Official controls on the use of pharmacologically active substances and their residues

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Uniform rules on national control plans for residues of pharmacologically active products in food-producing animals and animal products

Commission Implementing Regulation (EU) 2022/1646 of 23 September 2022 on uniform practical arrangements for the performance of official controls as regards the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on specific content of multi-annual national control plans and specific arrangements for their preparation

Update

The EU has published new Regulations on official controls of residues of pharmacologically active substances in food-producing animals and animal products. Exporting countries must submit their risk-based control plan, giving guarantees at least equivalent to those for food produced in the EU, and taking into account the minimum sampling frequency requirements.

Impacted products

cattle, sheep, goat, pigs, horses, aquaculture, rabbit, farmed game, reptiles, insects, meat, edible offal, casings, eggs, milk, dairy, honey

What is changing?

Two new Regulations, (EU) 2022/1646 and (EU) 2022/1644, together replace the Official Controls Directive 96/23/EC on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives in live animals and animal products.

Controls of commodities from exporting countries to the EU take place at two levels:

- by exporting countries themselves
- by the Member State authorities at the border control post of the Member State.

Control plans in exporting countries

Exporting countries' control plans for food of animal origin must be at least equivalent to those required from EU Member States (2022/2292, Art. 4 and 9). Controls must be based on:

- the combinations of substances and species, products in accordance with Regulation (EU) 2022/1644 (Annex II)
- the sampling strategy (Annex III)
- the actual sampling frequencies, taking into account the annual minimum control frequencies (Annex I)
- analytical methods to be used.

The new element is that the controls must be **risk-based**. Exporting countries must now explain their risk analysis to support the control plan they have adopted.

When a substance is not authorised in the EU, but is authorised in the exporting country, that country must demonstrate the absence of residues in the exported commodities (Regulation (EU) 2021/808, Annex I, or equivalent requirements).

When a substance forbidden in the EU is authorised in the exporting country, it must have a separate production system in place for its exports to the EU. It must also be able to guarantee compliance with strict conditions, including an appropriate animal identification and traceability system that is able to control distribution of the prohibited substances, and must maintain records of administration of veterinary medicinal products) (Delegated Regulation (EU) 2022/2292, Art. 10). Substances forbidden in the EU include beta-agonists; any stilbene, thyrostatic, oestrogenic, androgenic or gestagenic substances; chloramphenicol; nitrofurans.

The minimum sampling frequencies are set out in 2022/1646, Annex I (see Table 1). The control plan can cover the total national production, or only production eligible for export to the EU. For the latter option, a description of the system in place is needed so that only animals and products from this controlled production can be exported to the EU.

For composite products, a control plan is not needed if the components of animal origin originate from a Member State or an exporting country with an approved control plan for food-producing animals or products of animal origin. If that is the case, the exporting country must detail the procedures in place to guarantee traceability from that origin (2022/2292, Art. 8).

Controls at the EU border

EU Member States must have a **national risk-based control plan for third country imports** (Art. 6).

The required minimum sampling frequency is set out in Implementing Regulation (EU) 2022/1646 (Annex III) (see Table 2). This covers all farmed food-producing animals and their

products (mainly unprocessed), including horses and casings.

The European Commission updated its Guidelines on control plans in May 2023.

Why?

Directive 96/23/EC and Decision 97/747/EC were repealed on 14 December 2022 and replaced by Regulation (EU) 2022/1646 concerning:

- the content of the multiannual national control plan (MANCP) that Member States must develop, according to the Official Controls Regulation (2017/625) to ensure plans are harmonised, allowing data comparisons
- official controls of residues of substances with pharmacological action, the minimum sampling frequency of their metabolites, and of other substances transmissible to animal products that are likely to be harmful to human health.

Timeline

Date of publication: 26 September 2022.

Date of application: 15 December 2022.

What are the major implications for exporting countries?

