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ANNEX

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) …/...

amending Delegated Regulation (EU) 2020/687 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the prevention and control of certain listed diseases

Annex I

‘ANNEX I

CLINICAL EXAMINATIONS, SAMPLING PROCEDURES, DIAGNOSTIC METHODS OF CATEGORY A DISEASES AND TRANSPORT OF SAMPLES

(as referred to in Article 3 of this Regulation)

A. Sampling procedures

A.1 SAMPLING OF ANIMALS FOR CLINICAL EXAMINATIONS

1. Clinical examinations must include, if possible:

(a) animals showing clinical signs of category A diseases;

(b) animals likely to have recently died from the suspected/confirmed disease;

(c) animals with epidemiological link to a suspected or confirmed case; and

(d)animals that obtained positive or non-conclusive results in previous laboratory examinations.

2. Animals to examine must be selected at random, in a number large enough to allow the detection of the disease, if present, where there are no obvious signs of disease or post-mortem lesions suggesting category A diseases.

3. The animals to examine and the sampling method must be chosen in accordance with the instructions of the competent authority taking into account the available scientific evidence for the relevant category A disease, and with the relevant contingency plan as referred to in Article 43 of Regulation (EU) 2016/429. The animals to examine and the sampling method must take into account the disease profile and:(a) the purpose of the sampling;

(b) the listed species kept in the establishment;

(c) the number of animals of listed species kept in the establishment;

(d) the category of the kept animals;

(e) the available production, health and traceability records of the kept animals relevant for the investigation;

(f) the type of establishment and the husbandry practices;

(g) the level of exposure risk:

(i) likelihood of exposure to the disease agent or to the vector;

(ii) absence of immunisation of the animals due to vaccination or maternal immunity; and

(iii) history of residence in the establishment;

(h) other relevant epidemiological factors.

4. The minimum number of animals to examine must be in accordance with the instructions of the competent authority ~~taking into account the available scientific evidence for the relevant category A disease~~, and with the relevant contingency plan as referred to in Article 43 of Regulation (EU) 2016/429. The minimum number of animals to examine must take into account the disease profile and in particular:

(a) the expected prevalence in the establishment;

(b) the level of confidence desired of the survey results, which in any case must not be lower than 95 %; and

(c) international standards and available scientific evidence for the relevant category A disease.

A.2 SAMPLING OF ANIMALS FOR LABORATORY EXAMINATIONS

1. Sampling for laboratory examinations must take into account the outcome of the clinical examinations referred to in point A.1 and, if possible, must include animals referred to in paragraph 1 of point A.1.

2. If there are no obvious signs of disease or post-mortem lesions suggesting category A diseases, samples must be collected at random in each epidemiological unit of the establishment and must allow the detection of the disease, if present.

3. The animals to sample, the nature of the samples to collect and the sampling method must be in accordance with the instructions of the competent authority taking into account the available scientific evidence for the relevant category A disease, the relevant details and guidance made available on the websites of the European Union Reference Laboratories (EURL) and of the Commission, and with the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The animals to sample, the nature of the samples to collect and the sampling method must take into account the disease profile and the criteria set out in paragraph 3 of point A.1.

4. The minimum number of animals to sample must be in accordance with the instructions of the competent authority taking into account the available scientific evidence for the relevant category A disease, the relevant details and guidance made available on the websites of the European Union Reference Laboratories (EURL) and of the Commission and the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The minimum number of animals to sample must take into account the criteria set out in paragraph 4 of point A.1 and the performance of the tests used.

5. In the case of wild animals, samples must be collected from animals shot, found dead or purposely trapped or must be obtained on the basis of non-invasive methods such as salt licks and chewing ropes or baits. The minimum number and the nature of the samples must take into account the estimated size of the wild population and the relevant criteria set out in paragraph 3 and 4 of point A.1.

A.3 SAMPLING OF ESTABLISHMENTS FOR VISITS

1. The choice of establishments to sample and the sampling method must be in accordance with the instructions of the competent authority taking into account the available scientific evidence for the relevant category A disease, and with the relevant contingency plan as referred to in Article 43 of the Regulation (EU) 2016/429. The choice of establishments to sample and the

sampling method must take into account the disease profile and the criteria set out in paragraph 3 of point A1.2. The minimum number of establishments to visit must be in accordance with the instructions of the competent authority and with the relevant contingency plan, as referred to in Article 43 of the Regulation (EU) 2016/429.

