 December 2024

SUBMISSION AND EVALUATION OF THE CONTROL PLANS ON RESIDUES OF VETERINARY MEDICINAL PRODUCTS (CDR (EU) 2022/1644 AND CIR (EU) 2022/1646)

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.

Submission of the plans is done via EFSA:

- see the MS Teams EFSA channel EFSA Chemical Monitoring Data Network
- see publication Chemical monitoring reporting guidance: 20xx data collection (published by the end of January/beginning of February of each year)
- support: data.collection@efsa.europa.eu

The Commission shall evaluate those plans on the basis of Commission Delegated Regulation (EU) 2022/1644 and Commission Implementing Regulation (EU) 1646 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.

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.

1. NATIONAL RISK-BASED CONTROL PLAN FOR PRODUCTION IN THE MEMBER STATES

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

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

A1 Substances with hormonal and thyrostatic action and beta agonists the use of which is prohibited under Council Directive 96/22/EC:

A1a Stilbenes
A1b Antithyroid agents
A1c Steroids
A1d Resorcylic acid lactones, including zeranol
A1e Beta-agonists

A2 Prohibited substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010:

A2a Chloramphenicol
A2b Nitrofurans
A2c Dimetridazole, metronidazole, ronidazole and other nitro-imidazoles
A2d Other substances

A3 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:

A3a Dyes
A3b Plant protection products as defined in Regulation (EU) No 1107/2009 and biocides as defined in Regulation (EU) No 528/2012 which may be used in animal husbandry of food-producing animals
A3c Antimicrobial substances
A3d Coccidiostats, histomonostats and other antiparasitic agents
A3e Protein and peptide hormones
A3f Anti-inflammatory substances, sedatives and any other pharmacologically active substances
A3g Antiviral substances

1. Combinations of substance groups and commodity groups:

	Commodity group									
Substance 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, reptiles and insects	Honey	Casings*
A1a	X	X						X**		
A1b	X	X	X					X***		
A1c	X	X	X		X****			X***		
A1d	X	X						X***		
A1e	X	X	X	X				X***		
A2	X	X	X	X	X	X	X	X	X	X
A3a					X					
A3b	X	X	X	X	X		X	X		
A3c	X	X	X	X	X	X	X	X**	X	
A3d	X	X		X			X	X**		

A3e										
A3f	X	X	X	X		X		X	X	
A3g										

* 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 food-producing 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.

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 EMA, EFSA 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 – Pharmacologically active substances authorised for use in food-producing animals

B1 Pharmacologically active substances listed in Table 1 of the Annex to Regulation (EU) No 37/2010:
B1a Antimicrobial substances
B1b Insecticides, fungicides, anthelmintics and other antiparasitic agents
B1c Sedatives
B1d Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and glucocorticoids
B1e Other pharmacologically active substances
B2 Coccidiostats and histomonostats authorised according to Union legislation, for which maximum levels and maximum residue limits are set under Union legislation

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 veterinary medicinal products 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

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

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

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 substance within therapeutic class of veterinary medicinal products.

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:
    - criteria for selecting specific Group A 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 EMA, EFSA 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
    - criteria for selecting specific Group B 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 veterinary medicinal products 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

- 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.

(c) the actual sampling frequencies as decided by the Member State taking into account the annual minimum control frequencies laid down in Annex I to Implementing Regulation (EU) 2022/1646

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)
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 (b) and 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 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.

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

- CCα, CCβ, limit of detection (LOD), limit of quantification (LOQ), type of (legal) limit used to assess the result (MRL, RPA, ML etc.) – according to EFSA tools for plans submission

(e) the detailed information

1. the details on species to be sampled and on place of sampling
2. 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
3. information about the competent authorities responsible for the implementation of the plans
4. 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
5. a justification on how cases of non-compliance in the relevant Member State detected in the previous three calendar years were taken into account for optimising the plans

