



Directorate-General for Health and Food Safety

**Guidelines on EU requirements for entry of
animals and products of animal origin**

**Control plans for residues of
veterinary medicines,
pesticides and contaminants**

2 April 2024

Health and
Food Safety

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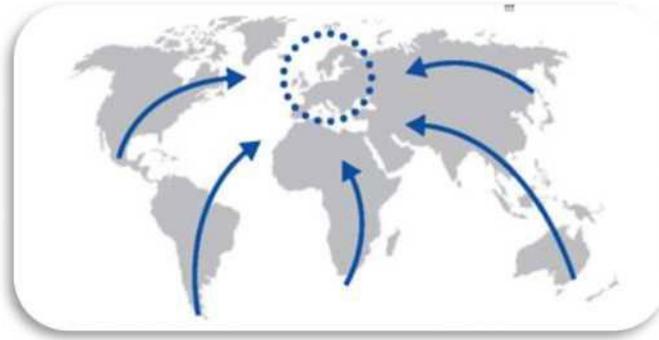


1. Objective of this document

This document aims to help third countries interested in exporting products of animal origin intended for human consumption to the European Union (EU) to better understand the new EU legislation and the requirements for official controls on residues of pharmacologically active substances, pesticides and contaminants in such products.

It gives guidance on how to design a residue control plan which will satisfy the requirements for listing the third country in Annex -1 to [Commission Implementing Regulation \(EU\) 2021/405](#).





2. Key requirements for entry of products of animal origin into the EU

TO NOTE: The web links to legislation cited in this document refer to the original version in [EUR-Lex](#) ⁽¹⁾, the official website of European Union law. Legislation is regularly updated. Please check for amendments, as it is these acts which are applicable and consolidated versions (listing all of the amendments with the date of their production) if available, may also be consulted on the EUR-lex website.

The EU is the world's biggest food importer and one of the biggest food exporters and has a comprehensive legal framework in place governing food safety.

To be able to export animals intended for human consumption and certain products of animal origin intended for human consumption to the EU, a third country needs to fulfil **animal health, public health** and **residue** control requirements. **This document deals only with the requirements in relation to residues.** Further general information on EU entry requirements, including animal and public health requirements, is available on the [Access2Market](#) webpage of the Commission's Directorate-General for Trade.

[Commission Delegated Regulation \(EU\) 2022/2292](#) ⁽²⁾ replaces the requirements applicable to third country controls on residues of pharmacologically active substances (in veterinary medicinal products), pesticides and contaminants in animals and animal products for human consumption and intended for the EU market, that were previously set out in (the now repealed) Council Directive 96/23/EC.

The European Commission establishes the **list of third countries with approved residue control plans** for animals and relevant ⁽³⁾ animal products, based on its evaluation of plans

(1) The EURLEX search page can be found here: <https://eur-lex.europa.eu/advanced-search-form.html>

(2) 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. Available at: https://eur-lex.europa.eu/eli/reg_del/2022/2292/oj

(3) The requirement to have approved residue control plans for animal products does **not** apply to **gelatine** and raw materials for the production of gelatine, referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004; **collagen** and raw materials for the production of collagen, referred to in Section XV, Chapter I, point 1, of Annex III to that Regulation; **highly refined products of animal origin; insects; frogs' legs; snails; reptiles** and **reptile meat**.

and supporting documentation submitted by third countries wishing to be so listed. The legal basis for this listing is set out in [Commission Delegated Regulation \(EU\) 2022/2292](#). Countries with approved residue control plans are listed in Annex -1 to [Regulation \(EU\) 2021/405](#). The lists are updated by the Commission on a regular basis in light of new information. Amendments to the lists are adopted, subject to a positive opinion of EU Member States.



3. EU legislation - residue control plans in animals & products of animal origin

There is a comprehensive framework of EU legislation governing the production of products of animal origin intended for human consumption and obliging EU Member States to verify that food producers in the EU abide by the rules and provide assurances that food is safe. With regard to **residues of pharmacologically active substances** in animals and food derived therefrom, official controls carried out by competent authorities and **annual control plans** are required by [Regulation \(EU\) 2022/1644](#)⁽⁴⁾ and the arrangements for performing these are laid down in [Regulation \(EU\) 2022/1646](#)⁽⁵⁾. In addition, controls on residues of **pesticides** and **contaminants** in these commodities is required⁽⁶⁾.

Enforcement is a key aspect of residue controls; Member States must take appropriate follow-up action to minimise the occurrence of residues in food which exceeds maximum residue limits for residues of pharmacologically active substances (veterinary medicinal products)⁽⁷⁾. The European Commission evaluates Member States' residue control plans

⁽⁴⁾ 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 (available at: https://eur-lex.europa.eu/eli/reg_del/2022/1644/oj)

⁽⁵⁾ 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 (available at: https://eur-lex.europa.eu/eli/reg_impl/2022/1646/oj)

⁽⁶⁾ Commission Implementing Regulation (EU) 2021/1355 of 12 August 2021 on multiannual national control programmes for pesticides residues to be established by Member States (available at: https://eur-lex.europa.eu/eli/reg_impl/2021/1355/oj) and Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation (available at https://eur-lex.europa.eu/eli/reg_impl/2022/932/oj)

⁽⁷⁾ 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

annually to determine their compliance with EU requirements.

Member States also test **imported products** of animal origin intended for human consumption for residues ⁽⁸⁾. If consignments are found to contain residues above the regulatory limits or levels applicable in the EU, the competent authority in the Member State must take measures in relation to those consignments ⁽⁹⁾.

Member States may intensify official controls on consignments entering the Union (Point 4 of Article 65 of [Regulation \(EU\) 2017/625](#)) and the Commission may, when warranted, impose safeguard measures e.g. import bans, compulsory pre-export testing and/or compulsory testing at the point of entry until the third country finds a satisfactory resolution.



4. Residue control plans in third countries seeking EU market access

Article 6(1) of [Commission Delegated Regulation \(EU\) 2022/2292](#) sets out that food-producing animals, products of animal origin and composite products may enter the European Union *only* from a third country that has in place a **control plan** setting out guarantees as regards **compliance** with:

- EU requirements on the use of pharmacologically active substances;
- the maximum residue limits of pharmacologically active substances, maximum

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. Available at: https://eur-lex.europa.eu/eli/reg_del/2019/2090/oj

⁽⁸⁾ [Article 6 of Regulation \(EU\) 2022/1646](#)

⁽⁹⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (consolidated version available at: <https://eur-lex.europa.eu/eli/reg/2017/625/2022-01-28>) and Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation (available at https://eur-lex.europa.eu/eli/reg_impl/2022/932/oj)

residue levels of pesticides and maximum levels of contaminants established in the EU and;

- the additional requirements specified in Articles 9 to 12 of that Regulation.

Article 6(2) of the same Regulation requires that, prior to the inclusion in the list of third countries with approved residue plans, a third country must submit to the Commission services evidence and guarantees of compliance with Article 6(1) together with the information set out in Part II of Annex I to said Regulation. Countries which are already listed for residues must submit annually up-dated evidence and guarantees of compliance with Article 6(1), as set out in Part III of Annex I, by **31 March each year**.

Article 9(1) of the Regulation specifies that the controls on the use of pharmacologically active substances in listed third countries must be at **least equivalent to** those required from EU Member States as set out in [Article 4 of Regulation \(EU\) 2022/1646](#).

Thus, when preparing residue control plans for submission to the Commission services for approval, third countries may follow the *same* approach set out for EU Member States in [Regulation \(EU\) 2022/1644](#) and [Regulation \(EU\) 2022/1646](#) or they may apply an **equivalent approach**. Third countries could, for example, consider the Codex Alimentarius *Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of Veterinary drugs in food production animals* – [CAC/GL 71-2009](#) – when drawing up their residue control plan for pharmacologically active substances. This document covers, *inter alia*, sampling strategies (biased and non-biased sampling) and advocates a risk-based approach to control and verification which is very much in line with the EU approach.

With regard to the use of (steroid) hormones and beta-agonists for growth promotion and certain steroid hormones for therapeutic and zootechnical purposes in food-producing animals, pursuant to Article 11 (2) of [Directive 96/22/EC](#) ⁽¹⁰⁾, EU countries cannot permit the entry of:

- animals (and/or products derived therefrom ⁽¹¹⁾) to which stilbenes, thyrostats and oestradiol have been administered for *any* purpose, or;
- animals (and/or products derived therefrom to which certain steroid hormones and beta- agonists have been administered for growth promotion.

These requirements are stipulated in Article 10 (1) of [Commission Delegated Regulation \(EU\) 2022/2292](#) and, **in addition**, this article indicates that the **use** of any of the substances included in Table 2 of the Annex to [Regulation \(EU\) No 37/2010](#) is prohibited in animals (and animal products) intended for the EU market.

