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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and 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) ([1]), and in particular Article 19(3), points (a) and (b), thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States to verify compliance with Union legislation in the area of food and feed safety. In particular, Article 9 of that Regulation requires competent authorities to perform official controls on all operators regularly, on a risk basis and with an appropriate frequency. Article 109 of that Regulation obliges Member States to ensure that official controls are performed by the competent authorities on the basis of a multi-annual national control plan ('MANCP'). Regulation (EU) 2017/625 furthermore specifies the general content of the MANCP, including the requirement for Member States to provide in their MANCP 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. Regulation (EU) 2017/625 empowers the Commission to lay down specific additional content of the MANCP and specific additional arrangements for its preparation, as well as a uniform minimum frequency of official controls, having regard to the hazards and risks related to substances referred to in Article 19(1) of that Regulation.

(2) Regulation (EU) 2017/625 repealed Council Directive 96/23/EC ([2]) with effect from 14 December 2019 and lays down the relevant transitional measures. Those transitional measures provide that, until 14 December 2022, competent authorities are to continue to perform official controls necessary in accordance with Directive 96/23/EC to detect the presence of certain substances and groups of residues. Specifically, the transitory measures set requirements for Member States' monitoring plans for the detection of residues or substances within its scope.

(3) This Regulation ensures the continuity of the rules laid down in Directive 96/23/EC concerning the content of the MANCP and its preparation, as well as the minimum frequency of official controls, as regards official controls of residues of substances having a pharmacological action, of their metabolites and of other substances transmissible to animal products that are likely to be harmful to human health.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

(4) Regulation (EU) 2019/6 of the European Parliament and the Council ([3]) establishes the regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products. Furthermore, pharmacologically active substances, which are not authorised in veterinary medicinal products, may not be used in food-producing animals in the EU, with the exception of substances that are essential for the treatment of equine animals as provided for in Commission Regulation (EC) No 1950/2006 ([4]).

(5) Member States are required to include 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 in both food-producing animals and in products of animal origin in their MANCPs. In order to ensure harmonised and effective controls among Member States to combat the illegal use of growth and productivity promoters in kept animals in all Member States, uniform practical arrangements for the MANCPs should be further defined.

(6) In order to verify compliance with Union legislation 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, Member States shall carry out risk-based controls on food-producing animals and products of animal origin, produced in Member States or entering the Union from third countries. Those controls shall be included in each Member State's MANCP and comprise three plans: a risk-based control plan for production in the Member State, a risk-based control plan for third-country imports, and, in order to collect information useful to orientate future risk-based controls for production in the Member States, Member States should include a randomised surveillance plan.

(7) Commission Delegated Regulation (EU) 2022/1644 ([5]) lays down rules for the performance of official controls as regards the range of samples and the stage of production, processing and distribution at which the samples are to be taken 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.

(8) Both the sampling strategy and risk criteria for defining the content of the risk-based control plan for production in the Member State should be set in accordance with Delegated Regulation (EU) 2022/1644 and a justification should be included in that plan regarding the implementation of the risk criteria. Where, in the course of the execution of this control plan during a specific year, new information becomes available on illegal treatments, for example through the surveillance plan, Member States should update the risk-based control plan for production in the Member State without delay in order to ensure responsible use of pharmacologically active substances and a high level of human health protection. In order to guarantee a uniform minimum frequency of controls, this Regulation should define minimum control frequencies to be included in the MANCP.

(9) Member States shall also include in their MANCPs a dedicated surveillance plan, based on random sampling and testing for a wide range of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof which might not be included in the risk-based national plans.

([3]) Regulation (EU) 2019/6 of the European Parliament and the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([4]) Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae and of substances bringing added clinical benefit (OJ L 367, 22.12.2006, p. 33).

([5]) 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 (see page 3 of this Official Journal).

