COMMISSION OF THE EUROPEAN COMMUNITIES

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COM(2008) 345 final

2008/0110 (COD)

Proposal for a

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## laying down health rules as regards animal by-products not intended for human consumption (Animal by-products Regulation)

(presented by the Commission)

{SEC(2008)1994}
{SEC(2008)1995}

# EXPLANATORY MEMORANDUM

## 1. BACKGROUND

In response to several crises linked to products of animal origin which threatened the safety of public and animal health (TSE, dioxin, FMD), the Community introduced a comprehensive legislative framework to maintain a high level of safety along the whole production and distribution chain, from "farm to fork". In this context, Regulation (EC) No 1774/2002 laying down health rules concerning animal by-products not intended for human consumption[1] (hereinafter: "the Regulation ") was adopted. The Regulation consolidated and recast the various existing rules covering animal by-products (ABP). It also introduced stricter rules concerning the approval of premises handling ABP, the channelling and traceability of certain products and the implementation of processing standards which ensure that products produced on the basis of ABP are safe, if they are intended for feed or for technical uses. The Regulation applied as of 1 May 2003.

## 2. THE COMMISSION REPORT

Article 35 of the Regulation requires Member States to inform the Commission of the measures taken to ensure compliance with the Regulation. On the basis of the information received, the Commission submitted a report to the European Parliament and the Council on 24 October 2005 reflecting the experience of all 25 Member States in applying the legislation[2].

In addition, the Commission's Food and Veterinary Office (FVO) carried out a round of inspections in all 25 Member States throughout 2004 and 2005 to assess the level of compliance of the Member States.

On the basis of information supplied by Member States and the findings of the FVO, the Commission report concludes that it has been challenging for all Member States and economic operators to ensure compliance with the provisions of the Regulation. Nonetheless, Member States' compliance has been generally satisfactory. The official controls for most Category 1 and 2 materials are satisfactory to a large extent. However, more effort is needed to guarantee the necessary traceability of the flow of materials based on ABP throughout the various production chains. The report recommended a number of measures which could improve the uniform application of the law and the effectiveness of official controls. It also served as a basis for a wide debate with the Member States and with the wide range of stakeholders affected by the rules on ABP.

## 3. THE ISSUE

The following major issues emerged from consultations on the report as meriting reconsideration:

- ► The basic framework of safeguards applicable to all ABP should be maintained.
- ► The scope of the rules on ABP should be adjusted.

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1 OJ L 273, 10.10.2002, p. 1.

2 COM (2005)521 final.

- ► The interaction of the rules on ABP with other Community legislation should be clarified.
- ► A more risk-based approach for the categorisation of ABP, as well as controls, should be introduced.

These major issues should be addressed in a way which ensures that the level of protection against risks to public and animal health in the Community is not compromised. Operators and competent authorities remain responsible for ensuring that ABP are only being sent to outlets authorised by the law. Adjustments to the rules may only be made insofar as progress in science and technology allows.

## 4. CONSULTATION AND IMPACT ASSESSMENT

### 4.1. Consultation of interested parties

*4.1.1. Consultation method, sectors targeted*

Upon presentation of the report to the Council at the end of 2005, Member States indicated their broad consensus with the main areas identified as requiring review. Further technical questions were brought to the Commission's attention during discussions and are considered in the present context.

In preparing the current proposal, a number of interested parties (stakeholders, technical experts and competent authorities of the Member States, and international trading partners) have been consulted. More than 36 European associations with an interest in the food chain, animal and public health (ABP producers, processors, traders and users, and consumer organisations) have been given the opportunity to express their views on various occasions, via bilateral meetings or through an open consultation.

Owing to the interaction between the rules on ABP and other Community legislation, the Commission set up an Inter-Service Steering Group (ISSG), which met twice between February and September 2006.

Six working groups with Member States experts were held between July 2006 and December 2006, in order to discuss the major issues related to the review.

The consultations were carried out in two steps:

– As a first step, a general consultation on the issues identified and possible options to resolve them was held.

– As a second step, once the potential solutions were identified, stakeholders were asked to provide information on the likely impact of the policy options identified.

*4.1.2. Responses and follow-up*

Generally, interested parties agree that the issues which have emerged from consultations reflect the major areas which merit reconsideration In particular, the majority of participants in the open consultation support the conclusion that the Regulation should be amended in order for the necessary adjustments to the rules to be made.

**4.2. Collection and use of expertise**

*4.2.1. Scientific opinions*

Since the entry into application of the Regulation, the Community's scientific advisory body (the Scientific Steering Committee, which has been replaced by the European Food Safety Authority since 2002) has adopted a number of opinions in relation to ABP. These scientific opinions advised on the capacity to contain risks via treatment standards. In general terms, the advice obtained suggests that the key principle of the Regulation, which is the exclusion of ABP derived from animals unfit for human consumption from the feed chain, should be maintained.