Meeting the requirements on non-use of hormones, beta-agonists and substances such as chloramphenicol, nitrofurans and nitroimidazoles, can be achieved either by a total ban on use in the third country in those production sectors or, implementing a 'split' or segregated production system guaranteeing non-use in animals (and products derived

⁽¹⁰⁾ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (available at: <https://eur-lex.europa.eu/eli/dir/1996/22/2008-12-18>)

⁽¹¹⁾ With the exception of gelatine, collagen and those highly refined products listed in Section XVI, point 1 of Annex III to Regulation (EC) No 853/2004.

therefrom) intended for the EU market.

Requirement for a 'split system'

If a third country authorises the use of hormones and beta-agonists for growth promotion, 17-beta-estradiol for therapeutic or zootechnical purposes, or the use of any of the substances included in Table 2 of the Annex to [Regulation \(EU\) No 37/2010](#), its residue control plan **can only be approved** if there is a segregated production system ('split system') in place guaranteeing that animals (or their products) for export to the EU have not been treated with these substances at any time during their rearing.

The split system should include specific requirements for participation, including advance approval and certification procedures, record-keeping requirements, identification systems for segregation and traceability of the animals (and products derived therefrom) produced under the split system.



4.1. Submission of residue control plans to the Commission

New applications for listing can be submitted at any time. The **templates** linked in section 4.4 of this document should be used as this will ensure that **all** of the required information necessary for the evaluation of the control plans is provided and help avoid delays in evaluation of submissions.

Third countries which have already been listed for residues must submit their up-dated residue plans and the results of the previous years' testing each year. The templates provided for this purpose by the Commission services should be used to facilitate the efficient exchange of information. Submission should be made in **electronic form only**, by **31 March** each year, to:

Director, Health and Food, Audits and Analysis
Directorate-General for Health and Food Safety
European Commission
E-mail: SANTE-TCRESIDUEPLANS@ec.europa.eu

The Commission evaluates whether the documentation provided, with regards to the third country's residue control system can offer guarantees at least equivalent to those in the relevant EU legislation.

Based on a favourable evaluation by the Commission, and subject to a favourable opinion of the Member States of the EU, a third country will be listed for the commodity concerned in [Annex -I to Regulation \(EU\) 2021/405](#). Remaining on the list is contingent upon **implementation** of the residue control plan. In the event that a Commission audit were to find that the guarantees provided on paper did not reflect reality, the third country may be removed from the list and would no longer be able to access the EU market for the commodities in question, regardless of its animal health listing in [Regulation \(EU\) 2021/404](#) and/or public health listing in [Regulation \(EU\) 2021/405](#).



4.2. Key elements of a third country residue control plan

4.2.1. The initial residue control plan

For each of the commodities for which a third country seeks Commission approval and listing for residues, they must submit residue control plans covering **four discrete areas**. These are (1) for substance groups (**pharmacologically active substances**) listed in Group A - see [Annex I to Regulation \(EU\) 2022/1644](#); (2) for substance groups (**pharmacologically active substances**) listed in Group B - see [Annex I to Regulation \(EU\) 2022/1644](#); (3) **pesticides** and (4) **contaminants**.

For each of the four separate **control plans**, competent authorities must submit the information required in [Part II of Annex I to Commission Delegated Regulation \(EU\) 2022/2292](#) and provide:

- Details of the basis for the **determination of sample numbers**; and the selection of analytes (see point 4.3. below);
- Details of the **number of samples to be analysed for each substance**, the **matrices** used for analyses, the **methods** of analysis used for both screening and confirmation, and their **performance parameters**;
- Details of the **laboratories** used, their **accreditation** status and the **validation** status of each method used in the relevant matrices;

To that end, use of the Excel templates drawn up by the Commission services allows for this information to be provided in a concise and efficient manner (See section 4.4.).

4.2.1.1. The control plan for residues of pharmacologically active substances

The Group A and Group B substance groups are listed in [Appendix 1](#) to this guideline, for ease of reference.

The **control plans for pharmacologically active substances** must include all of the information set out in [Annex II to Commission Delegated Regulation \(EU\) 2022/2292](#). Competent authorities should consult Annex II, base their submission on it, and ensure that all of the required information is included. Failure to provide the required information will lead to a negative evaluation of the submission. For ease of reference, the relevant requirements are included in [Appendix 3](#) to this guideline.

For **Group A substances (prohibited or unauthorised pharmacologically active substances)**, those which are required to be tested for in each commodity are laid down in [Annex II to Regulation \(EU\) 2022/1644](#) and the **frequency of sampling** in [Annex I to Regulation \(EU\) 2022/1646](#). Third countries must test for these substance groups at the specified sampling rate – see [Appendix 2](#) to this guideline – and certain minima apply for some of the Group A substance groups.

For **Group B substances (pharmacologically active substances authorised in the European Union for use in food-producing animals)**, third countries should use the criteria laid down in [Annex II to Regulation \(EU\) 2022/1644](#) to decide which of the substance groups should be controlled in each commodity. The **frequency of sampling** is laid down in [Annex I to Regulation \(EU\) 2022/1646](#). For ease of reference this is provided in [Appendix 2](#) to this guideline. Whilst there is an overall sampling frequency for all Group B substances, third countries (like EU Member States) may decide on a risk-basis, the number of samples tested in *each* substance group. The total number of samples must be respected.

4.2.1.2. Derogations to having a residue control plan

Third countries referred to in Article 8(1) and (2) of [Commission Delegated Regulation \(EU\) 2022/2292](#), which benefit from a **derogation** from the requirement to have an approved residue control plan, by using only food-producing animals and/or products of animal origin, including those used in composite products, originating in a Member State or in a third country included in the list set out in [Annex 1 to Regulation \(EU\) 2021/405](#) are not required to submit a residue plan but must instead provide:

- a statement by the competent authority of the third country confirming that products of animal origin intended for entry into the Union as such, or as ingredients of composite products, only originate in approved third countries included in the list of third countries with an approved control plan for pharmacologically active substances, pesticides and contaminants for those food-producing animals or products of animal origin, and that the procedures it has in place for this purpose are sufficient to guarantee the traceability and origin of those products of animal origin;
- a comprehensive description, by the competent authority of the third country, of the procedures in place in that country, to substantiate the statement referred to in the point above.

4.2.1.3. The control plan for contaminants

For **contaminants**, those which are required to be tested for in each commodity and the frequency of sampling are laid down in [Regulation \(EU\) 2022/931](#) and [Regulation \(EU\) 2022/932](#) respectively.

For ease of reference, the relevant requirements are included in [Appendix 7](#) to this guideline.

4.2.1.4. The control plan for pesticides

For **pesticides** no minimum number of samples is laid down in EU legislation. Third countries should ensure that representative controls on residues are performed in order to demonstrate that the products intended for the European Union comply with the maximum residue levels laid down in [Regulation \(EC\) No 396/2005](#). The guarantees provided by these third country control plans must be at least equivalent to those provided for by the plans that European Union Member States are obliged to implement ⁽¹²⁾.

4.2.2. Subsequent residue control plans

When submitting plans in the years following first listing, competent authorities must provide all of the information set out in [Part III of Annex I to Commission Delegated Regulation \(EU\) 2022/2292](#). For ease of reference the text is provided in [Appendix 6](#) to this guideline. Competent authorities should consult Part III, base their submission on it, and ensure that all of the required information is included. Failure to provide the required information will lead to a negative evaluation of the submission.

In summary, competent authorities should submit:

- Details of changes introduced in the updated control plans for pharmacologically active substances, pesticides and contaminants, including up-dated production data, details of any changes that have occurred since the previous submission that alter the information previously provided under Part II, points A to M, *or* a statement that no such changes have occurred, as applicable;
- Results of the implementation of the previous year's control plans for pharmacologically active substances, pesticides and contaminants, the up-dated

⁽¹²⁾ This refers to the multiannual national control plans set out in Commission Implementing Regulation (EU) 2021/1355

control plan, a justification for any shortfalls in implementation of the previous year's plan, details of non-compliant results found and a brief description of the follow-up actions taken.

When submitting the subsequent plans, competent authorities should use the Commission's 'Table 1' (Word template) and the Excel results templates linked in Section 4.4. of this guideline.

4.3. Structure of the residue control plan

Third countries are asked to use the Microsoft Excel and Word templates for constructing their plans and providing the supporting information as described in section 4.4. These templates outline the information the Commission expects to see in the residue control plans. Using the templates facilitates the presentation of data in a common format and allows for a more rapid evaluation of the plan.

