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(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

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

[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.

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 ([1]), 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 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 ([2]), lays down rules for handling of meat and animal by-products from wild game. Those rules

([1]) OJ L 273, 10.10.2002, p. 1.

([2]) OJ L 139, 30.4.2004, p. 55.

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 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 ([1]) and in Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste ([2]) 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 ([3]) 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 ([4]) 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 ([5]) 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

([1]) OJ L 147, 31.5.2001, p. 1.
([2]) OJ L 312, 22.11.2008, p. 3.
([3]) OJ L 358, 18.12.1986, p. 1.
([4]) OJ L 328, 24.11.2006, p. 14.
([5]) OJ L 182, 16.7.1999, p. 1.

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 ([1]).

(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 Community legislation on food hygiene should not be required to be approved or registered under this Regulation, as approvals or registrations under that Community legislation 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 Community legislation 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.

([1]) OJ L 62, 15.3.1993, p. 69.

(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 ([1]).

(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 ([2]) 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 ([3]). 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 ([4]) 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 Community legislation, 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 Community legislation 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 ([5]) 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 ([6]) 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 ([7]), namely Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([8]), 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 ([9]), and to which Regulation (EC) No 1774/2002 is complementary, places the primary duty of complying with Community legislation, 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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 224, 18.8.1990, p. 1.
([3]) OJ L 125, 23.5.1996, p. 3.
([4]) OJ L 125, 23.5.1996, p. 10.
([5]) OJ L 109, 6.5.2000, p. 29.
([6]) OJ L 229, 1.9.2009, p. 1.
([7]) OJ L 31, 1.2.2002, p. 1.
([8]) OJ L 139, 30.4.2004, p. 1.
([9]) OJ L 35, 8.2.2005, p. 1.

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 Community legislation 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 Community legislation. 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 [1]. 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 [2].

(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

[1] OJ L 332, 28.12.2000, p. 91.

[2] OJ L 189, 20.7.2007, p. 1.

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 [1] 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

[1] OJ L 343, 27.12.2007, p. 1.

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 ([1]).

(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 ([2]) 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 ([3]).

(57) For the sake of coherence of Community legislation, it is necessary to clarify the relationship between the rules laid down in this Regulation and Community legislation 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 ([4]). 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 ([5]), 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 ([6]), 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 ([7]) 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 Community legislation. 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.

([1]) OJ L 165, 30.4.2004, p. 1.
([2]) OJ L 94, 31.3.2004, p. 63.
([3]) OJ L 395, 30.12.1989, p. 13.
([4]) OJ L 190, 12.7.2006, p. 1.
([5]) OJ L 39, 16.2.1993, p. 1.
([6]) OJ L 272, 4.10.1997, p. 45.
([7]) OJ L 226, 6.9.2000, p. 3.

(61) Community legislation 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 ([1]), 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 ([2]), 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 ([3]), 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 ([4]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([5]) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ([6]) (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 ([7]) 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 Community legislation, 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 ([8]).

(69) In order to improve coherence and clarity of Community legislation, the technical rules concerning specific operations involving animal by-products, which are currently

([1]) OJ L 262, 27.9.1976, p. 169.
([2]) OJ L 311, 28.11.2001, p. 67.
([3]) OJ L 311, 28.11.2001, p. 1.
([4]) OJ L 189, 20.7.1990, p. 17.
([5]) OJ L 169, 12.7.1993, p. 1.
([6]) OJ L 331, 7.12.1998, p. 1.
([7]) OJ L 105, 26.4.2003, p. 18.
([8]) OJ L 184, 17.7.1999, p. 23.

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 [1], 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 [2].

(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:

TITLE I

GENERAL PROVISIONS

CHAPTER I

Common provisions

Section 1

Subject matter, scope and definitions

Article 1

Subject matter

This Regulation lays down public health 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.

Article 2

Scope

1. This Regulation shall apply to:

(a) animal by-products and derived products which are excluded from human consumption under Community legislation; and

[1] 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).

[2] OJ L 275, 25.8.2004, p. 17.

(b) the following products which pursuant to a decision by an operator, which shall be irreversible, are destined for purposes other than human consumption:

(i) products of animal origin which may be destined for human consumption under Community legislation;

(ii) raw materials for the production of products of animal origin.

2. This Regulation shall not apply to the following animal by-products:

(a) entire bodies or parts of wild animals, other than wild game, 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;

(b) entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice, without prejudice to Regulation (EC) No 853/2004;

(c) animal by-products from wild game and from wild game meat referred to in Article 1(3)(e) of Regulation (EC) No 853/2004;

(d) oocytes, embryos and semen destined for breeding purposes;

(e) raw milk, colostrum and products derived therefrom which are obtained, kept, disposed of or used on the farm of origin;

(f) shells from shellfish with the soft tissue and flesh removed;

(g) catering waste, except if it:

(i) originates from means of transport operating internationally;

(ii) is destined for feeding purposes;

(iii) is destined for processing by pressure sterilisation or for processing by methods referred to in point (b) of the first subparagraph of Article 15(1) or for transformation into biogas or for composting;

(h) without prejudice to Community environmental legislation, material from vessels complying with Regulations (EC) No 852/2004 and (EC) No 853/2004, which has arisen in the course of their fishing operations and is disposed of at sea, except material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;

(i) raw pet food originating from retail shops, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;

(j) raw pet food derived from animals which are slaughtered on the farm of origin for private domestic consumption; and

(k) excrement and urine other than manure and non-mineralised guano.

3. This Regulation shall be without prejudice to Community veterinary legislation having as its objective the control and eradication of animal diseases.

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'animal by-products' means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen;

2. 'derived products' means products obtained from one or more treatments, transformations or steps of processing of animal by-products;

3. 'products of animal origin' means products of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;

4. 'carcase' means carcase as defined in point 1.9 of Annex I to Regulation (EC) No 853/2004;

5. 'animal' means any invertebrate or vertebrate animal;

6. 'farmed animal' means:

(a) any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any other product obtained from animals or for other farming purposes;

(b) equidae;

7. 'wild animal' means any animal not kept by humans;

8. 'pet animal' means any animal belonging to species normally nourished and kept but not consumed, by humans for purposes other than farming;

9. 'aquatic animals' means aquatic animals as defined in Article 3(1)(e) of Directive 2006/88/EC;

10. 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that competence has been delegated; it also includes, where appropriate, the corresponding authority of a third country;

11. 'operator' means the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users;

12. 'user' means the natural or legal persons using animal by-products and derived products for special feeding purposes, for research or for other specific purposes;

13. 'establishment' or 'plant' means any place where any operation involving the handling of animal by-products or derived products is carried out, other than a fishing vessel;

14. 'placing on the market' means any operation the purpose of which is to sell animal by-products or derived products to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;

15. 'transit' means movement through the Community from the territory of a third country to the territory of another third country, other than by sea or by air;

16. 'export' means movement from the Community to a third country;

17. 'transmissible spongiform encephalopathies (TSEs)' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001;

18. 'specified risk material' means specified risk material as defined in Article 3(1)(g) of Regulation (EC) No 999/2001;

19. 'pressure sterilisation' means the processing of animal by-products, after reduction in particle size to not more than 50 mm, to a core temperature of more than 133 °C for at least 20 minutes without interruption at an absolute pressure of at least 3 bar;

20. 'manure' means any excrement and/or urine of farmed animals other than farmed fish, with or without litter;

21. 'authorised landfill' means a landfill for which a permit has been issued in accordance with Directive 1999/31/EC;

22. 'organic fertiliser' and 'soil improver' means materials of animal origin used to maintain or improve plant nutrition and the physical and chemical properties and biological activities of soils, either separately or together; they may include manure, non-mineralised guano, digestive tract content, compost and digestion residues;

23. 'remote area' means an area where the animal population is so small, and where disposal establishments or plants are so far away that the arrangements necessary for the collection and transport of animal by-products would be unacceptably onerous compared to local disposal;

24. 'food' or 'foodstuff' means food or foodstuff as defined in Article 2 of Regulation (EC) No 178/2002;

25. 'feed' or 'feedingstuff' means feed or feedingstuff as defined in Article 3(4) of Regulation (EC) No 178/2002;

26. 'centrifuge or separator sludge' means material collected as a by-product after purification of raw milk and separation of skimmed milk and cream from raw milk;

27. 'waste' means waste as defined in point 1 of Article 3 of Directive 2008/98/EC.