(10) For the surveillance plan, it is appropriate that about 8 000 samples across the Union are taken. The controls and the associated sampling should be apportioned across the Member States. Those minimum sampling frequencies should be included in the MANCP.

(11) In order to ensure that the results obtained under the surveillance plan are comparable, this plan should specify the type of analytical methods to be used and the method requirements. For the surveillance plan for prohibited and unauthorised substances, in addition to confirmatory methods, targeted and non-targeted screening methods are effective to identify unexpected illegal uses of authorised, prohibited and unauthorised pharmacologically active substances. For the surveillance plan for authorised substances, screening or confirmatory methods capable of quantifying residues below the maximum residue limit ('MRL') should be used and the concentrations which are quantified below the MRL should be reported in addition to those at or above the MRL.

(12) In addition to controls on Member States' production, Member States should include a control plan for products, which are intended for the entry into the Union from third countries in their MANCP in order to verify the effectiveness of third countries' residue controls and the compliance of imported products of animal origin with the Union rules. In order to guarantee a uniform minimum frequency of the controls carried out under the plan for third-country imports and to ensure that they are carried out at least at a frequency which is equal to the control frequency for risk-based control plan for production in Member States, this Regulation should define the minimum frequencies for those controls to be applied by Member States, through whose border control posts the animals and products of animal origin enter the Union.

(13) In order to ensure a harmonised and comprehensive content of the MANCP on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances in food-producing animals and residues thereof in animals and products of animal origin, the relevant aspects of its content should be defined.

(14) Sampling procedures, handling and transport conditions have an influence on the ability to detect the presence of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof in samples. Therefore, Member States should follow the rules laid down in Commission Implementing Regulation (EU) 2021/808 ([6]).

(15) It is necessary to ensure that the analytical results gathered under the control plans 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 and the interpretation of the results are comparable. Therefore, the plans should describe the analytical methods to be used as well as their performance requirements, in accordance with the provisions of Implementing Regulation (EU) 2021/808.

(16) In order to ensure that Member States' risk-based control plans for both Union production and for third-country imports, as well as their surveillance plans for production in the Member States, comply with this Regulation, Member States should submit these control plans to the Commission for evaluation annually. The Commission should communicate its comments to the Member States if needed. Member States should prepare a revised and updated plan incorporating the comments no later than 31 March of the following year. However, where the Commission considers that the plans would impair the effectiveness of official controls, it should be able to request the Member State to submit an updated plan addressing the Commission's comments at an earlier date.

([6]) Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC (OJ L 180, 21.5.2021, p. 84).

(17) In accordance with Article 33 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([7]), the data collected by the Member States through official controls in respect of 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 must be submitted to the European Food Safety Authority ('EFSA'). In order to allow for the monitoring of recent data, all Member States should submit data on a regular basis and by the same date.

(18) Commission Decision 97/747/EC ([8]), fixing levels and frequencies of sampling in addition to those provided for in the Annexes to Directive 96/23/EC, should be repealed as its provisions are replaced by the provisions of this Regulation.

(19) As the rules laid down in the Annexes to Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and products of animal origin are to be applied until 14 December 2022, this Regulation should apply from 15 December 2022.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

For the purpose 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, this Regulation lays down the following:

(a) the annual uniform minimum sampling frequency as part of official controls, having regard to the hazards and risks related to the substances concerned;

(b) specific additional arrangements and specific additional content for the Member States' multi-annual national control plan ('MANCP'), in addition to those provided for in Article 110 of Regulation (EU) 2017/625.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Regulation (EC) No 178/2002, Commission Delegated Regulation (EU) 2019/2090 ([9]), Implementing Regulation (EU) 2021/808 and Delegated Regulation (EU) 2022/1644 apply.

([7]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([8]) 97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12).

([9]) Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances (OJ L 317, 9.12.2019, p. 28).

