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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annexes I and III to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards a surveillance programme for chronic wasting disease in cervids in Estonia, Finland, Latvia, Lithuania, Poland and Sweden and repealing Commission Decision 2007/182/EC
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Delegations will find attached document D050237/03 ANNEX 1.

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ANNEX 1

ANNEX

to the

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

**amending Annexes I and III to Regulation (EC) No 999/2001 of the European
Parliament and of the Council as regards a surveillance programme for chronic wasting
disease in cervids in Estonia, Finland, Latvia, Lithuania, Poland and Sweden and
repealing Commission Decision 2007/182/EC**

ANNEX

Annexes I and III to Regulation (EC) No 999/2001 are amended as follows:

1. In Annex I the following items are added to point 2:
 - (o) 'farmed and captive cervids' means animals of the family *Cervidae* which are kept by humans in an enclosed territory.
 - (p) 'wild cervids' means animals of the family *Cervidae* which are not kept by humans.
 - (q) 'semi-domesticated cervids' means animals of the family *Cervidae* which are kept by humans although not in an enclosed territory.'
2. Annex III is amended as follows:
 - (a) In Chapter A, Part III is replaced by the following:

'III. MONITORING IN CERVIDS

A. *Three-year monitoring programme for chronic wasting disease (CWD)*

 1. General
 - 1.1. The Member States which have a wild and/or farmed and/or semi-domesticated population of moose and/or reindeer (Estonia, Finland, Latvia, Lithuania, Poland and Sweden) shall carry out a three-year monitoring programme for CWD in cervids, from 1 January 2018 to 31 December 2020. The TSE tests performed for the purpose of this monitoring programme shall take place between 1 January 2018 and 31 December 2020, however, the collection of samples for the purpose of the monitoring programme may, however, start in 2017.
 - 1.2. The three-year CWD monitoring programme shall cover the following cervid species:
 - Eurasian tundra reindeer (*Rangifer tarandus tarandus*);
 - Finnish forest reindeer (*Rangifer tarandus fennicus*);
 - Moose (*Alces alces*);
 - Roe deer (*Capreolus capreolus*);
 - White-tailed deer (*Odocoileus virginianus*);
 - Red deer (*Cervus elaphus*).
 - 1.3. By way of derogation from point 1.2, a Member State may, based on a documented risk assessment submitted to the European

Commission, select for the three-year CWD monitoring programme a subset of the species listed in that point.

2. Sampling design

2.1. The Member States referred to in point 1.1 shall identify Primary Sampling Units (PSU), which shall cover all territories in which cervid populations are present, using at least the following elements:

- (a) for farmed and captive cervids, each farm and each facility in which cervids are kept in an enclosed territory shall be considered as a PSU.
- (b) for wild and semi-domesticated cervids, PSU shall be defined geographically based on the following criteria:
 - (i) the areas in which wild and semi-domesticated animals of a species covered by the monitoring programme gather in at least a certain period of the year;
 - (ii) if no gathering takes place for a species, the areas delimited by natural or artificial barriers in which animals of the species covered by the monitoring programme are present;
 - (iii) the areas in which animals of the species covered by the monitoring programme are hunted and areas connected to other relevant activities related to the species covered by the monitoring programme.

2.2. The Member States referred to in point 1.1 shall select farmed, captive, wild and semi-domesticated cervids for TSE testing using the following two-stage sampling approach:

- (a) in the first stage, those Member States shall:
 - (i) for farmed and captive cervids:
 - select, on a random basis ensuring geographical representativeness, and if relevant taking into account relevant risk factors identified in a documented risk assessment carried out by the Member State, 100 PSU to be covered over the three-year period of the monitoring programme, or
 - if the Member State was unable to identify 100 PSU for farmed and captive cervids, select all PSU identified.
 - (ii) For wild and semi-domesticated cervids:
 - select, on a random basis ensuring geographical representativeness, and if relevant taking into account

relevant risk factors identified in a documented risk assessment carried out by the Member State, 100 PSU to be covered over the three-year period of the monitoring programme, or

- if the Member State was unable to identify 100 PSU for wild and semi-domesticated cervids, select all PSU identified.

