Commission Regulation (EU) No 1148/2014 of 28 October 2014 amending Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1148/2014

of 28 October 2014

amending Annexes II, VII, VIII, IX and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(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 the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. 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.

(2) Annex II to Regulation (EC) No 999/2001 lays down rules governing the determination of the bovine spongiform encephalopathy (BSE) status of Member States or third countries or regions thereof. These rules are based on the international standard established by the World Organisation for Animal Health (OIE) in the Terrestrial Animal Health Code (the Code). In the BSE chapter of the 2013 version of the Code, the expression ‘release assessment’ has been replaced by ‘entry assessment’, and the table providing the points targets for a country or region has been significantly amended to better meet the needs of countries with a small or very small cattle population. These amendments should be reflected in Annex II.

(3) Point 2.2.1 of Chapter B of Annex VII to Regulation (EC) No 999/2001 refers to the methods and protocols set out in Annex X. The wording of this point should be amended to reflect amendments to Annex X brought by this act.

(4) Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down rules governing intra-Union trade in live animals, semen and embryos, including the exemption of homozygous ovine ARR embryos from any other classical scrapie related requirement

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1148/2014. (See end of Document for details)*

in intra-Union trade. On 24 January 2013, the European Food Safety Authority (EFSA) adopted a scientific opinion on the risk of transmission of classical scrapie via in vivo derived embryo transfer in ovine animals[(2)], where it concluded that the risk of transmitting classical scrapie by the implantation of homozygous or heterozygous ovine ARR embryos could be considered negligible providing that the OIE recommendations and procedures relating to embryo transfer are adhered to. The relevant provisions of Annex VIII should therefore be amended to also exempt intra-Union trade of heterozygous ovine ARR embryos from any other classical scrapie related requirement.

(5) In certain language versions of Regulation (EC) No 999/2001, there is a terminology incoherence between Points 1.2. and 1.3 of Section A of Chapter A of Annex VIII to that Regulation and the rest of the text. For the sake of coherence, the same term should be used in the language versions concerned.

(6) Point 2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down the rules governing the approval of the negligible risk status for classical scrapie of a Member State or zone of a Member State. On 4 July 2013, Austria submitted to the Commission the appropriate supporting documentation. Given the favourable outcome of the assessment of this application by the Commission, Austria should be listed as a Member State with a negligible risk of classical scrapie.

(7) Point 3.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001 lists Member States with an approved national control programme for classical scrapie. Considering that Austria should be listed as a Member State with a negligible risk of classical scrapie, it should simultaneously be deleted from the list of Member States with an approved national control programme for classical scrapie, as this status offers guarantees over and above those offered in the control programme.

(8) Chapter H of Annex IX to Regulation (EC) No 999/2001 lays down rules for the import in the Union of ovine and caprine semen and embryos. These import rules should be updated to reflect amendments to Annex VIII brought by this act.

(9) Annex X to Regulation (EC) No 999/2001 lays down the methods of analysis applicable to TSE testing in bovine, ovine and caprine animals. This Annex should be reviewed to update the information on the designated laboratories, adjust the reference to various guidelines, harmonize some technical terms, and clarify the discriminatory testing process in case of positive TSE cases in ovine and caprine animals, in accordance with the latest scientific knowledge and current practices in the Union.

(10) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out the lists of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals. On 18 September 2013, IDEXX made an application in order that the name of the test IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA be changed to HerdChek BSE-Scrapie Antigen (IDEXX Laboratories). The new package insert for this test has been approved by the European Union Reference laboratory for TSEs on 2 May 2013. Furthermore, on 6 December 2013, the Enfer Group informed that it has ceased the manufacture of the Enfer Version 3 TSE diagnostic kit and requested the deletion of this kit from the list of approved BSE rapid tests in bovine animals. The lists in point 4 of Chapter C of Annex X should therefore be adapted accordingly.

(11) In order to offer sufficient time to Member States to align their scrapie-related certification procedures for ovine embryos, certain amendments introduced by this Regulation should apply from 1 January 2015.

(12) Regulation (EC) No 999/2001 should therefore be amended accordingly.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, VII, VIII, IX and X 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*.

Paragraphs (a), (b) and (e) of point 3 and point 4 of the Annex shall apply from 1 January 2015.

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

Done at Brussels, 28 October 2014.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1148/2014. (See end of Document for details)*

ANNEX

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

(1) Annex II is amended as follows:

(a) Points 1 and 2 of Chapter B are replaced by the following:

1. **Structure of the risk analysis**

The risk analyses shall comprise an entry assessment and an exposure assessment.

2. **Entry assessment (external challenge)**

2.1. The entry assessment shall consist of assessing the likelihood that the BSE agent has either been introduced into the country or region via commodities potentially contaminated with a BSE agent, or is already present in the country or region.

The following risk factors shall be taken into account:

(a) the presence or absence of the BSE agent in the country or region and, if the agent is present, its prevalence based on the outcome of surveillance activities;

(b) the production of meat-and-bone meal or greaves from the BSE indigenous ruminant population;

(c) imported meat-and-bone meal or greaves;

(d) imported bovine and ovine and caprine animals;

(e) imported animal feed and feed ingredients;

(f) imported products of ruminant origin for human consumption, which may have contained tissues listed in point 1 of Annex V and may have been fed to bovine animals;

(g) imported products of ruminant origin for *in vivo* use in bovine animals.

2.2. Special eradication schemes, surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the bovine animals population) relevant to the risk factors listed in point 2.1 should be taken into ac-count in carrying out the entry assessment.

(b) In point 3 of Chapter D, Table 2 is replaced by the following:

TABLE 2

Points targets for different adult bovine animals population sizes in a country or region

Points targets for country or region		
Adult bovine animals population size(24 months and older)	**Type A surveillance**	**Type B surveillance**

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> 1 000 000	300 000	150 000
900 001-1 000 000	214 600	107 300
800 001-900 000	190 700	95 350
700 001-800 000	166 900	83 450
600 001-700 000	143 000	71 500
500 001-600 000	119 200	59 600
400 001-500 000	95 400	47 700
300 001-400 000	71 500	35 750
200 001-300 000	47 700	23 850
100 001-200 000	22 100	11 500
90 001-100 000	19 900	9 950
80 001-90 000	17 700	8 850
70 001-80 000	15 500	7 750
60 001-70 000	13 000	6 650
50 001-60 000	11 000	5 500
40 001-50 000	8 800	4 400
30 001-40 000	6 600	3 300
20 001-30 000	4 400	2 200
10 001-20 000	2 100	1 050
9 001-10 000	1 900	950
8 001-9 000	1 600	800
7 001-8 000	1 400	700
6 001-7 000	1 200	600
5 001-6 000	1 000	500
4 001-5 000	800	400
3 001-4 000	600	300
2 001-3 000	400	200
1 001-2 000	200	100

(2) In Annex VII, the first paragraph in point 2.2.1 of Chapter B is replaced by the following:

> If BSE cannot be excluded after the results of the secondary molecular testing carried out in accordance with the methods and protocols set out in Annex X, Chapter C, point 3.2(c) (ii), the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).

(3) In Annex VIII, Section A of Chapter A is amended as follows: