SANTE 11987-2017 Rev5

ANNEX

to the

COMMISSION REGULATION (EU) No .../...

on rules applicable to national and coordinated official control programmes and annual reports by Member States on residues of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and prohibited or unauthorised pharmacologically active substances.

ANNEX I

GROUP A – Prohibited or unauthorised pharmacologically active substances, used on food producing animals.

1. Substances with hormonal and thyreostatic action and beta agonists, whose use is prohibited under Directive 96/22/EC.
    a. Stilbenes
    b. Antithyroid agents
    c. Steroids
    d. Resorcylic acid lactones, including zeranol
    e. Beta-agonists
2. Prohibited substances, listed in Table 2 of the Annex to Regulation (EU) No 37/2010.
3. Pharmacologically active substances, not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 or not authorised according to Regulation (EU) No 1831/2003.
    a. Dyes
    b. Pesticides as defined in Reg. (EU) No 1107/2009[1] and biocides as defined in Reg. (EU) No 528/2012[2], which may be used to treat food producing animals.
    c. Antimicrobial substances
    d. Coccidiostats and histomonostats
    e. Protein and peptide hormones
    f. Any other pharmacologically active substance not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 or not authorised according to Regulation (EU) No 1831/2003 and which may be misused on food producing animals.

GROUP B – Pharmacologically active substances authorised for the use in food producing animals according to Union legislation.

1. Pharmacologically active substances listed in table 1 of the Annex to Regulation (EU) No 37/2010.
    a. Antimicrobial substances,
    b. Insecticides, fungicides, anti-helmintics and anti-parasite agents
    c. Sedatives
    d. Non-steroidal anti-inflammatory drugs (NSAIDs)
    e. Other pharmacologically active substances listed in table 1 of the Annex to Regulation (EU) No 37/2010.
2. Coccidiostats and histomonostats authorised according to Regulation (EU) No 1831/2003, for which MRLs are set under Union legislation and for which maximum levels are set under Regulation (EC) No 124/2009.

[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 250, 15.9.2012, p. 17.

ANNEX II

A) Risk-based control programme for EU production for group A substances:

1. Minimum residue or substance groups, to be detected by type of animal, and primary animal products

Substance group	Bovine, ovine and caprine	Porcine	Equine	Poultry	Aqua-culture (fresh and sea water)	Bovine, ovine and caprine milk	Hen eggs and other eggs	Rabbits, farmed and wild game, reptiles and insects	Honey
A1a	**X**	**X**						**X**[3,4]	
A1b	**X**	**X**	**X**						
A1c	**X**	**X**	**X**		**X**[5]				
A1d	**X**	**X**							
A1e	**X**	**X**	**X**	**X**	**X**				
A2	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
A3a					**X**				
A3b	**X**	**X**	**X**	**X**		**X**	**X**	**X**	**X**
A3c	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**[3, 4]	**X**
A3d	**X**	**X**	**X**	**X**			**X**	**X** [3]	

[3] Not relevant for insects
[4] Not relevant for wild game
[5] Only relevant for finfish

A3e	**X**	**X**	**X**		**X**[6]	**X**			
A3f	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X** [4]	**X**

- Each sub-group in group A, listed for a specific species or product, shall be controlled each year in minimum 5% of the samples taken according to the minimum sampling frequency set under Annex III for that species or product. By exception this does not apply to group A.3.f.
- Within the group bovine, ovine and caprine, all species shall be sampled, where relevant when taking into account their production volume. Sampling shall cover both animals for dairy production and for meat production.
- Within the group poultry, broiler chickens, spent hens, turkey and other poultry shall be sampled, where relevant when taking into account their production volume.
- Within the group aquaculture both fresh and seawater aquaculture, shall be sampled where relevant when taking into account their production volume.
- The residue or substance groups shall be analysed in specific types of animals, their excrements, body fluids and parts, tissues, feed, water, animal by-products and animal products, including the primary animal products listed in the table of this Annex.
- 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, also these controls shall be included in the risk-based control programme fo EU production.

2. **Relevant criteria to be considered for selecting specific substances within the substance group**
   - Pharmacologically active substances for which residues were previously detected in the Member Sates' samples, in other EU Member States' samples or in third country samples, especially when reported under the RASFF or AAC system.
   - Availability of suitable laboratory methods and analytical standards.
   - Pharmacologically active substances likely to be misused in order to gain commercial benefits.
   - Prohibited or non-allowed substances for which there are indications of misuse. Such indications may be available from the sector, internet, other Member States or via intercepted products, containing prohibited or non-allowed substances.

[6] Only relevant for salmon.

- Possible risk of the residues for consumers, taking into account the relevant information available from EMA, EFSA and JECFA publications or from a national risk assessment.

3. **Relevant criteria to be considered for the selection of farms or producers:**
    - History of non-compliances of the farm or producer, shortcomings in the application of veterinary medicinal products, deficiencies noted in earlier 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 regards to the administration of particular pharmacological active substances in the respective farm or production system.
    - Indications of the use of pharmacologically active substances.
    - The non-existence or unreliability of self-regulatory approaches or the insufficient supervision by veterinarians.
    - Outcome of the own checks.
    - Representative sampling in different sizes of production systems: very small, very large, highly integrated production systems.
4. **Relevant criteria to be considered for the selection of slaughter establishments, dairies, fish processing plants, honey and egg collecting and packing centres**
    - The respective slaughter establishment's, dairy's or egg packing centre’s share in the country's total production volume.
    - Residues findings in earlier controls.
    - Origins and transport routes of the slaughtered animals, milk or eggs.
    - The lacking participation of participation in quality assurance programmes.
5. **Relevant criteria to be considered for the selection of animals and products of animal origin:**
    - Indication of the use of pharmacological 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 chronical disorders, different health status of specific animals within a group.
    - Sex, age and pregnancy of the animals.
    - Veterinary history of the animal and health certificate.
    - Level of development a specific animal in a group of animals.
    - Animals showing a good conformation and well-developed muscles with little fat.
6. **Relevant criteria to be considered for the selection of the matrix or product**

- Likeliness of residues or pharmacologically active substances to be detected in a specific organ, body part, tissue, body fluid, excrement, animal product, animal by-products, animal feed and water.

B) Risk-based control programme for EU productions for group B substances: relevant criteria to be considered for the design of the programmes

1. **Relevant criteria to be considered for the selection of farms or producers:**
   - The criteria listed in Annex II point A3
2. **Relevant criteria to be considered for the selection of slaughter establishments, dairies, fish processing plants, honey and egg collecting and packing centres**
   - The criteria listed in Annex II point A4
3. **Relevant criteria to be considered for the selection of animals and products of animal origin:**
   - The criteria listed in Annex II point A5
4. **Relevant criteria to be considered for the selection of the matrix or product**
   - The criteria listed in Annex II point A6
5. **Relevant criteria to be considered for selecting specific substances**
   - Availability of suitable laboratory methods and analytical standards.
   - Information on the quantities of the veterinary medicinal product produced, imported, exported, marketed and sold for a specific food producing 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 prescriptions.
   - Information on the rates of antimicrobial resistance in certain animal production sectors.
   - The lacking availability of information or training on the appropriate use of the pharmacologically active substance.
   - Maximum residue limit requirements of authorised pharmacologically active substances: maximum residue limit established with or without restrictions or no maximum residue limit required.
   - Pharmacologically active substances substances for which long withdrawal periods are established in the veterinary medicinal product or feed additive authorisation.
   - Possible treatment of animals under Articles 113 and 114 of the new VMP Regulation (currently Article 11 of Directive 2001/82/EC).
   - Pharmacologically active substances for which residues were previously detected in EU or third country samples in a concentration above the maximum

residue limit or the maximum level, especially when reported via the RASFF or AAC system.

- Specific pharmacologically active substances on which controls are needed to fulfil export requirements.
- Possible risk of the residues for consumers, taking into account the relevant information available from EMA or EFSA publications or from a national risk assessment.

6. **Relevant criteria to be considered for the timing of sampling:**
    - Seasonal aspects of treatments with specific pharmacologically active substances or meteorological influence on such treatments.

ANNEX III

Risk-based control programmes for EU production: sampling strategy

1) Sampling shall be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Member States shall take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained, where practical.

Sampling shall be carried out in variable intervals spread over the whole year. In this context it shall be considered that a number of pharmacologically active substances are administered only in particular seasons.

Sampling shall be performed at or close to harvest, collection or harvest.

2) For Group A substances controls shall be targeted at detecting the illegal treatment with prohibited or unauthorised substances.

All the samples shall be targeted according to the criteria laid down in the national control programme.

3) For Group B substances, sampling shall be targeted at detecting non-compliance with the maximum residue limits or maximum levels for residues of pharmacologically active substances and at the abusive administration of pharmacologically active substances substances, authorised as veterinary medicinal products or as feed additives.

All the samples shall be targeted according to the criteria laid down in the national control programme.

4) In addition to the analyses of live or slaughtered animals, also analyses of water, feed, excrements and all other appropriate matrices shall be undertaken at farm level, where required for the controls on the use and residues of prohibited or unauthorised pharmacologically active substances.

