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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Animal by-products not intended for human consumption are a potential source of risks to public and animal health. Past crises related to outbreaks of foot-and-mouth disease, the spread of transmissible spongiform encephalopathies such as bovine spongiform encephalopathy (BSE) and the occurrence of dioxins in feedingstuffs have shown the consequences of the improper use of certain animal by-products for public and animal health, the safety of the food and feed chain and consumer confidence. In addition, such crises may also have a wider adverse impact on society as a whole, by their impact on the socioeconomic situation of the farmers and of the industrial sectors concerned and on consumer confidence in the safety of products of animal origin. Disease outbreaks could also have negative consequences for the environment, not only due to the disposal problems posed, but also as regards biodiversity.

(2) Animal by-products arise mainly during the slaughter of animals for human consumption, during the production of products of animal origin such as dairy products, and in the course of the disposal of dead animals and during disease control measures. Regardless of their source, they pose a potential risk to public and animal health and the environment. This risk needs to be adequately controlled, either by directing such products towards safe means of disposal or by using them for different purposes, provided that strict conditions are applied which minimise the health risks involved.

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(3) The disposal of all animal by-products is not a realistic option, as it would lead to unsustainable costs and risks for the environment. Conversely, there is a clear interest for all citizens that, provided the health risks are minimised, a wide range of animal by-products are safely used for various applications in a sustainable manner. A wide range of animal by-products are indeed commonly used in important productive sectors, such as the pharmaceutical, feed and leather industries.

(4) New technologies have widened the possible use of animal by-products or derived products to a large number of productive sectors, in particular for the generation of energy. However, the use of those new technologies might pose health risks that must also be minimised.

(5) Community health rules for collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use or disposal of animal by-products should be laid down in a coherent and comprehensive framework.

(6) Those general rules should be proportionate to the risk to public and animal health which animal by-products pose when they are dealt with by operators at different stages of the chain from collection to their use or disposal. The rules should also take into account the risks for the environment posed during those operations. The Community framework should include health rules on the placing on the market, including intra-Community trade and import, of animal by-products, where appropriate.

(7) In Regulation (EC) No 1774/2002[(3)], the European Parliament and the Council laid down Community health rules concerning animal by-products not intended for human consumption. Based on scientific advice and as an action under the Commission White Paper of 12 January 2000 on Food Safety, that Regulation introduced a set of rules aimed at protecting the safety of the food and feed chain, which is complementary to Community legislation on food and feed. Those rules have significantly improved the level of protection in the Community against the risks posed by animal by-products.

(8) Regulation (EC) No 1774/2002 introduced the classification of animal by-products into three categories according to the degree of risk involved. It requires operators to keep animal by-products of different categories separate from each other if they wish to make use of animal by-products which do not pose a significant risk to public or animal health, in particular if such products are derived from material fit for human consumption. That Regulation also introduced the principle that high-risk material should not be fed to farmed animals, and that material derived from animals is not to be fed to animals of the species from which it is derived. Pursuant to that Regulation, only material from animals which have undergone veterinary inspection is to enter the feed chain. In addition, it lays down rules for processing standards which ensure the reduction of risks.

(9) Under Article 35(2) of Regulation (EC) No 1774/2002, the Commission is to submit a report to the European Parliament and to the Council on the measures taken by the Member States to ensure compliance with that Regulation. The report is to be accompanied, if appropriate, by legislative proposals. The report was submitted on 21 October 2005 and emphasised that the principles of Regulation (EC) No 1774/2002 should be maintained. In addition, it highlighted the areas where amendments to

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that Regulation were considered necessary, in particular clarifications as regards the applicability of the rules to finished products, the relationship with other Community legislation and the classification of certain material. The findings of a series of fact-finding missions carried out in the Member States by the Food and Veterinary Office of the Commission (FVO) in 2004 and 2005 support those conclusions. According to the FVO, improvements are necessary as regards the traceability of the flow of animal by-products and the effectiveness and harmonisation of official controls.

(10) The Scientific Steering Committee, which was superseded by the European Food Safety Authority (EFSA) in 2002, has adopted a number of opinions concerning animal by-products. Those opinions demonstrate the need to maintain the main principles of Regulation (EC) No 1774/2002; in particular that animal by-products derived from animals shown not to be fit for human consumption as a result of a health inspection should not enter the feed chain. However, those animal by-products may be recovered and used for the production of technical or industrial products under specified health conditions.

(11) The conclusions of the Presidency of the Council on the Commission report of 21 October 2005 which were adopted in December 2005, and the subsequent consultations carried out by the Commission, have highlighted that the rules laid down in Regulation (EC) No 1774/2002 should be improved. The chief objectives of the rules on animal by-products, namely the control of risks to public and animal health and the protection of the safety of the food and feed chain, should be clearly laid down. The provisions of this Regulation should permit the achievement of those objectives.

(12) The rules on animal by-products laid down in this Regulation should apply to products that may not be used for human consumption under Community legislation, in particular where they do not comply with food hygiene legislation or where they may not be placed on the market as food since they are unsafe either because they are injurious to health or unfit for human consumption (animal by-products 'by law'). Those rules should, however, also apply to products of animal origin which do comply with certain rules regarding their possible use for human consumption, or which are raw materials for the production of products for human consumption, even if they are eventually destined for other purposes (animal by-products 'by choice').

(13) In addition, in order to prevent risks arising from wild animals, bodies or parts of bodies of such animals suspected of being infected with a transmissible disease should be subject to the rules laid down in this Regulation. This inclusion should not imply an obligation to collect and dispose of bodies of wild animals that have died or that are hunted in their natural habitat. If good hunting practices are observed, intestines and other body parts of wild game may be disposed of safely on site. Such practices for the mitigation of risks are well-established in Member States and are in some cases based on cultural traditions or on national legislation which regulates the activities of hunters. Community legislation, in particular 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[(4)], lays down rules for handling of meat and animal by-products from wild game. Those rules also place the responsibility for the prevention of risks

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on trained persons such as hunters. In view of the potential risks for the food chain, animal by-products from killed wild game should only be subject to this Regulation in so far as food hygiene legislation applies to the placing on the market of such game and involves operations carried out by game-handling establishments. In addition, animal by-products for the preparation of game trophies should be covered by this Regulation in order to prevent animal health risks arising from such by-products.

(14) The rules laid down in this Regulation should apply to animal by-products derived from aquatic animals, other than material from vessels operating under Community food hygiene legislation. However, risk-proportionate measures should be adopted as regards the handling and disposal of material which arises on board fishing vessels from the evisceration of fish and which shows signs of disease. Such measures for the implementation of this Regulation should be adopted on the basis of a risk assessment carried out by the appropriate scientific institution in view of the available evidence regarding the effectiveness of certain measures to combat the spread of diseases communicable to humans, in particular of certain parasites.

(15) Due to the limited risks arising from materials used as raw pet food on farm or supplied to end users by food businesses, certain activities related to such raw pet food should not be covered by the rules laid down in this Regulation.

(16) It is appropriate to clarify in this Regulation which animals are to be classified as pet animals, so that by-products derived from such animals are not used in feed for farmed animals. In particular, animals kept for purposes other than farming, such as for companionship, should be classified as pet animals.

(17) For the sake of consistency of Community legislation, certain definitions set out in 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[(5)] and in Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste[(6)] should be used in this Regulation. The reference to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[(7)] should be clarified.

(18) For the sake of consistency of Community legislation, the definition of ‘aquatic animal’ as laid down in Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals[(8)] should be used in this Regulation. At the same time, aquatic invertebrates which are not covered by that definition and which pose no risk of disease transmission should be subject to the same requirements as aquatic animals.

(19) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste[(9)] specifies the conditions for the issuing of a permit for a landfill. This Regulation should provide for the disposal of animal by-products on landfills for which such a permit has been issued.

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(20) The primary responsibility for carrying out operations in accordance with this Regulation should rest with operators. At the same time, the public interest in preventing risks to public and animal health requires that a collection and disposal system is in place to ensure the safe use or the safe disposal of animal by-products which may not be used, or which are not used for economic reasons. The scope of the collection and disposal system should take into account the actual amount of animal by-products which accrue in the particular Member State. It should also reflect, on a precautionary basis, the need for extended disposal capacities in the event of major outbreaks of transmissible diseases or of temporary technical failures in an existing disposal facility. Member States should be permitted to cooperate with each other and third countries provided that the objectives of this Regulation are met.

(21) It is important to determine the starting point in the life cycle of animal by-products from which the requirements of this Regulation should apply. Once a product has become an animal by-product, it should not re-enter the food chain. Special circumstances apply for the handling of certain raw materials, such as hides, handled in establishments or plants integrated at the same time into the food chain and the animal by-products chain. In those cases, the necessary measures should be taken by means of segregation to mitigate potential risks for the food chain which can arise from cross-contamination. For other establishments, risk-based conditions should be determined to prevent cross-contamination, in particular through separation between the animal by-products chain and the food chain.

(22) For reasons of legal certainty and proper control of potential risks, an end point in the manufacturing chain should be determined for products which no longer have direct relevance for the safety of the feed chain. For certain products regulated under other Community legislation, such an end point should be determined at the stage of manufacturing. Products which have reached this end point should be exempt from controls under this Regulation. In particular, products beyond the end point should be allowed to be placed on the market without restriction under this Regulation and to be handled and transported by operators which have not been approved or registered in accordance with this Regulation.

(23) However, it should be possible to modify such an end point, particularly in the case of newly emerging risks. Regulation (EC) No 1774/2002 exempts certain products, notably guano, certain hides to which particular forms of treatment such as tanning have been applied, and certain game trophies from its requirements. Similar exemptions should be provided for in the implementing measures to be adopted under this Regulation for products such as oleochemical products and the end products resulting from the production of biodiesel, under appropriate conditions.

(24) In order to ensure a high level of protection of public and animal health, Member States should continue to take the necessary measures to prevent the dispatch of animal by-products from restricted areas or establishments, in particular in the event of an outbreak of a disease listed in Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease[10].