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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION (EU) .../... supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the prevention and control of certain listed diseases

Delegations will find attached document C(2019) 4057 final ANNEXES 1 to 15.

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ANNEXES 1 to 15

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

**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

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 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 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.

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 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 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 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 Regulation (EU) xx/xxx *as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases* [document C(2019)4056].

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

MONITORING PERIOD

(as referred to in Articles 8, 17, 27, 32, 48, 57 and 59 of this Regulation)

Category A diseases	Monitoring period
Foot and mouth disease (FMD)	21 days
Infection with rinderpest virus (RP)	21 days
Infection with Rift Valley fever virus (RVFV)	30 days
Infection with lumpy skin disease virus (LSD)	28 days
Infection with <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia) (CBPP)	45 days
Sheep pox and goat pox (SPGP)	21 days
Infection with peste des petits ruminants virus (PPR)	21 days
Contagious caprine pleuropneumonia (CCPP)	45 days
African horse sickness (AHS)	14 days
Infection with <i>Burkholderia mallei</i> (Glanders)	6 months
Classical swine fever (CSF)	15 days
African swine fever (ASF)	15 days
Highly pathogenic avian influenza (HPAI)	21 days
Infection with Newcastle disease virus (NCD)	21 days

ANNEX III
CONDITIONS FOR CERTAIN DEROGATIONS FROM ARTICLE 12(1)(a)
IN EQUINE ANIMALS

(as referred to in Article 13(4))

1. In the event of an outbreak of African horse sickness the competent authority may derogate from Article 12(1)(a) the affected and the unaffected animals, provided that:
 - (a) the affected animals subject to the derogation are isolated in vector-protected premises which avoid any transmission of the disease agent from the animals to the relevant vectors until 40 days, corresponding to the infective period established in the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), have elapsed after the entry of the animals into the vector protected premises; and
 - (b) surveillance, including if needed laboratory examinations, carried out by the competent authority, indicates that none of the animals in the vector protected premises poses a risk of virus transmission.

2. In the event of an outbreak of infection with *Burkholderia mallei* (Glanders) the competent authority may derogate from Article 12(1)(a) the unaffected animals, provided that the animals subject to the derogation are quarantined until:
 - (a) the affected animals have been killed and destroyed;
 - (b) after the killing, the cleaning and disinfection of the establishment has been completed as provided for in Article 15; and
 - (c) the remaining animals have been subjected to a complement fixation test carried with negative result at a serum dilution of 1 in 5 on samples taken at least 6 months after the cleaning and disinfection referred to in point (b).

ANNEX IV

PROCEDURES FOR CLEANING, DISINFECTION AND WHEN NECESSARY CONTROL OF INSECTS AND RODENTS

(as referred to in Articles 12, 15, 16, 39, 45 and 57 of this Regulation)

A. General requirements

1. The choice of biocidal products and procedures for cleaning and disinfection operations must take into account:
 - (a) the causal agent of infection;
 - (b) the nature of the establishments, vehicles, objects and materials which are to be treated; and
 - (c) the applicable legislation.
2. The conditions under which biocidal products are used must ensure that their efficacy is not impaired. In particular technical parameters provided by the manufacturer, such as pressure, temperature, required contact time or storage must be observed. The activity of the disinfectant must not be compromised by interaction with other substances.
3. Re-contamination of the previously cleaned parts must be avoided, in particular where washing is carried out with liquids applied under pressure.
4. The water used for cleaning operations must be contained and disposed of in a way that avoids any risk of spreading category A disease agents.
5. Biocidal products must be used in a way that reduces as much as possible any adverse impact on the environment and on public health that may arise from their use.

B. Preliminary cleaning and disinfection

For preliminary cleaning and disinfection under Article 15, to avoid spreading the category A disease:

- (a) entire bodies or parts of dead kept animals of listed species must be sprayed with disinfectant and removed from the establishment, in closed and leak-proof vehicles or containers for processing and disposal;
- (a) any tissue or blood which may have been spilled during killing, slaughter or post-mortem examination must be carefully collected and disposed of;
- (b) as soon as the entire bodies or parts of dead kept animals of listed species have been removed for processing or disposal, the parts of the establishment in which these animals were kept and any parts of other buildings, surfaces or equipment contaminated during killing or post-mortem examination must be sprayed with disinfectant;
- (c) manure, including litter and used bedding, must be thoroughly soaked with disinfectant;
- (d) the disinfectant must remain on the treated surface for at least 24 hours;
- (e) equipment, containers, consumption utensils, surfaces or any material likely to be contaminated after the washing and disinfecting must be destroyed.

