New legislative framework in the area of control of residues of veterinary medicines, supplementing and implementing Regulation (EU) 2017/625 ‘Official Control Regulation’

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Overview of new legislative framework

- Commission Implementing Regulation (EU) 2021/808 on performance criteria of analytical methods:
- Commission Delegated Regulation (EU) 2022/1644 with specific requirements for the performance of official controls (control plan)
- Commission Implementing Regulation (EU) 2022/1646 on uniform practical arrangements for the performance of official controls (control plan)
- Commission Delegated Regulation (EU) 2022/2292 on import requirements of food-producing animals and certain goods intended for human consumption
- Commission Implementing Regulation (EU) 2022/2293 as regards the list of third countries with an approved control plan.

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- Decisions 2002/657/EC and 98/179/EC were based on Directive 96/23/EC – repealed by Regulation (EU) 2017/625 → new Regulation based on Regulation (EU) 2017/625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 residues of veterinary medicinal products (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

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

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)

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

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

Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC

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	2 µg/kg	0.5 µg/kg

Exemptions to the Reference Points for Action for SEM (point 2 relates to a Regulation under adoption which will be applicable as from 28 November 2022)

- ([1]) Due to the natural occurrence of SEM in crayfish at levels above the RPA, only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in crayfish shall only be applied when the illegal use of nitrofurazone or SEM on crayfish has been established, i.e. at least one of the other nitrofuran metabolites has been detected.
- ([2]) Due to the occurrence of SEM at levels above the RPA as the consequence of processing in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in these products shall only be applied, when the illegal use of nitrofurazone or SEM has been established, i.e. at least one of the other nitrofuran metabolites has been detected.

Exemptions to the Reference Points for Action for SEM (point 2 relates to a Regulation under adoption which will be applicable as from 28 November 2022)

- ([2]) Food business operators and other interested parties shall communicate by 1 March 2024 to the Commission the results of investigations on the parameters and factors in the processing steps resulting in the formation of SEM in these products during processing.

  They shall also communicate the measures taken to ensure that the levels of SEM in these products are kept as low as reasonably achievable.

  In the absence of satisfactory data and information, measures shall be taken to end this exemption.’

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/contaminants/pesticide residues provided for in 96/23/EC were applicable 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

DA (EU) 2022/1644
IA (EU) 2022/1646

control plans (control based, surveillance and import control) on pharmacologically active substances and their residues

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

pesticide residues (coordinated multiannual control programme for pesticide residues)

DA (EU) 2022/931
IA(EU) 2022/932

control plans on contaminants in food 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

Commission 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

- 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

Commission Delegated Regulation (EU) 2022/1644

- 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)

Commission Delegated Regulation (EU) 2022/1644

- Criteria for the selection of specific combination of substance group and commodity group established for each of the 3 plans (national risk-based control plan for national production – Annex II, national randomised surveillance plan for national production – Annex IV, national risk-based control plan for third country imports – Annex VI (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 (Annexes III, V and VII) : 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)

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

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

Commission Implementing Regulation (EU) 2022/1646

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)

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

The Delegated Regulation enables the continuation of the current requirements for the entry of animals and animal products into the EU and guarantees 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.

Commission Delegated Regulation (EU) 2022/2292

- Requirements for the entry of animals and animal products into the EU as regards the use of pharmacologically active substances and residues thereof, prohibition of certain substances pesticide residues and contaminants are merged with existing 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 one single Delegated Regulation.
- Specific provisions as regards residue requirements are provided in Articles 5 to 12 of the Delegated Regulation
- The Delegated Regulation applies from 15 December 2022 onwards.

Commission Delegated Regulation (EU) 2022/2292 –Article 5 – Scope

- Specific residue requirements for import from third countries apply to food producing animals, products of animal origin and composite products
- Specific residue requirements for import from third countries are **not** applicable to:
    - gelatine and raw materials for the production of gelatine
    - collagen and raw materials for the production of collagen
    - highly refined products of animal origin
    - insects, frogs, frogs' legs, snails, reptiles and reptile meat.

Commission Delegated Regulation (EU) 2022/2292 – Article 6 (1) : Specific residue requirements

- In addition to the requirements laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products shall enter the Union only from a third country that has in place a control plan for pharmacologically active substances, pesticides and contaminants setting out guarantees as regards compliance with:

  (a) the Union requirements on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants; and

  (b) the additional requirements specified in Articles 9 to 12 of this Regulation.

  Article 9 : use of pharmacologically active substances and residues thereof

  Article 10: prohibition of certain substances

  Article 11: pesticide residues

  Article 12: contaminants

Commission Delegated Regulation (EU) 2022/2292 – Article 9 - use of pharmacologically active substances and residues thereof

1, Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that the controls on the use of pharmacologically active substances referred to in Annex I to Delegated Regulation 2022/1644 and on the residues thereof are at least equivalent to those required for the multiannual national control plans of Member States referred to in Article 4 of Implementing Regulation 2022/1646

2. Where a third country authorises the use in food-producing animals of pharmacologically active substances which are not authorised for such animals in the Union, food-producing animals, products of animal origin and composite products shall only enter the Union insofar as that third country provides guarantees that no residues thereof are present in those animals and products. The methods of analysis used to demonstrate the absence of such residues shall comply with the requirements laid down in Annex I to Implementing Regulation (EU) 2021/808 or with requirements equivalent thereto

Commission Delegated Regulation (EU) 2022/2292 – Article 10 - prohibition of certain substances

1, Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees of compliance with the prohibition of the use of beta-agonists and any stilbene, thyrostatic, oestrogenic, androgenic and gestagenic substances in farm animals laid down in Directive 96/22/EC, and with the prohibition of the use of the substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010 (i.e. *Aristolochia sp.,* chloramphenicol, chlorpromazine, colchicine, dapsone, dimetridazole, metronidazole, nitrofurans, ronidazole) .

2. For third countries authorizing or having no rules on the use of prohibited substances, there is the possibility to export to the Union on the condition that they provide sufficient guarantees for having set up a segregated production system ensuring that animals under that system are not treated with prohibited substances, combined with guarantees of compliance with strict conditions (appropriate animal identification and traceability system, system for control of distribution of the prohibited substances, record keeping of administration of veterinary medicinal products)

Commission Delegated Regulation (EU) 2022/2292 – Article 7 : Inclusion of a third country in list of third countries compliant with Union requirements on pharmacologically active substances and residues thereof, contaminants and pesticide residues

In addition to the conditions laid down in Regulation (EU) 2017/625, consignments of food producing animals, products of animal origin and composite products, shall enter the Union only from a third country that complies with the requirements provided for in Article 6(1) and is included in the list of third countries approved for the entry into the Union of the concerned food-producing animals or products of animal origin, set out in Annex -I to Implementing Regulation (EU) 2021/405 (*).

(*) “Third country residue list” provided for in Annex – I to Reg (EU) 2021/405: Commission Implementing Regulation (EU) 2022/2293 of 18 November 2022 amending Implementing Regulation (EU) 2021/405 as regards the list of third countries with an approved control plan on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances and pesticides and the maximum levels of contaminants

Commission Delegated Regulation (EU) 2022/2292 – Article 7 & Annex I :

Annex I of the Delegated Regulation sets out the information on the control plan for pharmacologically active substances, pesticides and contaminants and updated control plan for pharmacologically active substances, pesticides and contaminants which a third country has to submit for the purpose of its inclusion and maintenance in the “third country residue list”

Inclusion in the list is subject to submission and approval of the control plan by the Commission (i.e. Health and Food Audits and Analysis services of the Commission)

These control 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 pharmacologically active substances, 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).

Thank you for your attention

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