B. Diagnostic methods

The techniques, reference materials, their standardisation and the interpretation of the results of tests carried out using the relevant diagnostic methods for category A diseases must comply with Article 6 and Part III of Annex VI to Delegated Regulation (EU) 2020/689.

The diagnostic methodology must aim to maximise the sensitivity of the surveillance. In certain circumstances this surveillance may include the use of laboratory examinations in order to assess previous exposure to disease.

C. Transport of samples

1. All samples taken to confirm or rule out the presence of a category A disease must be sent, with a proper labelling and identification, to an official laboratory which has been informed of their arrival. These samples must be accompanied by the appropriate forms, in accordance with the requirements established by the competent authority and the laboratory receiving the samples. These forms must include at least:

(a) the establishment of origin of the sampled animals;

(b) information on the species, age and category of the sampled animals;

(c) the clinical history of the animals, if available and relevant;

(d) the clinical signs and post-mortem findings; and

(e) any other relevant information.

2. All samples must be:

(a) stored in watertight and unbreakable containers and packages and in accordance with applicable international standards;

(b) kept at the most appropriate temperature and other conditions during transport taking into account the factors that may affect the sample quality.

3. The exterior of the package must be labelled with the address of the recipient laboratory and the following message must be prominently displayed:

‘Animal pathological material; perishable; fragile; do not open outside the laboratory of destination.’

4. The person responsible in the official laboratory receiving the samples must be informed in due time of the arrival of the samples. ‘

Annex II

ANNEX V to Delegated Regulation (EU) 2020/687 is replaced by the following:

‘ ANNEX V

AREA OF PROTECTION AND SURVEILLANCE ZONES

(as referred to in Article 21)

Indicated as radius of a circle centred on the establishment

Category A diseases	**Protection Zone**	**Surveillance Zone**
Foot and mouth disease	3 km	10 km
Infection with rinderpest virus	~~3~~ 4 km	10 km
Infection with Rift Valley fever virus	20 km	50 km
Infection with lumpy skin disease virus	20 km	50 km
Infection with *Mycoplasma mycoides subsp. mycoides SC* (Contagious bovine pleuropneumonia)	~~Establishment~~ 1 km	3 km
Sheep pox and goat pox	~~3~~ 5 km	~~10~~ 20 km
Infection with peste des petits ruminants virus	~~3~~ 5 km	~~10~~ 20 km
Contagious caprine pleuropneumonia	~~Establishment~~ 1 km	3 km
African horse sickness	100 km	150 km
Infection with *Burkholderia mallei* (Glanders)	Establishment	Establishment
Classical swine fever	3 km	10 km
African swine fever	3 km	10 km
Highly pathogenic avian influenza	3 km	10 km
Infection with Newcastle disease virus	3 km	10 km

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Annex III

ANNEX VI to Delegated Regulation (EU) 2020/687 is replaced by the following:

‘ANNEX VI

PROHIBITIONS IN THE RESTRICTED ZONE

(as referred to in Articles 27 of this Regulation)

Table: Prohibitions of activities concerning animals of listed species and products from those animals

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS RELATED TO CATEGORY A DISEASES[1]	**FMD**	**RP**	**RVFV**	**LSD**	**CBPP**	**SPGP**	**PPR**	**CCPP**	**CSF**	**ASF**	**AIS**	**GLANDERS**	**HPAI**	**NCD**
Movements of kept animals of listed species from establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of kept animals of listed species to establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Restocking of game animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Fairs, markets, shows and other gatherings of kept animals of listed species including collection and dispersion of those species	X	X	X	X	X	X	X	X	X	X	X	NA	X	X
Movements of semen, oocytes and embryos obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X[2]	X	X	X	X	X	X	X	NA	NA	NA

[1] Abbreviations for Category A diseases in accordance with Annex II
[2] Only oocytes and embryo
NA = Not applicable
X = prohibition