CHAPTER II

SPECIFIC ADDITIONAL CONTENT OF THE MANCP

Article 3

General provisions

Member States shall ensure that the part of the MANCP concerning 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 in live animals and products of animal origin contains the following:

(a) a 'national risk-based control plan for production in the Member States', as set out in Article 4;

(b) a 'national randomised surveillance plan for production in the Member States' as set out in Article 5;

(c) a 'national risk-based control plan for third-country imports' as set out in Article 6.

Article 4

National risk-based control plan for production in the Member States

Member States shall prepare a national risk-based control plan for substances in groups A and B of Annex I to Delegated Regulation (EU) 2022/1644 to verify compliance of food-producing animals and products of animal origin produced in the Member States with Union legislation governing 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 and the applicable maximum residue limits ('MRL') and maximum levels ('ML') in food.

The national risk-based control plan for production in the Member States shall contain the following:

(a) the list of combinations of substances and species, products and matrices in accordance with Annex II to Delegated Regulation (EU) 2022/1644;

(b) the sampling strategy as decided by the Member State in accordance with Annex III to Delegated Regulation (EU) 2022/1644;

(c) the actual sampling frequencies as decided by the Member State taking into account the annual minimum control frequencies laid down in Annex I;

(d) the analytical methods to be used and their performance characteristics;

(e) the detailed information referred to in Article 7(1) and (2).

Pursuant to Article 111(2) of Regulation (EU) 2017/625, during the course of the execution of the MANCP, Member States shall review the national risk-based plan for production in the Member States to take account of illegal treatments identified, in particular, through the surveillance plan.

Article 5

National randomised surveillance plan for production in the Member States

Member States shall prepare a national randomised surveillance plan for the control of production in the Member States, ensuring random monitoring for a wide range of substances.

The national randomised surveillance plan for production in each Member State shall contain the following:

(a) the list of combinations of substances and species, products and matrices in accordance with Annex IV to Delegated Regulation (EU) 2022/1644;

(b) the sampling strategy as decided by the Member State set out in accordance with Annex V to Delegated Regulation (EU) 2022/1644;

(c) the actual sampling frequencies as decided by the Member State taking into account the minimum sampling frequencies prescribed in Annex II to this Regulation;

(d) the detailed information referred to in Article 7(1).

In accordance with the requirements for methods of analysis provided for in Implementing Regulation (EU) 2021/808, Member State shall use analytical methods for the analysis of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof in products of animal origin, which provide quantitative or semi-quantitative results, including when these residues are identified and quantified at levels below the MRL.

Member States shall include reporting requirements for the controls on the use of authorised substances, which ensure the reporting of all concentrations at or above the detection capability for screening ('CCβ') of the method, while ensuring that the lowest CCβ, which is reasonably achievable, is obtained for the methods, which are used to perform the screening analyses. For testing carried out with confirmatory methods only, all quantifiable results shall be reported. In case of use of targeted and non-targeted screening methods, Member States shall report on the use and the findings of these analytical methods.

Article 6

National risk-based control plan for third-country imports

Member States shall prepare a national risk-based control plan for food-producing animals and products of animal origin entering into the Union and intended for placing on the Union market through their border control posts ('BCP') and other points of entry such as on vessels according to Commission Implementing Regulation (EU) 2019/627 ([10]) to verify compliance with Union legislation on the use of pharmacologically active substances as listed in Annex I to Delegated Regulation (EU) 2022/1644 and compliance with applicable MRLs and MLs.

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 shall be carried out as part of the official controls at BCP provided for in Article 47 and Article 65 of Regulation (EU) 2017/625.

