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ANNEXES 1 to 2

## **ANNEXES**

**to the**

### **Commission Delegated Regulation**

**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 and repealing Commission Delegation Regulation (EU) 2019/625**

## **ANNEX I**

This Annex sets out the information on the control plans and updated control plans third countries are to submit for the purpose of their inclusion and maintenance in the list referred to in Article 6.

### **Part I**

#### ***General requirements as regards the submission of control plans and updated control plans***

1. The control plans third countries are to submit, together with their request for the inclusion in the list referred to in Article 6 for specific food-producing animals or products of animal origin, shall include the information specified in Part II of this Annex.
2. After a third country is included in the list referred to in point (1), for the purposes of maintenance on that list it shall submit annually updated control plans, with the information specified in Part III of this Annex.
3. Additional information to complement the control plans and updated control plans referred to in points (1) and (2) may be provided by third countries anytime.
4. The relevant guidance documents as regards contaminants, residues of veterinary medicinal products, prohibited substances and pesticides made publicly available by the Commission shall be taken into account by third countries for the submission of the control plans and updated control plans.
5. The control plans shall be sent to the Commission electronically, in the format described in the guidance documents referred to in point (4) or in another format, provided that it includes all of the information listed in Parts II and III, where applicable.

## Part II [

### *Third country control plan – required information*

The following information shall be provided:

#### **A) Scope of the control plan**

- (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, 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, 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 Union Member States. If the food-producing animals and animal products are not produced in the third country submitting the control plan, 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 the entry into the Union as such or as ingredients of composite products intended for entry into the Union.
- (3) National production data from the previous year for the animal species and animal products covered by the control plan.
- (4) An explanation of whether, for the animals and products of animal origin concerned, the control plan covers the total national production or a proportion of the national production (for example, the production of certain farms/producers and the throughput of establishments intending for the 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 are eligible for the Union market shall be provided.

#### **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 plans (e.g., email addresses, telephone details).
- (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 plans, including on aspects related to the drawing up of the control plan, the coordination and supervision of the implementation of the control plan, 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, and the submission of updated control plans to the Commission.
- (4) The legal basis of the control plan, 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 followed by the control plan, in particular whether such requirements are those referred to in Article 4 of Implementing Regulation (EU) 2022/xx (C(2022) 4401)[or equivalent. In the latter case, further details should be provided on how these requirements address all of the points listed under Part II, Sections C) to K), of this Annex.
- (2) The list of groups of substances covered by the control plan for each animal species and products as specified in Part I of this Annex and as specified in:
  - (1) point A)(1) of Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400) ] for group A substances as referred to in Annex I to Delegated Regulation (EU) 2022/xx (C(2022) 4400
  - (2) point B)(1) of Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400[for group B substances as referred to in Annex I to Delegated Regulation (EU) 2022/xx (C(2022) 4400)[.
- (3) For group B substances, the selection of groups covered by the control plan shall take into account the authorisation and use of such substances and the risks of residues in animals and products of animal origin intended for the entry into the Union.
- (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/x (C(2022) 4400)[ .
- (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/xx (C(2022) 4401) [or providing equivalent guarantees. A description of the criteria for selection of sampling points and animals or animal products to be sampled based on the criteria laid down in Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400) [
- (6) A description of the sampling strategy, explaining how it addresses the provisions of Annex III to Delegated Regulation (EU) 2022/x (C(2022) 4400) [

### **D) Pesticides**

- (1) The list of substances tested for in the control plan and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control programme 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, in particular that the range of substances tested for is representative of the pesticides used.
- (3) The controls should 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 should 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 animal products intended for entry into the Union.

#### **E) Contaminants**

- (1) The list of contaminants tested for in the control plan and the corresponding number of samples per category of food-producing animals and animal products covered by the control plan, 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 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 the animal products covered by the control plan.

#### **F) Analytical methods and laboratories**

- (1) The list of official laboratories or contracted laboratories, or both, involved in carrying out analyses for the control plans.
- (2) The accreditation status, including the scope of accreditation, of each of the official laboratories carrying out analyses for the control plans.
- (3) For each of the laboratories, a list of all the methods used in the control plan, with an indication on whether they are included or not in the scope of accreditation for the specific matrices of animal origin covered by the control plan.
- (4) For each of the laboratories, a list of the methods used in the control plan, with an indication of whether they are validated in accordance with the relevant Union rules, or equivalent, or not validated, for the specific matrices covered by the control plans, specifying the standard used for validation.
- (5) For each of the substances tested for in the control plan, a list of the analytical methods and regulatory standards to be used for interpreting analytical results and the performance requirements of the analytical methods, including information on:
  - (1) The analysed substance and marker residues;
  - (2) The analysed matrix;
  - (3) The analytical method identification (e.g. Elisa, LC-MS/MS, AAS);
  - (4) The analytical method type (screening or confirmatory);
  - (5) For the screening and confirmatory methods used, the limits of detection and limits of quantification or, if relevant, the decision limit for

confirmation (CC $\alpha$ ) and detection capability for screening (CC $\beta$ ) as defined in Article 2 of Implementing Regulation (EU) 2021/808;

- (6) The concentration above which a result is considered non-compliant for the purpose of the control plan. In particular, compliance with the limits set out in Union legislation should be verified and differences 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, including references to the relevant provisions covering the aforementioned points.
- (2) The list of authorised veterinary medicinal products for the food-producing animal species covered by the control plan 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 plans, 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 animal products intended for entry into the Union. Evidence shall be provided that such substances are tested for in the appropriate matrix in the control plan for the relevant animals and animal products.
- (4) A statement on whether any of the substances included in Table 2 of Regulation (EU) No 37/2010 are authorised for use in the food-producing animal species covered by the control plan. 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 the 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, 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 a oestrogenic, androgenic or gestagenic action and beta-agonists are authorised for growth promotion purposes in the food-producing animal species covered by the control plans. If such substances are authorised, a detailed description of the system in place to ensure that treated animals are not eligible for the 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 treated animals and the products derived therefrom are not eligible for the 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 eligible for the entry into the Union from a third country included in the list of third countries with approved control plans referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

**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 plans as referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

**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 the entry into the Union from a third country included in a list of third countries with approved control plans as referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

**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 derived from such animals are not eligible for entry into the Union for human consumption. The following elements of such a system should be described:
  - (1) Identification and traceability of equine animals;
  - (2) Record keeping of administration of veterinary medicinal products;

- (3) 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 the entry into the Union until six months have elapsed since the last treatment.
- (3) Food-producing equine animals eligible for the entry into the Union shall originate from the territory of the third country, which intends to import equine animals or in other countries implementing a control plan approved by the Commission.

**L) Specific information to be provided by the third countries referred to in Articles 7(1) and 7(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 approved control plans as referred to in Implementing Regulation (EU) 2021/405 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.

### **Part III**

#### ***Updated control plans***

The following information shall be provided:

**A) Changes introduced in the updated control plan**

- (1) Updated production data of the animals and animal products covered by the control plan 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 and which alter the information previously provided under Part II, Sections A) to M).
- (3) In the absence of changes, a statement that no changes have occurred shall be included under Part II, Sections A) to M), when relevant.

**B) Results of the implementation of the previous year's control plan**

- (1) The results of the implementation of the previous year's control plan, together with the updated control plan.
- (2) A justification for any discrepancies between the number of samples or the substance planned and the number of samples and/or the substances analysed.
- (3) Details on results non-compliant with the Union maximum residue levels, maximum residue limits or maximum limits, 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.

## **ANNEX II**

### **Correlation table referred to in Article 24, second paragraph**

Regulation (EU) 2019/625	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 13
Article 6	Article 14
Article 7	Article 15
Article 8	Article 16
Article 9	Article 17
Article 10	Article 18
Article 11	Article 19
Article 12	Article 20
Article 13	Article 21
Article 14	Article 22