Commission Regulation (EU) 2015/9 of 6 January 2015 amending Regulation (EU) No 142/2011 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) 2015/9

of 6 January 2015

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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 the Act of Accession of Croatia, and in particular Article 50 thereof,

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 Article 15(1)(b), (c), (d) and (g), Article 18(3)(b)(i), Article 19(4)(c), Article 20(11), Article 21(6)(d), Article 23(3), Article 27(c), Article 31(2), Article 40(f), Article 41(3) and Article 42(2) thereof,

Whereas:

(1) Regulation (EC) No 1069/2009 lays down public and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products. It also determines an end point in the manufacturing chain for certain derived products, beyond which they are no longer subject to the requirements of that Regulation.

(2) Commission Regulation (EU) No 142/2011[(2)] lays down implementing rules for Regulation (EC) No 1069/2009, including rules on the adoption of alternative methods of use or disposal of animal by-products or derived products and the requirements for placing on the market of organic fertilisers and certain other animal by-products.

(3) In accordance with Article 19(1)(d) of Regulation (EC) No 1069/2009, Member States may authorise the collection, transport and disposal of Category 3 materials, as referred to in Article 10(f) of that Regulation, by the other means set out in Chapter IV of Annex VI to Regulation (EU) No 142/2011. In accordance with Article 36(3) of Regulation (EU) No 142/2011, this possibility was limited to the transitional period

until 31 December 2014. Certain Member States authorise the collection, transport and disposal by the other means set out in Chapter IV of Annex VI to Regulation (EU) No 142/2011 of small quantities of former foodstuffs up to 20 kg per week.

(4) In the absence of reported negative consequences for animal health and taking into account that in certain instances the disposal in accordance with Article 14 of Regulation (EC) No 1069/2009 would be unacceptably onerous compared to local disposal, it appears justified to establish the transitional derogation as a permanent option, provided such disposal does not cause unacceptable health risks. Article 15 of Regulation (EU) No 142/2011, providing special rules for the application of Article 19(1)(a), (b), (c), (e) and (f) of Regulation (EC) No 1069/2009, should therefore be supplemented with reference to the measures provided for in Chapter IV of Annex VI to Regulation (EU) No 142/2011, which should also be amended accordingly. After consultation with Member Stats and stakeholders organisations, the option that Member States may decide to increase the volume to a maximum of 50 kg per week shall be removed when the transitional derogation becomes a permanent option. In addition, paragraph 3 of Article 36 of Regulation (EU) No 142/2011 should be deleted.

(5) Given the low risk of possible contacts of farmed animals with organic fertilisers and soil improvers handled by certain operators and users, in particular when they operate outside the food and feed chain, the competent authorities should be allowed to exempt those operators and users from the registration obligation under Article 23 of Regulation (EC) No 1069/2009. Those operators and users should be added to the list of operators exempted from the obligation to notify the competent authorities in accordance with Article 20(4) of Regulation (EU) No 142/2011. Article 20(4) of Regulation (EU) No 142/2011 should be amended accordingly.

(6) Growing media, including potting soil, with a small content of animal by-products or derived products packaged for use by the final consumer do not present a risk of being used as feed for farmed animals. The limitation to a content of less than 5 % in volume of derived products of Category 2 or 3 materials in the growing media, including potting soil, mitigates the risk to use it as feed for farmed animals, since the high content of soil and other materials renders such products unpalatable for farmed animals. In the production of growing media, processed manure may be used. However, the processed manure shall not be the only component of the growing media. It should present not more than 50 % in volume in the growing media. Processed manure shall not be used for the production of growing media when the place of origin is subject to prohibition due to a suspected or confirmed outbreak of a serious transmissible disease affecting farmed animals. Therefore, such products may be exempted from veterinary controls for placing on the market other than imports. Article 22(2) of Regulation (EU) No 142/2011 should be amended accordingly.

