Public health requirements for exporting live animals, products of animal origin, composite products and sprouted seeds to the EU

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European Commission lays down conditions for live animals, products of animal origin, composite products and sprouted seeds exported to the EU

Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption

Update

The European Commission is merging and replacing two Regulations focusing on the public health requirements that countries exporting to the EU must meet. It sets out, in particular, the obligations for exporting countries to:

- be listed in the Annexes to Regulation (EU) 2021/405 as approved for entry of the products concerned into the EU
- approve the operators exporting to the EU
- ensure the traceability of the raw material
- issue the official certificate or attestation that must accompany the commodities
- lay down a control plan for pesticides, contaminants and pharmacological substances.

Impacted products

animals, animal products, snails, pollen flour, sprouted seeds

What is changing?

For simplification, the Commission is merging (and replacing) the provisions of both:

- Directive 96/23/EC dealing with contaminants and residues of veterinary medicinal products and pesticides in food-producing animals and goods, and

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- Delegated Regulation (EU) 2019/625 dealing with the public health requirements for countries exporting to the EU certain animals and goods intended for human consumption.

This new Delegated Regulation, (EU) 2022/2292, will ensure that food-producing animals, products of animal origin, and composite products exported to the EU meet requirements that are at least equivalent to the EU legislation on contaminants and residues.

Exporting countries that authorise the use of such substances, that are prohibited in the EU, in their production process must have a separate production system for export to the EU which does not allow the use of these substances (Art. 10). They must also have traceability and control systems for these prohibited substances.

Consignments must:

- come from exporting countries listed as compliant with public health requirements regarding food safety and residues under Regulation (EU) 2021/405
- come from establishments approved by national competent authorities
- be accompanied by an official certificate or attestation
- provide a level of human health protection equivalent to that provided by EU legislation on food and food safety, including pharmacologically active substances and their residues in food-producing animals, and contaminants and pesticide residues in products of animal origin and composite products.

Detailed requirements are laid down for:

- residues of pharmacologically active substances (2022/1644 and 2022/1646; see Official controls of veterinary drug residues and Official controls on the use of pharmacologically active substances
- contaminants (2022/931 and 2022/932)
- pesticides (2021/1355).

National control plan

Annex I of Regulation 2022/2292 sets out the information to be submitted in the national control plan.

Part I concerns general requirements; in particular, exporting countries must follow the Commission Guidelines to submit their control plan.

Part II gives details on:

- the information that exporting countries must submit on their plans for controlling pharmacologically active substances, pesticides and contaminants

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- the methodology
- specific information for bovine, caprine and ovine animals and products of animal origin (including milk), and specific information for honey, aquaculture, horses and casings
- a statement that guarantees the traceability of raw materials coming from other exporting countries, and that these are subject to the same rules.

Part III explains the information needed to update a control plan, which must be done by 31 March each year. For plans due by 31 March 2024, the updated templates must be used (Commission Guidelines, 4.4).

Why?

The aim is to ensure that imported food is subject to the same level of protection on the EU market as food produced within the EU. This is in line with the principles of the General Food Law, Regulation (EC) 178/2002.

Timeline

Date of publication: 24 November 2022

Date of entry into application: 15 December 2022

What are the major implications for exporting countries?

Opportunities

- Complying with the EU legislation means ensuring a high level of food safety and public health. The European Commission audits for compliance. Exporting countries can request assistance and training from their EU Delegation.
- The Regulation foresees the possibility of equivalent rather than identical requirements.
- For some requirements, such as residue plans, reference laboratories of other countries may be used. This offers a way to progress step-by-step and to put in place partnerships with other countries.

Challenges

- The EU compliance requirements, which reflect EU food safety and public health concerns, are demanding.

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- Contaminants, pharmacologically active substances, and pesticide use and needs may differ between exporting countries, depending on the geographical area and the diseases encountered, among others. In cases where substances and pesticides are allowed in the exporting country but not in the EU, compliance with the EU legislation may be challenging.
- If consignments are found to contain residues above the regulatory limits, the competent authority in the EU Member State must take measures. Member States may intensify official controls on consignments entering the EU (Official Controls Regulation 2017/625, Art. 65(4)). The European Commission may impose import bans or compulsory testing pre-export and/or at the point of entry, until the exporting country finds a satisfactory solution.
- The EU regularly audits its partner countries and the Member States. The work programme and reports are published by the Directorate-General for Health and Food Safety (DG SANTE) on the webpage Health and Food Audits and Analysis.

Exceptions

- Consignments of food-producing animals, products of animal origin and composite products may enter the EU from exporting countries that do not have an approved control plan for pharmacologically active substances, pesticides and contaminants only if they can ensure that those consignments, including composite products that contain processed products of animal origin, originate in a Member State or a third country included in the list in Annex-I of Implementing Regulation 2021/405. If that is the case, the exporting country must detail the procedures in place to guarantee traceability from that origin (2022/2292, Art. 8).
- The risk associated with composite products depends on the type of ingredients and on the conditions of storage. Specific requirements for composite products presenting a risk, including those that contain processed products of animal origin, or for which a residue-monitoring plan is required, are laid down in Annex III to Regulation 853/2004.
- No control plan is necessary for gelatine and collagen, or raw materials for their production; highly refined products of animal origin; insects; frogs, frogs' legs; snails; reptiles and reptile meat (Art. 5.2).

Recommended Actions

Competent authorities

For competent authorities of countries exporting food-producing animals and products of animal origin to the EU:

- if already listed as approved for entry of the products concerned into the EU, the competent authority needs to produce an updated control plan

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- if not yet listed, the competent authority needs to start the procedure for recognition of the country's public health requirements as soon as possible, making full use of assistance available from the EU.

Competent authorities may raise questions by emailing sante-tcresidueplans@ec.europa.eu. They can also ask the EU Delegation in their country to organise training.

Companies

For companies in countries exporting these products to the EU:

- inform the competent authority of your interest in exporting to the EU
- stay in regular contact with the competent authority to support the approval process
- follow the procedure for acceptance on the EU list of approved establishments.

Background

The main public health Regulations with which exporting countries must comply to be allowed to export to the EU are as follows.

- General Food Law (178/2002)
- Hygiene package (852/2004 and 853/2004)
- Bovine spongiform encephalopathy (BSE) (999/2001)
- Official controls on the use of pharmacologically active substances and their residues (2022/1644 and 2022/1646)
- Official controls on products of animal origin intended for human consumption (2019/624 and 2019/627).

The Official Controls Regulation (EU) 2017/625 puts in place the EU rules for official controls for both production in the EU, and products exported to the EU. It came into application on 14 December 2019.

This basic Regulation is supplemented by several Delegated and Implementing Acts. Most of these were laid down by 14 December 2019, but some were adopted later to align with the Animal Health Law (2016/429) which applies since 21 April 2021, and in particular the new animal health certificates that apply since 15 March 2022.

Resources

Online resources from the European Commission:

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- Commission Notice on a guidance document on requirements for multi-annual national control plans
- Guidelines on EU requirements for entry of animals and products of animal origin: Control plans for residues of veterinary medicines, pesticides and contaminants
- Official controls on imported products

Sources

Commission Delegated Regulation (EU) 2022/2292

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