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.

(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 **[**[F1]retained EU law**]** 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

that Regulation were considered necessary, in particular clarifications as regards the applicability of the rules to finished products, the relationship with other **[**F1retained EU law**]** 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 **[**F1retained EU law**]**, 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. **[**F1Retained EU law**]**, 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 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 **[**F1retained EU law**]**, 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 **[**F1retained EU law**]**, 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.

(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 **[**[F1]retained EU law**]**, 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)].

(25) Operations with animal by-products which give rise to a considerable degree of risk to public and animal health should only be carried out in establishments or plants which have been approved in advance for such operations by the competent authority. That condition should apply in particular to processing establishments or plants and other establishments or plants which handle or store animal by-products with a direct relevance for the safety of the feed chain. It should be permitted for animal by-products of more than one category to be handled in the same establishment or plant provided cross-contamination is prevented. It should further be permitted to amend those conditions if the amount of material for disposal and processing rises due to a major outbreak of disease, provided it is ensured that the temporary use under such amended conditions does not lead to the propagation of disease risks.

(26) However, such approvals should not be necessary for establishments or plants which process or handle certain safe materials, such as products processed to such an extent that they no longer pose a risk to public and animal health. Such establishments or plants should be registered so as to permit official control over the flow of material and ensure their traceability. That registration requirement should apply also to operators who transport animal by-products or derived products, unless they are no longer subject to any control since an end point in the chain has been determined.

(27) Establishments or plants should be approved following the submission of information to the competent authority and following a visit carried out on site which demonstrates that the requirements of this Regulation for the infrastructure and equipment of the establishment or plant will be met, so that any risks to public and animal health arising from the process used will be adequately contained. It should be possible to grant the approvals conditionally in order to allow operators to rectify deficiencies before the establishment or plant obtains full approval.

(28) Establishments or plants whose operations have already been approved in accordance with **[**[F1]retained EU law**]** on food hygiene should not be required to be approved or registered under this Regulation, as approvals or registrations under that **[**[F1]retained EU law**]** already take into account the objectives of this Regulation. However, establishments or plants which have been approved or registered under hygiene legislation should be obliged to comply with the requirements of this Regulation and subject to official controls carried out for the purposes of verifying compliance with the requirements of this Regulation.

(29) Animal by-products and derived products should be classified into three categories which reflect the degree of risk that they pose to public and animal health, on the basis of risk assessments. While animal by-products and derived products posing a high risk should only be used for purposes outside the feed chain, their use posing a lower risk should be permitted under safe conditions.

(30) Progress in science and technology may lead to the development of processes which eliminate or minimise the risks to public and animal health. Amendments to the lists of animal by-products set out in this Regulation should be possible, in order to take account of such progress. Prior to any such amendments, and in accordance with the general principles of **[**[F1]retained EU law**]** aimed at ensuring a high level of protection of public

and animal health, a risk assessment should be carried out by the appropriate scientific institution, such as EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of animal by-products for which risks are to be assessed. However, it should be clear that once animal by-products of different categories are mixed, the mixture should be handled in accordance with the standards laid down for the proportion of the mixture belonging to the highest risk category.

(31) Due to the high risk to public health, animal by-products giving rise to a risk of transmissible spongiform encephalopathy (TSE) should, in particular, not be used for feed. This restriction should also apply to wild animals through which a communicable disease may be transmitted. The restriction on the feeding of animal by-products giving rise to a TSE risk should be without prejudice to the feeding rules laid down in Regulation (EC) No 999/2001.

(32) Animal by-products from animals used for experiments as defined in Directive 86/609/EEC should also be excluded from use in feed, due to the potential risks arising from those animal by-products. However, Member States may allow the use of animal by-products from animals which have been used for experiments to test new feed additives, in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(11)].

(33) The use of certain substances and products is unlawful under Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in food stuffs of animal origin[(12)] and Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß agonists[(13)]. In addition, Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products[(14)] lays down further rules on the monitoring of certain substances and residues thereof in live animals and animal products. Directive 96/23/EC also lays down rules which apply where the presence of residues of authorised substances or contaminants exceeding certain permitted levels has been established. In order to ensure the coherence of **[**[F1]retained EU law**]**, products of animal origin in which substances are detected in breach of Regulation (EEC) No 2377/90 and Directives 96/22/EC and 96/23/EC should be classified as Category 1 or Category 2 material, as appropriate, in view of the risk they pose to the food and feed chain.

(34) Manure and digestive tract content should not need to be disposed of, provided that proper treatment ensures that diseases are not transmitted during their application to land. Animal by-products from animals that die on farm and animals killed for the eradication of diseases should not be used in the feed chain. This restriction should also apply to imported animal by-products which are allowed into the Community, where they do not comply with **[**[F1]retained EU law**]** upon inspection at the Community border post, and to products which do not comply with the applicable requirements during checks carried out within the Community. Non-compliance with Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising

of foodstuffs[15] and with 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[16] should not result in the exclusion from the feed chain of products presented for border inspection.

(35) Since the date of entry into force of Regulation (EC) No 1774/2002, the classification of certain animal by-products by default as Category 2 material limits their possible uses severely, while not necessarily being proportionate to the risks involved. Accordingly those animal by-products should be reclassified as Category 3 material, so as to allow their use for certain feeding purposes. For any other animal by-products which are not listed under one of the three categories, the categorisation by default as Category 2 material should be maintained for precautionary reasons, in particular to reinforce the general exclusion of such material from the feed chain for farmed animals, other than fur animals.

(36) Other legislation which has entered into force following the adoption of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[17], namely Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[18], Regulation (EC) No 853/2004 and Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[19], and to which Regulation (EC) No 1774/2002 is complementary, places the primary duty of complying with **[**F1retained EU law**]**, aimed at protecting public and animal health, on the food and feed business operators. In line with that legislation, operators carrying out activities under this Regulation should also be primarily responsible for ensuring compliance with this Regulation. That obligation should be further clarified and specified as regards the means by which traceability is ensured, such as separate collection and channelling of animal by-products. Established systems ensuring traceability for products exclusively circulating at national level by other means should continue to operate, if they provide equivalent information. Every effort should be made to promote the use of electronic and other means of documentation which do not involve paper records, as long as they ensure full traceability.

(37) A system of own checks is necessary to ensure that, within an establishment or plant, the requirements of this Regulation are fulfilled. During official controls the competent authorities should take into account the performance of own checks. In certain establishments or plants own checks should be carried out through a system based on the hazard analysis and critical control points (HACCP) principles. The HACCP principles should be based on the experience of their implementation under **[**F1retained EU law**]** on food and feed hygiene. In this respect, national guides to good practice could serve as a useful tool to facilitate the practical implementation of the HACCP principles, and of other aspects of this Regulation.

(38) Animal by-products should only be used if the risks to public and animal health are minimised in the course of their processing and the placing on the market of derived products manufactured on the basis of animal by-products. If this option is

not available, the animal by-products should be disposed of under safe conditions. The options available for the use of animal by-products of the different categories should be clarified in coherence with other **[**[F1]retained EU law**]**. In general, the options for a higher risk category should be available for the lower risk categories as well, unless special considerations apply in view of the risk attached to certain animal by-products.

(39) Disposal of animal by-products and derived products should take place in accordance with environmental legislation regarding landfilling and waste incineration. In order to ensure consistency, incineration should take place in accordance with Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste[(20)]. Co-incineration of waste – either as a recovery or disposal operation – is subject to similar conditions regarding approval and operation to those regarding waste incineration, in particular as to air emission limit values, waste water and residue discharge, control and monitoring and measurement requirements. Consequently, direct co-incineration, without prior processing, of all three categories of materials should be permitted. In addition, specific provisions should be enacted for the approval of low and high-capacity incineration plants.

(40) The use of animal by-products or derived products as a fuel in the combustion process should be authorised and should not be considered as a waste disposal operation. However, such use should take place under conditions which ensure the protection of public and animal health, as well as the appropriate environmental standards.

(41) This Regulation should provide for the possibility to lay down parameters for processing methods regarding time, temperature and pressure for animal by-products, in particular for the methods currently referred to as methods 2 to 7 under Regulation (EC) No 1774/2002.

(42) Shells from shellfish from which the soft tissue or flesh have been removed, should be excluded from the scope of the Regulation. Due to the various practices in the Community regarding the removal of such soft tissue or flesh from shells, it should be possible to use shells from which the entire soft tissue or flesh has not been removed, provided such use does not lead to a risk arising to public and animal health. National guides to good practice could assist in the dissemination of knowledge regarding proper conditions under which such use would be possible.

(43) In view of the limited risk to public or animal health arising from such products, the competent authority should be able to authorise the preparation and application to land of biodynamic preparations, on the basis of Category 2 and Category 3 materials, as referred to in Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products[(21)].

(44) Novel technologies which are being developed offer advantageous ways of generating energy on the basis of animal by-products or of providing for the safe disposal of such products. Safe disposal may take place through a combination of methods for the safe containment of animal by-products on site with established disposal methods, and through a combination of authorised processing parameters with new standards which have been favourably assessed. In order to take account of the related progress in science and technology, such technologies should be authorised as alternative methods for the

disposal or use of animal by-products throughout the Community. If a technological process has been developed by an individual, an application checked by the competent authority should be examined by EFSA before such authorisation is granted, in order to ensure that an assessment of the risk reduction potential of the process is carried out and that the rights of individuals, including the confidentiality of business information, is preserved. In order to provide advice to applicants a standard format for application should be adopted. Since that document is intended only to be indicative it should be adopted in accordance with the advisory procedure in collaboration with EFSA.

(45) It is appropriate to clarify the requirements applicable to the placing on the market of animal by-products and derived products intended for feeding purposes and of organic fertilisers and soil improvers, so as to ensure the protection of the food and feed chain. Only Category 3 material should be used for feeding farmed animals other than fur animals. Fertilisers produced on the basis of animal by-products may affect the safety of the feed and food chain. Where they have been manufactured from meat-and-bone meal derived from Category 2 material or from processed animal protein, a component, such as an inorganic or an indigestible substance, should be added in order to prevent their direct use for feeding purposes. Such mixing should not be required if the composition or packaging of products, in particular of products destined for use by the final consumer, prevents the misuse of the product for feeding purposes. When determining the components, different circumstances regarding climate and soil and the objective for the use of particular fertilisers should be taken into account.

(46) Regulation (EC) No 1523/2007 of the European Parliament and of the Council of 11 December 2007 banning the placing on the market and the import to, or export from, the Community of cat and dog fur, and products containing such fur[(22)] lays down a general prohibition on the placing on the market and the import and export of cat and dog fur and products containing such fur. However, that prohibition should not affect the obligation under this Regulation to dispose of animal by-products from cats and dogs, including fur.

(47) The promotion of science and research, and artistic activities may require the use of animal by-products or derived products of all categories, sometimes in quantities below the scale of commercial exchanges. In order to facilitate the import and use of such animal by-products or derived products, the competent authority should be able to fix the conditions for such operations on a case-specific basis. Harmonised conditions should be laid down where action at a Community level is necessary.

(48) Regulation (EC) No 1774/2002 contains detailed provisions which allow, by way of derogation, the feeding of Category 2 and Category 3 materials to zoo animals. Similar provisions should be laid down in this Regulation and the feeding of certain Category 1 material should be allowed and complemented by the possibility to lay down detailed rules to control any possible risks arising to public or animal health.

(49) Regulation (EC) No 1774/2002 allows for the feeding of Category 1 material to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity. In order to provide an adequate tool for the preservation of those species, that feeding practice should continue to be

permitted under this Regulation, in accordance with conditions laid down to prevent the spread of diseases. At the same time, health conditions should be laid down in the implementing measures permitting the use of such Category 1 material for feeding purposes in extensive grazing systems and for feeding to other carnivore species, such as bears and wolves. It is important that such health conditions take into account the natural consumption patterns of the species concerned as well as Community objectives for the promotion of biodiversity as referred to in the Communication from the Commission of 22 May 2006 entitled 'Halting the loss of biodiversity by 2010 – and beyond'.

(50) Burial and burning of animal by-products, in particular of dead animals may be justified in specific situations, in particular in remote areas, or in disease control situations requiring the emergency disposal of the animals killed as a measure to control an outbreak of a serious transmissible disease. In particular, disposal on site should be allowed under special circumstances, since the available rendering or incinerator capacity within a region or a Member State could otherwise be a limiting factor in the control of a disease.

(51) The current derogation concerning burial and burning of animal by-products should be extended to areas where access is not practically possible or presents a risk to the health and safety of the collection personnel. Experience gained with the application of Regulation (EC) No 1774/2002 and with natural disasters such as forest fires and floods in certain Member States has shown that under such exceptional circumstances, disposal by burial or burning on site can be justified so as to ensure the swift disposal of animals and to avoid the propagation of disease risks. The overall size of remote areas in a Member State should be limited, on the basis of the experience gained with the application of Regulation (EC) No 999/2001 so as to ensure that the general obligation to have in place a proper disposal system which complies with the rules laid down in this Regulation is fulfilled.

(52) Certain establishments or plants which handle only small quantities of animal by-products which do not pose a risk to public and animal health should be allowed to dispose of such by-products by means other than disposal in accordance with this Regulation, under official supervision. However, the criteria for such exceptional circumstances should be laid down at Community level, so as to ensure their uniform application, based on the actual situation of certain sectors and the availability of other disposal systems in certain Member States.

(53) The possible courses of action which the competent authority can take when carrying out official controls should be specified in order to ensure legal certainty, in particular regarding the suspension or permanent prohibition of operations or the imposition of conditions to ensure the proper application of this Regulation. These official controls should be carried out in the framework of multi-annual control plans under Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(23)].

(54) In order to ensure that Member States may control the quantity of material which is introduced for disposal into their territory, the competent authority should authorise the receipt of such material to its territory.

(55) Pressure sterilisation and auxiliary transport conditions may be imposed so as to ensure the control of possible risks. In order to ensure traceability and cooperation between the competent authorities of Member States controlling the dispatch of animal by-products or derived products, the Traces system introduced by Commission Decision 2004/292/EC[(24)] should be used to provide information on the dispatch of Category 1 and Category 2 materials and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials, and processed animal protein derived from Category 3 material. For materials typically sent in small quantities for research, educational, artistic or diagnostic use, special conditions should be laid down to facilitate the movement of such materials within the Community. Bilateral arrangements facilitating the control of materials moved between the Member States sharing a common border should be permitted under special circumstances.

(56) In order to facilitate the transport of consignments through third countries neighbouring more than one Member State, a special regime for the dispatch of consignments from the territory of one Member State to another through the territory of a third country should be introduced in order to ensure, in particular, that consignments re-entering Community territory are subject to veterinary checks in accordance with Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[(25)].

(57) For the sake of coherence of **[**[F1]retained EU law**]**, it is necessary to clarify the relationship between the rules laid down in this Regulation and **[**[F1]retained EU law**]** on waste. In particular, consistency should be ensured with the prohibitions on waste exports laid down in Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste[(26)]. In order to prevent potentially detrimental effects for the environment, the export of animal by-products and derived products destined for disposal by incineration and by landfill should be prohibited. The export of animal by-products and derived products should also be prevented where the objective is to use them in a biogas or composting plant to third countries which are not members of the Organisation for Economic Cooperation and Development (OECD), in order to prevent potentially adverse environmental impacts and risks to public and animal health. When applying the provisions to derogate from the export ban, the Commission is obliged to fully respect in its decisions the Basel Convention on the control of transboundary movements of hazardous waste and their disposal, as concluded, on behalf of the Community, by Council Decision 93/98/EEC[(27)], and the amendment to this Convention laid down in Decision III/1 of the Conference of the Parties, as approved, on behalf of the Community, by Council Decision 97/640/EC[(28)], and implemented by Regulation (EC) No 1013/2006.

(58) In addition, it should be ensured that animal by-products mixed or contaminated with hazardous waste, as listed in Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of

Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste[29] are only imported, exported or dispatched between Member States in accordance with Regulation (EC) No 1013/2006. It is also necessary to lay down rules concerning the dispatch of such material within a Member State.

(59) The Commission should be able to carry out controls in Member States. Community controls in third countries should be carried out in accordance with Regulation (EC) No 882/2004.

(60) The import of animal by-products and derived products into the Community and the transit of such material should take place in accordance with rules which are at least as strict as those applicable within the Community. Alternatively, the rules applicable to animal by-products and derived products in third countries may be recognised to be equivalent to the rules laid down in **[**F1retained EU law**]**. Due to the potential risk arising from them, a simplified set of import rules should be applicable to products which are destined for uses outside the feed chain.

