Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (Text with EEA relevance)

COMMISSION REGULATION (EU) No 142/2011

of 25 February 2011

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(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 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)[(1)], and in particular Articles 5(2) and 6(1)(b)(ii) and the second subparagraph of Article 6(1), the second subparagraph of Article 6(2), Article 11(2)(b) and (c) and the second subparagraph of Article 11(2), Article 15(1)(b), (d), (e), (h) and (i) and the second subparagraph of Article 15(1), Articles 17(2) and 18(3), Article 19(4)(a), (b) and (c) and the second subparagraph of Article 19(4), Article 20(10) and (11), Article 21(5) and (6), Articles 22(3) and 23(3), Article 27(a), (b), (c) and (e) to (h) and the second subparagraph of Article 27, Articles 31(2), 32(3), Article 40, the first and third subparagraph of Article 41(3), Article 42, Articles 43(3), 45(4), 47(2), Article 48(2), Article 48(7)(a) and (8)(a) and the second subparagraph of Article 48(8) thereof,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries[(2)], and in particular Article 16(3) thereof,

Whereas:

(1) Regulation (EC) No 1069/2009 lays down animal and public health rules for animal by-products and products derived thereof. That Regulation determines the circumstances under which animal by-products are to be disposed of, in order to prevent the spreading of risks for public and animal health. In addition, that Regulation specifies under which conditions animal by-products may be used for applications in animal feed and for various purposes, such as in cosmetics, medicinal products and technical

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applications. It also lays down obligations for operators to handle animal by-products within establishments and plants which are subject to official controls.

(2) Regulation (EC) No 1069/2009 provides that detailed rules for the handling of animal by-products and derived products, such as processing standards, hygiene conditions and the format for documentary evidence which has to accompany consignments of animal by-products and derived products for the purposes of traceability are to be adopted by means of implementing measures.

(3) The detailed rules for the use and disposal of animal by-products in this Regulation should be laid down with a view to the achievement of the objectives of Regulation (EC) No 1069/2009, notably the sustainable use of animal materials, and a high level of protection of public and animal health in the European Union.

(4) Regulation (EC) No 1069/2009 does not apply to entire bodies or parts of wild animals, which are not suspected of being infected or affected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes. In addition, it does not apply to entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice. Regarding those animal by-products from hunting, disposal should be carried out in a way which prevents the transmission of risks, as appropriate for specific hunting practices and in accordance with the good practice as it has been described by the hunting profession.

(5) Regulation (EC) No 1069/2009 applies to animal by-products for the preparation of game trophies. The preparation of such trophies, as well as the preparations of animals and parts of animals for which other methods, such as plastination, are used, should take place under conditions which prevent the transmission of risks for human or animal health.

(6) Regulation (EC) No 1069/2009 applies to catering waste if it originates from means of transport operating internationally, such as materials derived from foodstuffs served on board an airplane or a ship arriving in the European Union from a third country destination. Catering waste also falls within the scope of that Regulation, if it is destined for feeding purposes, for processing in accordance with one of the authorised processing methods under this Regulation or for transformation into biogas or for composting. Regulation (EC) No 1069/2009 prohibits the feeding of catering waste to farmed animals, other than fur animals. Therefore, in accordance with Regulation (EC) No 1069/2009, catering waste may be processed and subsequently used, provided that the derived product is not fed to such animals.

(7) For the sake of consistency of Union legislation, the definition of feed materials in Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EEC and 96/25/EC and Commission Decision 2004/217/EC[(3)] should be used as a basis for defining feed materials of animal origin in this Regulation.

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(8) Regulation (EC) No 1069/2009 prohibits the dispatch of animal by-products and of derived products from susceptible species from holdings, establishments, plants or zones which are subject to restrictions due to the presence of a serious transmissible disease. In order to provide for a high level of protection of animal health in the Union, the list of diseases in the Terrestrial and Aquatic Animal Health Codes of the World Organisation of Animal Health (hereinafter referred to as 'OIE') should be specified as the list of serious transmissible diseases for the purpose of determining the scope of this prohibition.

(9) Since the incineration and the co-incineration of certain animal by-products do not fall within the scope of Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste[(4)], adequate rules for the prevention of health risks arising from such operations should be laid down in this Regulation, taking into account the possible effects on the environment. Residues from the operation of the incineration or co-incineration of animal by-products or derived products should be recycled or disposed of, in accordance with Union environmental legislation, since in particular, that legislation allows for the use of the phosphorous component of ashes in fertilisers and for the handover of ashes from the cremation of pet animals to the owners.

(10) Products of animal origin or foodstuffs containing such products, should only be disposed of in a landfill, in accordance with Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste[(5)], if they have been processed as defined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(6)], in order to mitigate potential health risks.

(11) The disposal of animal by-products or derived products via the wastewater stream should be prohibited, since that stream is not subject to requirements which would ensure an appropriate control of public and animal health risks. Appropriate measures should be taken to prevent unacceptable risks from accidental disposal of liquid animal by-products, such as from the cleaning of floors and equipments used for processing.