(7) The definitions of ‘intermediate products’ and ‘trade samples’ in points 35 and 39 respectively of Annex I to Regulation (EU) No 142/2011 should be clarified in order to avoid unjustified trade barriers. The definition of ‘intermediate products’ includes also a destination of those intermediate products. It is justified to extend the current definition with possible additional uses in the cosmetic industry. Derived products

which comply with the requirements of Council Directive 76/768/EEC[3] may be in accordance with Article 5(1) of Regulation (EC) No 1069/2009 declared as the end point in the manufacturing chain. Furthermore, it is necessary to clarify that pet food may be introduced into the EU as a trade sample for purposes of feeding trials, testing of machinery or of equipment. The definition of 'intermediate products' and 'trade samples' in points 35 and 39 of Annex I to Regulation (EU) No 142/2011 should be amended accordingly.

(8) Although, in accordance with Article 3(6) of Regulation (EC) No 1069/2009, equidae are considered to be farmed animals, certain individual equine animals enjoy a particular close relationship to their keepers. It is therefore justified to provide the possibility of cremating dead equidae in incinerators approved for that purpose by the competent authority, provided the equidae originate from holdings which are not subject to prohibition orders for notifiable diseases. Council Directive 2009/156/EC[4] provides for animal health conditions governing amongst others the movement of equidae, including conditions for the identification of equidae. Only dead equidae which comply with that Directive may be individually cremated in low-capacity incinerators. Chapter III of Annex III to Regulation (EU) No 142/2011 should be amended accordingly.

(9) Article 13(g) of Regulation (EC) No 1069/2009 provides that animal by-products originating from aquatic animals of Category 2 material may be ensiled, composted or transformed into biogas. The European Food Safety Authority ('EFSA') published a Scientific Opinion on the evaluation of a new processing method for animal by-products of Category 2 materials of fish origin[5]. According to EFSA's opinion, risks arising from Category 2 materials of fish origin are adequately reduced by the processing method, and derived products may therefore be used for the production of organic fertilisers, composted, transformed into biogas or used for the manufacture of feed for fur animals or other animals not intended for human consumption. EFSA's opinion concludes that there is no increase in risk, if the processing method is also applied for the processing of by-products originating from aquatic animals of Category 3 materials. Category 3 material obtained from aquatic animals may therefore be destined for purposes listed in Article 14 of Regulation (EC) No 1069/2009.

(10) Following the successful outcome of EFSA's risk assessment, the ensilage of fish material should be added to the list of alternative processing methods in Chapter IV of Annex IV to Regulation (EU) No 142/2011. Annex IV to Regulation (EU) No 142/2011 should be amended accordingly.

(11) Digestion residues and compost of animal origin may in practice be mixed with materials of non-animal origin. Operators should know which rules apply for the disposal of such digestion residues and compost. In addition, it is necessary to clarify in which cases compost and digestion residues derived from catering waste may be disposed of in an authorised landfill. Chapter III of Annex V to Regulation (EU) No 142/2011 should be amended accordingly.

(12) Croatia notified a list of species of wild necrophagous birds which should be subject to the derogation on special feeding purposes laid down in Article 18 of Regulation (EC)

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/9. (See end of Document for details)*

No 1069/2009. The list of species of necrophagous birds in Annex VI to Regulation (EU) No 142/2011 should be amended accordingly.

(13) EFSA assessed the risk posed by composting containment and subsequent incineration of dead-on-farm porcine animals[6] and concluded that the composting containment as referred to in the alternative parameters laid down in Section 2 of Chapter III of Annex V to Regulation (EU) No 142/2011 is not a sufficient treatment for the safe disposal of Category 2 material and can therefore not be described as an alternative processing method in Chapter IV of Annex IV to that Regulation. Following the aforementioned EFSA's assessment the 'aerobic maturation and storage of dead-on-farm pigs with subsequent incineration or co-incineration' should be seen as a specific containment method for the storage of animal by-products pending their subsequent disposal in accordance with Regulation (EC) No 1069/2009. In order to differentiate that method from the approved methods of composting and to avoid the approval procedure required for composting plants laid down in Annex V to Regulation (EU) No 142/2011, it is appropriate to include that method in a new Chapter in Annex IX to that Regulation together with the method 'Hydrolysis with subsequent disposal', currently referred to in point H of Section II of Chapter IV of Annex IV, which is based on the same principles. Furthermore the reference to Annex IV in Section 11 of Chapter II of Annex XVI should be adapted accordingly. Annexes IV, IX and XVI to Regulation (EU) No 142/2011 should therefore be amended accordingly.