C. Final cleaning and disinfection:

For final cleaning and disinfection for the purpose of Article 57:

1. Manure, including litter and used bedding, must be removed and treated as follows:
 - (a) the solid phase of manure, including litter and used bedding, must either:
 - (i) undergo a steam treatment at a temperature of at least 70°C;
 - (ii) be destroyed by burning;
 - (iii) be buried deep enough to prevent access by animals; or
 - (iv) be stacked to heat, sprayed with disinfectant and left for at least 42 days, during which the stack must be either covered or re-stacked to ensure thermic treatment of all layers;
 - (b) the liquid phase of manure must be stored for at least 42 days, and in the case of highly pathogenic avian influenza 60 days, after the last addition of infective material.
2. Buildings, surfaces and equipment must be thoroughly washed and cleaned by removing the remaining grease and dirt and sprayed with disinfectants.
3. After 7 days the establishments must be cleaned and disinfected again.

ANNEX V

MINIMUM RADIUS OF PROTECTION AND SURVEILLANCE ZONES (as referred to in Article 21 of this Regulation)

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 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 <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia)	Establishment	3 km
Sheep pox and goat pox	3 km	10 km
Infection with peste des petits ruminants virus	3 km	10 km
Contagious caprine pleuropneumonia	Establishment	3 km
African horse sickness	100 km	150 km
Infection with <i>Burkholderia mallei</i> (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

ANNEX VI

PROHIBITIONS IN THE RESTRICTED ZONE

(as referred to in Article 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	FMD ¹	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	GLAND	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*	X	X	X	X	X	X	X	NA	NA	NA
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

¹ Disease abbreviations in accordance with Annex II

NA = Not applicable

X = prohibition

NP = Not prohibited

* only oocytes and embryo

PROHIBITIONS OF ACTIVITIES CONCERNING ANIMALS AND PRODUCTS (cont.)	FMD ²	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	GLAND	HPAI	NCD
Itinerant natural service of kept animals of listed species	X	X	X	X	X	X	X	X	X	X	X	NA	NA	NA
Movements of hatching eggs 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	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
Movement of manure, including litter and used bedding from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X
Movement of hides, skins, wool, bristles and feathers from kept animals of listed species from establishments in the restricted zone	X	X	X	X	NP	X	X	NP	X	X	NP	NA	X	X
Movement of feed material of plant origin and straw obtained in the protection zone*	X	X	NP	NP	NP	NP	NP	NP	NP	NP	NP	NA	NP	NP

² Disease abbreviations in accordance with Annex II

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 Regulation)

Treatment	FMD ³	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
MEAT													
Heat treatment in an hermetically sealed container, to achieve a minimum F ₀ ⁴ value of 3	X						X		X	X		X	X
Heat treatment to achieve a core temperature of 80°C	X						X		X	X		X	X
Heat treatment to achieve a core temperature of 70°C	X						X		X			X	X
Heat treatment (to meat previously de-boned and defatted) to achieve a core temperature of 70°C for a minimum of 30 minutes	X						X		X				
In an hermetically sealed container, applying 60°C for a minimum of 4 hours	X						X		X	X			
Core temperature of 73,9 °C for a minimum of 0,51 seconds ⁵	X											X	X
Core temperature of 70,0 °C for a minimum of 3.5 seconds ⁵												X	X
Core temperature of 65,0 °C for a minimum of 42 seconds ⁵												X	X
Core temperature of 60 °C for a minimum of 507 seconds ⁵												X	X
Heat treatment to achieve desiccation to maximum values of Aw of 0, 93 and pH of 6													
Heat treatment to achieve a core temperature of 65°C for a period of time to achieve a minimum pasteurisation value of 40							X						

³ Disease abbreviations in accordance with Annex II

⁴ F₀ is the calculated killing effect on bacterial spores. An F₀ value of 3 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121°C (250°F) in three minutes with instantaneous heating and chilling

⁵ Only for poultry meat

Treatment		FMD ⁶	RP	RVEV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
MEAT (cont.)														
Natural fermentation and maturation for bone-in meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6		X								X				
Natural fermentation and maturation for de-boned meat: minimum 9 months, to achieve maximum values of Aw of 0,93 and pH of 6		X								X	X			
Natural fermentation for loins: minimum 140 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁷										X	X			
Natural fermentation for hams: minimum 190 days to achieve maximum values of Aw of 0,93 and pH of 6 ⁷										X	X			
Drying after salting Italian style bone-in hams: minimum 313 days ⁷										X				
Drying after salting Spanish style bone-in hams and loins ⁷ :														
– Iberian hams: minimum 252 days														
– Iberian shoulders: minimum 140 days		X								X	X			
– Iberian loins: minimum 126 days														
– Serrano hams: minimum 140 days														
Maturation of carcasses at a minimum temperature of 2°C for a minimum of 24 hours following slaughter				X										
Removal of offal					X	X			X					
CASINGS														
Salting with sodium chloride (NaCl) either dry or as saturated brine (Aw < 0,80), for a continuous period of 30 days or longer at an ambient temperature of 20°C or above		X						X		X	X			
Salting with phosphate supplemented salt 86,5 % NaCl, 10,7 % Na2HPO4 and 2,8 % Na3PO4 either dry or as saturated brine (Aw < 0,80) for a continuous period of 30 days or longer at an ambient temperature of 20°C or above		X			SC ⁸			X		X	X			
Salting with sodium chloride (NaCl) minimum 30 days ⁹														

⁶ Disease abbreviations in accordance with Annex II

⁷ Only for porcine animals

⁸ Safe commodity

⁹ Not for bovine, ovine, caprine and porcine casings

Treatment		FMD ¹⁰	RP	RVFV	LSD	CBPP	SPGP	PPR	CCPP	CSF	ASF	AHS	HPAI	NCD
CASINGS (cont.)														
Bleaching ¹¹														
Drying ¹¹														
MILK														
Heat treatment (sterilization process) to achieve a minimum F ₀ value of 3		X												
Heat treatment UHT (Ultra high temperature): Minimum 132°C for a minimum of 1 second		X						X						
Heat treatment UHT (Ultra high temperature): Minimum 135°C for a suitable holding time		X												
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is lower than 7, minimum 72°C for a minimum of 15 seconds		X						X						
Heat treatment HTST (High temperature short time pasteurisation) if milk pH is 7 or higher, minimum 72°C for a minimum of 15 seconds, applied twice		X						X						
Heat treatment HTST (High temperature short time pasteurisation) combined with a physical treatment to achieve pH value below 6 for a minimum of 1 hour or to achieve a minimum of 72°C, combined with desiccation		X												
Pasteurisation consisting in a single heat treatment with an effect at least equivalent to that achieved by applying 72°C for 15 seconds		X		X										

¹⁰

Disease abbreviations in accordance with Annex II

¹¹

Not for bovine, ovine, caprine and porcine casings

¹²

Safe commodity

Treatment	HPAI	NCD
EGGS Heat treatment: – Whole egg: ○ 60,0°C - 188 sec. ○ completely cooked – Whole egg blends: ○ 60°C - 188 sec. ○ completely cooked ○ 61,1°C - 94 sec. – Liquid egg white: ○ 55,6°C - 870 sec. ○ 56,7°C - 232 sec. – Plain or pure egg yolk: ○ 60°C - 288 sec. – 10% salted yolk: ○ 62,2°C - 138 sec. – Dried egg white: ○ 67°C - 20 hours ○ 54,4°C - 50,4 hours ○ 51,7°C - 73,2 hours	X	

<p>Heat treatment:</p> <ul style="list-style-type: none"> - Whole egg: <ul style="list-style-type: none"> o 55°C – 2 521 sec. o 57°C - 1596 sec. o 59°C - 674 sec. o completely cooked - Liquid egg white: <ul style="list-style-type: none"> o 55°C – 2 278 sec. o 57°C - 986 sec. o 59°C – 301 sec. - 10% salted egg yolk: <ul style="list-style-type: none"> o 55°C - 176 sec. - Dried egg white: <ul style="list-style-type: none"> o 57°C - 54,0 hours 	X
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ANNEX VIII

RISK-MITIGATING TREATMENTS FOR PRODUCTS NOT OF ANIMAL ORIGIN FROM THE PROTECTION ZONE

(as referred to in Articles 36 and 52 of this Regulation)

Treatment	FMD¹³	RP
Heat treatment, minimum temperature of 80°C and for a minimum of 10 minutes, steam in a closed chamber	X	X
Storage in package or bales under shelter at premises situated not closer than 2 km to the nearest outbreak and releasing from the premises do not take place before at least three months have elapsed following the completion of cleaning and disinfection according to Article 15	X	X