2. NATIONAL RANDOMISED SURVEILLANCE PLAN FOR PRODUCTION IN THE MEMBER STATES

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

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

A1 Substances with hormonal and thyrostatic action and beta agonists the use of which is prohibited under Council Directive 96/22/EC:
A1a Stilbenes
A1b Antithyroid agents
A1c Steroids
A1d Resorcylic acid lactones, including zeranol
A1e Beta-agonists
A2 Prohibited substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010:
A2a Chloramphenicol
A2b Nitrofurans
A2c Dimetridazole, metronidazole, ronidazole and other nitro-imidazoles
A2d Other substances
A3 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:
A3a Dyes
A3b Plant protection products as defined in Regulation (EU) No 1107/2009 and biocides as defined in Regulation (EU) No 528/2012 which may be used in animal husbandry of food-producing animals
A3c Antimicrobial substances
A3d Coccidiostats, histomonostats and other antiparasitic agents
A3e Protein and peptide hormones
A3f Anti-inflammatory substances, sedatives and any other pharmacologically active substances
A3g Antiviral substances

The samples that consist in combinations of substance groups and commodity groups shall be different from the samples taken referred to in the national risk-based control plans for production in the Member States.

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

B1 Pharmacologically active substances listed in Table 1 of the Annex to Regulation (EU) No 37/2010:
B1a Antimicrobial substances
B1b Insecticides, fungicides, anthelmintics and other antiparasitic agents
B1c Sedatives
B1d Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and glucocorticoids
B1e Other pharmacologically active substances
B2 Coccidiostats and histomonostats authorised according to Union legislation, for which maximum levels and maximum residue limits are set under Union legislation

Combinations of substance groups and commodity groups:

Substance 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, reptiles and insects	Honey
B1a	X	X	X	X	X	X	X	X	X
B1b	X	X	X	X	X	X	X	X	X
B1c	X	X	X					X	
B1d	X	X	X	X		X		X	
B1e									
B2	X	X	X	X			X	X	

Each sample for a specific type of animal or product shall be analysed for as wide range of the substance groups listed in the table included in this Annex as practically feasible.
It shall be ensured that for a specific type of animal or product all substance groups listed in the table are covered by the surveillance plan. The controls shall be performed for as many pharmacologically active substances as possible, for which maximum residue limits have been set in Table 1 of the Annex to Regulation (EU) No 37/2010 or for feed additives, for which maximum residue limits and maximum levels have been set pursuant to Regulation (EC) No 1831/2003.

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

1. Sampling shall be random and shall be performed at or close to slaughter, collection or harvest and representative of the Member States' production/consumption pattern:
   - for Group A substances, sampling shall be performed throughout the production process of food-producing animals and unprocessed products of animal origin on live food-producing animals, their body parts, excrements and body fluids and in tissue, products of animal origin, animal by-products, animal feed and water, whichever matrix is the most relevant.
   - for Group B substances, only fresh or frozen meat, edible offal, eggs, milk or honey (as close as possible to the production date), which have not undergone further processing or mixing, shall be sampled.
2. In case several substance categories are to be analysed in one sample, the sample size shall be adjusted accordingly.

(c) the actual sampling frequencies as decided by the Member State taking into account the minimum sampling frequencies prescribed in Annex II to Implementing Regulation (EU) 2022/1646

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 Implementing Regulation (EU) 2022/1646, 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.

(d) the detailed information

1. the details on species to be sampled and on place of sampling
2. 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
3. information about the competent authorities responsible for the implementation of the plans

In accordance with the requirements for methods of analysis provided for in Commission Implementing Regulation (EU) 2021/808, Member State shall use analytical methods, 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.

3. NATIONAL RISK-BASED CONTROL PLAN FOR THIRD-COUNTRY IMPORTS

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

I. The relevant criteria listed in Annex II

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

A1 Substances with hormonal and thyrostatic action and beta agonists the use of which is prohibited under Council Directive 96/22/EC:

A1a Stilbenes

A1b Antithyroid agents

A1c Steroids

A1d Resorcylic acid lactones, including zeranol

A1e Beta-agonists

A2 Prohibited substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010:

A2a Chloramphenicol

A2b Nitrofurans

A2c Dimetridazole, metronidazole, ronidazole and other nitro-imidazoles

A2d Other substances

A3 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:

A3a Dyes

A3b Plant protection products as defined in Regulation (EU) No 1107/2009 and biocides as defined in Regulation (EU) No 528/2012 which may be used in animal husbandry of food-producing animals