- As before, countries exporting animals and animal products to the EU must prepare their own control plan, ensuring that their exports are in compliance with the EU legislation. The new element is that controls must now be risk-based. The risk analysis must explain how the controls comply with the minimum frequencies (see Table 1).
- Regarding controls at EU border control posts, exports to the EU will be systematically checked according to the stated sampling frequency (see Table 2).
- Exporting countries that submit control plans giving guarantees equivalent to those of the Member States, validated by the European Commission, will be included in the list of countries authorised to export the relevant animals or animal products.
- No control plan is necessary for gelatine and collagen, and raw materials for their production; highly refined products of animal origin; insects; frogs, frogs' legs; snails; reptiles and reptile meat (2022/2292, Art. 5.2).

Recommended Actions

Countries exporting bovine (cattle and beef), ovine (sheep, lamb, sheepmeat), caprine (goat and goatmeat), porcine (pigs and pork), equine (horses and horsemeat), aquaculture, poultry, milk, eggs, rabbit, wild game, honey, and casings must lay down annual control plans to monitor Group A and Group B substances.

These control plans must give the same guarantees as those of the Member States. The new element is that the control plans must be risk-based. This means that competent authorities must be able to justify their sampling strategy according to the minimum frequency (see Table 1).

Food-producing animals and animal products from exporting countries are systematically controlled at EU border control posts. To prevent non-compliance, the risk analysis determined in the control plan and required sampling frequency should rigorously follow the criteria in Table 2. EU Member States will consider any history of non-compliance, especially cases reported under the Rapid Alert System for Food and Feed (RASFF), when checking commodities at their border control posts. Controls are likely to be reinforced when non-compliances are detected.

Control plans must be submitted every year by 31 March. The updated templates (Guidelines on control plans, 4.4) must be used to report the 2023 results by 31 March 2024.

The Excel template is comprehensive, thus more complicated than before. For ease of use, exporting countries are advised to delete is the sections not relevant to them. The template covers residues of pharmacologically active substances, pesticides and contaminants under different tabs. Tabs (a) to (e) provide additional information and guidance.

Background

The Official Controls Regulation (EU 2017/625) foresees that competent authorities have to perform official controls, at any stage of production, processing and distribution, on residues of relevant substances in food and feed (including substances to be used in food contact materials, contaminants, non-authorised, prohibited and undesirable substances).

Delegated Regulation (EU) 2022/2292 supplements the Official Controls Regulation regarding specific public health requirements for food-producing animals and animal products exported to the EU.

The package of Regulations in Table 3 replaces Directive 96/23/EC.

Commission Regulation (EU) No 37/2010 sets maximum residue limits (MRLs) of pharmacologically active substances in foodstuffs of animal origin.

Implementing Regulation (EU) 2021/808 complements Regulations (2022/1644 and 2022/1646. It lays down rules concerning methods of sampling and laboratory analyses for residues of pharmacologically active substances in live food-producing animals, their body parts and fluids, excrements, tissues, products of animal origin, animal by-products, feed and water. It also lays down rules for interpretation of analytical results.

Implementing Regulation (EU) 2021/405 lays down the lists of exporting countries (or regions) permitted to export animals and animal products for human consumption to the EU.

Resources

Online resources from the European Commission:

- 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
- Commission Notice on a guidance document on implementation of the requirements for multi-annual national control plans

Sources

Delegated Regulation (EU) 2022/1644

Implementing Regulation (EU) 2022/1646

Visit the AGRINFO website to view the latest AGRINFO Update newsletters and search the database.

Table & Figures

Table 1 Official controls in exporting countries on pharmacologically active substances and residues		
Product	Sampling frequency for exporting country MANCP[a]	
	Group A substances	Group B substances
Bovine	Minimum 0.25% of slaughtered animals (minimum 25% of samples to be taken from live animals on the farm; minimum 25% to be taken at the slaughterhouse)	Minimum 0.10% of slaughtered animals
Sheep and goats	Minimum 0.01% of slaughtered animals per species	Minimum 0.02% of slaughtered animals per species
Porcine	Minimum 0.02% of slaughtered animals	Minimum 0.02% of slaughtered animals
Equine	Minimum 0.02% of slaughtered animals	Minimum 0.02% of slaughtered animals
Poultry	For each category of poultry (broiler chickens, spent hens, turkeys and other poultry) minimum 1 sample per 400 t annual production (dead weight)	For each category of poultry (broiler chickens, spent hens, turkeys and other poultry) minimum 1 sample per 500 t annual production (dead weight)
Aquaculture (finfish, crustaceans, other)	Minimum 1 sample per 300 t annual production of aquaculture for first 60,000 t production; then 1 additional sample for each additional 2,000 t	Minimum 1 sample per 300 t annual production of aquaculture for first 60,000 t production; then 1 additional sample for each additional 2,000 t
Bovine, ovine and caprine milk	Minimum 1 sample per 30,000 t annual production of milk per species	Minimum 1 sample per 30,000 t annual production of milk per species
Hen eggs and other eggs	Minimum 1 sample per 2,000 t annual production of eggs per species	Minimum 1 sample per 2,000 t annual production of eggs per species
Rabbits, farmed game, reptiles and insects	Minimum 1 sample per 100 t annual production (dead weight) of rabbits, farmed game or reptiles for first 3,000 t production; 1 sample for each additional 1,000 t Minimum 1 sample per 25 t annual production of insects	Minimum 1 sample per 50 t annual production (dead weight) of rabbits, farmed game or reptiles for first 3,000 t production; 1 sample for each additional 500 t Minimum 1 sample per 25 t annual production of insects
Honey	Minimum 1 sample per 50 t annual production for first 5,000 t production; then 1 additional sample for each additional 500 t	Minimum 1 sample per 50 t annual production for first 5,000 t production; then 1 additional sample for each additional 500 t
Casings	Minimum 1 sample per 300 t annual production	

a Multiannual national control plan.

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Source: based on Regulation (EU) 2022/1646, Annex III

Table 2
Official controls at the EU border on pharmacologically active substances and residues

Product	Sampling frequency[a]
Bovine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	7
Ovine/caprine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	3
Porcine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	3
Equine (includes live animals intended for slaughter for human consumption, meat, minced meat, mechanically separated meat, meat preparations and meat products)	3
Poultry (includes live animals, poultry meat and poultry meat products)	7
Aquaculture (finfish, crustaceans and other aquaculture products)	7
Milk (includes raw milk, dairy products, colostrum and colostrum-based products of all species)	7
Eggs (includes eggs and egg products from all bird species)	12
Rabbits, farmed and wild game, reptiles and insects (includes live animals, meat and meat products of the mentioned species and products derived from these species)	12
Honey (includes honey and other apiculture products)	7
Casings	2

a Sampling frequency for Group A and Group B substances (minimum % of imported consignments).

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Source: based on Regulation (EU) 2022/1646, Annex I

Table 3
Legislation based on the Official Controls Regulation[1]

New rules apply from 15 Dec 2022 (1 Jan 2023 for contaminants)[2]

New legislation	Control plans/programmes for exporting countries[3] are required for:		
	Pharmacologically active substances and their residues	Pesticide residues	Contaminants in food
	Risk-based, surveillance and import control	Coordinated multi-annual control programme	Food of animal origin and other foods
Delegated Act[4]	2022/1644	2021/2244	2022/931
Implementing Act[5]	2022/1646	2021/1355	2022/932

1 Official Controls Regulation (EU) 2017/625 (Art. 19).
2 New rules replace Directive 96/23/CE.
3 Control plans/programmes based on Regulation 2022/2292.
4 Delegated Acts supplement or amend non-essential elements of the basic law, and are adopted after consulting expert groups.
5 Implementing Acts aim to ensure uniform conditions for implementation, and are adopted with the agreement of Member States (a qualified majority) through a procedure called "comitology".

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