4.3.1. Commodities to be tested

The plans should include **only** those commodities for which the third country is *currently* listed for export to the EU and those for which a *new* listing is being requested. Residue control plans should be submitted, with a formal listing request from the responsible competent authority, for any new commodities which the third country wishes to export to the EU.

4.3.2. Calculation of sample numbers

For the **control plans for pharmacologically active substances (Group A and B)** – for list see [Appendix 1](#) -, the required number of samples to be taken for each commodity is set out in Annex I to [Regulation \(EU\) 2022/1646](#) which also includes additional provisions regarding sample numbers. Third country competent authorities should consider these provisions carefully when developing their plans.

Each sample can be analysed for one or more substances within a substance group.

The calculation of sample numbers is based on **annual national production figures**. For third countries however, there is some latitude in this respect. If the number of samples to be taken follows the rules laid down in Annex I to the above Regulation (i.e. as a proportion of the production), the number of samples can:

- either be based on the national production
- or only on that part of the national production which is eligible for export to the EU.

For example, in countries where animals and products from *any* farm are eligible for export to the EU, the proportion of animals sampled should be based on the annual national production figures i.e. in line with the sampling levels and frequencies applied in EU Member States.

For third countries where only a certain population of animals is eligible for export with a (split or segregated) system guaranteeing that only those animals (or products therefrom) from those farms are eligible for export to the EU, the number of sampled animals can be calculated relative to that defined population rather than the national population. (See point 4 above on split or segregated production systems).

4.3.3. Sampling strategy

For the control plans for pharmacologically active substances (Group A and B) detailed criteria for the sampling strategy are set out in [Annex III to Regulation \(EU\) 2022/1644](#). Third country competent authorities should consider these provisions carefully when developing their plans. The text is included in [Appendix 5](#) to this guideline, for ease of reference.

In relation to the control plan for contaminants, detailed criteria for sampling are set out in [Annex II to Regulation \(EU\) 2022/931](#). For ease of reference, these requirements are set out in [Appendix 7](#) to this guideline.

4.3.4. Selection of residues to be tested for

For the control plans for pharmacologically active substances (Group A and B), [Annex II to Regulation \(EU\) 2022/1644](#) sets out criteria for the selection of specific combinations of substance groups and commodities. For ease of reference the text is available in [Appendix 4](#) to this guideline and in section 4.4. of this guideline.

Those countries following [the Codex Alimentarius guidelines](#) should also justify the selection of substances and the absence of testing of any Group A or B substances on the basis of risk.

4.3.5. Maximum Residue Limits, Maximum Residue Levels and Maximum Levels in products of animal origin intended for human consumption

Residues of pharmacologically active substances in veterinary medicinal products:

[Regulation \(EC\) No 470/2009](#) lays down the procedure in the EU for setting Maximum Residue Limits (MRLs) for residues of pharmacologically active substances (in veterinary medicinal products) in products of animal origin. The list of pharmacologically active substances and their MRLs is in the Annex to [Regulation \(EU\) No 37/2010](#). Note that some 'dual use' substances may also have pesticide Maximum Residue Levels for pesticides which are set for animal tissues and these may differ from the Maximum Residue Limits set for pharmacologically active substances. Those substances listed in Table 2 of the Annex to [Regulation \(EU\) No 37/2010](#) are not authorised for use in food-producing animals in the EU and must also not be used in animals from which products for human consumption are destined for the EU market (see section 4 of this guidance document).

Residues of pesticides (plant protection products)

[Regulation \(EC\) No 396/2005](#) establishes EU MRLs for pesticides in matrices including food of animal origin. The MRLs are publicly available in a [database](#) which is maintained by the Commission. The list of EU MRLs for pesticides can be viewed in Excel after downloading the xml files from this [webpage](#).

Residues of contaminants

[Regulation \(EC\) No 2023/915](#) lays down maximum levels (MLs) for certain environmental contaminants e.g. heavy metals.

Residues of feed additives

Some other substances classified as 'feed additives' in the EU (coccidiostats and

histomonostats) may also leave residues in food derived from animals reared using feed containing these substances. To see which coccidiostats and histomonostats are authorised as feed additives, please consult the [European Union Register of Feed Additives](#).

Some of these coccidiostats and histomonostats are authorised either as veterinary medicines and/or as feed additives ('dual-use' substances). For dual-use substances, the MRL for the substance as a veterinary medicine is that which takes precedence for regulatory control purposes and these are listed in the Annex to [Regulation \(EU\) No 37/2010](#).

For coccidiostats and histomonostats authorised *only* as feed additives, MRLs are established for individual formulations of each feed additive. The information as to which MRLs apply, can be found in the individual legal authorisation acts mentioned in the Annexes to the European Union Register of Feed Additives in the column called "Reference(s) of Community legal act".

Cross-contamination of animal feedingstuffs can occur, i.e. trace quantities of feed additives can end up in feed for species for which the substances were not authorised. This may lead to residues in food derived from those animals. [Regulation \(EC\) No 124/2009](#) lays down maximum levels for coccidiostats or histomonostats in food from such 'non-target' species.

4.3.5.1. Which MRLs and MLs apply in the third country control plans

It is recognised that different jurisdictions may have different MRLs and MLs. **Commission approval of a residue control plan does not require third countries to adopt EU MRLs or MLs and use these as their 'action levels' (i.e. concentrations above which regulatory actions would occur).** However, if there are substances for which the national MRLs/MLs are greater than the corresponding EU MRLs/MLs, or where there is no EU MRL established:

- a) the competent authority should inform those food business operators who are eligible to export food to the EU about those differences and remind them that any detection of a residue above the EU MRLs/MLs (if applicable) at the EU border would result in rejection of the consignment;
- b) In the event that testing carried out under the residue control plan identifies cases where an EU MRL is exceeded, or there is no EU MRL (but the result complies with a national MRL), the competent authority should inform the operator and the operator should take the necessary steps to recall the animal product in question if it is intended for export to, or is in the process of being exported to the EU;
- c) Farmers supplying animals (and/or, eggs, milk and honey) to food business operators intending to export food to the EU, should have measures in place to guarantee that where there is no EU MRL established for a given pharmacologically active substance, that nationally authorised veterinary medicinal products containing that substance are not used in animals, products from which are intended for the EU market;
- d) Where EU MRLs are lower than national MRLs for a given pharmacologically active substance, that the pre-harvest drug withholding period (drug withdrawal period) applied following the use of a nationally authorised veterinary medicinal product should be extended to ensure that residues in edible tissues will comply with the lower EU MRL.

The competent authority should be in a position to verify that farmers and food business operators satisfy the conditions in point c).

4.3.6. Reference points for action in products of animal origin

Reference points for action (RPAs) apply to several substances which are **expressly prohibited** or are not authorised for use in food-producing animals in the EU e.g. chloramphenicol, nitrofurans and malachite green. These substances do not have an EU MRL. RPAs have been established for some of these substances for food control purposes only on the basis of the principles described in [Regulation \(EC\) No 470/2009](#).

If food contains residues at or in excess of the RPA, it cannot be placed on the EU market. Conversely, food containing residues below the RPA can be placed on the EU market but, since the substances concerned are not authorised for use in food-producing animals in the EU, Member States must take further follow-up measures.

In the event that sub-RPA concentrations are repeatedly found in imported food, the Commission may impose safeguard measures on the implicated product from the third country in question.

The list of RPAs has recently been updated by the Commission and the table below lists the current RPAs and those which apply after November 2022.

<i>Until 27 Nov 2022 ⁽³⁾</i>			<i>From 28 Nov 2022 ⁽⁴⁾</i>		
Substance	Matrix	RPA (µg/kg)	Substance	Matrix	RPA (µg/kg)
<i>Chloramphenicol</i>	<i>Food of animal origin</i>	0.3	<i>Chloramphenicol</i>	<i>Food of animal origin</i>	0.15
<i>Nitrofurans Metabolites for: (furazolidone, furaltidone, nitrofurantoin, nitrofurazone)</i>	<i>Food of animal origin</i>	1	<i>Nitrofurans Metabolites for: (furazolidone, furaltidone, nitrofurantoin, nitrofurazone, nifursol)</i>	<i>Food of animal origin</i>	0.5
<i>Sum of malachite green and leucomalachite green</i>	<i>Food of animal origin</i>	2	<i>Sum of malachite green and leucomalachite green</i>	<i>Food of animal origin</i>	0.5

⁽³⁾ [Annex II to Decision 2002/657/EC \(see last amended version\) and Article 7 of Commission Implementing Regulation \(EU\) 2021/808](#)

⁽⁴⁾ [As of 28 Nov 2022: Annex to Commission Regulation \(EU\) 2019/1871](#)

⁽⁵⁾ 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 on crayfish has been established.



4.4. Templates and reference documents for residue control plans and results

The following documents/templates summarise the information the Commission needs to evaluate if the third country residue control plan offers guarantees equivalent to those in EU legislation:

- [Table 1](#) (Microsoft Word) (Updated October 2023) - to be completed by the competent authority. It has 6 sections: competent authority; residue control plan; residue testing results, laboratory network; authorisation and controls on veterinary medicines; and additional information. Each section must be completed. Even if such a table has been filled in previously, it should be up-dated and submitted with the residue control plans each year.
- [Plan Template](#) (Microsoft Excel) (Updated 2 April 2024), provides instructions on how each of the plan templates should be completed, lists the substance groups for residues of pharmacologically active substances (Group A and B), pesticides and contaminants, provides the sampling frequencies for Group A and B substances laid down in [Annex I to Regulation \(EU\) 2022/1646](#) allows competent authorities to submit the necessary details on the analytes tested for, the matrices tested, the screening and confirmation methods of analysis used and their validation status, the method performance parameters, the level of action applied, the national and EU MRLs and MLs for each analyte, the action level and the name of the laboratories carrying out analyses for each analyte or group of analytes. The plan template contains 59 separate tabs covering all of the commodity types listed in [Annex II to Regulation \(EU\) 2022/1644](#) for each of the four plans (Group A, Group B, pesticides and contaminants) where applicable.
- It is important that the analytical methods used are capable of detecting the residues in question at the same levels/limits as applied in the EU (see 4.3.5), and that they are validated and fit for purpose. Details of analytical methods for pharmacologically active substances and the performance characteristics thereof as well as methods for sampling are given in [Regulation \(EU\) 2021/808](#). Similar information is included in [Directive 2002/63/EC](#) (pesticides), [Regulation \(EC\) No 333/2007](#) (contaminants), [Regulation \(EC\) No 401/2006](#) (mycotoxins) and [Regulation \(EU\) 2017/644](#) (dioxins/PCBs).

- [Tables of results](#) (Microsoft Excel) (Updated 20 September 2023) for each species/commodity allow the uniform presentation of results for all third countries. The relevant Excel tabs should be filled in for each species/commodity and each of the four control plans (if applicable). [The proforma](#) (Microsoft Word) (Updated 16 October 2023) should also be completed in respect of the non-compliant results.



5. Requirements for residue testing laboratories

The results of residue testing must be reliable. This is a vital requirement for the Commission's approval of the residue control plans and listing of the third country as eligible to export products of animal origin intended for human consumption to the EU.

The laboratories carrying out the testing need to demonstrate that their analytical methods are fit for purpose – i.e. capable of accurately detecting residues at the level of interest – typically the maximum residue limit applicable in the EU – and are reliable i.e. perform consistently.

5.1. Validation of analytical methods

Laboratories must use only analytical methods which are validated in the matrix concerned and demonstrated to work in the laboratory in a reliable way. For the analysis of residues of pharmacologically active substances, Official laboratories in the EU Member States must validate methods following the rules laid down in [Regulation \(EU\) 2021/808](#).

Laboratories in third countries may use the approach described in this Regulation as the basis for their method validation. Alternatively, laboratories may adopt the approaches described in international guidelines such as that from the [Codex Alimentarius \(CAC/GL 71-2009\)](#) or the International Union of Pure and Applied Chemistry's [Harmonized guidelines for single-laboratory validation of methods of analysis](#).

Regardless of the approach employed, laboratories must have documentary evidence supporting their claims for reliable analytical method performance. In the event that a Commission audit is carried out in the third country, this aspect is always checked.

5.2. Ongoing quality assurance

The initial validation of analytical methods, while important, does not demonstrate the ongoing consistent performance of the methods. Laboratories must have a documented quality assurance system in place which will demonstrate that methods perform reliably over time.

Typically such assurance would comprise elements such as running known 'positive' and 'negative' control samples in each analytical run, maintaining control charts to assess ongoing performance and, where available, participating in interlaboratory comparison tests (proficiency tests). There are a number of commercial proficiency test providers providing test materials relevant for veterinary drug residues⁽¹³⁾. The [European Union Reference Laboratories](#) (EURLs) for residues⁽¹⁴⁾ also organise regular proficiency tests and governmental laboratories from third countries can participate in these tests at their own cost.

5.3. Laboratory accreditation

In the EU Member States, Article 37 of the Official Controls Regulation ([Regulation \(EU\) 2017/625](#)) requires that every laboratory carrying out official controls must not only be accredited to the international standard [ISO/IEC 17025](#) but each analytical method used for official testing must be included within the scope of accreditation. Scopes of accreditation may either be fixed or flexible⁽¹⁵⁾.

Commission approval of a third country residue control plan is contingent upon the competent authority in that third country using an ISO/IEC 17025 accredited laboratory.

There is no obligation for the laboratory to be located in that third country but, regardless of where it is situated, it must be accredited to this international standard.

Ideally, the methods used for residue analysis should be included in the laboratory's scope of accreditation. This provides the competent authority contracting the laboratory with confidence that the laboratory is operating to an internationally recognised standard and that the methods have been assessed by an independent accreditation body.

⁽¹³⁾ The EPTIS database is a useful resource for identifying available proficiency testing schemes, world-wide. See <https://www.eptis.org/>

⁽¹⁴⁾ Contact details for the EURLs are available here: https://food.ec.europa.eu/horizontal-topics/european-union-reference-laboratories_en#food_and_feed

⁽¹⁵⁾ See International Laboratory Accreditation Cooperation (ILAC) Guidance document ILAC-G18:12/2021 available here <https://ilac.org/publications-and-resources/ilac-guidance-series/>

Appendix 1

[See Annex I to Regulation \(EU\) 2022/1644](#)

Group A – Prohibited or unauthorised pharmacologically active substances in food-producing animals

1. Substances with hormonal and thyrostatic action and beta agonists the use of which is prohibited under Council Directive 96/22/EC:
 - (a) Stilbenes;
 - (b) Antithyroid agents;
 - (c) Steroids;
 - (d) Resorcylic acid lactones, including zeranol;
 - (e) Beta-agonists.
2. Prohibited substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010:
 - (a) Chloramphenicol;
 - (b) Nitrofurans;
 - (c) Dimetridazole, metronidazole, ronidazole and other nitro-imidazoles;
 - (d) Other substances.
3. Pharmacologically active substances, not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 or substances not authorised for use in feed for food-producing animals in the Union according to Regulation (EU) No 1831/2003 of the European Parliament and of the Council:
 - (a) Dyes;
 - (b) Plant protection products as defined in Regulation (EU) No 1107/2009 of the European Parliament and of the Council and biocides as defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council which may be used in animal husbandry of food-producing animals;
 - (c) Antimicrobial substances;
 - (d) Coccidiostats, histomonostats and other antiparasitic agents;
 - (e) Protein and peptide hormones;
 - (f) Anti-inflammatory substances, sedatives and any other pharmacologically active substances;
 - (g) Antiviral substances.

Group B – Pharmacologically active substances authorised for use in food-producing animals

1. Pharmacologically active substances listed in Table 1 of the Annex to Regulation (EU) No 37/2010:
 - (a) Antimicrobial substances;
 - (b) Insecticides, fungicides, anthelmintics and other antiparasitic agents;
 - (c) Sedatives;
 - (d) Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and glucocorticoids;
 - (e) Other pharmacologically active substances.
2. Coccidiostats and histomonostats authorised according to Union legislation, for which maximum levels and maximum residue limits are set under Union legislation

Appendix 2

[See Annex I to Regulation \(EU\) 2022/1646](#)

Minimum sampling frequency per Member State in the national risk-based control plan for production in the Member States (as referred to in Article 4(c))

The minimum number of samples is as follows:

	Sampling frequency - Group A substances
Bovine	Minimum 0.25 % of the slaughtered animals, (minimum 25 % of the samples to be taken from live animals on the farm and minimum 25 % of the samples to be taken at the slaughterhouse)
Sheep and goats	Minimum 0.01 % of the slaughtered animals per species
Porcine	Minimum 0.02 % of the slaughtered animals
Equine	Minimum 0.02 % of the slaughtered animals
Poultry	For each category of poultry considered (broiler chickens, spent hens, turkeys and other poultry) minimum 1 sample per 400 tons of annual production (deadweight)
Aquaculture (finfish, crustaceans and other aquaculture products)	Minimum 1 sample per 300 tonnes of annual production of aquaculture for the first 60 000 tonnes of production and then 1 additional sample for each additional 2 000 tonnes
Bovine, ovine and caprine milk	Minimum 1 sample per 30 000 tonnes of annual production of milk per species
Hen eggs and other eggs	Minimum 1 sample per 2 000 tonnes of annual production of eggs per species
Rabbits, farmed game, reptiles [†] and insects [†]	Minimum 1 sample per 100 tonnes of annual production (dead weight) of rabbits, farmed game or reptiles [†] for the first 3 000 tonnes of production and 1 sample for each additional 1 000 tonnes. Minimum 1 sample per 25 tonnes annual production of insects [†]
Honey	Minimum 1 sample per 50 tonnes of annual production for the first 5 000 tonnes of production and then 1 additional sample for each additional 500 tonnes
Casings [*]	Minimum 1 sample per 300 tonnes of annual production

* As defined in Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

[†] Residue control plans for reptiles and insects are not required from third countries - see Article 5(2) of [Commission Delegated Regulation \(EU\) 2022/2292](#).