A3c Antimicrobial substances

A3d Coccidiostats, histomonostats and other antiparasitic agents

A3e Protein and peptide hormones

A3f Anti-inflammatory substances, sedatives and any other pharmacologically active substances

A3g Antiviral substances

1. Combinations of substance groups and commodity groups:

	Commodity group									
Substance 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, reptiles and insects	Honey	Casings*
A1a	X	X						X**		
A1b	X	X	X					X***		
A1c	X	X	X		X****			X***		
A1d	X	X						X***		
A1e	X	X	X	X				X***		
A2	X	X	X	X	X	X	X	X	X	X
A3a					X					
A3b	X	X	X	X	X	X	X	X	X	
A3c	X	X	X	X	X	X	X	X**	X	
A3d	X	X		X			X	X**		
A3e										

A3f	X	X	X	X	X	X	X	X	X	
A3g										

* 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 food-producing 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.

2. Criteria for selecting specific substances for testing within each substance group:
   - frequency of the detection of non-compliance 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 third countries' samples, especially when reported under the RASFF or AAC.
   - availability of suitable laboratory methods and analytical standard;
   - information on the quantities of veterinary medicinal products 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.

II. Information where available and relevant, on:
   - the RASFF notifications and AAC system for residues in imported food;
   - the outcome of Commission controls in third countries;
   - level of guarantees provided by the importer on the compliance of imported food of animal origin with Union legislation on pharmacologically active substances including compliance with Union maximum residue limits and maximum levels or attestations on non-use of certain substances;
   - records of non-compliances for individual food business operators or importers identified in earlier Member State import controls.

III. Relevant information provided by the Commission services, where available, on:
   - the use in the third country of pharmacologically active substances that are prohibited or not authorised in the Union, existence of information on the restrictions on such use, administration practices for veterinary medicinal products (e.g. with or without the involvement of authorised animal health professionals);
   - the distribution of veterinary medicinal products and whether they are available over the counter or are subject to a veterinary prescription;
   - whether there is an obligation to keep veterinary medicinal product treatment records on farms in the third country;
   - whether and how animals are identified (and can thus be linked to treatments).

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

1. Sampling shall be targeted according to rules set out in Annex VI, supplemented by the relevant rules laid down in Annex III.
   - For Group A substances, sampling shall be targeted at detecting the illegal treatment with prohibited or unauthorised substances.

- For Group B substances, sampling shall be targeted at controlling the compliance with maximum residue limits or maximum levels for residues of pharmacologically active substances established under Union legislation.

2. Samples shall be taken at the point of entry into the Union.

(c) the sampling frequencies

- The actual sampling frequencies for controls carried out at BCP as decided by the Member State taking into account the annual minimum sampling frequencies. 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.
- 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 Regulation (EU) 2019/2130.
- Controls carried out under the established emergency measures and the intensified official controls, on the basis of Article 53 of Regulation (EC) 178/2002 and of Article 65(4) of Regulation (EU) 2017/625, shall not be counted towards achieving the minimum sampling frequencies.
- Controls of food products from certain third countries listed in Annex II to Regulation (EU) 2019/2129, with which the Union has concluded agreements of equivalence for physical checks, shall not be counted towards achieving the minimum sampling frequencies.

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

* 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 years 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.

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

- CCα, CCβ, limit of detection (LOD), limit of quantification (LOQ), Type of (legal) limit used to assess the result (MRL, RPA, ML etc.) – according to EFSA tools for plans submission

(e) the detailed information (where available)

1. the details on species to be sampled and on place of sampling
2. 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 by Unin legislation
3. information about the competent authorities responsible for the implementation of the plans
4. 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
5. a justification on how cases of non-compliance in the relevant Member State detected in the previous three calendar years were taken into account for optimising the plans

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 and the surveillance plan. Those data shall also contain 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 were detected in the previous year.

- Tools for reporting Chemical Contaminants Occurrence Data in the SSD2 data model format
- https://doi.org/10.5281/zenodo.3714966; please check updates regularly
- https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2024.EN-8596; please check updates regularly
- Support: data.collection@efsa.europa.eu

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