Official controls of veterinary drug residues in products of animal origin

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EU updates rules on official controls of veterinary drug residues in animal products

Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on 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

Update

The EU is updating its rules concerning official controls of residues of pharmacologically active substances used in veterinary medicines or feed additives. This includes controls on animals and animal products imported to the EU. The objective is to detect illegal treatment with prohibited or unauthorised substances, and to verify compliance with maximum residue limits and maximum levels for pharmacologically active substances authorised for use in food-producing animals.

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) 2022/1644 and (EU) 2022/1646, together replace the Official Controls Directive 96/23/EC for its part on residues.

(Regulation (EU) 2022/1646 covers Official controls on the use of pharmacologically active substances and their residues.)

Regulation (EU) 2022/1644 sets rules to ensure a harmonised approach when performing official controls on residues of pharmacologically active substances, including for imported animals and food of animal origin.

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Groups A and B

The Regulation (Annex 1) sets out the list of substances to be controlled (see Tables 1 and 2 below). The key change is that it now distinguishes two clear categories of **pharmacologically active substances**, in Groups A and B (see Table 3 below).

Group A

Pharmacologically active substances prohibited or not authorised in food-producing animals. (Prohibited substances are listed as expressly forbidden; non-authorised substances are those not authorised for the EU market).

These are:

- substances with hormonal and thyrostatic action, and beta agonists (prohibited in the EU under Council Directive 96/22/EC)
- substances listed as prohibited in Regulation (EU) 37/2010 (Table 2 of the Annex)
- non authorised pharmacologically active substances (including “antiviral substances”).

Example: Plant protection products used in animal husbandry

- Plant protection products that may be used in animal husbandry of food-producing animals are covered by the Regulations on residues of veterinary drugs and feed additives (2022/1644 and 2022/1646). An example is fipronil, which is covered by Regulation 2022/1644, Annex I, Group A3(b). For substances in Group A3(b), producers must take measures to prevent any accidental mixing with animal feed.
- Other plant protection products that can’t be used in animal husbandry are covered by the residues of pesticides Regulations (2021/2244 and 2021/1355). Examples include imidacloprid, a pesticide residue with “limited” possibility to be misused; and DDT, a pesticide that is no longer used. Both these substances are exclusively sampled for under the pesticide residues control plan.

Group B

Pharmacologically active substances authorised for use in food-producing animals.

- Pharmacologically active substances are listed in Regulation (EU) 37/2010 (Table 1 of the Annex).
- Coccidiostats and histomonostats are authorised according to Regulation (EU) 1831/2003 (feed additives legislation).

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Contaminants

Groups A and B are now limited to “pharmacologically active substances”. Contaminants, which were previously listed in Groups A and B, are now removed and listed in Regulations 2022/931 and 2022/932.

National control plan

Countries exporting to the EU

Regulation 2022/1644 addresses the national control plan that countries must adopt when exporting to the EU.

- Annex II sets the criteria for selecting combinations of substances, species and products for national risk-based control plans at the production level.
- Annex III lays down the criteria for the sampling strategy (when, where, what)

EU Member States

The Regulation also addresses the control plan to be adopted by EU Member States to control commodities arriving from exporting countries into the EU.

- Annex VI lists the information Member State authorities must use to assess risks, and to target controls on imported products deemed to be most at risk. It also includes criteria for specific combinations of substance groups and commodity groups for imports from outside the EU.
- Annex VII provides that samples should be taken at the point of entry into the EU and targeted in accordance with the rules set out in Annex VI (supplemented by Annex III).

Annex IV does not apply to exporting countries.

Why?

From 15 December 2022, a new EU legal framework for official controls replaces Directive 96/23/EC. It sets requirements for Member States to prepare monitoring plans to detect residues of veterinary products. The new Regulation enables continued and harmonised controls. It aligns the requirements with other legislation (such as rules on veterinary medicinal products and feed additives).

Timeline

Date of publication: 26 September 2022

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Date of application: 15 December 2022

What are the major implications for exporting countries?

Groups A and B

Groups A and B deal only with **pharmacologically active substances.** Contaminants and pesticides are tackled by separate Regulations.

All pharmacologically active substances are either prohibited (Group A) or authorised under certain conditions (Group B).

Risk-based annual control plans

The annual control plan is risk-based. The sampling strategy must be justified by a risk analysis (see Official controls on the use of pharmacologically active substances and Public health requirements for exporting live animals).

Exporting countries that submit control plans giving guarantees equivalent to those of the Member States, after being validated by the European Commission, will be included in the list of countries authorised to export the relevant animals or animal products to the EU (the list is in Regulation 2021/405, Annex I).

Exclusions

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 the following products – 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 relevant Group A and Group B substances.

These control plans must give the same guarantees as those of EU Member States, described in Regulation 2022/1646. The new element is that the control plan must be **risk-based**. This means that competent authorities must be able to justify their sampling strategy according to the minimum frequency set in Regulation 2022/1646 (Annex I).

The control plan must be submitted by **31 March each year**. For plans due by 31 March 2024, the updated templates must be used (Guidelines on control plans, 4.4).

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

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 the required sampling frequency should rigorously follow the criteria in Annex III of Regulation 2022/1644. 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.
- Farmers, vets and livestock technicians in exporting countries need to be informed about the list of prohibited substances for food-producing animals (Group A).
- Farmers, vets, livestock technicians and abattoirs need to be aware of the waiting times required following administration of drugs before an animal can be sent for slaughter to produce food. Local actors should ensure that waiting times indicated on packaging of medicines are respected (Group B).

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).

Import requirements for food-producing animals and animal products are laid down in Regulation (EU) 2022/2292. The new framework for official controls of residues of pharmacologically active substances, pesticide residues, and contaminants is explained in Table 4 below). Countries exporting food-producing animals, products of animal origin and composite products must provide guarantees that the controls of residues are **at least equivalent to those required from EU Member States** (2022/2292, Art. 9).

Regulation (EU) 2022/1644 (the subject of this record) lays down the substances to be monitored and selection of combinations per commodities; Regulation (EU) 2022/1646 covers the content of the control plans, including minimum sampling frequencies.

Maximum residue limits (MRLs) for pharmacologically active substances on foodstuffs of animal origin are set by Regulation 37/2010.

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Rules concerning **methods of sampling and laboratory analysis** are given in Regulation 2021/808. These rules cover 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. This Regulation also lays down rules for the interpretation of analytical results.

Lists of non-EU countries or regions permitted to export animals and animal products for human consumption to the EU, with regard to food safety and residues, are in Regulation 2021/405.

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
- Notice on a guidance document on the implementation of the requirements for the multi-annual national control plans as set out in Articles 109 to 111 of Regulation (EU) 2017/625

Sources

Delegated Regulation (EU) 2022/1644

Commission Implementing Regulation (EU) 2022/1646

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Tables & Figures

Table 1
Group A: Prohibited or unauthorised pharmacologically active substances in food-producing animals

Description	Substance
A.1 Substances with hormonal and thyrostatic action and beta-agonists prohibited under Council Directive 96/22/EC	Stilbenes Antithyroid agents Steroids Resorcylic acid lactones, including zeranol Beta-agonists
A.2 Prohibited substances listed in Regulation (EU) No 37/2010 (Annex, Table 2)	Chloramphenicol Nitrofurans Dimetridazole, metronidazole, ronidazole and other nitro-imidazoles "Other substances", i.e: • *Aristolochia* spp. and preparations thereof • Chloroform • Chlorpromazine • Colchicine • Dapsone
A.3 Pharmacologically active substances	Dyes Plant protection products as defined in Regulation (EU) No 1107/2009 and biocides as defined in Regulation (EU) No 528/2012 which may be used in animal husbandry of food-producing animals Antimicrobial substances Coccidiostats, histomonostats and other antiparasitic agents Protein and peptide hormones Anti-inflammatory substances, sedatives and any other pharmacologically active substances Antiviral substances
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Source: Delegated Regulation (EU) 2022/1644, Annex I

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Table 2
Group B: Pharmacologically active substances authorised for use in food-producing animals

Until 14 December 2022[a]	From 15 December 2022
Antibacterial substances including sulphonomides, quinolones	**B.1** Pharmacologically active substances listed in Regulation (EU) No 37/2010 (Annex, Table 1). MRLs are set for some of these. Antimicrobial substances Insecticides, fungicides, anthelmintics and other antiparasitic agents Sedatives Non-steroidal anti-inflammatory drugs, cortico-steroids and glucocorticoids Other pharmacologically active substances
Other veterinary drugs Anthelmintics Anticoccidials, including nitroimidazoles Carbamates and pyrethroids Sedatives Non-steroidal anti-inflammatory drugs Other pharmacologically active substances	**B.2** Coccidiostats and histomonostats authorised with maximum levels and maximum residue limits
Other substances and environmental contaminants Organochlorine compounds including PcBs Organophosphorus compounds Chemical elements Mycotoxins Dyes	

a Directive 96/23/EC, Annex I.

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Source: Delegated Regulation (EU) 2022/1644, Annex I

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Table 3 Official controls of veterinary drug residues in products of animal origin	
New Regulation 2022/1644/EU	Old Directive 96/23/EC
Group A: prohibited and unauthorised pharmacologically active substances	**Group A**: prohibited substances
Group B: authorised pharmacologically active substances	**Group B**: veterinary drugs and contaminants
Specific plan for contaminants (2022/931 and 2022/932)	
Specific plan for plant protection products (2021/1355)	
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Table 4
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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