Current activities of the European Commission in the area of residues of veterinary medicines and the implementation of Reg. (EU) 2017/625

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Overview

- New legislative act on performance criteria of analytical methods: Commission Implementing Regulation (EU) 2021/808
- Legislative acts in preparation – replacement of Council Directive 96/23/EC
  - Implementing act (IA) + delegated act (DA) on veterinary medicinal product residue (VMPR) control plans
  - Delegated act (DA) on import requirements of food-producing animals, products of animal origin and composite products intended for human consumption as regards pharmacologically active substances, pesticides and contaminants

Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC

(and Commission Implementing Regulation (EU) 2021/810 of 20 May 2021 amending Implementing Regulation (EU) 2021/808 as regards transitional provisions for certain substances listed in Annex II to Decision 2002/657/EC)

- Decisions 2002/657/EC and 98/179/EC were based on Directive 96/23/EC – repealed by Regulation (EU) 2017/625 → new Regulation based on Regulation (EU) 2017/625
- Improvement/development of analytical methods since 2002
- <u>The scope:</u>
  - Methods/procedures used for sampling (Annex II) and for laboratory analyses (Annex I) for VMPR in live food producing animals, their body parts and fluids, excrements, tissues, products of animal origin, animal by-products, feed and water
  - Interpretation of analytical results of these laboratory analyses
  - Applies to official controls aimed at verifying compliance with the requirements on the presence of VMPR
- Entry into force on 10 June 2021

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Transitional provisions:

- until 10 June 2026, the requirements laid down in points 2 (performance criteria and other requirements for analytical methods) and 3 (validation) of Annex I to Decision 2002/657/EC shall continue to apply to methods, which have been validated before the date of entry into force of Reg. 2021/808
- Annex II to Decision 2002/657/EC shall continue to apply until 27 November 2022 (MRPLs laid down in Annex II to Decision 2002/657/EC = Reference Points of Action (RPA) for the purpose of Reg. 2019/1871 until 27 November 2022) (see within 2 slides)

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Transitional provisions:

- for the calculation of decision limit for confirmation (CCα) for unauthorised or prohibited pharmacologically active substances (see point 2.6 of the Annex) :
  - in case of methods validated before the date of entry into force of this Regulation Method 2 (i.e. analysing at least 20 blank materials to be able to calculate the signal to noise ration at the time window in which the analyte is expected – 3 times the signal to noise ratio can be used as decision limit) can only be used until 1 January 2026
  - Methods validated after the entry into force of this Regulation - only Method 1 (i.e. calibration curve procedure according to ISO 11843-1:1997) or Method 3 (lowest calibrated level + expanded measurement uncertainty) shall be used

Changes in Reference Points for Action

Substance	MRPL (2002/657/EC)	RPA (Reg (EU) 2019/1871
Chloramphenicol	0.3 µg/kg	0.15 µg/kg
Medroxyprogesterone acetate	1 µg/kg	---
Nitrofurans and their metabolites	1 µg/kg for all: furazolidone, furaltadone nitrofurantoin, nitrofurazone	0.5 µg/kg for each of the metabolites of furazolidone (AOZ), furaltadone (AMOZ), nitrofurantoin (AHD), nitrofurazone (SEM), and nifursol (DNSH)
Sum of malachite green and leucomalachite green	2µg/kg	0.5 µg/kg

Council Directive 96/23/EC and Regulation (EU) 2017/625

Directive 96/23/EC was repealed by Regulation (EU) 2017/625 (Official Control Regulation -OCR), which entered into force on 14 December 2019

The rules set out in Directive 96/23/EC ensured the harmonised enforcement of the EU food safety legislation related to the use and residues of pharmacologically active substances.
In order to rationalise and simplify the overall legislative framework, the rules applicable to official controls in specific areas of the agri-food chain legislation have been integrated into the framework for official controls defined by Regulation (EU) 2017/625.

In order to ensure a continued and harmonised enforcement, the rules of Directive 96/23/EC related to the follow-up to non-compliances, have been integrated in the new legal framework under Regulation (EU) 2017/625.

Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances

Council Directive 96/23/EC and Regulation (EU) 2017/625

The provisions on monitoring of residues of VMP provided for in 96/23/EC shall continue to apply until 14 December 2022 (transitional measure provided in Article 150)

96/23/EC: pharmacologically active substances and their residues, some pesticide residues and some contaminants

Legal basis (OCR): Art. 19(2) for DAs, Art. 19(3) for IAs

new delegated and implementing acts on control plans on VMPR are **consulted/discussed**

pharmacologically active substances and their residues

IA (EU) 2021/1355
DA (EU) 2021/2244

pesticide residues (coordinated multiannual control programme for pesticide residues)

new delegated and implementing acts on control plans on contaminants in food are in **process/discussed**

contaminants in food of animal origin and in other food

They shall apply from 15 December 2022 onwards

European Commission

Control plan for VMPR

- As a general rule, official controls must be performed by the competent authorities regularly, on a risk basis and with appropriate frequency.
- EU rules set out the general requirements of content of the national control programmes, while leaving the risk-based design up to the Member States, in line with the general approach of the Official Control Regulation (EU) 2017/625 (OCR).
- A direct application of the risk criteria by Member States' competent authorities, ensures an administrative simplification and will afford Member States sufficient flexibility to amend without delay the national plans when new risks arise or fraudulent practices are identified during the course of the execution of the plan.
- The annually updated national plans, with a justification on how the risk criteria were applied, are to be submitted to the Commission.

Regulation (EU) 2017/625: **Article 19(2) for DA** and 19(3) for IA

Article 19 (2) The Commission is empowered to adopt delegated acts to supplement this Regulation by laying down rules for the performance of the official controls of this Article and for action to be taken by the competent authorities following those official controls. Those delegated acts shall lay down rules on:

(a) specific requirements for the performance of official controls, including, where appropriate, the range of samples and the stage of production, processing and distribution where the samples are to be taken, having regard to the specific hazards and risks related to the substances

Draft DA 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 on prohibited or unauthorised pharmacologically active substances and residues thereof

- Regrouping of substances → new groups A (Prohibited or unauthorised pharmacologically active substances which maybe used for illegal treatment in food-producing animals and group B (Pharmacologically active substances authorised for use in food-producing animals under Union legislation)

- Group A
  1) substances with hormonal and thyrostatic action and beta agonists the use of which is prohibited in the Union under Council Directive 96/22/EC
  2) prohibited substances listed in Table 2 of the Annex to Regulation (EU) 37/2010
  3) non authorised pharmacologically active substances

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

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- Defined combinations of substances and commodities to be controlled for each of the 3 plans (national risk-based control plan for national production, national randomised surveillance plan for national production, national risk-based control plan for third country imports (for more details on the 3 plans see slides under IA)
- For the risk based control plans: Relevant criteria for the selection substances for testing, farms/producers for sampling, selection of slaughterhouses and establishments, selection of animals, selection of matrix. For third country imports some additional criteria identified.
- Sampling strategy for all plans: timing, stage, targeted

Regulation (EU) 2017/625: Article 19(2) for DA and **19(3) for IA**

Article 19 (3) The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls and for action to be taken by the competent authorities following those official controls, regarding:

(a) uniform minimum frequency of such official controls, having regard to the hazards and risks;
(b) specific additional arrangements and specific additional content for the preparation of the relevant parts of the multi-annual national control plan (MANCP)

Draft IA on uniform practical arrangements of multi-annual national control plans (MANCPs) and annual reports by Member States on 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

3 control plans:

- Plan 1: National risk-based control plan for production in the Member States
  - controls on a wide range of substances within the sub-groups of Group A and Group B

- Plan 2: National surveillance plan for production in the Member States
  - use of unauthorised pharmacologically active substances (A), which are not included in the national risk-based plan, but they may be misused for the treatment of food-producing animals
  - controls on authorised pharmacologically active substances (B), ensuring that at a minimum, each sample is analysed for all of the substance groups listed in group B.

