II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2022/2246

of 15 November 2022

amending Annexes VIII and IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards chronic wasting disease in live cervids

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (1), and in particular Article 23a, points (j) and (m), thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies in the Union. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof. Annex VIII to Regulation (EC) No 999/2001 sets out the rules for intra-Union trade and Annex IX to that Regulation sets out the rules relating to imports into the Union. It also provides, inter alia, for the adoption of safeguard measures in the event of outbreaks of TSEs.
- (2) Chronic wasting disease is a transmissible spongiform encephalopathy of cervids which is infectious and thus can cause disturbance to trade within the Union, imports into the Union and exports to third countries.
- (3) Norway informed the Commission, on 1 April 2016, of the first case of chronic wasting disease confirmed in its territory, in a wild reindeer. That was the first time that chronic wasting disease had been detected in Europe and the first natural case in a reindeer in the world. From this first case until October 2021, Norway confirmed at least one case each year, with a total of thirty one cases: twenty in wild reindeer, two in red deer and nine in moose.
- (4) Norway adopted on 11 July 2016 a measure to prohibit the export from Norway of live cervids, without prejudice to specific derogations.
- (5) Since chronic wasting disease is an infectious disease, there is a risk that it can spread to other cervid populations and to other regions in the Union and in the European Free Trade Association States. Commission Implementing Decision (EU) 2016/1918 (²) was therefore adopted. It prohibited the movement of live cervids from Norway into the Union and provided for specific derogations.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ Commission Implementing Decision (EU) 2016/1918 of 28 October 2016 concerning certain safeguard measures in relation to chronic wasting disease (OJ L 296, 1.11.2016, p. 21).

- (6) On 2 December 2016, the European Food Safety Authority (EFSA) adopted a scientific opinion on chronic wasting disease in cervids (the 2016 EFSA Opinion) (³). This opinion recommended the implementation of a 3-year surveillance programme for chronic wasting disease in cervids in Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland and Sweden, which are the Member States and the EFTA States with a reindeer or a moose population, or with both populations, in order to detect and to estimate the prevalence and geographical spread of chronic wasting disease. The 2016 EFSA Opinion also concluded that the most likely pathway of introduction and spread of chronic wasting disease was the movement of live cervids and highlighted that the use of natural cervid urine hunting lures increased the probability of introduction of chronic wasting disease. It therefore recommended minimising the movements of live cervids and discontinuing the use of cervid urine hunting lures.
- (7) Following the adoption of the 2016 EFSA Opinion, Annex III to Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) 2017/1972 (4) in order to provide for a 3-year monitoring programme for chronic wasting disease in cervids, while Commission Implementing Decision (EU) 2017/2181 (5) extended the validity of Implementing Decision (EU) 2016/1918 until the end of 2020 to allow for the safeguard measures to remain applicable until the end of that 3-year monitoring programme. Implementing Decision (EU) 2017/2181 also added prohibitions and restrictions regarding cervid urine hunting lures to the safeguard measures.
- (8) In 2018, Finland detected the first case of chronic wasting disease in the Union and an additional case in November 2020. Sweden detected three cases of chronic wasting disease in 2019 and an additional case in September 2020. All cases of chronic wasting disease detected in Finland and Sweden were confirmed in the context of the 3-year monitoring programme for chronic wasting disease in cervids and were found in wild moose.
- (9) On 11 November 2019, the EFSA published the Scientific Opinion 'Update on chronic wasting disease (CWD) III' (6) (the 2019 EFSA Opinion) with various recommendations to the Commission, including in relation to the risk factors that can facilitate the spread of chronic wasting disease in the Union.
- (10) Taking into account the detection of new cases of chronic wasting disease in Norway, Finland and Sweden, pending the scientific assessment of the results of the monitoring programme, and considering that additional time was needed to reflect on the recommendations of the 2019 EFSA Opinion, the period of application of Implementing Decision (EU) 2016/1918 was again extended by Commission Implementing Decision (EU) 2020/2167 (7), until 31 December 2022, to reflect the more recent confirmations of chronic wasting disease in Finland and Sweden.
- (11) Considering that the safeguard measures of Implementing Decision (EU) 2016/1918 have been applied since 2016, that the latest epidemiological situation regarding chronic wasting disease does not allow to envisage its eradication anytime soon, that it would be legally inappropriate to extend again the application of the safeguard measures based on article 4 of Regulation (EC) No 999/2001, and that measures should nevertheless remain applicable to keep on preventing chronic wasting disease from spreading further in the Union and the EFTA States, Annexes VIII and IX to Regulation (EC) No 999/2001 should be amended to include the measures currently laid down in Implementing Decision (EU) 2016/1918, adjusted as necessary to take into account the confirmation of chronic wasting disease in Finland and Sweden.

⁽³⁾ EFSA Journal 2017;15(1):4667.

^(*) Commission Regulation (EU) 2017/1972 of 30 October 2017 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 (OJ L 281, 31.10.2017, p. 14).

⁽⁵⁾ Commission Implementing Decision (EU) 2017/2181 of 21 November 2017 amending Implementing Decision (EU) 2016/1918 concerning certain safeguard measures in relation to chronic wasting disease (OJ L 307, 23.11.2017, p. 58).

⁽⁶⁾ EFSA Journal 2019;17(11)5863.

⁽⁷⁾ Commission Implementing Decision (EU) 2020/2167 of 17 December 2020 amending Implementing Decision (EU) 2016/1918 concerning certain safeguard measures in relation to chronic wasting disease by extending its period of application (OJ L 431, 21.12.2020, p. 70).

- (12) Consequently, based on conclusions from the 2016 and 2019 EFSA opinions, it is necessary to maintain the prohibition of the movement of live cervids from Norway into the Union. For practical reasons, that prohibition should continue to apply to live cervids moved in conjunction with human activity, but not to movements of wild cervids crossing the border of Norway without any human intervention. Specific derogations from that prohibition should be laid down to allow certain movements of live cervids from Norway into the Union, including the cross-border seasonal grazing of semi-domesticated reindeer, and the movements of semi-domesticated reindeer to be used in cultural or sportive events in Sweden. However, due to the animal health risk that the movements allowed by those derogations represents, notably in terms of environmental contamination with chronic wasting disease prions in the areas of destination, such movements should remain restricted to defined areas in Finland and Sweden, and movements of live cervids from those areas should remain prohibited, without prejudice to specific derogations.
- (13) Considering that chronic wasting disease has now been confirmed in two Member States, and based on conclusions from the 2016 and 2019 EFSA opinions on the risk factors that can facilitate the spread of chronic wasting disease in the Union, it is necessary to provide for a prohibition of the movement of live cervids from a Member State concerned by that disease to the rest of the Union. For practical reasons, that prohibition should apply to live cervids moved in conjunction with human activity, but not to movements of wild cervids without any human intervention. Specific derogations to that prohibition should be laid down to allow certain movements of live cervids from the Member States concerned by the chronic wasting disease, including with the purpose to ensure safe access to, and valorisation of, valuable cervid genetic resources between Member States concerned.
- (14) The prohibition of import of urine hunting lures derived from cervids and the prohibition of movement of urine hunting lures derived from cervids originating in Norway should be maintained. In addition, the movements of cervid urine hunting lures derived from cervids originating in Member States where cases of chronic wasting disease have been confirmed should be prohibited.
- (15) Annexes VIII and IX to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VIII and IX to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 January 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 November 2022.

For the Commission The President Ursula VON DER LEYEN

ANNEX

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

- 1. Annex VIII is amended as follows:
 - (a) Chapter A is amended as follows:
 - (i) Section B is deleted;
 - (ii) the following Section C is added:

SECTION C

Conditions which apply to cervids

- 1. List of Member States and areas thereof established in relation to chronic wasting disease
 - 1.1. Member States where cases of chronic wasting disease have been confirmed:
 - (a) Finland
 - (b) Sweden
 - 1.2. Areas of Finland and Sweden defined in relation to the risk of chronic wasting disease linked to traditional cross-border movements of live semi-domesticated reindeer to and from Norway:
 - (a) in Finland: the area located between the Norwegian-Finnish border and the Norwegian-Finnish Reindeer Fence;
 - (b) in Sweden:
 - the county of Norrbotten,
 - the county of Västerbotten,
 - the county of Jämtland,
 - the county of Västernorrland,
 - the Älvdalen municipality in the county of Dalarna,
 - the municipalities of Nordanstig, Hudiksvall and Söderhamn in the county of Gävleborg.
- 2. Movements of live cervids from Norway into the Union
 - The movements of live cervids from Norway into the Union shall be prohibited.
 - 2.2. By way of derogation from point 2.1, the following movements of live cervids shall be permitted:
 - (a) movements from Norway to the areas in Sweden listed in point 1.2(b) of live semi-domesticated reindeer for seasonal grazing, provided that the competent authority of Sweden gives its prior written consent to such movements;
 - (b) the return from Norway to the areas in Sweden listed in point 1.2(b) of live semi-domesticated reindeer after seasonal grazing in Norway, provided that the competent authority of Sweden gives its prior written consent to such movements;
 - (c) movements from Norway to the areas in Finland listed in point 1.2(a) of live semi-domesticated reindeer for seasonal grazing;
 - (d) the return from Norway to Finland of live semi-domesticated reindeer which have grazed in Norway in the area located between the Norwegian-Finnish border and the Norwegian-Finnish Reindeer Fence;
 - (e) movements from Norway to Sweden or Finland of live cervids for direct slaughter, provided that the competent authority of the Member State of destination gives its prior written consent to such movements;

- (f) movements from Norway to the areas in Sweden listed in point 1.2(b) of live semi-domesticated reindeer for sportive or cultural events, provided that the competent authority of Sweden gives its prior written consent to the movement of each consignment;
- (g) the return from Norway to the areas in Sweden listed in point 1.2(b) of live semi-domesticated reindeer after having taken part in sportive or cultural events in Norway, provided that the competent authority of Sweden gives its prior written consent to the movement of each consignment;
- (h) transit of live cervids from Norway through Sweden or Finland and destined to Norway, provided that the competent authority of the Member State of transit gives its prior written consent.
- 3. Movements of live cervids out of the areas of Finland and Sweden with a tradition of cross-border movements with Norway of semi-domesticated reindeer
 - 3.1. The movements of live cervids out of the areas listed in point 1.2 shall be prohibited.
 - 3.2. By way of derogation from point 3.1, the following movements of live cervids out of the areas listed in point 1.2 shall be permitted:
 - (a) movements of live cervids to Norway, provided that the competent authority of Norway gives its prior written consent to such movements;
 - (b) movements of live cervids for direct slaughter in Finland or Sweden, provided that the competent authority of destination gives its prior written consent to such movements;
 - (c) movements from the areas of Sweden listed in point 1.2(b) to Finland of live forest reindeer, provided that the competent authority of Finland gives its prior written consent to such movements;
 - (d) movements of live cervids from a confined establishment as defined in Article 4(48) of Regulation (EU) 2016/429 of the European Parliament and of the Council (*) and located in an area listed in point 1.2(b) of this Annex, to a confined establishment, as defined in Article 4(48) of Regulation (EU) 2016/429, in Sweden, provided that the competent authority of Sweden gives its prior written consent to such movements.
- 4. Movements of live cervids out of a Member State where chronic wasting disease has been confirmed
 - 4.1. Without prejudice to the provisions laid down in point 3, the movements of live cervids out of a Member State listed in point 1.1 to other Member States shall be prohibited.
 - 4.2. By way of derogation from point 4.1, the following movements of live cervids out of a Member State listed in point 1.1 shall be permitted:
 - (a) movements of live cervids for direct slaughter in another Member State listed in point 1.1 or Norway;
 - (b) movements of live cervids for purposes other than direct slaughter to another Member State listed in point 1.1 or Norway, provided that the competent authority of destination gives its prior written consent to such movements;
 - (c) movements of live cervids from a confined establishment as defined in, Article 4(48) of Regulation (EU) 2016/429 to a confined establishment, as defined in Article 4(48) of Regulation (EU) 2016/429, in another Member State, provided that the competent authority of destination gives its prior written consent to such movements.';

^(*) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

(b) in Chapter C, the following Section C is added:

SECTION C

Urine hunting lures from cervids

- 1. The movement into the Union of consignments of urine hunting lures derived from cervids originating in Norway shall be prohibited.
- 2. The manufacture, placing on the market and use of urine hunting lures derived from cervids originating in the Member States listed in Chapter A, Section C, point 1.1 shall be prohibited.';
- 2. in Annex IX, in Chapter F, the following point 3 is added:
 - '3. The importation into the Union of urine hunting lures derived from cervids shall be prohibited.'.