	Sampling frequency - Group B substances
Bovine	Minimum 0.10 % of the slaughtered animals
Sheep and goats	Minimum 0.02 % of the slaughtered animals per species
Porcine	Minimum 0.02 % of the slaughtered animals
Equine	Minimum 0.02 % of the slaughtered animals
Poultry	For each category of poultry considered (broiler chickens, spent hens, turkeys and other poultry) minimum 1 sample per 500 tonnes of annual production (deadweight)
Aquaculture (finfish, crustaceans and other aquaculture products)	Minimum 1 sample per 300 tonnes of annual production of aquaculture for the first 60 000 tonnes of production and then 1 additional sample for each additional 2 000 tonnes
Bovine, ovine and caprine milk	Minimum 1 sample per 30 000 tonnes of annual production of milk per species
Hen eggs and other eggs	Minimum 1 sample per 2 000 tonnes of annual production of eggs per species

	Sampling frequency - Group B substances
Rabbits, farmed game, reptiles [†] and insects [†]	Minimum 1 sample per 50 tonnes of annual production (dead weight) of rabbits, farmed game or reptiles [†] for the first 3 000 tonnes of production and 1 sample for each additional 500 tonnes Minimum 1 sample per 25 tonnes annual production of insects [†]
Honey	Minimum 1 sample per 50 tonnes of annual production for the first 5 000 tonnes of production and then 1 additional sample for each additional 500 tonnes

Additional provisions

- (a) If relevant to verify compliance with Union legislation on the use of prohibited or unauthorised pharmacologically active substances, Member States may take samples from feed, water or another relevant matrix or environment and counted towards achieving the minimum sampling frequencies provided for in this Annex.
- (b) Controls on each combination of sub-groups of Group A substances and commodity groups as listed in Annex II to Delegated Regulation (EU) 2022/1644 shall be annually performed in minimum 5 % of the samples taken in accordance to the table of this Annex for that commodity group. This minimum percentage does not apply to casings and it does not apply to group A(3), point (f) for all commodity groups.
- (c) For the Group B substances, the selection of specific substances for testing within each substance group is to be decided according to criteria listed in Annex II Delegated Regulation (EU) 2022/1644.
- (d) Within bovine, ovine and caprine group, the samples shall be taken from all species, taking into account their relative production volume. Sampling shall cover both animals for dairy production and for meat production.
- (e) Within the poultry group, samples shall be taken from broiler chickens, spent hens, turkey and other poultry, taking into account their relative production volume.
- (f) Within the aquaculture group, samples shall be taken from fresh and seawater aquaculture species, taking into account their relative production volume.
- (g) When there is a reason to believe that pharmacologically active substances are being applied to the other aquaculture products, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.
- (h) The necessary number of targeted samples shall be taken in order to achieve the prescribed sampling frequency. This refers to the number of animals sampled (or group of animals likely to be treated in a certain group (e.g. fish)) irrespective of number of tests carried out per sample.
- (i) When substances from Group A and Group B are analysed in one sample from a single animal, this sample can be taken into account towards the minimum sampling frequency for both groups (Group A and Group B) given that it can be documented, and that the risk criteria for Group A and Group B are the same. If another sample of another matrix is taken from the same animal for the analysis of group A and/or group B substances, the result is not taken into account towards the minimum sampling frequency. However in case substances from Group A are analysed in a sample of one matrix from a single animal and substances from Group B are analysed in a sample of another matrix from the same animal, then both samples can be taken into account towards the minimum sampling frequency for both groups (Group A and Group B) given that it can be documented, and that the risk criteria for Group A and Group B have been applied.
- (j) Suspect samples taken during the follow-up of a non-compliance in accordance with Regulation (EU) 2019/2090 shall not be counted in order to achieve the prescribed sampling frequency for the risk-based plan for EU-production.
- (k) For calculating the minimum sampling frequencies, Member States shall use the most recent production data available, at least from previous or at maximum from penultimate year, adjusted, if relevant, to reflect known evolutions in production since the data were made available.
- (l) In case the sampling frequency calculated in accordance with this Annex would represent less than five samples per year, sampling may be carried out once per two years. In case that, within a two years period, the production corresponding to a minimum of one sample is not reached, a minimum of one sample once per two years shall be analysed provided that production takes place for that species or product in the Member State.
- (m) Samples taken for the purposes of other control plans relevant for analysis on pharmacologically active substances and residues thereof (e.g. on contaminants, on pesticide residues, etc.) may also be used for controls on pharmacologically active substances provided that the requirements concerning the controls on pharmacologically active substances are complied with.

Appendix 3

Commission Delegated Regulation (EU) 2022/2292, Annex I, Part II

Third country control plan for pharmacologically active substances, pesticides and contaminants – required information

A. Scope of the control plan for pharmacologically active substances, pesticides and contaminants

1. List of categories of food-producing animals, products of animal origin, including those used as ingredients in composite products, covered by the control plan for pharmacologically active substances, pesticides and contaminants, including details on the species and sub-species of animals.
2. Information on the origin of the food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants, in particular whether they are produced, within the third country, entirely from animals or products of animal origin that originate from that country or whether they include animals or products of animal origin that originate from other third countries or Member States. If the food-producing animals and products of animal origin are not produced in the third country submitting the control plan for pharmacologically active substances, pesticides and contaminants, information shall be provided on the countries of origin and the intended purpose of those animals and products of animal origin, in particular by explaining if the products of animal origin are intended for entry into the Union as such or as ingredients of composite products.
3. National production data from the previous year for the animal species and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants..
4. An explanation of whether, for the animals and products of animal origin concerned, the control plan for pharmacologically active substances, pesticides and contaminants covers the total national production or a proportion of the national production (for example, the production of certain farms/producers and the throughput of certain establishments, intended for entry into the Union). If only part of the national production is covered, a description of the system in place to ensure that only those animals and products of animal origin from that segregated population covered by the control plan for pharmacologically active substances, pesticides and contaminants are eligible for entry into the Union.

B. Competent authorities responsible and their legal powers

1. Contact details of the competent authorities: name and address of the central competent authority or authorities and contact point details for correspondence on the control plan for pharmacologically active substances, pesticides and contaminants (e.g., email addresses, telephone numbers).
2. A description of the structure of the competent authorities, including, where relevant, the various levels of organisation (e.g. central, regional, local), the departments involved and organisational charts.
3. A description of the role of the competent authorities involved in the implementation of the control plan for pharmacologically active substances, pesticides and contaminants, including on aspects related to the drawing up of the control plan for pharmacologically active substances, pesticides and contaminants, the coordination and supervision of the implementation of the control plan for pharmacologically active substances, pesticides and contaminants, the collection of samples, the collation and evaluation of results, the application of corrective measures, if required, that are effective, proportionate and dissuasive to stop re-occurrence of non-compliance, and the submission of an updated control plan for pharmacologically active substances, pesticides and contaminants to the Commission.
4. The legal basis of the control plan for pharmacologically active substances, pesticides and contaminants, including references to the specific provisions giving the competent authorities the right to enter the relevant premises, to collect samples, to carry out follow-up investigations where non-compliant results are detected and to impose corrective actions in such cases, for example, restrictions on the movement of animals, the destruction of animals or the imposition of fines.

C. Pharmacologically active substances

1. The requirements met by the control plan for pharmacologically active substances, pesticides and contaminants, in particular whether such requirements are those referred to in Article 4 of Implementing Regulation (EU) 2022/1646, or equivalent requirements. In the latter case, further details shall be provided on how these requirements address all of the points listed under Part II, points C to K, of this Annex.

2. The list of groups of substances covered by the control plan for pharmacologically active substances, pesticides and contaminants for each animal species and product as specified in:
 - a) point A.1 of Annex II to Delegated Regulation (EU) 2022/1644 for group A substances referred to in Annex I to Delegated Regulation (EU) 2022/1644;
 - b) point B.1 of Annex II to Delegated Regulation (EU) 2022/1644 for group B substances referred to in Annex I to Delegated Regulation (EU) 2022/1644.
3. Within the groups of substances covered by the control plan, the list of substances and their marker residues to be analysed for the specific animal species and products in the specific matrices, including a justification for their selection based on the risk criteria set in Annex II to Delegated Regulation (EU) 2022/1644.
4. Within the groups of substances covered by the control plan, the list of substances and their marker residues to be analysed for the specific animal species and products in the specific matrices, including a justification for their selection based on the risk criteria set in Annex II to Delegated Regulation (EU) 2022/1644.
5. The number of samples per animal species and products for each of the groups of substances covered by the control plan based on the control frequencies laid down in Annex I to Implementing Regulation (EU) 2022/1646, or equivalent guarantees. A description of the criteria for selection of sampling points and animals or products of animal origin to be sampled based on the criteria laid down in Annex II to Delegated Regulation (EU) 2022/1644
6. A description of the sampling strategy, explaining how it addresses the provisions of Annex III to Delegated Regulation (EU) 2022/1644.

D. Pesticides

1. The list of substances tested for in the control plan for pharmacologically active substances, pesticides and contaminants and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants in accordance with the requirements laid down in Implementing Regulation (EU) 2021/1355.
2. A justification for the selection of substances covered by the control plan for pharmacologically active substances, pesticides and contaminants, in particular that the range of substances tested for is representative of the pesticides used.
3. The controls shall provide guarantees on the compliance of food of animal origin intended for entry into the Union with the maximum residue levels referred to in Regulation (EC) No 396/2005. These guarantees shall be provided for all pesticides authorised in the third country, in particular for those pesticides, which are authorised in the third country, but not authorised in the Union.
4. A justification for the selection of pesticides covered by the plan, taking into account the risks from animal feed and the environment and the pesticides for which maximum residue levels are established in the Union, as well as a justification for the number of samples planned, based on the level of confidence achieved in identifying a certain percentage of exceedance of the maximum residue levels set out in Union legislation for the animals and products of animal origin intended for entry into the Union.

E. Contaminants

1. The list of contaminants tested for in the control plan for pharmacologically active substances, pesticides and contaminants and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants, in accordance with the requirements laid down in Delegated Regulation (EU) 2022/931 and Implementing Regulation (EU) 2022/932.
2. A justification for the selection of contaminants covered by the control plan for pharmacologically active substances, pesticides and contaminants taking into account the risks from animal feed and the environment, as well the contaminants for which maximum limits have been set in the Union in products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants.

F. Analytical methods and laboratories

1. The list of official laboratories or contracted laboratories, or both, involved in carrying out analyses for the control plan for pharmacologically active substances, pesticides and contaminants.
2. The accreditation status, including the scope of accreditation, of each of the official laboratories carrying out

analyses for the control plan for pharmacologically active substances, pesticides and contaminants.

3. For each of the laboratories, a list of all the methods used in the control plan for pharmacologically active substances, pesticides and contaminants, with an indication on whether they are included or not in the scope of accreditation for the specific matrices covered by the control plan for pharmacologically active substances, pesticides and contaminants.
4. For each of the laboratories, a list of the methods used in the control plan for pharmacologically active substances, pesticides and contaminants, with an indication of whether they are validated in accordance with the relevant Union rules, or equivalent rules, or not validated, for the specific matrices covered by the control plan for pharmacologically active substances, pesticides and contaminants, specifying the standard used for validation.
5. For each of the substances tested for in the control plan for pharmacologically active substances, pesticides and contaminants, a list of the analytical methods and regulatory standards used for interpreting analytical results and the performance requirements of the analytical methods, including information on:
 - a) the analysed substance and marker residues;
 - b) the analysed matrices;
 - c) the analytical method identification (e.g. ELISA, LC-MS/MS, AAS);
 - d) the analytical method type (screening or confirmatory);
 - e) the screening and confirmatory methods used, the limits of detection and limits of quantification or, if relevant, the decision limit for confirmation (CC α) and detection capability for screening (CC β) as defined in Article 2, second paragraph, points (14) and (15), of Implementing Regulation (EU) 2021/808;
 - f) the concentration above which a result is considered non-compliant for the purpose of the control plan for pharmacologically active substances, pesticides and contaminants. In particular, differences with the limits set out in the Union legislation shall be indicated.

G. Pharmacologically active substances authorised in veterinary medicinal products or as feed additives for use in food-producing animals and prohibitions on use in such animals

1. The national legislation governing the placing on the market and conditions for use of veterinary medicinal products in relation to food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, including references to the relevant provisions.
2. The list of authorised veterinary medicinal products for the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants indicating for each product, the product name, the pharmacologically active substance(s) contained therein and target species. Those substances which are authorised in the third country but which are not authorised for such use in the Union shall be highlighted in the list. The list shall also include feed additives that are pharmacologically active, such as antibiotics, coccidiostats and histomonostats.
3. A description of the system in place to ensure that, for each of the substances which are authorised in the third country for use in the animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, but not authorised for such use in the Union, there are no residues present at concentrations which can be reliably quantified in such animals or products of animal origin intended for entry into the Union. Evidence shall be provided that such substances are tested for in the appropriate matrices in the control plan for pharmacologically active substances, pesticides and contaminants for the relevant animals and products of animal origin.
4. A statement on whether any of the substances included in Table 2 of the Annex to Regulation (EU) No 37/2010 are authorised for use in the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants. If such substances are authorised, a description of the system ensuring that animals treated with such substances and products derived therefrom are not eligible for entry into the Union shall be provided. If use of such substances in food-producing animals is prohibited in the third country, a reference to the national legal basis for that prohibition shall be provided.
5. A confirmation that stilbene substances (i.e. stilbenes, stilbene derivatives, their salts and esters) or thyrostatic substances are not authorised for use in food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, regardless of their eligibility for entry into the Union, and a reference to the national legal basis for that prohibition.

6. A statement on whether substances having an oestrogenic, androgenic or gestagenic action and beta-agonists are authorised for growth promotion purposes in the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants. If such substances are authorised, a detailed description of the system in place to ensure that treated animals are not eligible for entry into the Union shall be provided. If such substances are either not authorised or are expressly prohibited, a reference to the national legal basis for the prohibition shall be provided.

H. Specific information for bovine, caprine and ovine animals and products of animal origin derived therefrom, including milk

1. A statement on whether 17-beta oestradiol and its ester-like derivatives are authorised and used in veterinary medicinal products for any purpose in the species in question, including zootechnical or therapeutic treatments. If such substances are authorised, a description of the system ensuring that animals treated with such substances and the products derived therefrom are not eligible for entry into the Union shall be provided. If such substances are prohibited, a reference to the national legal basis for the prohibition shall be provided.
2. Bovine, caprine and ovine animals and products of animal origin derived therefrom, including milk eligible for entry into the Union from a third country included in the list of third countries with an approved control plan for pharmacologically active substances, pesticides and contaminants, referred to in Annex -I to Implementing Regulation (EU) 2021/405, shall originate in that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

I. Specific information for honey

1. If antimicrobial substances are authorised for the treatment or prevention of diseases in honeybees, a description of the system in place to provide guarantees that no residues are present, at concentrations which can be quantified, in honey intended for entry into the Union.
2. Honey intended for entry into the Union from a third country included in a list of third countries with approved control plan for pharmacologically active substances, pesticides and contaminants as referred to in Annex -I to Implementing Regulation (EU) 2021/405 shall originate in the territory of that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

J. Specific information for aquaculture

1. If dyes are authorised for the treatment and prevention of disease at any stage of production, a description of the dyes used and the fishery products (including crustaceans) for which the treatment is authorised and of the system in place to provide guarantees that no residues are present at concentrations which can be quantified in aquaculture products intended for entry into the Union.
2. Aquaculture products intended for entry into the Union from a third country included in a list of third countries with approved control plan for pharmacologically active substances, pesticides and contaminants as referred to in Annex -I to Implementing Regulation (EU) 2021/405 shall originate in the territory of that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

K. Specific information for equine animals

1. A description of the system in place to ensure that equine animals treated with substances prohibited or not authorised in the Union for use in food-producing animals and products for human consumption derived from such animals are not eligible for entry into the Union. The following elements of such a system shall be described:
 - a) identification and traceability of equine animals;
 - b) record keeping of administration of veterinary medicinal products;
 - c) records indicating all treatments with pharmacologically active substances.
2. Where equine animals are treated with substances considered essential under Union rules, a description of the system in place to ensure that food derived from such animals is not eligible for entry into the Union until six months have elapsed since the last treatment.
3. Food-producing equine animals eligible for entry into the Union shall originate from the territory of the third country which intends to export equine animals or in other countries implementing a control plan for

pharmacologically active substances, pesticides and contaminants approved by the Commission.

L. Specific information to be provided by the third countries referred to in Article 8(1) and (2)

1. A statement by the competent authority of the third country confirming that products of animal origin intended for entry into the Union as such, or as ingredients of composite products, only originate in approved third countries included in the list of third countries with an approved control plan for pharmacologically active substances, pesticides and contaminants for those food-producing animals or products of animal origin, and that the procedures it has in place for this purpose are sufficient to guarantee the traceability and origin of those products of animal origin.
2. A comprehensive description, by the competent authority of the third country, of the procedures in place in the third country, to substantiate the statement referred to in point 1.

M. Specific information for casings

A description of the system in place to ensure that no antimicrobial substances, the use of which in food-producing animals is prohibited in the Union in accordance with Table 2 of the Annex to Regulation (EU) No 37/2010, are used in the treatment of casings.

Appendix 4

See Annex II to Regulation (EU) 2022/1644

Criteria for the selection of specific combination of substance groups and commodity groups for national risk-based control plan for production in the Member States

A. Group A substances

1. Combinations of substance groups and commodity groups:

Substance group by reference to Annex I	Commodity group									
	Bovine, ovine and caprine	Porcine	Equine	Poultry	Aquaculture (finfish, crustaceans and other aquaculture products)	Raw bovine, ovine and caprine milk	Hen eggs and other eggs	Rabbits, farmed game and, reptiles and insects	Honey	Casings*
A(1), point (a)	X	X						** X		
A(1), point (b)	X	X	X					*** X		
A(1), point (c)	X	X	X		**** X			*** X		
A(1), point (d)	X	X						*** X		
A(1), point (e)	X	X	X	X				*** X		
A(2)	X	X	X	X	X	X	X	X	X	X
A(3), point (a)					X					
A(3), point (b)	X	X	X	X	X	X	X	X	X	
A(3), point (c)	X	X	X	X	X	X	X	v**X	X	
A(3), point (d)	X	X		X			X	v**X		
A(3), point (e)										
A(3), point (f)	X	X	X	X	X	X	X	X	X	
A(3), point (g)										

* As defined in Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

** Not relevant for insects; *** Relevant only for reptiles; **** Relevant only for finfish

- The residue or substance groups shall be analysed in samples drawn from foodproducing animals including, where appropriate, their excrements, body fluids and unprocessed animal products, feed, water and animal by-products.
- When there are indications or suspicions that illegal treatments may take place for residue or substance groups in species or products not covered by the table of this Annex, these controls shall be also included in the risk-based control plan for production in the Member States.

Note that Residue control plans for reptiles and insects are not required from third countries - see Article 5 of Delegated Regulation (EU) 2022/2292.

2. Criteria for selecting specific substances for testing within each substance group:

- frequency of the detection of non-compliance in the Member State or reported in the results from other Member States, or in third countries' samples, especially when reported under the Rapid Alert System for Food and Feed ('RASFF') or the Administrative Assistance and Cooperation System ('AAC') or where there is evidence that substances not authorised for use in food-producing animals in the Union are used in third countries;
- availability of suitable laboratory methods and analytical standards;
- pharmacologically active substances likely to be misused in order to increase production or increase feed conversion efficiency;
- prohibited or unauthorised substances for which there are indications of misuse;
- possible risk for consumers or certain population groups arising from consumption of residues present in food, taking into account the relevant information available from, inter alia, the European Medicines Agency, European Food Safety Authority and the Codex Alimentarius Joint Expert Committee on Food Additives or in absence of such information, other sources of information such as scientific publications or national risk assessment.

3. Criteria for the selection of animals and products of animal origin:

- indication of the use of specific pharmacologically active substances, including mutilations at the ears or the tail or the presence of injection sites;
- secondary sexual characteristics, behavioural changes, signs of disease or chronic disorders, different health status of specific animals within a group;
- sex, age and pregnancy status of the animals;
- veterinary history of the animal and health certificate;
- animals showing a good physical conformation and well-developed muscles with little fat.

B. Group B substances

1. Criteria for selecting specific substances for testing within each substance group:

- frequency of the detection of non-compliance in the Member State's samples, in other Member States' samples or in third countries' samples, especially when reported under the RASFF or AAC.
- availability of suitable laboratory methods and analytical standard;
- information on the quantities of the veterinary medicinal product produced, imported, exported, marketed and sold for a specific food-producing animal species;
- information on the veterinary medicinal product distribution chain, the national register of pharmacologically active substances, authorised as veterinary medicinal products or feed additives, information on the most popular prescribing patterns;
- the likelihood of misuse of the pharmacologically active substances;
- maximum residue limits and maximum levels for pharmacologically active substances and feed additives including restrictions (e.g. not for use in lactating animals);
- formulations of veterinary medicinal products for which long withdrawal periods, post-animal treatment, have been established to ensure that edible unprocessed animal products comply with EU MRLs;
- possible treatment of food-producing animals under Articles 113 and 114 of the Regulation (EU) 2019/6 of the European Parliament and of the Council.

2. Criteria for the selection of substance groups and animals and products of animal origin:

- information on the marketing authorisations for veterinary medicinal products containing pharmacologically active substances for specific animal species and production classes;
- information on the marketing authorisations for feed additives for specific animal species and production classes;
- information on the frequency of the use of substances from specific substance categories in specific animal species;
- frequency of the detection of non-compliance for residues of pharmacologically active substances and feed additives per production category;
- information on the rates of antimicrobial resistance in certain animal production sectors.

Appendix 5

[See Annex III to Commission Delegated Regulation \(EU\) 2022/1644](#)

Criteria for sampling strategy for national risk-based control plan for production in the Member States (as referred to in Article 2(2))

1. Sampling shall be carried out in variable intervals spread evenly over all months of the year or relevant production period. In this context, it shall be considered that a number of pharmacologically active substances are administered only in particular seasons.
2. Sampling shall be performed at or close to slaughter, collection or harvest. However, for Group A substances sampling should also be performed at any relevant stage in the life cycle of the animals.
3. All samples shall be targeted according to the criteria laid down in the national control plan. For Group A substances, sampling shall be targeted at detection of illegal treatment with prohibited or unauthorised substances – thus animals which are most likely to have been treated are preferentially selected over those animals which are not, and, as much of this sampling is carried out on farm, samples of drinking water and feed may be appropriate in addition to inedible materials such as blood, urine, faeces, hair etc.
4. For Group B substances, samples shall comprise only edible tissues/products (the objective is to verify compliance with maximum residue limits and maximum levels). Sampling shall be targeted on products from those animals, which are most likely to have been treated with a specific pharmacologically active substance or therapeutic class of drug.
5. Samples from injection sites can be appropriate to control the illegal use of substances. In case samples are taken from injection sites, this shall be clearly mentioned when reporting analytical results from these samples.
6. Criteria for the selection of the animals or products to be controlled for each food business operator to be controlled:
 - history of non-compliance of the farm or producer;
 - shortcomings in the application of veterinary medicinal products, deficiencies identified in previous controls, reported increase of losses of animals on the farm, animal health status of the farm, epidemiological status of the region;
 - information on the farming system, fattening system, breed and sex of the animals;
 - common practices with regard to the administration of particular pharmacologically active substances in the respective farm or production system;
 - indications of the use of pharmacologically active substances;
 - the absence or the unreliability of own-checks, the membership of quality assurance schemes (when available) and results of testing under such schemes;
 - evidence of insufficient supervision of the farm by veterinarians;
 - representative sampling regardless the size of the food business operator.
7. Criteria for the selection of slaughterhouses, cutting plants, establishments for the milk production, establishments for the production and placing on the market of aquaculture products, establishments for honey and egg and egg packing centres from which samples should be taken:
 - the criteria listed under points A.2 and B.1 of Annex II and point 6 of Annex II;
 - the respective establishments' share of the country's total production volume;
 - non-compliance identified in earlier controls on the use of pharmacologically active substances and residues thereof in animals and animal products;
 - origins and transport routes of the slaughtered animals, milk, eggs or honey;
 - absence of participation in quality assurance programmes (when available);
 - the scope and results of own-checks for residues.
8. When taking the samples, efforts shall be made to avoid multiple sampling (i.e. the taking of several different samples from a single animal/product (unless the different samples are analysed for a different group of substances), or sampling several animals/products from a single producer on a given day when samples could be drawn from animals/products from several producers which would satisfy the targeting criteria) unless the operator has been identified on the basis of the criteria included in point 6 or an appropriate justification has been provided in the control plan. The compliance with the planned frequency of checks shall be ensured.

Appendix 6

Commission Delegated Regulation (EU) 2022/2292, Annex I, Part III

Updated control plan for pharmacologically active substances, pesticides and contaminants – required information

A. Changes introduced in the updated control plan for pharmacologically active substances, pesticides and contaminants

1. Updated production data of the animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants and the impact on the number of planned samples.
2. Details on any changes that have occurred since the previous annual submission of the control plan for pharmacologically active substances, pesticides and contaminants and that alter the information previously provided under Part II, points A to M.
3. In the absence of changes, a statement that no changes have occurred shall be included under Part II, points A to M, where relevant.

B. Results of the implementation of the previous year's control plan for pharmacologically active substances, pesticides and contaminants

1. The results of the implementation of the previous year's control plan for pharmacologically active substances, pesticides and contaminants, together with the updated control plan for pharmacologically active substances, pesticides and contaminants.
2. A justification for any discrepancies between the number of samples or the substances planned to be analysed and the number of samples and/or the substances actually analysed.
3. Details on results non-compliant with Union maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides or maximum levels of contaminants, including, for each of these non-compliant results, the dates of sampling, dates of availability of the analytical results, marker residues identified, concentrations measured, analytical methods used and the laboratories involved.
4. For each of the non-compliant results, a description of the outcome of the follow-up investigations undertaken by the competent authorities, what the reason for the non-compliance was and any measures taken to prevent recurrence.

Appendix 7

Extract from Commission Implementing Regulation (EU) 2022/932 – Annex I

Commodity	Control frequency
Unprocessed bovine meat (including edible offal)	Minimum 0,02 % of the total number of slaughtered animals
Unprocessed ovine and caprine meat (including edible offal)	Minimum 0,004 % of the total number of slaughtered animals
Unprocessed porcine meat (including edible offal)	Minimum 0,003 % of the total number of slaughtered animals
Unprocessed equine meat (including edible offal)	The number of samples is to be determined by each Member State according to the level of production and the problems identified
Unprocessed poultry meat (including edible offal)	For each category of poultry considered (broiler chickens, spent hens, turkeys and other poultry) minimum 1 sample per 3 000 tonnes of annual production (deadweight)
Unprocessed meat from other farmed terrestrial animals (*) (including edible offal)	The number of samples is to be determined by each Member State according to the level of production and the problems identified
Raw bovine milk	Minimum 1 sample per 110 000 tonnes of annual production of milk
Raw ovine and caprine milk	The number of samples is to be determined by each Member State according to the level of production and the problems identified
Fresh hen eggs and other eggs	Minimum 1 sample per 3 700 tonnes of annual production of eggs
Honey	Minimum 1 sample per 1 300 tonnes of annual production
Unprocessed fishery products (**) (excluding crustaceans)	Minimum 1 sample per 700 tonnes of annual production of aquaculture for the first 60 000 tonnes of production and then 1 sample for each additional 2 000 tonnes For wild caught fishery products, the number of samples is to be determined by each Member State according to the level of production and the problems identified
Crustaceans and bivalve molluscs	The number of samples is to be determined by each Member State according to the level of production and the problems identified

(*) Other farmed terrestrial animals as defined in entry 1017000 of Annex I, part A, to Regulation (EC) No 396/2005.

(**) Fishery products as defined in Regulation (EC) No 853/2004.

(***) Processed products as defined in Regulation (EC) No 852/2004.

- (a) Member States shall annually perform controls on 'metals' in minimum 10 % of the samples taken for each commodity group in accordance to the table of this Annex with the exception of the commodity groups 'crustaceans and bivalve molluscs', 'animal and marine fats and oils' and 'processed products of animal origin'.
- (b) Member States shall annually perform controls on 'mycotoxins' in minimum 10 % of the samples taken for the commodity group 'raw bovine milk' and 'raw ovine and caprine milk' in accordance to the table of this Annex.
- (c) Within the commodity group 'unprocessed bovine, ovine and caprine meat (including edible offal)', Member States shall take samples from all species, taking into account their relative production volume.
- (d) Within the commodity group 'unprocessed poultry meat (including edible offal)', Member States shall take samples from all species, taking into account their relative production volume.
- (e) For the determination of the number of samples for fishery products and bivalve molluscs, Member States shall also take into account the geographical aspects, landing/production volumes and specific contamination patterns in the areas from which they are harvested.
- (f) For calculating the minimum control frequencies, Member States shall use the most recent production data available, at least from previous or at maximum from penultimate year, adjusted, if relevant, to reflect known evolutions in production since the data were made available.

- (g) In case the control frequency calculated in accordance with this Annex would represent less than five samples per year, sampling may be carried out once per two years.
- (h) In case that, within a three years period, the production corresponding to a minimum of one sample is not reached, Member States shall analyse a minimum of two samples once per three years provided that production takes place for that product in their territory.
- (i) Samples taken for the purposes of other control plans relevant for analysis on contaminants (e.g. on pharmacologically active substances and residues thereof, on pesticide residues), may also be used for controls on contaminants provided that the requirements concerning the controls on contaminants are complied with.

Extract from Commission Delegated Regulation (EU) 2022/931 – Annexes I and II

Rules for the selection of specific combination of contaminants or contaminant groups and commodity groups

- (1) Member States shall control the following combinations of contaminants or contaminant groups in the following commodity groups:

Commodity groups	Halogenated persistent organic pollutants	Metals	Mycotoxins	Other contaminants
Unprocessed bovine, ovine and caprine meat (including edible offal)	x	x		x
Unprocessed porcine meat (including edible offal)	x	x		x
Unprocessed equine meat (including edible offal)		x		x
Unprocessed poultry meat (including edible offal)	x	x		x
Unprocessed meat from other farmed terrestrial animals* (including edible offal)		x		
Raw bovine, ovine and caprine milk	x	x	x	x
Fresh hen eggs and other eggs	x	x		x
Honey		x		x
Unprocessed fishery products** (excluding crustaceans)	x	x		x
Crustaceans and bivalve molluscs	x	x		x

* Other farmed terrestrial animals as defined in entry 1017000 of Annex I, Part A, to Regulation (EC) No 396/2005.

** Fishery products as defined in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

- (2) Member States shall consider all combinations of contaminants or contaminant groups and commodity groups of food of non-animal origin for which maximum levels or other regulatory levels are set under Union legislation.
- (3) Each Member State shall consider the following criteria for selecting specific combinations of contaminants or contaminant groups and commodity groups to be controlled:
- (a) frequency of the detection of non-compliance in the Member State's samples, in other Member States' samples or in third countries' samples, especially when reported under the Rapid Alert System for Food and Feed or the Administrative Assistance and Cooperation System;
 - (b) availability of suitable laboratory methods and analytical standards;
 - (c) possible risk for consumers or certain population groups arising from consumption of

contaminants present in food, taking into account the relevant information available from the European Food Safety Authority, or in absence of such information, other sources of information such as scientific publications or national risk assessments;

- (d) consumption data (dietary exposure patterns);
- (e) as regards food falling within the scope of the control plan for food of animal origin entering the Union as described in Article 5 of Regulation (EU) 2022/932, the following criteria shall also be considered, where available:
 - (i) the outcome of Commission controls in third countries;
 - (ii) any information casting doubt on the reliability of guarantees on the compliance of imported food with Union rules;
 - (iii) information on increased vigilance

Criteria for sampling strategy

- (1) For each food business operator to be controlled, the Member State shall consider the following criteria for the selection of the type of food to be controlled:
 - (a) history of non-compliance;
 - (b) shortcomings in the application of Hazard Analysis and Critical Control Point and related auto controls;
 - (c) shortcomings in record keeping addressing requirements as defined in Section III, Part A, of Annex I to Regulation (EC) No 852/2004;
 - (d) representative sampling regardless of the size of the food business operator;
 - (e) emerging situations (changes in consumption patterns, natural disasters or economic problems that cause changes in food trade chains etc.).
- (2) Each Member State shall consider the following criteria for the selection of slaughterhouses, cutting plants, establishments for the milk production, establishments for the production and placing on the market of fishery products and aquaculture products, establishments for honey and egg and egg packing centres:
 - (a) the criteria listed under point (3) of Annex I and under point (1) of this Annex;
 - (b) the respective establishments' share of the Member State's total production volume of the slaughterhouses, cutting plants, establishments for milk production, establishments for production and placing on the market of fishery products and aquaculture products, establishments for honey and egg and egg packing centres;
 - (c) relevant origins of the slaughtered animals, milk, aquaculture products, honey and eggs.
- (3) When taking the samples, efforts shall be made to avoid multiple sampling from one food business operator, unless the operator has been identified on the basis of the criteria included in point (1) or an appropriate justification has been provided in the control plan. The compliance with the planned frequency of checks shall be ensured.
- (4) As regards food within the scope of the control plan for food placed on the Union market as set out in Article 4 of Regulation (EU) 2022/932, sampling shall be performed on food placed on the market and on food intended for placing on the market (primary stage, free-range, slaughterhouses, during food processing, storage or sale, etc.).