(12) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives[(7)] lays down certain measures to protect the environment and human health. Article 2(2)(b) of that Directive provides that certain matters are excluded from the scope of that Directive to the extent that they are covered by other Union legislation, including animal by-products covered by Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[(8)], except those which are destined for incineration, landfilling or use in a biogas or composting plant. That Regulation has now been repealed and replaced by Regulation (EC) No 1069/2009 from 4 March 2011. In the interests of coherency of Union legislation, the processes whereby animal by-products and derived products are transformed into biogas and composted should comply with the health rules laid down in this Regulation, as well as the measures for the protection of the environment laid down in Directive 2008/98/EC.

(13) The competent authority of a Member State should be able to authorise alternative parameters for the transformation of animal by-products into biogas or for their

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composting on the basis of a validation according to a harmonised model. In that case, it should be possible to place digestion residues and compost on the market in the whole European Union. In addition, the competent authority of a Member State should be able to authorise certain parameters for specific animal by-products, such as catering waste and mixtures of catering waste with certain other materials, which are transformed into biogas or composted. Since such authorisations are not issued according to a harmonised model, digestion residues and compost should only be placed on the market within the Member State where the parameters have been authorised.

(14) In order to prevent the contamination of foodstuffs with pathogenic agents, establishments or plants processing animal by-products should operate on a separate site from slaughterhouses or other establishments in which foodstuffs are processed, in particular in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[(9)], unless the processing of the animal by-products takes place under conditions which have been approved by the competent authority, with a view to preventing the transmission of risks to public and animal health into the food-processing establishments.

(15) 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[(10)] provides that Member States are to carry out annual monitoring programmes for transmissible spongiform encephalopathies (TSEs). Bodies of animals which are used for feeding to certain species, for the purposes of promotion of bio-diversity, should be included in those monitoring programmes to the extent necessary to ensure that those programmes provide sufficient information regarding the prevalence of TSE in a particular Member State.

(16) Regulation (EC) No 1069/2009 allows the feeding of certain Category 1 material to endangered or protected species of necrophagous birds and to other species living in their natural habitat, for the promotion of biodiversity. Such feeding should be authorised for certain carnivore species referred to in Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora[(11)] and for certain species of birds of prey referred to in Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds[(12)], in order to take into account the natural feeding patterns of those species.

(17) Regulation (EC) No 1069/2009 has introduced a procedure for the authorisation of alternative methods of use or disposal of animal by-products or derived products. Such methods may be authorised by the Commission following receipt of an opinion from the European Food Safety Authority (hereinafter referred to as 'EFSA'). In order to facilitate the evaluation of applications by EFSA, a standard format should be laid down which illustrates to applicants the nature of the evidence to be submitted. In accordance with the Treaties, it should be possible to submit applications for alternative methods in the official languages of the Union, as laid down in EEC Council Regulation No 1 determining the languages to the used by the European Economic Community[(13)].

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(18) In accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[(14)], feed business operators, other than primary producers, are required to store and transport feed under certain hygienic conditions. Since those conditions provide for an equivalent mitigation of potential risks, compound feedingstuffs derived from animal by-products should not be subject to the requirements of this Regulation regarding storage and transport.

(19) For the promotion of science and research and to ensure the best possible use of animal by-products and of derived products in the diagnosis of human or animal diseases, the competent authority should be authorised to lay down conditions for samples of such materials for research, educational and diagnostic purposes. However, those conditions should not be laid down for samples of pathogenic agents for which special rules are provided in Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC[(15)].

(20) Directive 97/78/EC exempts animal by-products which are intended for exhibitions, provided that they are not intended to be marketed, and animal by-products intended for particular studies or analyses from veterinary checks in the border inspection post of entry into the Union. That Directive allows for the adoption of implementing measures for those exemptions. In this Regulation, appropriate conditions should be set out for the import of animal by-products and derived products intended for exhibitions and particular studies or analyses, to ensure that no unacceptable risks to public or animal health are spread where such products enter the Union. In the interests of coherency of Union legislation, and in order to provide legal certainty to operators, those conditions and the implementing measures for Directive 97/78/EC should be laid down in this Regulation.

(21) Following collection, animal by-products should be handled under appropriate conditions which ensure that no unacceptable risks to public or animal health are transmitted. Establishments or plants in which certain operations are carried out before animal by-products are submitted to further processing should be constructed and should operate in a manner which prevents such transmission. This should include establishments or plants where operations involving the handling of animal by-products in accordance with Union veterinary legislation, other than the handling of animal by-products in the course of curative activities of private veterinarians, are carried out.

(22) Pursuant to Regulation (EC) No 1069/2009, operators are to ensure that animal by-products and derived products are traceable at all stages of the chain of manufacturing, use and disposal, so as to avoid unnecessary disruptions of the internal market in the case of events which are linked to actual or potential risks to public or animal health. Traceability should therefore not only be ensured by operators generating, collecting or transporting animal by-products, but also by operators disposing of animal by-products or derived products, by incineration, co-incineration or landfilling.