(b) in the second stage:

(i) for farmed and captive cervids:

- a Member State having selected 100 PSU shall, within every selected PSU, sample all animals belonging to the target groups listed under point 2.4.(a) over the three-year period until a target of 30 animals tested per PSU is reached. If however certain PSU are not be able to reach the target of 30 animals tested over the three-year period due to the limited size of their cervid population, the sampling of animals belonging to the target groups listed under point 2.4.(a) may continue in larger PSU even after having reached the target of 30 animals tested, with the objective of reaching a total number of up to 3,000 farmed and captive cervids, where possible, tested at national level over the three-year period of the monitoring programme;
- a Member State having identified fewer than 100 PSU shall, within every PSU, sample all animals belonging to the target groups listed under point 2.4.(a) over the three-year period, with the objective of approaching a total number of up to 3,000 farmed and captive cervids, where possible, tested at national level over the three-year period of the monitoring programme.

(ii) for wild and semi-domesticated cervids:

- a Member State having selected 100 PSU shall, within every selected PSU, sample all animals belonging to the target groups listed under point 2.4.(b), over the three-year period until a target of 30 animals tested per PSU is reached, with the objective of reaching up to 3,000 wild and semi-domesticated cervids tested at national level over the three-year period;
- a Member State having identified fewer than 100 PSU shall, within every PSU, sample all animals belonging to the target groups listed under point 2.4.(b) over the three-year period, with the objective of approaching a total number of 3,000 wild and semi-domesticated cervids tested at national level over the three-year period of the monitoring programme.

- 2.3. All cervids selected must be over 12 months of age. The age shall be estimated on the basis of dentition, obvious signs of maturity, or any other reliable information.
- 2.4. The cervids must be selected from the following target groups:
- (a) for farmed and captive cervids:
 - (i) fallen/culled farmed or captive cervids, defined as farmed or captive cervids found dead on the enclosed territory in which they are kept, during transport or at slaughterhouse, as well as farmed or captive cervids killed for health/age reasons;
 - (ii) clinical/sick farmed or captive cervids, defined as farmed or captive cervids showing abnormal behavioural signs and/or locomotor disturbances and/or as being generally in poor condition;
 - (iii) slaughtered farmed cervids which have been declared unfit for human consumption;
 - (iv) slaughtered farmed cervids considered fit for human consumption if a Member State identifies fewer than 3,000 farmed and captive cervids from the groups (i) to (iii).
 - (b) for wild and semi-domesticated cervids:
 - (i) fallen/culled wild or semi-domesticated cervids, defined as cervids found dead in the wild as well as semi-domesticated cervids found dead or killed for health/age reasons;
 - (ii) road- or predator-injured or killed cervids, defined as wild or semi-domesticated cervids hit by road vehicles, by trains or attacked by predators;
 - (iii) clinical/sick wild and semi-domesticated cervids, defined as wild and semi-domesticated cervids which are observed as showing abnormal behavioural signs and/or locomotor disturbances and/or as being generally in poor health condition;
 - (iv) wild hunted cervids and slaughtered semi-domesticated cervids which have been declared unfit for human consumption;
 - (v) hunted wild game and slaughtered semi-domesticated cervids considered fit for human consumption if a Member State identifies fewer than 3,000 wild and semi-domesticated cervids from the groups (i) to (iv).

- 2.5. In case of a positive finding of TSE in a cervid, the number of samples from cervids collected in the zone where the positive TSE case was found must be increased, based on an assessment carried out by the Member State concerned.

3. Sampling and laboratory testing

- 3.1. For each cervid selected in accordance with point 2, a sample of obex shall be collected and tested for TSEs.

In addition, where feasible, a sample of one of the following tissues shall be collected in the following order of preference:

- (a) retropharyngeal lymph nodes;
- (b) tonsils;
- (c) other head lymph nodes.

For rapid testing a hemisection of obex shall be submitted in a fresh or frozen state. The remaining hemisection should be fixed. When collected, lymph nodes and tonsils should be fixed.

A portion of fresh tissue from each sample type shall be kept frozen until a negative result is obtained, in case bioassay is required.

- 3.2. Until the publication of guidelines on TSE testing in cervids of the EU Reference Laboratory for TSE, the following laboratory method shall be used for the purpose of the CWD monitoring programme:

- (a) rapid tests:

Rapid tests as referred to in point 4 of Chapter C of Annex X used for TSE detection in obex of bovine or small ruminant animals are considered suitable for TSE detection in obex of cervids. Rapid tests as referred to in point 4 of Chapter C of Annex X used for TSE detection in the lymph nodes of bovine or small ruminant animals are considered suitable for TSE detection in lymph nodes of cervids. Member States may also use immunohistochemistry for screening purposes for which purpose they shall satisfy a proficiency test organised by the EU Reference Laboratory for TSE.

- (b) confirmatory tests:

When the result of the rapid test is inconclusive or positive, the sample shall be subjected to confirmatory examinations using at least one of the following methods and protocols as laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE):

- the immunohistochemical (IHC) method;
- Western blot.

Where a Member State is unable to confirm a positive rapid test result, it shall send adequate tissue to the EU Reference laboratory for confirmation.

(c) isolate characterisation:

In the case of positive findings of TSE, further isolate characterisation should be undertaken, in consultation with the EU Reference Laboratory for TSE.

3.3. The prion protein genotype shall be determined for each positive finding of TSE in cervids.

In addition, for each cervid tested and found negative for TSE, either:

- the prion protein genotype of the animal tested and found negative for TSE is determined, or
- a sample of a tissue, which may be the obex, shall be kept frozen until at least 31 December 2021, to allow for genotyping if so decided.

B. Other monitoring in cervids

Member States shall carry out additional monitoring for TSEs in cervids based on a risk assessment which may take into account the detection of a TSE in cervids in the same or neighbouring regions.

Member States other than those mentioned under point 1.1 of Part A may on a voluntary basis carry out monitoring for TSEs in cervids.

After the end of the three-year monitoring programme referred to in Part A, the Member States mentioned under point 1.1 may on a voluntary basis carry out monitoring for TSEs in cervids.'

(b) In Chapter A, the following Part IV is added:

IV. MONITORING IN OTHER ANIMAL SPECIES

Member States may on a voluntary basis carry out monitoring for TSE in animal species other than bovine, ovine, caprine and cervid animals.'

(c) In Chapter B, Part I.(A), point 7 is replaced by the following:

- '7. In animals other than bovine, ovine and caprine animals, as well as in cervids other than those covered by the three-year CWD monitoring programme referred to in Part III.A of Chapter A of this Annex, the number of samples and confirmed TSE cases per species.'

(d) In Chapter B, Part I.(A), the following point 9 is added:

- '9. For Member States covered by the three-year CWD monitoring programme referred to in Part III.A of Chapter A of this Annex, the annual report for the years 2018, 2019 and 2020 shall include:
- (a) The number of cervid samples submitted for testing, by target group according to the following criteria:
 - primary Sampling Unit (PSU) identifier,
 - species,
 - management system: farmed, captive, wild or semi-domesticated,
 - target group,
 - sex,
 - (b) The results of the rapid and confirmatory tests (number of positives and negatives) and, where applicable, of further isolate characterisation investigations, the tissue sampled and the rapid test and confirmatory technique used.
 - (c) The geographical location, including the country of origin if not the same as the reporting Member State, of positive cases of TSE.
 - (d) The genotype and species of each cervid found positive for TSE.
 - (e) Where tested, the genotype of cervids tested and found negative for TSE.'