¹³ Disease abbreviations in accordance with Annex II

ANNEX IX

MARKING OF FRESH MEAT FROM THE PROTECTION ZONE

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

1. The mark to be applied to fresh meat of poultry originating in the protection zone and not intended to another Member State pursuant to Article 33(1)(b) must comply with the following:
 - (a) shape and content:

Where 'XY' means the relevant country code provided for in point 6 of Part B of Section I of Annex II of Regulation (EC) No 853/2004 and '1234' means the approval number of the establishment referred to in point 7 of Part B of Section I of Annex II of Regulation (EC) No 853/2004 .
 - (b) dimensions:
 - 'XY' width of 8 mm
 - '1234' width of 11 mm
 - width outer diameter of not less than 30 mm
 - line thickness of square of 3 mm
2. The mark to be applied to fresh meat intended for treatment in a processing plant pursuant to Article 33(2)(a) shall consist in, either:
 - (a) the identification mark provided for in Regulation (EC) 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:
 - on the upper part, the full name or ISO code of the Member State in capitals;
 - in the centre, the approval number of the slaughterhouse;
 - on the lower part, one of the following sets of initials CE, EC, EF, EG, EK, EY, EO, ES, EU, EB, WE or EZ;
 - two straight lines crossing at the centre of the stamp in such a way that the information is not obscured;
 - the letters must be at least 0,8 cm high and the figures at least 1 cm high.

ANNEX X

DURATION OF THE MEASURES IN THE PROTECTION ZONE

(as referred to in Article 39 of this Regulation)

Category A diseases	Minimum period of duration of measures in the protection zone (Article 39(1))	Additional period of duration of surveillance measures in the protection zone (Article 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 <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia)	45 days	Not applicable
Sheep pox and goat pox	21 days	9 days
Infection with peste des petits ruminants virus	21 days	9 days
Contagious caprine pleuropneumonia	45 days	Not applicable
African horse sickness	12 months	Not applicable
Infection with <i>Burkholderia mallei</i> (Glanders)	6 months	Not applicable
Classical swine fever	15 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

ANNEX XI

DURATION OF THE MEASURES IN THE SURVEILLANCE ZONE

(as referred to in Articles 55 and 56 of this Regulation)

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 <i>Mycoplasma mycoides subsp. mycoides SC</i> (Contagious bovine pleuropneumonia)	45 days
Sheep pox and goat pox	30 days
Infection with peste des petits ruminants virus	30 days
Contagious caprine pleuropneumonia	45 days
African horse sickness	12 months
Infection with <i>Burkholderia mallei</i> (Glanders)	Not applicable
Classical swine fever	30 days
African swine fever	30 days
Highly pathogenic avian influenza	30 days
Infection with Newcastle disease virus	30 days

ANNEX XII

SAMPLING PROCEDURES AND DIAGNOSTIC METHODS FOR CATEGORY A DISEASES IN AQUATIC ANIMALS

1. The following procedures apply to the clinical examination and collection of samples:
- (a) the clinical examination and the sampling for laboratory examinations must include:
 - (i) aquaculture animals of listed species showing clinical signs of the relevant category A disease; and
 - (ii) aquaculture animals likely to have recently died from the suspected/confirmed category A disease; and
 - (iii) aquaculture animals with an epidemiological link to a suspected or confirmed case of a category A disease.
 - (b) the minimum number of samples to be collected is:

	Scenario			
Type of animals	Report of increased mortality	Introduction of infected animals	Post-mortem or clinical signs observed	Suspicion based on other circumstances
Molluscs (the whole animal)	30	30	-	150
Crustaceans	10		10	150
Fish	-	-	10	30

- (c) the following additional criteria apply to the sampling of molluscs:
 - (i) animals suspected to be infected must be selected for sampling. If listed species are present in the population of animals concerned by the suspicion, those must be selected for sampling;
 - (ii) if weak, gaping or freshly dead but not decomposed molluscs are present, those must be selected first. If such molluscs are not present, the molluscs selected must include the oldest healthy molluscs;
 - (iii) if the establishment uses more than one water source for mollusc production, molluscs representing all water sources must be included for sampling to ensure that all parts of the establishment are proportionally represented in the sample;
 - (iv) when sampling from a group of mollusc farming establishments which apparently have identical epidemiological status, molluscs from a representative number of sampling points must be included in the sample.

The main factors to be considered when selecting those sampling points must be stocking density, water currents, the presence of listed species,

both susceptible and vector species, bathymetry and management practices. Natural beds within or adjacent to the mollusc farming establishment(s) must be included in the sample.

- (d) the following additional criteria apply when sampling crustaceans:
- (i) if weak or moribund crustaceans of listed species are present in the production units, those crustaceans must be selected first. If such animals are not present, the crustaceans selected must include crustaceans of different year classes, proportionally represented in the sample;
 - (ii) if more than one water source is used for crustacean production, crustaceans of listed species representing all water sources must be included in the sample to ensure that all parts of the establishment are proportionally represented in the sample;
 - (iii) when collection of samples from wild populations of listed species is required under Article 102(a) of this Regulation, the number and geographical distribution of the sampling points must be determined in a way that ensures a reasonable coverage of the area suspected to be infected.

The sampling points must be representative for the different ecosystems where the wild populations of susceptible species are located such as marine, estuary, river and lake systems.

- (e) the following additional criteria apply for sampling fish:
- (i) if weak, abnormally behaving or freshly dead but not decomposed fish are present, those fish must be selected. If such animals are not present, the fish selected must include fish of listed species, belonging to different year classes, proportionally represented in the sample;
 - (ii) if more than one water source is used for fish production, listed species representing all water sources must be included for sampling to ensure that all parts of the establishment are proportionally represented in the sample;
 - (iii) if rainbow trout (*Onchorynchus mykiss*) or European perch (*Perca fluviatilis*) are present, only fish of those species may be selected for sampling. If neither rainbow trout nor European perch are present, the sample must be representative of all other listed species present, following the criteria in points (a) to (d);
 - (iv) when collection of samples from wild populations of listed species is required under Article 102(a) of this Regulation, the number and geographical distribution of the sampling points must be determined in a way that ensures a reasonable coverage of the area suspected to be infected.

The sampling points must also be representative of the different ecosystems where the wild populations of susceptible species are located such as marine, estuary, river and lake systems.

- (f) the selection of organs to be sampled, preparation, storage and shipment of the samples to the laboratory must be carried out in compliance with

recommendations from the European Union reference laboratory for the relevant disease.

2. Samples must be examined in the laboratory using the diagnostic methods and procedures approved by the European Union reference laboratory for the relevant disease.

ANNEX XIII

MINIMUM PERIODS OF FALLOWING OF AFFECTED AQUACULTURE ESTABLISHMENTS

Periods for the fallowing provided for in Article 81 and for the synchronous fallowing provided for in Article 96(4) and (5) of this Regulation

Category A disease	Minimum period of fallowing of the affected establishment	Minimum period of synchronised fallowing of affected establishments in the same protection zone	Supplementary requirements
Infection with <i>Mikrocytos mackini</i>	6 months	4 weeks	Must include the coldest period of the year
Infection with <i>Perkinsus marinus</i>	6 months	4 weeks	Must include the warmest period of the year
Infection with <i>Taura syndrome virus</i>	6 weeks	4 weeks	Must include the warmest period of the year
Infection with <i>Yellow head syndrome virus</i>	6 weeks	3 weeks	Must include the warmest period of the year
<i>Epizootic haematopoietic necrosis</i>	8 weeks	4 weeks	Must include the warmest period of the year

ANNEX XIV

CRITERIA FOR ESTABLISHING RESTRICTED ZONES AS REGARDS CATEGORY A DISEASES IN AQUATIC ANIMALS

1. Restricted zones as referred to in Article 85 must be defined on a case-by-case basis taking into account at least the following factors:
 - (a) the accumulated number, the accumulated percentage and the distribution of the mortalities of molluscs/crustaceans/fish in the establishment or group of farming establishments infected with category A diseases;
 - (b) relevant information regarding movements to and from the infected establishment(s);
 - (c) the distance to and density of neighbouring establishments;
 - (d) the presence of wild aquatic animals;
 - (e) any knowledge concerning mortalities, suspected cases or outbreaks in wild aquatic animals which are, or could be related to the specific category A disease;
 - (f) the proximity to processing establishments, and the species present at those establishments, especially as regards listed species;
 - (g) farming practices applied in the affected and neighbouring establishments;
 - (h) hydrodynamic conditions and other identified factors of epidemiological significance.
2. For the geographical demarcation of the protection and surveillance zones for category A diseases affecting molluscs and crustaceans, the following minimum requirements apply:
 - (a) the protection zone must be established in the immediate vicinity of an establishment or group of farming establishments officially confirmed as infected with a category A disease and must correspond to an area determined according to appropriate hydrodynamic and epidemiological data;
 - (b) the surveillance zone must be established outside the protection zone and must correspond to an area surrounding the protection zone, determined according to appropriate hydrodynamic or epidemiological data.
3. For the geographical demarcation of the protection and surveillance zones for category A diseases affecting fish, the following minimum requirements must apply:
 - (a) the protection zone must be established around an establishment where *Epizootic hematopoietic necrosis* (EHN) has been confirmed. This zone shall correspond:
 - (i) in coastal areas: to an area included in a circle with a radius of at least one tidal excursion or at least 5 km, whichever is larger, centred on the establishment in which EHN has been officially confirmed, or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
 - (ii) in inland areas: to the entire water catchment area of the establishment in which EHN has been officially confirmed. The competent authority may limit the extension of the zone to parts of the water catchment area, or the

area of the establishment, provided this does not compromise prevention of the spread of the disease;

- (b) the surveillance zone must be established by the competent authority outside the protection zone and must:
 - (i) in coastal areas: correspond to an area, surrounding the protection zone, of overlapping tidal excursion; or an area, surrounding the protection zone, and included in a circle of radius 10 km from the centre of the protection zone; or an equivalent area determined according to appropriate hydrodynamic or epidemiological data;
 - (ii) in inland areas: be an extended area outside the established protection zone.

ANNEX XV

SURVEILLANCE SCHEME AND DURATION OF CONTROL MEASURES IN THE SURVEILLANCE ZONE FOR CATEGORY A DISEASES IN AQUACULTURE ANIMALS

(as referred to in Articles 98 and 101 of this Regulation)

1. Surveillance scheme

The establishments and groups of aquaculture establishments keeping listed species within a surveillance zone must undergo surveillance as provided for in Article 98 to check for infection with the relevant category A disease. The surveillance must include health visits, including sampling from production units. Those visits must be carried out by the competent authority in accordance with Tables 1 and 2.

The criteria set out in point 1 of Annex XII, as appropriate for the species, apply to sampling.

Table 1: *Scheme for surveillance comprising health visits and samplings in establishments and groups of establishments for category A diseases in aquatic animals, except epizootic hematopoietic necrosis*

Category A disease	Number of health visits per year	Number of laboratory examinations per year	Number of animals in the sample	Period of the year for sampling	Residency period of the sampled animals in the establishment
Infection with <i>Mikrocytos mackini</i>	1	1	150	When the prevalence of infection is known to be maximal or April-May, after 3-4 months period when seawater temperatures are less than 10°C	4 months
Infection with <i>Perkinsus marinus</i>	1	1	150	When the prevalence of infection is known to be maximal or in the month of September, October or November	4 months
Infection with <i>Taura syndrome virus</i>	2	2	150	In the period of the year when water temperature is likely to reach its highest annual level	2 months
Infection with <i>Yellow head syndrome virus</i>	2	2	150	In the period of the year when water temperature is likely to reach its highest annual level	2 months

Table 2: *Specific scheme for surveillance comprising health visits and samplings in establishments for epizootic haematopoietic necrosis (EHN) in aquatic animals* ⁽¹⁾

Type of establishment	Number of health inspections per year (2 years)	Number of samplings per year (2 years)	Number of fish in the sample	
			Number of growing fish	Number of brood stock fish ⁽²⁾
(a) Establishments with broodstock	2	2	150 (first and second inspection)	150 (first or second inspection)

(b) Establishments with broodstock only	2	1	0	150 ⁽²⁾ (first or second inspection)
(c) Establishments without broodstock	2	2	150 (first and second inspection)	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 inspections. 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 <i>Mikrocytos mackini</i>	3 years
Infection with <i>Perkinsus marinus</i>	3 years
Infection with <i>Taura syndrome virus</i>	2 years
Infection with <i>Yellow head syndrome virus</i>	2 years
<i>Epizootic haematopoietic necrosis</i>	2 years

When the period of surveillance has elapsed and there has been no new detection of infection with the relevant category A disease, the measures in the surveillance zone must be lifted as provided for in Article 101 of this Regulation.