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS RELATED TO CATEGORY A DISEASES[1]	FMD	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	GLANDERS	HPAI	NCD
Collection of semen, oocytes and embryo from kept animals of listed species	X	X	X	X	X	X	X	X	X	X	NP	NA	NA	NA
Itinerant artificial insemination of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Itinerant service for breeding of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Movements of hatching eggs to and from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X
Movements of fresh meat excluding offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	NP	NP	~~X~~ NP	X	NP	X	X	NP	NA	X	X
Movements of offal from kept and wild animals of listed species from slaughterhouses or game handling establishments in the restricted zone	X	X	X	X	X	X	X	X	X	X	NP	NA	X	X
Movements of meat products obtained from fresh meat of listed species from establishments in the restricted zone	X	X	X	NP	NP	NP	X	NP	X	X	NP	NA	X	X
Movement of raw milk and colostrum obtained from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movement of dairy products and colostrum based products from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	NA	NA	NP	NA	NA	NA
Movement of eggs for human consumption from establishments in the restricted zone	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	X	X

NP = Not prohibited

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS RELATED TO CATEGORY A DISEASES[1]		FMD	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	GLANDERS	HPAI	NCD
Movements of animal by-products from kept animals of listed species from establishments in the restricted zone, except entire bodies or parts of dead animals	Manure, including litter and used bedding	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X
	Hides, skins, wool, bristles and feathers	X	X	~~X~~ NP	X	NP	X	X	NP	X	X	NP	NA	X	X
	Animal by-products other than manure, including litter and used bedding, and other than hides, skins, wool, bristles and feathers	X	X	X	X	X	X	X	X	X	X	~~X~~ NP	NA	X	X
Movement feed materials of plant origin and straw obtained in the restricted zone		X	X	NP	NP	NP	NP	NP	NP	NP	NP	NP	NA	NP	NP.’

Annex IV

ANNEX VII to Delegated Regulation (EU) 2020/687 is replaced by the following:

‘ANNEX VII

RISK MITIGATING TREATMENTS FOR PRODUCTS OF ANIMAL ORIGIN FROM THE RESTRICTED ZONE

(as referred to in Articles 27, 33 and 49 of this)

WILL BE SENT SEPARATELY LATER

Annex V

ANNEX IX to Delegated Regulation (EU) 2020/687 is replaced by the following:

'ANNEX IX

MARKING OF FRESH MEAT FROM THE RESTRICTED ZONE

1. The special health mark to be applied to fresh meat not intended to another Member State or third country due to animal health reasons shall be a health mark with the characteristics mentioned in point 2(b) letters (i), (ii), (iii) and (v) or, where relevant, an identification mark as provided for in Article 5(1) of Regulation (EC) No 853/2004, with two additional diagonal parallel lines that shall remain in perfectly legible characters, when:

   (a) is obtained from poultry originating in the protection zone, pursuant Article 33(1)(b); or

   (b) is obtained from animals kept in the restricted zone, established pursuant rules adopted in accordance with Article 71(3) and (4) or Article 259 of Regulation (EU) 2016/429 for a category A disease relevant for those animals, when such special mark is provided for in those rules.

2. The mark to be applied to fresh meat intended for treatment in a processing plant pursuant Articles 33(2)(a) and 49(2)(a) shall consist in, either:

   (a) the identification mark provided for in Regulation (EU) No 853/2004 with an additional diagonal cross consisting of two straight lines intersecting at the centre of the stamp and enabling the information thereon to remain legible; or

   (b) a single oval stamp, 6,5 cm wide by 4,5 cm high, in which the following information must appear in perfectly legible characters:

      (i) on the upper part, the name or ISO code of the Member State in capitals provided for in point 6 of Part B of Section 1 of Annex II of Regulation (EC) No 853/2004,

      (ii) in the centre, the approval number of the establishment referred to in point 7 of Part B of Section 1 of Annex II of Regulation (EC) No 853/2004,

      (iii) on the lower part, one of the following sets of initials EC, EU, EL, UE, EE, AE, ES, EÚ,

      (iv) two straight lines crossing at the centre of the stamp in such a way that the information is not obscured,

      (v) the letters must be at least 0,8 cm high and the figures at least 1 cm high.

