Commission Regulation (EU) 2015/728 of 6 May 2015 amending the definition of specified risk material set out in Annex V 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) 2015/728

of 6 May 2015

amending the definition of specified risk material set out in Annex V 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 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) Regulation (EC) No 999/2001 provides that specified risk material (SRM) is to be removed and disposed of in accordance with Annex V to that Regulation. In accordance with that Annex, SRM includes the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages.

(3) The Communication from the Commission to the European Parliament and the Council — The TSE Roadmap 2 — A Strategy Paper on Transmissible Spongiform Encephalopathies for 2010-2015 of 16 July 2010[(2)] states that any amendment of the current list of SRM referred to in Annex V to Regulation (EC) No 999/2001 (the 'list of SRM') should be based on new evolving scientific knowledge, while maintaining the existing high level of consumer protection within the Union.

(4) On 13 February 2014, the European Food Safety Authority (EFSA) issued a Scientific Opinion on BSE risk in bovine intestines and mesentery[(3)] ('the EFSA Opinion') which provides a quantification of the amount of infectivity in the different parts of the bovine intestines and mesentery. According to the EFSA Opinion, in BSE infected bovine animals: (i) up to 36 months of age, more than 90 % of the BSE infectivity is associated

with the last 4 metres of small intestine and the caecum; (ii) between 36 and 60 months of age, there is a substantial inter-individual variability in the relative contribution of intestinal and mesenteric structures to the total infectivity; (iii) from 60 months of age, more than 90 % of the BSE infectivity is associated with the mesenteric nerves and the celiac and mesenteric ganglion complex; (iv) the duodenum, the colon and the mesenteric lymph nodes contribute less than 0,1 % to the total infectivity in an infected animal regardless of the age at slaughter. The EFSA Opinion also states that the total infectivity associated with those tissues varies with the age of the infected animal, with a peak in animals younger 18 months before a progressive drop in animals older than 60 months.

(5) The mesenteric nerves, the celiac and mesenteric ganglion complex are tissues which are associated with the mesentery and the mesenteric fat and therefore here is no practical way to efficiently separate them from each other.

(6) In order to ensure that rules for the removal of SRM are operational and not unnecessarily complex, and to facilitate controls, differences in the list of SRM applicable based on the age of the slaughtered animal should be avoided where appropriate. To preserve a high level of human health protection, the last four meters of the small intestine, the caecum and the mesentery (which cannot be dissociated from the mesenteric nerves, the celiac and mesenteric ganglion complex and the mesenteric fat) should therefore be maintained in the list of SRM for animals of all ages.

(7) The EFSA Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins (PAPs) published in 2011[(4)] states that 90 % of the total infectivity amount in a BSE clinical case is associated with central and peripheral nervous system tissues, with about 10 % associated with the distal ileum. The residual infectivity in the parts of the intestines other than the last four meters of the small intestine and the caecum can be considered as negligible. The complete elimination of risk is not a realistic objective for any risk management decision.

(8) The exclusion from the list of SRM of the duodenum, the colon and the small intestine except for the last four meters would bring the EU list of SRM closer to international standards. Indeed, as regards bovine intestines and mesentery, Article 11.4.14 of the OIE Terrestrial Animal Health Code recommends that the distal ileum (the last part of the small intestine) of bovine animals of all ages originating from countries with a controlled BSE risk or an undetermined BSE risk should not be traded. Therefore, there is no recommendation of the OIE not to trade the remaining parts of the bovine intestines or the mesentery.

(9) On the basis of the EFSA Opinion and of the recommendations of the OIE Terrestrial Animal Health Code, the list of SRM concerning bovine animals should be amended so as to include the last four meters of the small intestine, the caecum and the mesentery (which cannot be dissociated from the mesenteric nerves, the celiac and mesenteric ganglion complex and the mesenteric fat), but to exclude the remaining parts of the bovine intestines, namely the duodenum, the colon and the small intestine except for the last four meters.

(10) Annex V to Regulation (EC) No 999/2001 should therefore be amended accordingly.

(11) 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

In Annex V to Regulation (EC) No 999/2001, point 1(a)(iii) is replaced by the following:

(iii) the tonsils, the last four meters of the small intestine, the caecum and the mesentery of animals of all ages.

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*.

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

Done at Brussels, 6 May 2015.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 147, 31.5.2001, p. 1.

(**2**) Communication from the Commission to the European Parliament and the Council — The TSE Road map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015; COM(2010) 384 final.

(**3**) EFSA Journal 2014; 12(2):3554.

(**4**) EFSA Journal 2011; 9(1):1947.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2015/728.