5) When taking the samples, efforts shall be made to avoid multiple sampling from one producer.

ANNEX IV

A) Risk-based control programme for EU production: minimum overall sampling frequency per Member State for Group A substances

- Member States shall comply with the minimum sampling frequencies of this Annex for the risk- based national control programmes for EU production.

	Group A
Bovine	Minimum 0.25% of the slaughtered animals, by derogation 25% of the samples analysed for group A1e substances can be taken from feed, water or another relevant matrix.
Sheep and goats	Minimum 0.01% of the slaughtered animals
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 (fresh and sea water)	Minimum 1 sample per 300 tons of annual production of aquaculture
Bovine, ovine and caprine milk	Minimum 1 sample per 30.000 tons of annual production of milk
Hen eggs and other eggs	Minimum 1 sample per 2000 tons of annual production of eggs
Rabbits, farmed and wild game, reptiles and insects	Minimum 1 sample per 100 tons of annual production (dead weight) of rabbits, farmed game or reptiles for the first 3000 tons of production and 1 sample for each additional 1000 tons.

	Minimum 1 sample per 25 tons annual production of insects.
Honey	1 samples per 100 tons of annual production for the first 3000 tons and one sample for each additional 1000 tons.

B) Risk-based control programme for EU production: minimum overall sampling frequency per Member State for Group B substances.

- Member States shall comply with the minimum sampling frequencies of this Annex for the risk- based national control programmes for EU production.

	Sampling frequency Group B
Bovine	Minimum 0.10% of the slaughtered animals
Sheeps and goats	Minimum 0.02% of the slaughtered animals
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 tons of annual production (deadweight)
Aquaculture (fresh and sea water)	Minimum 1 sample per 300 tons of annual production of aquaculture
Bovine, ovine and caprine milk	Minimum 1 sample per 30000 tons of annual production of milk
Hen eggs and other eggs	Minimum 1 sample per 2000 tons of annual production of milk

Rabbits, farmed and wild game, reptiles and insects	Minimum 1 sample per 50 tons of annual production (dead weight) of rabbits, farmed game or reptiles for the first 3000 tons of production and 1 sample for each additional 500 tons. Minimum 1 sample per 25 tons annual production of insects.
Honey	Minimum 1 sample per 50 tons of annual production

C) Risk-based control programme for EU production: additional provisions for the sampling frequency for Group A and Group B substances.

- In case the sampling frequency, established in this Annex and calculated on the basis of production size, would represent less than 5 samples per year, sampling may be carried out bi-annually. In case within a period of two years the production size corresponding to minimum 1 sample, is not reached, 1 sample shall be analysed bi-annually provided that in the Member State production takes place for that species or product.

ANNEX V

Risk-based control programmes for third country imports: relevant criteria to be considered for the design of the programmes.

The relevant criteria listed in Annex II shall be considered for the design of the national risk based control programmes for third country imports. In addition the following aspects shall be considered, where available and relevant.

- Information from the AAC system or RASFF notifications.
- The outcome of Commissions' audits in third countries.
- The use of prohibited or non-authorised pharmacologically active substances in the third country or the lacking restrictions on such uses, the possibility of free administrations of veterinary medicinal products without the intervention of authorised professionals.
- The availability of pharmacologically active substances over the counter without medical prescription.
- The absence of an obligation of keeping treatment records in the third country.
- The non-availability of an animal identification system in the third country with group- or individual identification of animals.
- The lack of guarantees provided by the importer on the compliance with the Union legislation on pharmacologically active substances or the insufficient reliability of the provided guarantees.

ANNEX VI

Risk-based control programmes for third country imports: sampling strategy

(a) Sampling shall be targeted according to criteria for the design of the national control programmes for products imported from third countries as laid down in Annex V.

(b) For Group A substances, sampling shall be targeted at detecting the illegal administration of prohibited or unauthorised substances.

(c) 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.

(d) Samples shall be taken at the point of entry into the EU.

ANNEX VII

Risk-based control programmes for third country imports: minimum sampling frequency per Member State

In addition to the established safeguard measures and the intensified official controls, laid down in Art. 65 of Regulation (EU) 2017/625, Member States shall comply with the minimum sampling frequency of this Annex for the risk- based national control programmes for third country imports.

	Sampling frequency for group A substances
Bovine	Minimum 1 sample per 200 tons of imported products
Sheep and goats	Minimum 1 sample per 1200 tons of imported products
Porcine	Minimum 1 sample per 1200 tons of imported products
Equine	Minimum 1 sample per 1200 tons of imported products
Poultry	Minimum 1 sample per 400 tons of imported products (deadweight)
Aquaculture (fresh and sea water)	Minimum 1 sample per 300 tons of imported products
Bovine, ovine and caprine milk	Minimum 1 sample per 300 tons of imported products
Hen eggs and other eggs	Minimum 1 sample per 200 tons of imported products
Rabbits, farmed and wild game, reptiles and insects	Minimum 1 sample per 100 tons of imported rabbits and farmed game and reptiles. Minimum 1 sample per 10 tons of imported insects and reptiles
Honey	Minimum 1 sample per 100 tons of imported products

	Sampling frequency for group B substances

Bovine	Minimum 1 sample per 500 tons of imported products
Sheep and goats	Minimum 1 sample per 1200 tons of imported products
Porcine	Minimum 1 sample per 1200 tons of imported products
Equine	Minimum 1 sample per 1200 tons of imported products
Poultry	Minimum 1 sample per 500 tons of imported products (deadweight)
Aquaculture (fresh and sea water)	Minimum 1 sample per 300 tons of imported products
Bovine, ovine and caprine milk	Minimum 1 sample per 300 tons of imported products
Hen eggs and other eggs	Minimum 1 sample per 200 tons of imported products
Rabbits, farmed and wild game, reptiles and insects	Minimum 1 sample per 50 tons of imported rabbits and farmed game and reptiles. Minimum 1 sample per 10 tons of imported insects and reptiles.
Honey	Minimum 1 sample per 50 tons of imported products

- The minimum sampling frequency shall be calculated on the basis of the imported volume in the Member State on the basis of the sampling frequencies listed in this Annex. The imported weight of dehydrated products of animal origin shall be converted by means of the processing factor, to the corresponding weight of the fresh product and the weight of the fresh product shall be counted for the calculation of the imported volume.
- In case the imported volume is lower than the volume corresponding to one sample, the sampling may be performed on a bi- or tri-annual basis. In case the volume imported over a period of 3 years is lower than the volume corresponding to 1 sample, at least 1 sample shall be taken tri-annually.

ANNEX VIII

Surveillance programme for EU production: residue or substance groups, to be detected by type of animal and primary animal products

A) Surveillance programme for group A substances:

Unauthorised pharmacologically active substances, which are currently not included in the Member States' risk based national programme, but which may be misused for the treatment of food producing animals shall be analysed in the relevant species, product or matrix.

B) Surveillance programme for group B substances: minimum residue or substance groups to be detected by type of animal and primary animal products.

Substance group	Bovine, ovine and caprine	Porcine	Equine	Poultry	Aqua-culture (fresh and sea water)	Bovine, ovine and caprine milk	Hen eggs and other eggs	Rabbits, farmed game, wild game, reptiles and insects	Honey
B1a	X	X	X	X	X	X	X	X[4]	X
B1b	X	X	X	X	X	X	X	X	X
B1c	X	X	X					X[4]	
B1d	X	X	X	X		X		X[4]	
B1e	X	X	X	X	X	X	X	X[4]	X
B2	X	X	X	X		[2]	X	X[4]	

- Each sample for a specific type of animal or product, which is taken under the surveillance programme for EU productions, shall be analysed for all the substance groups listed in the table included in this annex.

ANNEX IX

Surveillance programme for EU production: sampling strategy

(a) Random sampling shall be performed at or close to slaughter, collection or harvest.

(b) For Group A substances sampling shall be performed on live animals, their body parts, excrements and body fluids and in tissue, animal products, animal by-products, animal feed and water, whichever matrix is the most relevant.

(c) For Group B substances only fresh or frozen meat, eggs, milk or honey, which have not undergone further processing beyond temperature control, shall be sampled.

(d) In case several substance categories are to be analysed in one sample, the sample size shall be adjusted accordingly.

ANNEX X

Surveillance programme for EU production: minimum sampling frequencies

- Each Member State shall take a minimum number of samples under its surveillance programme according to the frequency listed in this Annex.
- Each Member State shall ensure that the samples taken under its surveillance program are distributed over the different species and products according to the proportion they represent under its national production.
- 25% of the samples, taken under this programme, shall be analysed for group A substances.
- 75% of the samples taken under this programme, shall be analysed for group B substances.

BE	196
BG	122
CZ	180
DK	99
DE	1419
EE	23
IE	82
EL	185
ES	801
FR	1154
HR	72
IT	1054
CY	15
LV	34
LT	49
LU	10
HU	169
MT	8
NL	296
AT	151
PL	654
PT	177
RO	338
SI	36
SK	94
FI	95
SE	174
Sum	7683