- Plan 3: National risk-based control plan for third country imports
  - controls on a wide range of substances within the sub-groups of Group A and Group B

Draft IA on uniform practical arrangements of multi-annual national control plans (MANCPs) and annual reports by Member States on 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

Minimum sampling frequency:

- Plan 1: National risk-based control plan for production in the Member States
  - based on the Member States' production data

- Plan 2: National surveillance plan for production in the Member States
  - fixed numbers for each Member State (mainly based on population size) (in total about 7700 samples)

- Plan 3: National risk-based control plan for third country imports
  - Based on the number of imported consignments (specific minimum percentage of imported consignments per animal species/animal product)

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

The Delegated Regulation will enable the continuation of the current requirements for the entry of animals and animal products into the EU and will guarantee the third countries' commitment to ensure equivalence with the Union restrictions on the use of veterinary medicinal products and regarding the Union requirements on contaminants and residues of veterinary medicinal products and pesticides in animals and products thereof.

By making the authorisation for import of specific animals or animal products from specific third countries subject to the submission of a residues control plan, which is equivalent to the requirements of national control plans of EU Member States, guarantees are made available of the third countries' commitment to ensure equivalence with the EU legislation on VMPs, pesticides and contaminants.

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

- Rules need to be fixed regarding the format and content of the plans to be submitted to the Commission in order to ensure completeness and comparability. The authorisation of the imports is made subject to the approval of the control plans by the Health and food audits and analysis services of the Commission.

- The Commission shall approve by means of implementing acts on the basis of article 127 of Regulation (EU) 2017/625, the import of specific products or animals from specific third countries.

- Only imports of animals or animal products from third countries which appear on the positive list in the above mentioned implementing act, can be imported into the EU.

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

- Furthermore the plans, submitted by the third countries, are used as a basis for inspections of the Commission in the third countries, in order to control the third countries' capability of ensuring equivalence with the requirements in EU legislation on VMPs, pesticides and contaminants.

- When it appears that equivalence is no longer ensured with the EU requirements, the concerned third country will be removed from the positive list (and is no longer allowed to export live animals and products of animal origin from the animals species/categories for which it has been delisted). .

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

- Replaces Art. 29 (1) and 29 (2) of Dir. 96/23/EC – legal basis for the DA : Art. 126 of OCR

Article 126 of OCR provides that:

The Commission is empowered to adopt delegated acts concerning the conditions to be respected by animals and goods entering the Union from third countries which are necessary to ensure that the animals and goods comply with the relevant requirements established by the Union rules or with requirements recognised to be at least equivalent thereto.

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for thee into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

Article 126 (cont'd)

The import conditions laid down in the delegated acts may include (not exhaustive):

- the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose (i.e. the already mentioned implementing act on the basis of article 127 of the OCR) .
- the requirement that consignments of certain animals and goods are to be accompanied by an official certificate, an official attestation, or by any other evidence certifying/attesting that the consignments comply with the relevant Union requirements or with requirements recognised to be at least equivalent thereto, including the results of the analysis performed by an accredited laboratory.

Draft Commission Delegated Regulation supplementing Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegated Regulation (EU) 2019/625

- It shall apply from 15 December 2022
- Merged with current provisions set out in Reg. (EU) 2019/625 (food hygiene/public health requirements): The purpose of merging is to lay down all supplementary requirements in accordance with Article 126(1) of Regulation (EU) 2017/625, into a single Delegated Regulation

Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (“The veterinary Medicines Regulation”)

- Regulation (EU) 2019/6 on veterinary medicinal products prohibits the use antimicrobials for growth promotion and yield increase, as well as the use of antimicrobials reserved for treatment of infections in humans.
- Article 118(1) of the Regulation bans the use of such antimicrobials in respect of animals and products of animal origin that are imported into the Union.
- Article 118(2) requires the Commission to adopt delegated acts on the detailed rules on the application of this prohibition.
- For the application of the ban in Article 118(1), an implementing act designating the list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans needs to be adopted.

Article 118 of Regulation (EU) 2019/6 on veterinary medicinal products (“the Veterinary Medicines Regulation)

- The delegated act under Article 118(2) should define the requirements that must be met for the entry into the Union of consignments of animals and products of animal origin pursuant to Article 118(1) of Regulation (EU) 2019/6.
- Regulation (EU) 2017/625 (OCR) has been recently amended by Regulation (EU) 2021/1756 to include verification of compliance with the prohibitions in Article 118(1) of the Veterinary Medicines Regulation within the scope of the Official Controls Regulation.

Thank you for your attention

European Commission