Section 2

Obligations

Article 4

Starting point in the manufacturing chain and obligations

1. As soon as operators generate animal by-products or derived products falling within the scope of this Regulation, they shall identify them and ensure that they are dealt with in accordance with this Regulation (starting point).

2. Operators shall ensure at all stages of collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that animal by-products and derived products satisfy the requirements of this Regulation which are relevant to their activities.

3. Member States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products as referred to in paragraph 2. For that purpose, they shall maintain a system of official controls in accordance with relevant Community legislation.

4. Member States shall ensure that an adequate system is in place on their territory ensuring that animal by-products are:

(a) collected, identified and transported without undue delay; and

(b) treated, used or disposed of in accordance with this Regulation.

5. Member States may fulfil their obligations under paragraph 4 in cooperation with other Member States or third countries.

Article 5

End point in the manufacturing chain

1. Derived products referred to in Article 33 which have reached the stage of manufacturing regulated by the Community legislation referred to in that Article shall be regarded as having reached the end point in the manufacturing chain, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

The end point in the manufacturing chain may be modified:

(a) for products referred to in Article 33(a) to (d), in case of risks to animal health;

(b) for products referred to in Article 33(e) and (f), in case of risks to public or animal health.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(6).

2. For derived products referred to in Articles 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

3. In the event of risks to public or animal health, Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency measures shall apply mutatis mutandis to the derived products referred to in Articles 33 and 36 of this Regulation.

Section 3

Animal health restrictions

Article 6

General animal health restrictions

1. Animal by-products and derived products from susceptible species shall not be dispatched from holdings, establishments, plants or zones which are subject to restrictions:

(a) pursuant to Community veterinary legislation; or

(b) due to the presence of a serious transmissible disease:

(i) listed in Annex I to Directive 92/119/EEC; or

(ii) laid down in accordance with the second subparagraph.

The measures referred to in point (b)(ii) of the first subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. Paragraph 1 shall not apply where animal by-products and derived products are dispatched under conditions designed to prevent the spread of diseases transmissible to humans or animals.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(5).

Section 4

Categorisation

Article 7

Categorisation of animal by-products and derived products

1. Animal by-products shall be categorised into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.

2. Derived products shall be subject to the rules for the specific category of animal by-products from which they have been derived, unless otherwise specified in this Regulation, or provided for in measures for the implementation of this Regulation which may specify the conditions under which derived products are not subject to those rules adopted by the Commission.

3. Articles 8, 9 and 10 may be amended in order to take into account scientific progress as regards the assessment of the level of risk, provided such progress can be identified on the basis of a risk assessment carried out by the appropriate scientific institution. However, no animal by-products listed in those Articles may be removed from those lists, only changes of categorisation or additions may be made.

4. The measures referred to in paragraphs 2 and 3, designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 8

Category 1 material

Category 1 material shall comprise the following animal by-products:

(a) entire bodies and all body parts, including hides and skins, of the following animals:

(i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed;

(ii) animals killed in the context of TSE eradication measures;

(iii) animals other than farmed and wild animals, including in particular pet animals, zoo animals and circus animals;

(iv) animals used for experiments as defined by Article 2(d) of Directive 86/609/EEC without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;

(v) wild animals, when suspected of being infected with diseases communicable to humans or animals;

(b) the following material:

(i) specified risk material;

(ii) entire bodies or parts of dead animals containing specified risk material at the time of disposal;

(c) animal by-products derived from animals which have been submitted to illegal treatment as defined in Article 1(2)(d) of Directive 96/22/EC or Article 2(b) of Directive 96/23/EC;

(d) animal by-products containing residues of other substances and environmental contaminants listed in Group B(3) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;

(e) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:

(i) from establishments or plants processing Category 1 material; or

(ii) from other establishments or plants where specified risk material is being removed;

(f) catering waste from means of transport operating internationally;

(g) mixtures of Category 1 material with either Category 2 material or Category 3 material or both.

Article 9

Category 2 material

Category 2 material shall comprise the following animal by-products:

(a) manure, non-mineralised guano and digestive tract content;

(b) animal by-products collected during the treatment of waste water required by implementing rules adopted under point (c) of the first paragraph of Article 27:

(i) from establishments or plants processing Category 2 material; or

(ii) from slaughterhouses other than those covered by Article 8(e);

(c) animal by-products containing residues of authorised substances or contaminants exceeding the permitted levels as referred to in Article 15(3) of Directive 96/23/EC;

(d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;

(e) products of animal origin, other than Category 1 material, that are:

(i) imported or introduced from a third country and fail to comply with Community veterinary legislation for their import or introduction into the Community except where Community legislation allows their import or introduction subject to specific restrictions or their return to the third country; or

(ii) dispatched to another Member State and fail to comply with requirements laid down or authorised by Community legislation except where they are returned with the authorisation of the competent authority of the Member State of origin;

(f) animals and parts of animals, other than those referred to in Article 8 or Article 10,

(i) that died other than by being slaughtered or killed for human consumption, including animals killed for disease control purposes;

(ii) foetuses;

(iii) oocytes, embryos and semen which are not destined for breeding purposes; and

(iv) dead-in-shell poultry;

(g) mixtures of Category 2 material with Category 3 material;

(h) animal by-products other than Category 1 material or Category 3 material.

Article 10

Category 3 material

Category 3 material shall comprise the following animal by-products:

(a) carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;

(b) carcases and the following parts originating either from animals that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem inspection or bodies and the following parts of animals from game killed for human consumption in accordance with Community legislation:

(i) carcases or bodies and parts of animals which are rejected as unfit for human consumption in accordance with Community legislation, but which did not show any signs of disease communicable to humans or animals;

(ii) heads of poultry;

(iii) hides and skins, including trimmings and splitting thereof, horns and feet, including the phalanges and the carpus and metacarpus bones, tarsus and metatarsus bones, of:

— animals, other than ruminants requiring TSE testing, and

— ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;

(iv) pig bristles;

(v) feathers;

(c) animal by-products from poultry and lagomorphs slaughtered on the farm as referred to in Article 1(3)(d) of Regulation (EC) No 853/2004, which did not show any signs of disease communicable to humans or animals;

(d) blood of animals which did not show any signs of disease communicable through blood to humans or animals obtained from the following animals that have been slaughtered in a slaughterhouse after having been considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation:

(i) animals other than ruminants requiring TSE testing; and

(ii) ruminants which have been tested with a negative result in accordance with Article 6(1) of Regulation (EC) No 999/2001;

(e) animal by-products arising from the production of products intended for human consumption, including degreased bones, greaves and centrifuge or separator sludge from milk processing;

(f) products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;

(g) petfood and feedingstuffs of animal origin, or feedingstuffs containing animal by-products or derived products, which are no longer intended for feeding for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arises;

(h) blood, placenta, wool, feathers, hair, horns, hoof cuts and raw milk originating from live animals that did not show any signs of disease communicable through that product to humans or animals;

(i) aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals;

(j) animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption;

(k) the following material originating from animals which did not show any signs of disease communicable through that material to humans or animals:

(i) shells from shellfish with soft tissue or flesh;

(ii) the following originating from terrestrial animals:

— hatchery by-products,

— eggs,

— egg by-products, including egg shells,

(iii) day-old chicks killed for commercial reasons;

(l) aquatic and terrestrial invertebrates other than species pathogenic to humans or animals;

(m) animals and parts thereof of the zoological orders of Rodentia and Lagomorpha, except Category 1 material as referred to in Article 8(a)(iii), (iv) and (v) and Category 2 material as referred to in Article 9(a) to (g);

(n) hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article;

(o) adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation;

(p) catering waste other than as referred to in Article 8(f).

CHAPTER II

Disposal and use of animal by-products and derived products

Section 1

Restrictions on use

Article 11

Restrictions on use

1. The following uses of animal by-products and derived products shall be prohibited:

(a) the feeding of terrestrial animals of a given species other than fur animals with processed animal protein derived from the bodies or parts of bodies of animals of the same species;

(b) the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste;

(c) the feeding of farmed animals with herbage, either directly by grazing or by feeding with cut herbage, from land to which organic fertilisers or soil improvers, other than manure, have been applied unless the cutting or grazing takes place after the expiry of a waiting period which ensures adequate control of risks to public and animal health and is at least 21 days; and

(d) the feeding of farmed fish with processed animal protein derived from the bodies or parts of bodies of farmed fish of the same species.

2. Measures relating to the following may be laid down:

(a) the checks and controls to be carried out to ensure the application of the prohibitions referred to in paragraph 1, including detection methods and tests to be used to verify the presence of materials originating from certain species and thresholds for insignificant amounts of processed animal proteins referred to in points (a) and (d) of paragraph 1 which are caused by adventitious and technically unavoidable contamination;

(b) the conditions for the feeding of fur animals with processed animal protein derived from bodies or parts of bodies of animals of the same species; and

(c) the conditions for the feeding of farmed animals with herbage from land to which organic fertilisers or soil improvers have been applied, in particular a modification of the waiting period as referred to in paragraph 1(c).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 2

Disposal and use

Article 12

Disposal and use of Category 1 material

Category 1 material shall be:

(a) disposed of as waste by incineration:

(i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(b) recovered or disposed of by co-incineration, if the Category 1 material is waste:

(i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(c) in the case of Category 1 material other than material referred to in Article 8(a)(i) and (ii), disposed of by processing by pressure sterilisation, permanent marking of the resulting material and burial in an authorised landfill;

(d) in the case of Category 1 material referred to in Article 8(f), disposed of by burial in an authorised landfill;

(e) used as a fuel for combustion with or without prior processing; or

(f) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

Article 13

Disposal and use of Category 2 material

Category 2 material shall be:

(a) disposed of as waste by incineration:

(i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(b) recovered or disposed of by co-incineration, if the Category 2 material is waste:

(i) directly without prior processing; or

(ii) following processing, by pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material;

(c) disposed of in an authorised landfill, following processing by pressure sterilisation and permanent marking of the resulting material;

(d) used for the manufacturing of organic fertilisers or soil improvers to be placed on the market in accordance with Article 32 following processing by pressure sterilisation, when applicable, and permanent marking of the resulting material;

(e) composted or transformed into biogas:

(i) following processing by pressure sterilisation and permanent marking of the resulting material; or

(ii) in the case of manure, digestive tract and its content, milk, milk-based products, colostrum, eggs and egg products which the competent authority does not consider to present a risk for the spread of any serious transmissible disease, following or without prior processing;

(f) applied to land without processing, in the case of manure, digestive tract content separated from the digestive tract, milk, milk-based products and colostrum which the competent authority does not consider to present a risk for the spread of any serious transmissible disease;

(g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;

(h) used as a fuel for combustion with or without prior processing; or

(i) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles.

Article 14

Disposal and use of Category 3 material

Category 3 material shall be:

(a) disposed of as waste by incineration, with or without prior processing;

(b) recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;

(c) disposed of in an authorised landfill, following processing;

(d) processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:

(i) for the manufacturing of feed for farmed animals other than fur animals, to be placed on the market in accordance with Article 31, except in the case of material referred to in Article 10(n), (o) and (p);

(ii) for the manufacturing of feed for fur animals, to be placed on the market in accordance with Article 36;

(iii) for the manufacturing of pet food, to be placed on the market in accordance with Article 35; or

(iv) for the manufacturing of organic fertilisers or soil improvers, to be placed on the market in accordance with Article 32;

(e) used for the production of raw petfood, to be placed on the market in accordance with Article 35;

(f) composted or transformed into biogas;

(g) in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;

(h) in the case of shells from shellfish, other than those referred to in Article 2(2)(f), and egg shells, used under conditions determined by the competent authority which prevent risks arising to public and animal health;

(i) used as a fuel for combustion with or without prior processing;

(j) used for the manufacture of derived products referred to in Articles 33, 34 and 36 and placed on the market in accordance with those Articles;

(k) in the case of catering waste referred to in Article 10(p) processed by pressure sterilisation or by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or composted or transformed into biogas; or

(l) applied to land without processing, in the case of raw milk, colostrum and products derived therefrom, which the competent authority does not consider to present a risk of any disease communicable through those products to humans or animals.

Article 15

Implementing measures

1. Measures for the implementation of this Section may be laid down relating to the following:

(a) special conditions for the on-board handling and the disposal of material derived from on-board evisceration of fish showing signs of disease, including parasites, that are communicable to humans;

(b) processing methods for animal by-products other than pressure sterilisation, in particular as regards the parameters to be applied for those processing methods, in particular the time, temperature, pressure and size of particles;

(c) parameters for the transformation of animal by-products, including catering waste, into biogas or compost;

(d) conditions for the incineration and co-incineration of animal by-products and derived products;

(e) conditions for the combustion of animal by-products and derived products;

(f) conditions for the generation and handling of animal by-products referred to in Article 10(c);

(g) ensilage of material originating from aquatic animals;

(h) permanent marking of animal by-products;

(i) the application to land of certain animal by-products, organic fertilisers and soil improvers;

(j) the use of certain animal by-products for feeding to farmed animals; and

(k) the level of risk to public or animal health with respect to certain material which is considered as unacceptable as referred to in Article 14(d).

Those measures designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. Pending the adoption of rules referred to:

(a) in points (c), (f) and (g) of the first subparagraph of paragraph 1, Member States may adopt or maintain national rules for:

(i) the generation and handling of animal by-products referred to in Article 10(c);

(ii) the transformation of animal by-products referred to in Article 10(p); and

(iii) for the ensilage of material originating from aquatic animals;

(b) in point (a) of the first subparagraph of paragraph 1, animal by-products referred to therein may be disposed of at sea, without prejudice to Community environmental legislation.

Section 3

Derogations

Article 16

Derogations

By way of derogation from Articles 12, 13 and 14, animal by-products may be:

(a) in the case of animal by-products referred to in point (a) of the first subparagraph of Article 15(1), handled and disposed of in accordance with special conditions laid down pursuant to that point;

(b) used for research and other specific purposes in accordance with Article 17;

(c) in the case of animal by-products referred to in Article 18, used for special feeding purposes in accordance with that Article;

(d) in the case of animal by-products referred to in Article 19, disposed of in accordance with that Article;

(e) disposed of or used in accordance with alternative methods which have been authorised in accordance with Article 20, based on parameters which may include pressure sterilisation or other requirements of this Regulation or the implementing measures thereof;

(f) in the case of Category 2 and Category 3 materials and if authorised by the competent authority, used for the preparation and application to land of bio-dynamic preparations as referred to in Article 12(1)(c) of Regulation (EC) No 834/2007;

(g) in the case of Category 3 material and, if authorised by the competent authority, used for feeding to pet animals;

(h) in the case of animal by-products, except for Category 1 material, which arise in the course of surgical intervention on live animals or during birth of animals on farm and, if authorised by the competent authority, disposed of on that farm.

Article 17

Research and other specific purposes

1. The competent authority may, by way of derogation from Articles 12, 13 and 14, authorise the use of animal by-products and derived products for exhibitions, artistic activities, and for diagnostic, educational or research purposes under conditions which ensure the control of risks to public and animal health.

Such conditions shall include:

(a) the prohibition of any subsequent use of the animal by-products or derived products for other purposes; and

(b) the obligation to dispose of the animal by-products or derived products safely, or to re-dispatch them to their place of origin, if appropriate.

2. In the case of risks to public and animal health which require the adoption of measures for the whole territory of the Community, in particular in the case of newly emerging risks, harmonised conditions for the import and use of the animal by-products and derived products referred to in paragraph 1 may be laid down. Such conditions may include requirements regarding storage, packaging, identification, transport and disposal.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 18

Special feeding purposes

1. The competent authority may, by way of derogation from Articles 13 and 14, authorise, under conditions which ensure the control of risks to public and animal health, the collection and use of Category 2 material, provided that it comes from animals which were not killed or did not die as a result of the presence or suspected presence of a disease communicable to humans or animals, and of Category 3 material for feeding to:

(a) zoo animals;

(b) circus animals;

(c) reptiles and birds of prey other than zoo or circus animals;

(d) fur animals;

(e) wild animals;

(f) dogs from recognised kennels or packs of hounds;

(g) dogs and cats in shelters;

(h) maggots and worms for fishing bait.

2. The competent authority may authorise, by way of derogation from Article 12, and in accordance with the conditions laid down pursuant to paragraph 3 of this Article:

(a) the feeding of the Category 1 material referred to in Article 8(b)(ii) and of material derived from zoo animals for feeding to zoo animals; and

(b) the feeding of the Category 1 material referred to in Article 8(b)(ii) to endangered or protected species of necrophagous birds and other species living in their natural habitat, for the promotion of biodiversity.

3. Measures for the implementation of this Article may be laid down relating to the following:

(a) conditions under which the collection and use as referred to in paragraph 1 may be authorised with respect to the movement, storage and use of Category 2 material and of Category 3 material for feeding, including in the case of newly emerging risks; and

(b) conditions under which, in certain cases by way of derogation from the obligation laid down in Article 21(1), the feeding of Category 1 material as referred to in paragraph 2 of this Article may be authorised, including:

(i) the endangered or protected species of necrophagous birds and other species in certain Member States to which such material may be fed;

(ii) measures to prevent risks to public and animal health.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 19

Collection, transport and disposal

1. The competent authority may, by way of derogation from Articles 12, 13, 14 and 21, authorise the disposal:

(a) by burial of dead pet animals and equidae;

(b) by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(a)(v) and (b)(ii), Category 2 and Category 3 materials in remote areas;

(c) by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health of Category 1 material referred to in Article 8(b)(ii), Category 2 and Category 3 materials in areas where access is practically impossible or where access would only be possible under circumstances, related to geographical or climatic reasons or due to a natural disaster, which would pose a risk to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionate means of collection;

(d) by means other than burning or burial on site, under official supervision, in the case of Category 2 and Category 3 materials which do not pose a risk to public and animal health, when the amounts of materials do not exceed a particular volume per week, this volume being determined in relation to the nature of the activities carried out and the species of origin of the animal by-products concerned;

(e) by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of animal by-products other than Category 1 material referred to in Article 8(a)(i) in the event of an outbreak of a notifiable disease, if transport to the nearest plant approved for processing or disposal of the animal by-products would increase the danger of propagation of health risks or, in case of a widespread outbreak of an epizootic disease, would mean that the disposal capacities of such plants were exceeded; and

(f) by burning or burial on site, under conditions which prevent the transmission of risks to public and animal health, of bees and apiculture by-products.

2. The animal population of a particular species in the remote areas referred to in paragraph 1(b) shall not exceed a maximum percentage of the animal population of this species in the Member State concerned.

3. Member States shall make available to the Commission information on:

(a) the areas that they categorise as remote areas for the purpose of applying paragraph 1(b) and the reasons for that categorisation, and updated information concerning any change to such categorisation; and

(b) the use they make of the authorisations provided for in points (c) and (d) of paragraph 1 with respect to Category 1 and Category 2 materials.

4. Measures for the implementation of this Article shall be laid down relating to the following:

(a) conditions aimed at ensuring control of risks to public and animal health in the event of burning and burial on site;

(b) the maximum percentage of the animal population as referred to in paragraph 2;

(c) the volume of animal by-products, in relation to the nature of activities and the species of origin, as referred to in paragraph 1(d); and

(d) the list of diseases referred to in paragraph 1(e).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 4

Alternative methods

Article 20

Authorisation of alternative methods

1. The procedure for authorisation of an alternative method of use or disposal of animal by-products or derived products may be initiated either by the Commission or, following an application, by a Member State or by an interested party, which may represent several interested parties.

2. Interested parties shall send their applications to the competent authority of the Member State where they intend to use the alternative method.

The competent authority shall evaluate, within a period of two months following receipt of a complete application, whether the application complies with the standard format for applications referred to in paragraph 10.

3. The competent authority shall communicate the applications of the Member States and interested parties, together with a report on its evaluation to the European Food Safety Authority (EFSA) and inform the Commission thereof.

4. When the Commission initiates the procedure for authorisation, it shall send a report on its evaluation to EFSA.

5. EFSA shall assess, within six months following receipt of a complete application, whether the method submitted ensures that risks to public or animal health are:

(a) controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or

(b) reduced to a degree which is at least equivalent, for the relevant category of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

EFSA shall issue an opinion on the application submitted.

6. In duly justified cases where EFSA requests additional information from applicants, the period provided for in paragraph 5 may be extended.

After consulting the Commission or the applicant, EFSA shall decide on a period within which that information shall be provided to it and inform the Commission and the applicant as appropriate of the additional period needed.

7. Where applicants wish to submit additional information on their own initiative, they shall send it directly to EFSA.

In that case the period provided for in paragraph 5 shall not be extended by an additional period.

8. EFSA shall forward its opinion to the Commission, the applicant and the competent authority of the Member State concerned.

9. Within three months following receipt of the opinion of EFSA and taking account of that opinion, the Commission shall inform the applicant of the proposed measure to be adopted in accordance with paragraph 11.

10. A standard format for applications for alternative methods shall be adopted in accordance with the advisory procedure referred to in Article 52(2).

11. Following receipt of the opinion of EFSA, the following shall be adopted:

(a) either a measure authorising an alternative method of use or disposal of animal by-products or derived products; or

(b) a measure rejecting the authorisation of such an alternative method.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

TITLE II

OBLIGATIONS OF OPERATORS

CHAPTER I

General obligations

Section 1

Collection, transport and traceability

Article 21

Collection and identification as regards category and transport

1. Operators shall collect, identify and transport animal by-products without undue delay under conditions which prevent risks arising to public and animal health.

2. Operators shall ensure that animal by-products and derived products are accompanied during transport by a commercial document or, when required by this Regulation or by a measure adopted in accordance with paragraph 6, by a health certificate.

By way of derogation from the first subparagraph, the competent authority may authorise the transport of manure between two points located on the same farm or between farms and users of manure within the same Member State without a commercial document or health certificate.

3. Commercial documents and health certificates accompanying animal by-products or derived products during transport shall at least include information on the origin, the destination and the quantity of such products, and a description of the animal by-products or derived products and their marking, when such marking is required by this Regulation.

However, for animal by-products and derived products transported within the territory of a Member State, the competent authority of the Member State concerned may authorise transmission of the information referred to in the first subparagraph by way of an alternative system.

4. Operators shall collect, transport and dispose of Category 3 catering waste, in accordance with national measures foreseen in Article 13 of Directive 2008/98/EC.

5. The following shall be adopted in accordance with the regulatory procedure referred to in Article 52(3):

(a) models for commercial documents which are required to accompany animal by-products during transport; and

(b) models for health certificates and the conditions governing the way they must accompany animal by-products and derived products during transport.

6. Measures for the implementation of this Article may be laid down relating to the following:

(a) cases where a health certificate is required, having regard to the level of risk to public and animal health arising from certain derived products;

(b) cases where, by way of derogation from the first subparagraph of paragraph 2 and having regard to the low level of risk to public and animal health arising from certain animal by-products or derived products, transport of derived products may take place without the documents or certificates referred to in that paragraph;

(c) requirements for the identification, including labelling, and for the separation of different categories of animal by-products during transport; and

(d) conditions to prevent risks to public and animal health arising during the collection and transport of animal by-products, including conditions for the safe transport of those products with respect to containers, vehicles and packaging material.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 22

Traceability

1. Operators consigning, transporting or receiving animal by-products or derived products shall keep a record of consignments and related commercial documents or health certificates.

However, the first subparagraph shall not apply when an authorisation to transport animal by-products or derived products without commercial documents or health certificates has been granted in accordance with the second subparagraph of Article 21(2) or in accordance with implementing measures adopted under Article 21(6)(b).

2. The operators referred to in paragraph 1 shall have in place systems and procedures to identify:

(a) the other operators to which their animal by-products or derived products have been supplied; and

(b) the operators from whom they have been supplied.

This information shall be made available to the competent authorities on request.

3. Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

(a) the information to be made available to the competent authorities;

(b) the period of time during which this information must be kept.

Section 2

Registration and approval

Article 23

Registration of operators, establishments or plants

1. With a view to registration, operators shall:

(a) before commencing operations, notify the competent authority of any establishments or plants under their control which are active at any stage of the generation, transport, handling, processing, storage, placing on the market, distribution, use or disposal of animal by-products and derived products;

(b) provide the competent authority with information on:

(i) the category of animal by-products or derived products under their control;

(ii) the nature of the operations performed using animal by-products or derived products as starting material.

2. Operators shall provide the competent authority with up-to-date information on any establishments or plants under their control as referred to in point (a) of paragraph 1, including any significant change in activities such as any closure of an existing establishment or plant.

3. Detailed rules regarding registration as referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

4. By way of derogation from paragraph 1, no notification with a view to registration shall be required for activities with respect to which establishments generating animal by-products have already been approved or registered in accordance with Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004; and for activities with respect to which establishments or plants have already been approved in accordance with Article 24 of this Regulation.

The same derogation shall apply for the activities involving the generation of animal by-products on site only, which are carried out on farms or other premises where animals are kept, bred or taken care of.

Article 24

Approval of establishments or plants

1. Operators shall ensure that establishments or plants under their control are approved by the competent authority, where such establishments or plants carry out one or more of the following activities:

(a) processing of animal by-products by pressure sterilisation, by processing methods referred to in point (b) of the first subparagraph of Article 15(1) or by alternative methods authorised in accordance with Article 20;

(b) disposal, as waste, by incineration of animal by-products and derived products, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;

(c) disposal or recovery of animal by-products and derived products, if they are waste, by co-incineration, excluding establishments or plants which have a permit to operate in accordance with Directive 2000/76/EC;

(d) use of animal by-products and derived products as fuel for combustion;

(e) manufacturing of pet food;

(f) manufacturing of organic fertilisers and soil improvers;

(g) transformation of animal by-products and/or derived products into biogas or compost;

(h) handling of animal by-products after their collection, by way of operations such as sorting, cutting, chilling, freezing, salting, removal of hides and skins or of specified risk material;

(i) storage of animal by-products;

(j) storage of derived products intended to be:

(i) disposed of by landfill or incineration or intended to be recovered or disposed of by co-incineration;

(ii) used as fuel for combustion;

(iii) used as feed, excluding establishments or plants approved or registered in accordance with Regulation (EC) No 183/2005;

(iv) used as organic fertilisers and soil improvers, excluding storage at a place of direct application.

2. The approval referred to in paragraph 1 shall specify if the establishment or plant is approved for operations with animal by-products and/or derived products of:

(a) a particular category referred to in Articles 8, 9 or 10; or

(b) more than one category referred to in Articles 8, 9 or 10, indicating if such operations are carried out:

(i) permanently under conditions of strict separation which prevent any risk to public and animal health; or

(ii) temporarily under conditions which prevent contamination, in response to a shortage of capacity for such products arising due to:

— a widespread outbreak of an epizootic disease, or

— other extraordinary and unforeseen circumstances.

Article 25

General hygiene requirements

1. Operators shall ensure that establishments or plants under their control carrying out the activities referred to in Article 24(1)(a) and (h):

(a) are constructed in a way permitting their effective cleaning and disinfection and where appropriate the construction of floors facilitates the draining of liquids;

(b) have access to adequate facilities for personal hygiene such as lavatories, changing rooms and washbasins for staff;

(c) have appropriate arrangements for protection against pests, such as insects, rodents and birds;

(d) keep installations and equipment in good condition and ensure that measuring equipment is calibrated regularly; and

(e) have appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.

2. Any person working in the establishment or plant referred to in paragraph 1 shall wear suitable, clean and, where necessary, protective clothing.

Where appropriate in a particular establishment or plant:

(a) persons working in the unclean sector shall not enter the clean sector without first changing their work clothes and shoes or without having disinfected them;

(b) equipment and machinery shall not be moved from the unclean to the clean sector without first being cleaned and disinfected; and

(c) the operator shall establish a procedure relating to the movements of persons in order to monitor their movements and describe the correct use of footbaths and wheel baths.

3. In establishments or plants carrying out the activities referred to in Article 24(1)(a):

(a) animal by-products shall be handled in such a way as to avoid risks of contamination;

(b) animal by-products shall be processed as soon as possible. After processing, derived products shall be handled and stored in such a way as to avoid risks of contamination;

(c) where appropriate, during any processing applied to animal by-products and derived products every part of the animal by-product and derived products shall be treated to a given temperature for a given period of time and risks of re-contamination shall be prevented;

(d) the operators shall check regularly the applicable parameters, particularly temperature, pressure, time, size of particles, where appropriate by automatic devices;

(e) cleaning procedures shall be established and documented for all parts of the establishments or plants.

Article 26

Handling of animal by-products within food businesses

1. The treatment, processing or storage of animal by-products in establishments or plants approved or registered in accordance with Article 4 of Regulation (EC) No 853/2004 or in accordance with Article 6 of Regulation (EC) No 852/2004 shall be carried out under conditions which prevent cross-contamination and if appropriate in a dedicated part of the establishment or plant.

2. Raw materials for the production of gelatine and collagen not intended for human consumption may be stored, treated or processed in the establishments specifically authorised in accordance with Regulation (EC) No 853/2004, Annex III, Section XIV, Chapter I, point 5, and Section XV, Chapter I, point 5, provided the transmission of disease risk is prevented by segregation of such raw materials from the raw materials for the production of products of animal origin.

3. Paragraphs 1 and 2 shall apply without prejudice to more specific requirements laid down in Community veterinary legislation.

Article 27

Implementing measures

Measures for the implementation of this Section and Section 1 of this Chapter shall be laid down relating to the following:

(a) infrastructure and equipment requirements applicable within establishments or plants;

(b) hygiene requirements applicable to all types of handling of animal by-products and derived products, including measures modifying hygiene requirements for establishments or plants referred to in Article 25(1);

(c) conditions and technical requirements for the handling, treatment, transformation, processing and storage of animal by-products or derived products and conditions for treatment of waste water;

(d) evidence to be presented by the operator for the purpose of validation of the treatment, transformation and processing of animal by-products or derived products, on their ability to prevent public and animal health risks;

(e) conditions for the handling of animal by-products or derived products of more than one category referred to in Articles 8, 9 or 10 in the same establishment or plant:

(i) where such operations are carried out separately;

(ii) where such operations are carried out temporarily in certain circumstances;

(f) conditions for the prevention of cross-contamination when animal by-products are stored, treated or processed in a dedicated part of an establishment or plant referred to in Article 26;

(g) standard transformation parameters for biogas and composting plants;

(h) requirements applicable to the incineration or co-incineration in plants of high and low capacity as referred to in Article 24(1)(b) and (c); and

(i) requirements applicable to the combustion of animal by-products and derived products as referred to in Article 24(1)(d).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 3

Own checks and hazard analysis and critical control points

Article 28

Own checks

Operators shall put in place, implement and maintain own checks in their establishments or plants in order to monitor compliance with this Regulation. They shall ensure that no animal by-products or derived products suspected or discovered not to comply with this Regulation leave the establishment or plant, unless destined for disposal.

Article 29

Hazard analysis and critical control points

1. Operators carrying out one of the following activities shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (HACCP) principles for the:

(a) processing of animal by-products;

(b) transformation of animal by-products into biogas and compost;

(c) handling and storage of more than one category of animal by-products or derived products in the same establishment or plant;

(d) manufacturing of pet food.

2. Operators as specified in paragraph 1 shall in particular:

(a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;

(c) establish critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;

(d) establish and implement effective monitoring procedures at critical control points;

(e) establish corrective action when monitoring indicates that a critical control point is not under control;

(f) establish procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;

(g) establish documents and records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in points (a) to (f).

3. When any modification is made to a product, process or any stage of production, processing, storage or distribution, operators shall review their procedures and make the necessary changes.

4. Measures to facilitate the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

Article 30

National guides to good practice

1. Where necessary, competent authorities shall encourage the development, dissemination and voluntary use of national guides to good practice in particular for the application of HACCP principles as referred to in Article 29. Operators may use such guides on a voluntary basis.

2. The competent authority shall assess national guides to ensure that:

(a) they have been developed in consultation with representatives of parties whose interests may be substantially affected, and have been disseminated by sectors of operators; and

(b) their contents are practicable for the sectors to which they refer.

CHAPTER II

Placing on the market

Section 1

Animal by-products and derived products for feeding to farmed animals excluding fur animals

Article 31

Placing on the market

1. Animal by-products and derived products destined for feeding to farmed animals, excluding fur animals, may only be placed on the market provided:

(a) they are or they are derived from Category 3 material other than material referred to in Article 10(n), (o) and (p);

(b) they have been collected or processed, as applicable, in accordance with the conditions for pressure sterilisation or other conditions to prevent risks arising to public and animal health in accordance with measures adopted pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 2 of this Article; and

(c) they come from approved or registered establishments or plants, as applicable for the animal by-product or derived product concerned.

2. Measures for the implementation of this Article may be laid down relating to the public and animal health conditions for the collection, processing and treatment of animal by-products and derived products referred to in paragraph 1.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 2

Organic fertilisers and soil improvers

Article 32

Placing on the market and use

1. Organic fertilisers and soil improvers may be placed on the market and used provided:

(a) they are derived from Category 2 or Category 3 material;

(b) they have been produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health, in accordance with the requirements laid down pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 3 of this Article;

(c) they come from approved or registered establishments or plants, as applicable; and

(d) in the case of meat-and-bone meal derived from Category 2 material and processed animal proteins intended to be used as or in organic fertilisers and soil improvers, they have been mixed with a component to exclude the subsequent use of the mixture for feeding purposes and marked when required by measures adopted under paragraph 3.

In addition, digestion residues from transformation into biogas or compost may be placed on the market and used as organic fertilisers or soil improvers.

Member States may adopt or maintain national rules imposing additional conditions for or restricting the use of organic fertilisers and soil improvers, provided that such rules are justified on grounds of the protection of public and animal health.

2. By way of derogation from point (d) of paragraph 1, mixing shall not be required for materials whose use for feeding purposes is excluded due to their composition or packaging.

3. Measures for the implementation of this Article may be laid down relating to the following:

(a) public and animal health conditions for the production and use of organic fertilisers and soil improvers;

(b) components or substances for the marking of organic fertilisers or soil improvers;

(c) components to be mixed with organic fertilisers or soil improvers;

(d) supplementary conditions, such as the methods to be used for marking and the minimum proportions to be observed when preparing the mixture, in order to exclude the use of such fertilisers or soil improvers for feeding purposes; and

(e) cases where the composition or packaging allows the materials to be exempted from the mixing requirement.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Section 3

Derived products regulated by certain other Community legislation

Article 33

Placing on the market

Operators may place on the market the following derived products:

(a) cosmetic products as defined in Article 1(1) of Directive 76/768/EEC;

(b) active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC;

(c) medical devices as defined in Article 1(2)(a) of Directive 93/42/EEC;

(d) in vitro diagnostic medical devices as defined in Article 1(2)(b) of Directive 98/79/EC;

(e) veterinary medicinal products as defined in Article 1(2) of Directive 2001/82/EC;

(f) medicinal products as defined in Article 1(2) of Directive 2001/83/EC.

Article 34

Manufacture

1. The import, collection and movement of animal by-products and derived products destined for establishments or plants for the manufacture of the derived products referred to in Article 33 and the manufacture of those derived products shall be carried out in accordance with the Community legislation referred to in that Article.

Unused material from such establishments or plants shall be disposed of in accordance with that legislation.

2. However, this Regulation shall apply where the Community legislation referred to in Article 33 does not provide for conditions controlling potential risks to public and animal health in accordance with the objectives of this Regulation.

Section 4

Other derived products

Article 35

Placing on the market of pet food

Operators may place pet food on the market provided:

(a) the products are derived:

(i) from Category 3 material, other than material referred to in Article 10(n), (o) and (p);

(ii) in the case of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c), subject to conditions laid down pursuant to point (a) of the first paragraph of Article 40; or

(iii) in the case of raw petfood, from material referred to in Article 10(a) and (b)(i) and (ii); and

(b) they ensure the control of risks to public and animal health by safe treatment in accordance with Article 38, where safe sourcing in accordance with Article 37 does not ensure sufficient control.

Article 36

Placing on the market of other derived products

Operators may place on the market derived products, other than the products referred to in Articles 31, 32, 33 and 35, provided:

(a) those products are:

(i) not intended for use for the feeding to farmed animals or for application to land from which such animals are to be fed; or

(ii) intended for feeding to fur animals; and

(b) they ensure the control of risks to public and animal health by:

(i) safe sourcing in accordance with Article 37;

(ii) safe treatment in accordance with Article 38, where safe sourcing does not ensure sufficient control; or

(iii) verifying that the products are only used for safe end uses in accordance with Article 39 where safe treatment does not ensure sufficient control.

Article 37

Safe sourcing

1. Safe sourcing shall include the use of material:

(a) from which no unacceptable risks to public and animal health arise;

(b) which has been collected and transported from the point of collection to the manufacturing establishment or plant under conditions which exclude risks to public and animal health; or

(c) which has been imported into the Community and transported from the point of first entry to the manufacturing establishment or plant under conditions which exclude risks to public and animal health.

2. For the purpose of safe sourcing, operators shall provide documentation of the requirements of paragraph 1, including, where necessary, proof of the safety of bio-security measures taken in order to exclude risks arising to public and animal health from starting material.

Such documentation shall be kept available to the competent authority upon request.

In the case referred to in point (c) of paragraph 1, the consignments shall be accompanied by a health certificate corresponding to a model adopted in accordance with the regulatory procedure referred to in Article 52(3).

Article 38

Safe treatment

Safe treatment shall include application of a manufacturing process to the material used which reduces to an acceptable level risks to public and animal health arising from the material used or from other substances resulting from the manufacturing process.

It shall be ensured that the derived product poses no unacceptable risks to public and animal health, in particular by means of testing of the end product.

Article 39

Safe end uses

Safe end uses shall include the use of derived products:

(a) under conditions which pose no unacceptable risks to public and animal health; or

(b) which may pose a risk to public and animal health, for specific purposes provided that such use is justified by objectives set out in Community legislation, in particular for the protection of public and animal health.

Article 40

Implementing measures

Measures for the implementation of this Section may be laid down relating to the following:

(a) conditions for the placing on the market of imported pet food or of pet food produced from imported materials, from Category 1 material referred to in Article 8(c);

(b) conditions for the safe sourcing and movement of material to be used under conditions which exclude risks to public and animal health;

(c) documentation as referred to in the first subparagraph of Article 37(2);

(d) parameters for the manufacturing process as referred to in the first paragraph of Article 38, in particular as regards the application of physical or chemical treatments to the material used;

(e) testing requirements applicable to the end product; and

(f) conditions for the safe use of derived products which pose a risk to public or animal health.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

CHAPTER III

Import, transit and export

Article 41

Import and transit

1. Animal by-products and derived products shall be imported into, or sent in transit through, the Community in accordance with:

(a) the relevant requirements of this Regulation and the implementing measures thereof for the particular animal by-product or derived product which are at least as stringent as those applicable to the production and marketing of such animal by-products or derived products within the Community;

(b) conditions recognised to be at least equivalent to the requirements applicable to the production and marketing of such animal by-products or derived products under Community legislation; or

(c) in the case of animal by-products and derived products referred to in Articles 33, 35 and 36, the requirements set out in those Articles.

The measures referred to in point (b) of the first subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

2. By way of derogation from paragraph 1, the import and transit of:

(a) specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;

(b) animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006;

(c) Category 1 material, Category 2 material and products derived therefrom which are not intended for the manufacture of derived products referred to in Articles 33, 35 and 36, shall only take place provided that rules for their import have been adopted in accordance with Article 42(2)(a);

(d) animal by-products and derived products destined for the purposes referred to in Article 17(1) shall take place in accordance with national measures which ensure the control of risks to public and animal health, pending the adoption of harmonised conditions referred to in Article 17(2).

3. In the case of import and transit of Category 3 material and products derived therefrom, the relevant requirements as referred to in point (a) of the first subparagraph of paragraph 1 shall be laid down.

Those requirements may specify that consignments:

(a) must come from a third country or part of a third country listed in accordance with paragraph 4;

(b) must come from establishments or plants approved or registered by the competent authority of the third country of origin and listed by that authority for that purpose; and

(c) must be accompanied at the point of entry into the Community where the veterinary checks take place by documentation such as a commercial document or a health certificate and where appropriate by a declaration, which corresponds to a model laid down pursuant to point (d) of the first subparagraph of Article 42(2).

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Pending the adoption of the requirements referred to in points (a) and (c) of the second subparagraph, the Member States shall specify those requirements in national measures.

4. Lists of third countries or parts of third countries from which animal by-products or derived products may be imported or transit through the Community shall be drawn up in accordance with the regulatory procedure referred to in Article 52(3), taking into account in particular:

(a) the legislation of the third country;

(b) the organisation of the competent authority and its inspection services in the third country, the powers of those services, the supervision to which they are subject, and their authority to monitor effectively the application of their legislation;

(c) the actual health conditions applied to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;

(d) the assurances the third country can give regarding compliance with the relevant health conditions;

(e) experience of marketing the product from the third country and the results of import checks carried out;

(f) the result of any Community inspections in the third country;

(g) the health status of the livestock, other domestic animals and wildlife in the third country, having particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community;

(h) the regularity and speed with which the third country supplies information about the existence of infectious animal diseases in its territory, in particular the diseases listed in the Terrestrial Animal Health Code and the Aquatic Animal Health Code of the World Organisation for Animal Health;

(i) the regulations on the prevention and control of infectious animal diseases in force in the third country and their implementation, including rules on imports from other third countries.

The lists of establishments or plants referred to in point (b) of the second subparagraph of paragraph 3 shall be kept up to date and communicated to the Commission and the Member States and made available to the public.

Article 42

Implementing measures

1. Measures for the implementation of Article 41 which may exclude animal by-products or derived products manufactured in certain establishments or plants from import or transit in order to protect public or animal health shall be adopted in accordance with the regulatory procedure referred to in Article 52(3).

2. Other measures for the implementation of Article 41 shall be laid down relating to the following:

(a) conditions for the import and transit of Category 1 and Category 2 materials and for products derived therefrom;

(b) restrictions regarding public or animal health applicable to imported Category 3 material or products derived therefrom which may be laid down by reference to Community lists of third countries or parts of third countries drawn up in accordance with Article 41(4) or for other public or animal health purposes;

(c) conditions for the manufacture of animal by-products or derived products in establishments or plants in third countries; such conditions may include the arrangements for controls of such establishments or plants by the competent authority concerned and may exempt certain types of establishments or plants handling animal by-products or derived products from approval or registration as referred to in point (b) of the second subparagraph of Article 41(3); and

(d) models for health certificates, commercial documents and declarations which are to accompany consignments, specifying the conditions under which it can be stated that the animal by-products or derived products concerned have been collected or manufactured in accordance with the requirements of this Regulation.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 43

Export

1. The export of animal by-products and derived products destined for incineration or landfill shall be prohibited.

2. The export of animal by-products and derived products to third countries which are not members of the OECD for use in a biogas or composting plant shall be prohibited.

3. Category 1 material, Category 2 material and products derived therefrom shall only be exported for purposes other than those referred to in paragraphs 1 and 2 provided that rules for their export have been laid down.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

4. Article 12 of Regulation (EC) No 178/2002 concerning food and feed exported from the Community shall apply mutatis mutandis to the export of Category 3 material or products derived therefrom in compliance with this Regulation.

5. By way of derogation from paragraphs 3 and 4, the export of:

(a) specified risk material shall take place only in accordance with Regulation (EC) No 999/2001;

(b) animal by-products or derived products mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006.

TITLE III

OFFICIAL CONTROLS AND FINAL PROVISIONS

CHAPTER I

Official controls

Article 44

Procedure for approval

1. The competent authority shall approve establishments or plants only where an on site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with Article 27.

2. The competent authority may grant conditional approval if it appears, from the on site visit, that the establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational procedures in compliance with this Regulation. It shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that the establishment or plant meets the other requirements referred to in paragraph 1. If clear progress has been made, but the establishment or plant still does not meet all of these requirements, the competent authority may extend conditional approval. However, conditional approval shall not exceed a total of six months.

3. Operators shall ensure that an establishment or plant ceases to operate if the competent authority withdraws its approval or in the case of conditional approval fails to extend it or to grant full approval.

Article 45

Official controls

1. Without prejudice to Article 5, the competent authority shall at regular intervals carry out official controls and supervision of the handling of animal by-products and derived products falling within the scope of this Regulation.

2. Articles 41 and 42 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to official controls carried out to verify compliance with this Regulation.

3. The competent authority may take into account adherence to guides to good practice, when carrying out its official controls.

4. Detailed arrangements for implementing this Article, including rules concerning the reference methods for microbiological analyses, may be laid down.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 46

Suspensions, withdrawals and prohibitions on operations

1. If the official controls and supervision carried out by the competent authority reveal that one or more of the requirements of this Regulation are not met, it shall take appropriate action.

The competent authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health:

(a) suspend approvals of establishments or plants approved pursuant to this Regulation, if:

  (i) the conditions for approving or operating the establishment or plant are no longer fulfilled;

  (ii) the operator can be expected to remedy the deficiencies within a reasonable period of time; and

  (iii) the potential risks to public and animal health do not require action in accordance with point (b);

(b) withdraw approvals of establishments or plants approved pursuant to this Regulation, if:

  (i) the conditions for approving or operating the establishment or plant are no longer fulfilled; and

  (ii) the operator cannot be expected to remedy the deficiencies within a reasonable period of time:

    — for reasons relating to the infrastructure of the establishment or plant,

    — for reasons relating to the personal capacity of the operator or the staff under his supervision, or

    — because of serious risks to public and animal health requiring major adjustments to the operation of the establishment or plant before the operator may apply for re-approval;

(c) impose specific conditions on establishments or plants in order to rectify existing deficiencies.

2. The competent authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibit operators referred to in Articles 23(1) and (3) and Article 24(1) from carrying out operations under this Regulation, as appropriate, following receipt of information indicating:

(a) that the requirements of Community legislation are not met; and

(b) potential risks to public or animal health arising from such operations.

Article 47

Lists

1. Each Member State shall draw up a list of establishments, plants and operators which have been approved or registered in accordance with this Regulation within its territory.

It shall assign an official number to each approved or registered establishment, plant or operator, which identifies the establishment, plant or operator with respect to the nature of its activities.

Member States shall indicate, if applicable, an official number which has been assigned to the establishment, plant or operator under other Community legislation.

Member States shall make the lists of approved or registered establishments, plants and operators available to the Commission and other Member States.

Member States shall keep up-to-date the lists of approved or registered establishments, plants and operators and make them available to other Member States and to the public.

2. Measures for the implementation of this Article may be laid down in accordance with the regulatory procedure referred to in Article 52(3), in particular on:

(a) the format for the lists referred to in paragraph 1; and

(b) the procedure for making the lists referred to in paragraph 1 available.

Article 48

Controls for dispatch to other Member States

1. Where an operator intends to dispatch Category 1 material, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials to another Member State, it shall inform the competent authority of the Member State of origin and the competent authority of the Member State of destination.

The competent authority of the Member State of destination shall decide upon application by the operator, within a specified time period:

(a) to refuse receipt of the consignment;

(b) to accept the consignment unconditionally; or

(c) to make receipt of the consignment subject to the following conditions:

(i) if the derived products have not undergone pressure sterilisation, it must undergo such treatment; or

(ii) the animal by-products or derived products must comply with any conditions for the dispatch of the consignment which are justified for the protection of public and animal health in order to ensure that animal by-products and derived products are handled in accordance with this Regulation.

2. Formats for applications by operators referred to in paragraph 1 may be adopted in accordance with the regulatory procedure referred to in Article 52(3).

3. The competent authority of the Member State of origin shall inform the competent authority of the Member State of destination, by means of the Traces system in accordance with Decision 2004/292/EC, of the dispatch of each consignment sent to the Member State of destination, of

(a) animal by-products or derived products referred to in paragraph 1;

(b) processed animal protein derived from Category 3 material.

When informed of the dispatch, the competent authority of the Member State of destination shall inform the competent authority of the Member State of origin of the arrival of each consignment by means of the Traces system.

4. Category 1 and Category 2 materials, meat-and-bone meal and animal fat referred to in paragraph 1 shall be transported directly to the establishment or plant of destination, which must have been registered or approved in accordance with Articles 23, 24 and 44 or, in the case of manure, to the farm of destination.

5. When animal by-products or derived products are sent to other Member States via the territory of a third country, they shall be sent in consignments which have been sealed in the Member State of origin and shall be accompanied by a health certificate.

The sealed consignments shall re-enter the Community only via a border inspection post, in accordance with Article 6 of Directive 89/662/EEC.

6. By way of derogation from paragraphs 1 to 5, animal by-products or derived products referred to therein which have been mixed or contaminated with any waste listed as hazardous in Decision 2000/532/EC shall be sent to other Member States only subject to the requirements of Regulation (EC) No 1013/2006.

7. Measures for the implementation of this Article may be adopted relating to the following:

(a) a specified time period for the decision of the competent authority as referred to in paragraph 1;

(b) supplementary conditions for the dispatch of animal by-products or derived products referred to in paragraph 4;

(c) models for the health certificates which have to accompany consignments sent in accordance with paragraph 5; and

(d) conditions under which animal by-products or derived products intended to be used for exhibitions, artistic activities, for diagnostic, educational or research purposes may be sent to other Member States, by way of derogation from paragraph 1 to 5 of this Article.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

8. Measures for the implementation of this Article may specify the conditions subject to which, by way of derogation from paragraphs 1 to 4, the competent authorities may allow:

(a) the dispatch of manure transported between two points located on the same farm or between farms located in the border regions of Member States sharing a common border;

(b) the dispatch of other animal by-products transported between establishments or plants located in the border regions of Member States sharing a common border; and

(c) the transport of a dead pet animal for incineration to an establishment or plant located in the border region of another Member State sharing a common border.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 52(4).

Article 49

Community controls in Member States

1. Experts from the Commission may make on-the-spot checks, in cooperation with the competent authorities of Member States, in so far as is necessary for the uniform application of this Regulation.

The Member State on whose territory the checks are made shall provide the experts with all the assistance necessary for carrying out their duties.

The Commission shall inform the competent authority of the results of the checks made.

2. Measures for the implementation of this Article may be adopted in accordance with the regulatory procedure referred to in Article 52(3), in particular on the procedure for the cooperation with national authorities.

Article 50

Application of Regulation (EC) No 882/2004 for the purposes of certain controls

1. Article 46 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to Community controls in third countries carried out to verify compliance with this Regulation.

2. Article 50(1)(a) of Regulation (EC) No 882/2004 shall apply mutatis mutandis to the phased introduction of the requirements of Article 41(3) of this Regulation.

3. Article 52 of Regulation (EC) No 882/2004 shall apply mutatis mutandis to third-country controls in Member States related to operations under this Regulation.

CHAPTER II

Final provisions

Article 51

National provisions

Member States shall communicate to the Commission the text of the provisions of national law they adopt in areas under their competence which directly concern the proper implementation of this Regulation.

Article 52

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits laid down in Article 5a(3)(c), (4)(b) and (4)(e) of Decision 1999/468/EC shall be two months, one month and two months respectively.

6. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 53

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 4 June 2011 and shall notify it without delay of any subsequent amendment affecting them.

Article 54

Repeal

Regulation (EC) No 1774/2002 shall be repealed with effect from 4 March 2011.

References to Regulation (EC) No 1774/2002 shall be construed as references to this Regulation and shall be read in accordance with the correlation table laid down in the Annex.

Article 55

Transitional measure

Establishments, plants and users approved or registered in accordance with Regulation (EC) No 1774/2002 before 4 March 2011 shall be deemed to be approved or registered, as required, in accordance with this Regulation.

Article 56

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 4 March 2011.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

ANNEX

CORRELATION TABLE

Regulation (EC) No 1774/2002	This Regulation
Article 1	Articles 1 and 2
Article 2	Article 3
Article 3(1)	Article 4(1) and(2)
Article 3(2)	Article 41(3), fourth subparagraph
Article 3(3)	Article 4(3), (4) and (5)
Article 4(1)	Article 8
Article 4(2)	Articles 12, 15 and 16
Article 4(3)	Article 24(h), (i) and (j)
Article 4(4)	Article 41(2)(c), Article 43(3) and (5)(a)
Article 5(1)	Article 9
Article 5(2)	Articles 13, 15 and 16
Article 5(3)	Article 24(h), (i) and (j)
Article 5(4)	Article 41(2)(c) and Article 43(3)
Article 6(1)	Article 10
Article 6(2)	Articles 14, 15 and 16
Article 6(3)	Article 24(h), (i) and (j)
Article 7	Article 21
Article 8	Article 48
Article 9	Article 22
Articles 10 to 15, 17 and 18	Articles 23, 24, 27 and 44
Article 16	Article 6
Article 19	Article 31
Article 20(1)	Articles 35 and 36
Article 20(2)	Article 32
Article 20(3)	Article 36
Article 21	—
Article 22	Article 11
Article 23	Articles 17 and 18
Article 24	Article 19
Article 25	Articles 28 and 29
Article 26	Articles 45, 46 and 47
Article 27	Article 49
Article 28	Article 35(a)(ii) and Article 41(1)
Article 29	Articles 41 and 42
Article 30	Article 41(1)(b)
Article 31	Article 50(1)
Article 32	—
Article 33	Article 52
Article 34	—
Article 35	Article 15(2) and Article 51
Article 36	—
Article 37	Article 54
Article 38	Article 56