be approved	
Products	Establishments
Live animals	Source: Animal Health Law, Regulation (EU) 2016/429, Art. 94
	Establishments for assembly operations of ungulates and poultry Germinal product establishments of bovine, ovine, caprine, porcine and equine animals (to another Member State) Hatcheries of poultry (eggs or poultry to another MS) Establishments keeping poultry (other than for slaughter or eggs to another MS) Establishments wishing to obtain the status of confined establishment Other type of establishment (assembly centres and animal shelters for dogs, cats and ferrets, control posts, environmentally isolated production establishments for bumble bees (to another MS) and quarantine establishments (within the MS, to another MS and for imports)
Animal products	Sources: Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin; Annex IV and Art. 13 of Delegated Regulation (EU) 2022/2292
Meat I Meat of domestic ungulates II Meat from poultry and lagomorphs III Meat of farmed game IV Wild game meat V Minced meat, meat preparations and mechanically separated meat (MSM) VI Meat products	Slaughterhouses Cutting plants Slaughter on farm (except for direct supply, by producers of small quantities of poultry/lagomorphs meat slaughtered on- farm, to final consumers and local retail establishments directly supplying final consumers) Game-handling establishment Establishments producing minced meat, meat preparations and MSM Establishments manufacturing meat products
Fish VII Live bivalve molluscs VIII Fishery products	Dispatch centres Purification centres Freezer vessels and factory vessels Establishments on land
IX Raw milk, colostrum, dairy products and colostrum-based products	Establishments processing raw milk into heat-treated milk and into dairy products made from raw milk Establishments making dairy products from already processed dairy products (e.g. butter from pasteurised cream, cheese from pasteurised milk or milk powder) Milk collection centres
X Eggs and egg products	Egg packing centres Establishments processing eggs
Frogs' legs and snails	Establishments preparing and/or processing frogs' legs and snails
Rendered animal fats and greaves	Establishments collecting, storing or processing raw materials
Stomachs and bladders	Establishments treating bladders, stomachs and intestines
Gelatine	Establishments processing raw materials
Collagen	Establishments processing raw materials
Sprouts	Other types of establishments
	Establishments re-wrapping products, whether or not associated with other operations such as slicing, cutting
	Cold stores of animal products for which there is a requirement of temperature control in Annex III of Regulation 853/2004
	Wholesale markets manufacturing products of animal origin
Animal by-products	Source: PAFF Committee (2021) Annex II, Chapter I.
	I Slaughterhouses and fishery vessels II Dairy plants III Other facilities for collection or handling of animal by-products (unprocessed/untreated materials) IV Processing plants V Petfood plants (including those manufacturing dogchews and flavouring innards) VI Plants handling game trophies VII Plants manufacturing intermediate products VIII Fertiliser and soil improvers IX Storage of derived products X Blood and blood products, excluding of Equidae (horses and related animals), for technical purposes other than feed for animals
 www.agrinfo.eu	

Disclaimer: *Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial support of the European Union. Its contents do not, however, reflect the views of the European Union.*