The national risk-based control plan for third-country imports shall contain the following:

(a) the list of combinations of substances and species, products and matrices in accordance with Annex VI to Delegated Regulation (EU) 2022/1644;

(b) the sampling strategy as decided by the Member State in accordance with Annex VII to Delegated Regulation (EU) 2022/1644;

(c) the actual sampling frequencies for controls carried out at BCP as decided by the Member State taking into account the annual minimum sampling frequencies in accordance with Annex III to this Regulation. The samples taken for the purpose of official controls carried out pursuant to Article 65(1), (2) and (4) of Regulation (EU) 2017/625, shall, however, not be considered as samples contributing to reach the minimum sampling frequencies of Annex III of this Regulation;

([10]) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

(d) the analytical methods to be used and their performance characteristics;

(e) the detailed information referred to in Article 7(1) and (2).

Article 7

Additional content of the national risk-based control plans and randomised surveillance plan

1. The national risk-based control plans, referred to in Articles 4 and 6, and national randomised surveillance plan, referred to in Article 5, shall specify the following information:

(a) the details on species to be sampled and on place of sampling;

(b) information on the national legislation on the use of pharmacologically active substances and, in particular, on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration, in so far as such legislation is not harmonised;

(c) information about the competent authorities responsible for the implementation of the plans;

(d) the type of follow-up measures taken by the competent authorities with regard to animals or products of animal origin in which non-compliant residues have been detected in the previous years

2. The national risk based control plans referred to in Articles 4 and 6 shall, in addition to the information specified in paragraph 1, provide the following:

(a) a justification for the selected substances, species, products and matrices included in the plans on the basis of the criteria listed in Annexes II and VI to Delegated Regulation (EU) 2022/1644, including a justification on how the criteria listed in those Annexes were taken into account, even if no changes were made compared to the plan of the previous year;

(b) a justification on how information from an overview of the non-compliances in the relevant Member State of the previous three calendar years provided by EFSA was taken into account for optimising the plan.

Member States do not need submit information already provided in the general part of the MANCP or described in Union legislation according to Article 110(2) of Regulation (EU) 2017/625.

CHAPTER III

SUBMISSION AND EVALUATION OF THE PLANS AND SUBMISSION OF DATA BY THE MEMBER STATES

Article 8

Submission and evaluation of the control plans

By 31 March of each year, Member States shall submit, in an agreed format, revised and updated national risk-based control plans and randomised surveillance plan for the current calendar year to the Commission electronically.

The Commission shall evaluate those plans on the basis of this Regulation and Delegated Regulation (EU) 2022/1644 and shall communicate its evaluation together with comments or recommendations, where needed, to each Member State within 4 months of receipt of the plans.

Member States shall provide the Commission with updated versions of the respective plans, outlining how the Commission's comments have been taken into account, at the latest by 31 March of the following year. Where a Member State decides not to update its control plans based on the Commission's comments, it shall justify its position.

Where the Commission considers that the plans would impair the effectiveness of official controls, updated versions of the concerned plans shall be submitted earlier upon request of, and within a reasonable time period set by the Commission.

Article 9

Submission of data by the Member State

By 30 June of each year, Member States shall transmit to EFSA all data from the previous year, including compliant results of screening methods where no confirmatory analyses were performed, gathered under the control plans referred to in Article 3.

By 31 August each year, the data validation, review and final acceptance in EFSA data repository systems shall be finalised by each Member State.

CHAPTER IV

GENERAL PROVISIONS

Article 10

Repeal of Decision 97/747/EC

Decision 97/747/EC is hereby repealed.

Article 11

References

References to Articles 3, 4, 5, 6, 7 and 8 of Directive 96/23/EC and Annexes I and IV to that Directive and to Decision 97/747/EC shall be construed as references to this Regulation.

Article 12

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 15 December 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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).

	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)

	Sampling frequency – Group B substances
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 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 to 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 our 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-year 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.