(14) Rendered fats from Category 3 material are subject to specific requirements under Section 3 of Chapter II of Annex X to Regulation (EU) No 142/2011. However, there are no animal health grounds to prohibit the processing of Category 3 material from aquatic animals and animal by-products from aquatic animals as referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 together with Category 3 animal by-products obtained from terrestrial animals into mixed rendered fats. Therefore it should be possible to use Category 3 materials from aquatic animals and animal by-products from aquatic animals as referred to in Article 10(i) and (j) of Regulation (EC) No 1069/2009 for the production of rendered fat. Point A(1) of Section 3 of Chapter II of Annex X to Regulation (EU) No 142/2011 should be amended accordingly.

(15) Requirements for the heat treatment of centrifuge or separator sludge which may be later used as or in the production of organic fertilisers and placed on the market are set out in Part III of Section 4 of Chapter II in Annex X to Regulation (EU) No 142/2011. It is opportune to introduce a derogation that the competent authority may authorise alternative parameters for the heat treatment of centrifuge or separator sludge destined for uses within the Member States, provided that the operators can demonstrate that the heat treatment carried out according to the alternative parameters guarantees at least the same risk reduction as the treatment carried out according to the already established parameters applicable for placing on the market. Part III of Section 4 of Chapter II of Annex X to Regulation (EU) No 142/2011 should be amended accordingly.

(16) Intermediate products may be used, inter alia, for the production of laboratory reagents or *in vitro* diagnostic for animal purposes. After checks at the border inspection post in accordance with Article 4 of Council Directive 97/78/EC[7] the product has to be

transported directly to the registered establishment or plant of destination. In order to clarify the requirements for the importation of intermediate products, Annex XII to Regulation (EU) No 142/2011 should be amended accordingly.

(17) Blood products intended for the production of feed for farmed animals, including spray dried blood and blood plasma of porcine animals, must have been produced in accordance with Section 2 of Chapter II of Annex X to Commission Regulation (EU) No 142/2011. With reference to point B of that Section, blood products are to be submitted to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV to that Regulation, or another method which ensures that the blood products comply with the microbiological standards for derived products set out in Chapter I of Annex X to Commission Regulation (EU) No 142/2011. Regulation (EU) No 142/2011 also provides, in particular in column 6 of row 2 in Table 1 of Section 1 of Chapter I of Annex XIV, that blood products not intended for human consumption that could be used as feed are to be accompanied by a health certificate in accordance with the model health certificate set out in Chapter 4(B) of Annex XV when they are intended for dispatch to or transit through the Union.

(18) Porcine epidemic diarrhoea, including infection of pigs with the porcine epidemic diarrhoea virus (PEDv) and swine delta coronavirus (SDCv), has been reported in Asia, North America, the Caribbean, Central and South America. SDCv has never been detected in the Union. Inappropriate heat treatment or contamination after heat treatment of spray dried blood and blood plasma of porcine animals, a traditional ingredient for feed for piglets, is incriminated in the spread of the virus.

(19) The Commission, acting on its own initiative, adopted Commission Implementing Regulation (EU) No 483/2014[(8)] as an interim safeguard measure in respect of the safety of spray dried blood and blood plasma of porcine animals intended for the production of feed for animals of the porcine species. Since the risk for animal health will remain, it is necessary to review the requirements for imports of spray dried blood and blood plasma of porcine animals intended for the production of feed for animals of the porcine species and implement the interim measures as a permanent requirement.

(20) Scientific observation indicates that porcine coronaviruses are inactivated in swine faeces if heated to and held at a temperature of 71 °C for 10 minutes or left at room temperature of 20 °C for 7 days. The virus did not survive in experimentally infected dry feed stored at room temperature of 24 °C for at least two weeks. In the Union and in third countries the commonly applied temperature for spray drying of blood and blood plasma is 80 °C throughout the substance.

(21) Based on the available information, it appears opportune to require that spray dried blood and blood plasma of porcine origin introduced from third countries and intended for feeding of porcine animals has been subjected to a high temperature treatment followed by subsequent storage for a certain time at room temperature in order to mitigate the risk of contamination after the treatment.

(22) Imports of bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intended for uses other than as feed material, organic fertilisers or soil improvers should also be