3. Until ~~1 January 2035~~ 31 December 2028, for the marking of fresh meat of poultry as referred in point (1)(a) the following mark may continue to be used:

   - a single square stamp with the sides of not less than 30 mm each and line thickness of square of 3 mm, in which the following information must appear in perfectly legible characters:

   (i) on the upper part, the name or ISO code of the Member State in capitals provided for in point 6 of Part B of Section 1 of Annex II of Regulation (EC) No 853/2004, with the letters of 8 mm hight,

(ii) in the lower part, the approval number of the establishment referred to in point 7 of Part B of Section 1 of Annex II of Regulation (EC) No 853/2004, with the numbers of 11 mm hight. ‘

Annex VI

ANNEX X to Delegated Regulation (EU) 2020/687 is replaced by the following:

‘ANNEX X

DURATION OF THE MEASURES IN THE PROTECTION ZONE

(as referred to in Article 39)

Category A diseases	**Minimum period of duration of measures in the protection zone (Art 39.1)**	**Additional period of duration of surveillance measures in the protection zone (Art. 39.3)**
Foot and mouth disease	15 days	15 days
Infection with rinderpest virus	21 days	9 days
Infection with Rift Valley fever virus	30 days	15 days
Infection with lumpy skin disease virus	28 days	17 days
Infection with *Mycoplasma mycoides subsp. mycoides SC* (Contagious bovine pleuropneumonia)	~~45~~ 90 days	Not applicable
Sheep pox and goat pox	21 days	9 days
Infection with peste des petits ruminants virus	21 days	~~9~~ 12 days
Contagious caprine pleuropneumonia	45 days	Not applicable
African horse sickness	12 months	Not applicable
Infection with *Burkholderia mallei* (Glanders)	6 months	Not applicable
Classical swine fever	~~15~~ 25 days	15 days
African swine fever	15 days	15 days
Highly pathogenic avian influenza	21 days	9 days
Infection with Newcastle disease virus	21 days	9 days

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Annex VII

ANNEX XI to Delegated Regulation (EU) 2020/687 is replaced by the following:

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ANNEX XI

DURATION OF THE MEASURES IN THE SURVEILLANCE ZONE

(as referred to in Article 55)

Category A diseases	**Minimum period of duration of measures in the surveillance zone**
Foot and mouth disease	30 days
Infection with rinderpest virus	30 days
Infection with Rift Valley fever virus	45 days
Infection with lumpy skin disease virus	45 days
Infection with *Mycoplasma mycoides subsp. mycoides SC* (Contagious bovine pleuropneumonia)	~~45~~ 90 days
Sheep pox and goat pox	30 days
Infection with peste des petits ruminants virus	~~30~~ 33 days
Contagious caprine pleuropneumonia	45 days
African horse sickness	12 months
Infection with *Burkholderia mallei* (Glanders)	Not applicable
Classical swine fever	~~30~~ 40 days
African swine fever	30 days
Highly pathogenic avian influenza	30 days
Infection with Newcastle disease virus	30 days

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Annex VIII

In ANNEX XV to Delegated Regulation (EU) 2020/687, Table 2 is replaced by the following:

‘Table 2

1. Specific scheme for surveillance comprising health visits and sampling in establishments for epizootic haematopoietic necrosis (EHN) in aquaculture establishments (1)

Type of establishment	Number of health visits per year	Number of samplings per year	Number of fish in the sample	
			Number of growing fish	Number of broodstock fish (2)
(a) Establishments with broodstock	2	2	150 (first and second visit)	150 (first or second visit)
(b) Establishments with broodstock only	2	1	0	150 (first or second visit)
(c) Establishments without broodstock	2	2	150 (first and second visits)	0
Maximum number of fish per pool: 10				

(1) The sampling of fish for laboratory examination must be carried out whenever the water temperature is between 11 and 20°C. The water temperature requirement must also apply to health visits. In establishments where the water temperature does not reach 11°C during the year, sampling and health visits must be carried out when the water temperature is at its highest level.

(2) Samples from broodstock must not include gonadal fluids, milt or ova as there is no evidence of EHN causing reproductive tract infection.

2. Duration of the control measures in the surveillance zone

Category A disease	Minimum periods of surveillance
Infection with *Mikrocytos mackini*	3 years
Infection with *Perkinsus marinus*	3 years
Infection with Taura syndrome virus	2 years
Infection with Yellow head syndrome virus	2 years
Epizootic haematopoietic necrosis	2 years

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