(61) **[**F1Retained EU law**]** on the manufacture of derived products intended for use as cosmetic products, medicinal products or medical devices comprises a comprehensive framework for the placing on the market of such products: Council Directive 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products[30], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[31], Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[32], Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[33], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[34] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[35] (the specific Directives). However, the specific Directives on cosmetic products and medical devices do not provide for protection against risks to animal health. In such cases, this Regulation should apply to those risks and recourse to safeguard measures in accordance with Regulation (EC) No 178/2002 should be possible.

(62) Animal by-products or derived products that are supplied as material or ingredients for the manufacture of such derived products should also be subject to the requirements of the specific Directives, in so far as they lay down rules controlling risks to public and animal health. Those specific Directives already regulate starting material of animal origin which may be used for the manufacture of the derived products referred to and impose certain conditions to ensure the protection of public or animal health. In particular, Directive 76/768/EEC excludes Category 1 and Category 2 materials as part of the composition of a cosmetic product and obliges manufacturers to apply good manufacturing practices. Commission Directive 2003/32/EC[36] introduces detailed specifications with respect to medical devices manufactured utilising tissues of animal origin.

(63) However, where those conditions have not yet been laid down in the specific Directives or where they do not cover certain risks to public and animal health, this Regulation should apply, and recourse to safeguard measures in accordance with Regulation (EC) No 178/2002 should be possible.

(64) Certain derived products do not enter the feed chain or are not applied to land which is grazed by farmed animals or from which herbage for feed is cut. Such derived products include products for technical uses, such as treated hides for leather production, processed wool for the textile industry, bone products for glue and processed material destined for petfood. Operators should be permitted to place such products on the market provided that they are either derived from raw material requiring no treatment or the treatment or the end use of the treated material ensures adequate risk control.

(65) Certain failures to comply with the rules laid down in Regulation (EC) No 1774/2002 have been revealed in a number of Member States. Accordingly, in addition to the strict enforcement of those rules, criminal and other sanctions against operators which do not comply with those rules are needed. Therefore, it is necessary that Member States lay down rules on penalties applicable to infringements of this Regulation.

(66) Since the objective of this Regulation, namely to lay 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 and, in particular, to protect the safety of the food and feed chain, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(67) In order to enhance legal certainty and in the light of the Commission's general objective to simplify **[**F1retained EU law**]**, a coherent framework of rules should be laid down in this Regulation, taking into account the rules laid down in Regulation (EC) No 1774/2002, as well as the experience gained and progress made since the date of entry into force of that Regulation. Regulation (EC) No 1774/2002 should therefore be repealed and replaced by this Regulation.

(68) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[37].

(69) In order to improve coherence and clarity of **[**F1retained EU law**]**, the technical rules concerning specific operations involving animal by-products, which are currently laid down in the Annexes to Regulation (EC) No 1774/2002, as well as in implementing measures adopted by the Commission on the basis of that Regulation[38], should be laid down in separate implementing acts. Consultation and information of consumers and socio-professional circles concerned with issues related to this Regulation should be carried out in accordance with Commission Decision 2004/613/EC of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health[39].

(70) In particular, the Commission should be empowered to adopt rules modifying the end point in the manufacturing chain of certain derived products and establishing such an end point for certain other derived products, rules in regard to serious transmissible diseases in the presence of which the dispatch of animal by-products and derived products should not be allowed and/or the conditions allowing such a dispatch, measures changing the categorisation of animal by-products and derived products, measures regarding restrictions on the use and disposal of animal by-products and derived products, measures laying down conditions for the application of certain derogations regarding the use, collection and disposal of animal by-products and derived products and measures authorising or rejecting a particular alternative method for the use and disposal of animal by-products and derived products.

(71) In addition, the Commission should be empowered to adopt more specific rules concerning collection and transport of animal by-products and derived products, the infrastructure, equipment and hygiene requirements for establishments or plants handling animal by-products and derived products, the conditions and technical requirements for the handling of animal by-products and derived products, including the evidence to be presented for the purpose of validation of such treatment, conditions for the placing on the market of animal by-products and derived products, requirements related to safe sourcing, safe treatment and safe end uses, conditions for the import, transit and export of animal by-products and derived products, detailed arrangements for implementing official controls including rules concerning the reference methods for microbiological analyses as well as conditions for the control of the dispatch of certain animal by-products and derived products between Member States. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(72) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of measures specifying the conditions for the dispatch of animal by-products from restricted holdings, plants or zones. On grounds of urgency, it is necessary to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures modifying the end point in the manufacturing chain for certain products,

HAVE ADOPTED THIS REGULATION:

Textual Amendments

F1 Words in Regulation substituted (E.W.S.) (31.12.2020) by The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1388), **reg. 12(2)**

(**1**) OJ C 100, 30.4.2009, p. 133.

(**2**) Opinion of the European Parliament of 24 April 2009 (not yet published in the Official Journal) and Council Decision of 7 September 2009.

(**3**) OJ L 273, 10.10.2002, p. 1.

(**4**) OJ L 139, 30.4.2004, p. 55.

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

(**6**) OJ L 312, 22.11.2008, p. 3.

(**7**) OJ L 358, 18.12.1986, p. 1.

(**8**) OJ L 328, 24.11.2006, p. 14.

(**9**) OJ L 182, 16.7.1999, p. 1.

(**10**) OJ L 62, 15.3.1993, p. 69.

(**11**) OJ L 268, 18.10.2003, p. 29.

(**12**) OJ L 224, 18.8.1990, p. 1.

(**13**) OJ L 125, 23.5.1996, p. 3.

(**14**) OJ L 125, 23.5.1996, p. 10.

(**15**) OJ L 109, 6.5.2000, p. 29.

(**16**) OJ L 229, 1.9.2009, p. 1.

(**17**) OJ L 31, 1.2.2002, p. 1.

(**18**) OJ L 139, 30.4.2004, p. 1.

(**19**) OJ L 35, 8.2.2005, p. 1.

(**20**) OJ L 332, 28.12.2000, p. 91.

(**21**) OJ L 189, 20.7.2007, p. 1.

(**22**) OJ L 343, 27.12.2007, p. 1.

(**23**) OJ L 165, 30.4.2004, p. 1.

(**24**) OJ L 94, 31.3.2004, p. 63.

(**25**) OJ L 395, 30.12.1989, p. 13.

(**26**) OJ L 190, 12.7.2006, p. 1.

(**27**) OJ L 39, 16.2.1993, p. 1.

(**28**) OJ L 272, 4.10.1997, p. 45.

(**29**) OJ L 226, 6.9.2000, p. 3.

(**30**) OJ L 262, 27.9.1976, p. 169.

(**31**) OJ L 311, 28.11.2001, p. 67.

(**32**) OJ L 311, 28.11.2001, p. 1.

(**33**) OJ L 189, 20.7.1990, p. 17.

(**34**) OJ L 169, 12.7.1993, p. 1.

(**35**) OJ L 331, 7.12.1998, p. 1.

(**36**) OJ L 105, 26.4.2003, p. 18.

(**37**) OJ L 184, 17.7.1999, p. 23.

(**38**) Regulation (EC) No 811/2003 on the intra-species recycling ban for fish, and the burial and burning of certain animal by-products (OJ L 117, 13.5.2003, p. 14); Decision 2003/322/EC on the feeding of certain necrophagous birds with certain Category 1 materials (OJ L 117, 13.5.2003,

p. 32); Decision 2003/324/EC on a derogation from the intra-species recycling ban for fur animals (OJ L 117, 13.5.2003, p. 37); Regulation (EC) No 92/2005 on means of disposal or uses (OJ L 19, 21.1.2005, p. 27); Regulation (EC) No 181/2006 on organic fertilisers and soil improvers other than manure (OJ L 29, 2.2.2006, p. 31); Regulation (EC) No 1192/2006 on lists of approved plants (OJ L 215, 5.8.2006, p. 10); Regulation (EC) No 2007/2006 on the importation and transit of certain intermediate products derived from Category 3 material (OJ L 379, 28.12.2006, p. 98).

(**39**) OJ L 275, 25.8.2004, p. 17.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1069/2009 of the European Parliament and of the Council, Introductory Text.