ANNEX II

Minimum sampling frequency per Member State in the national randomised surveillance plan for production in the Member States (as referred to in Article 5(c))

The minimum number of samples is as follows:

Member State	Minimum number of samples	Member State	Minimum number of samples
Belgium	195	Lithuania	50
Bulgaria	120	Luxembourg	10
Czechia	180	Hungary	165
Denmark	100	Malta	10
Germany	1 425	Netherlands	300
Estonia	25	Austria	150
Ireland	85	Poland	650
Greece	185	Portugal	175
Spain	805	Romania	335
France	1 150	Slovenia	35
Croatia	70	Slovakia	95
Italy	1 050	Finland	95
Cyprus	15	Sweden	175
Latvia	35	United Kingdom (Northern Ireland) *	30

* In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation, references to Member States include the United Kingdom in respect of Northern Ireland

Additional provisions:

(a) The samples taken under its surveillance plan shall be distributed over the different species and products according to the proportion they represent under the national production and consumption.

(b) 25 % of the samples, taken under this plan, shall be analysed for Group A substances.

(c) 75 % of the samples, taken under this plan, shall be analysed for Group B substances.

ANNEX III

Minimum sampling frequency per Member State in the national risk-based control plan for third-country imports (as referred to in Article 6(c))

The minimum sampling frequency can be used as a part of a monitoring plan at border control posts in accordance with point 5 of Annex II to Commission Implementing Regulation (EU) 2019/2130 ([1]).

Controls carried out under the established emergency measures and the intensified official controls, on the basis of Article 53 of Regulation (EC) No 178/2002 and of Article 65(4) of Regulation (EU) 2017/625, shall not be counted towards achieving the minimum sampling frequencies laid down in this Annex.

Controls of food products from certain third countries listed in Annex II to Commission Implementing Regulation (EU) 2019/2129 ([2]), with which the Union has concluded agreements of equivalence for physical checks, shall not be counted towards achieving the minimum sampling frequencies laid down in this Annex.

The minimum number of samples is as follows:

	Sampling frequency for Group A and Group B substances
Bovine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	Minimum 7 % of the imported consignments
Ovine/caprine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	Minimum 3 % of the imported consignments
Porcine (includes live animals, meat, minced meat, mechanically separated meat, meat preparations and meat products)	Minimum 3 % of the imported consignments
Equine (includes live animals intended for slaughter for human consumption, meat, minced meat, mechanically separated meat, meat preparations and meat products)	Minimum 3 % of the imported consignments
Poultry * (includes live animals, poultry meat and poultry meat products)	Minimum 7 % of the imported consignments
Aquaculture (finfish, crustaceans and other aquaculture products)	Minimum 7 % of the imported consignments
Milk (includes raw milk, dairy products, colostrum and colostrum-based products of all species)	Minimum 7 % of the imported consignments
Eggs (includes eggs and egg products from all bird species)	Minimum 12 % of the imported consignments
Rabbits, farmed and wild game **, reptiles and insects (includes live animals, meat and meat products of the mentioned species and products derived from these species)	Minimum 12 % of the imported consignments for each species
Honey (includes honey and other apiculture products)	Minimum 7 % of the imported consignments
Casings ***	Minimum 2 % of the imported consignments

([1]) Commission Implementing Regulation (EU) 2019/2130 of 25 November 2019 establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts (OJ L 321, 12.12.2019, p. 128).

([2]) Commission Implementing Regulation (EU) 2019/2129 of 25 November 2019 establishing rules for the uniform application of frequency rates for identity checks and physical checks on certain consignments of animals and goods entering the Union (OJ L 321, 12.12.2019, p. 122).

* As defined in point 1.3 of Annex I to 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).

** As defined in points 1.5 and 1.6 of Annex I to 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).

*** 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).

Additional provisions:

(a) For calculating the minimum sampling frequencies listed in this Annex, Member States shall use the most recent data of the number of consignments entering the Union through their border control posts, at least from previous or at maximum from penultimate year.

(b) In case the number of consignments entering the Union is lower than the number of consignments corresponding to one sample, the sampling once per two or three years may be performed. In case the number of consignments entering the Union over a three-year period is lower than the number of consignments corresponding to one sample, at least one sample once per three years shall be taken.

(c) 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.