The conclusions also suggest that certain unsafe by-products may be recovered and used safely for the production of, for instance, technical or industrial products under certain strict health conditions.

*4.2.2. Methodology used*

Two main methodologies were used:

(1) analysis of the report data submitted by the competent authorities of the 25 Member States and

(2) analysis of data collected by the Commission's Food and Veterinary Office during 2004 to 2005.

The data received and used is too extensive and varied to be summarised here.

A copy of the Commission reports can be found at:

http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.htm

http://ec.europa.eu/food/fvo/index_en.htm

**4.3. Impact Assessment**

The Commission carried out an in-house Impact Assessment (IA) as referred to in its work programme 2006. An assessment report is accessible on:

http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.htm

The IA considered three main options:

(a) No action

(b) Self-regulation, guidance or co-regulation

(c) Review of the legislation.

The IA concludes that to "no action" is likely to lead to trade disruption and severe negative socio-economic costs for operators. Self-regulation, guidance or co-regulation will not alleviate the burden resulting from disproportionate provisions in the legally binding text.

In line with the findings of the IA, option (c) a review of the legislation, is the solution which is most suitable to the existing problems.

## 5. LEGAL ELEMENTS OF THE PROPOSAL

### 5.1. Summary of the proposed action(s)

The proposal takes into account the results of the review carried out on Regulation and re-enacts the reviewed provisions, as well as the remaining part of the enacting provisions, in a single text. The provisions laid down in the Annexes to the Regulation, as well as provisions laid down in separate Community acts implementing or derogating from that Regulation, such as Regulations (EC) No 811/2003, 79/2005, 92/2005 or 181/2006, will be re-enacted in an implementing Regulation, under the comitology procedure. This will be prepared in parallel, so as to enter into application simultaneously with the current proposal.

### 5.2. Legal basis

The primary objective of the Regulation is the protection of animal and public health. Therefore, as the current Regulation, the proposal is based on Article 152(4)(b) of the Treaty.

### 5.3. Subsidiarity principle

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by Member States' actions.

Risks from animal by-products may seriously endanger the safety of the food and feed chain, as well as the health status of livestock throughout the Community. Experience in recent years with bovine spongiforme encephalopathy (BSE), foot-and-mouth disease (FMD), classical swine fever (CSF) and dioxin has shown that a response at Member State level alone does not sufficiently contain major health threats, not least because of the close interconnection of the economic sectors throughout the Common Market.

In addition, ABP and products manufactured on the basis of ABP are being imported from third countries into the Community. It should be ensured that imported consignments meet sanitary standards which are at least equivalent to those applicable within the Community.

The objectives of the proposal can be better achieved by the Community.

ABP are included in the list of products in Annex I to the Treaty. Their placing on the market constitutes an important source of income for parts of the farming population, as well as for industries which process certain ABP. To ensure the rational development in this sector, increase productivity and stimulate competitiveness, animal health and public health rules for the products in question are needed at Community level.

### 5.4. Proportionality and simplification

The proposal further simplifies the legislation, reducing the administrative burden for the competent authorities (EU, national and third countries) and for economic operators while preserving a high level of protection of the public and animal health.

It aims to allow for the consolidation of all the implementing measures and derogations (to date 14 acts in total) adopted since the application of the Regulation on the basis of a single text.

The interaction between the rules on animal by-products and other Community sector legislation (food, feed, waste, cosmetic products, pharmaceutical and medical devices) will be clarified. Wherever the necessary level of protection allows such a solution, duplication of approval and channelling requirements should be avoided.

The adoption of the proposal will lead to the repeal of the current Regulation.

## 6. SCOPE OF THE PROPOSAL

In the light of the practical and scientific experience gained and the outcome of the consultation, the main elements of the proposal are to maintain a high level of food and feed safety and consumer protection, and at the same time to provide:

**i. Clarification**

An *end point in the life-cycle* of ABP is being introduced so as to clarify the point from which ABP cease to be covered by the requirements of the Regulation along the manufacturing chain. This point can be fixed at various stages, depending on the nature of ABP used, the characteristics of a treatment process or the intended end use of the product manufactured on ABP basis.

With respect to *legal uncertainties regarding the scope* of the rules on ABP from wild game, potential sanitary gaps are being closed by introducing parallel provisions to the legislation on food hygiene.

With regard to the *interaction with other Community legislation*, the approval of establishments and the performance of official controls, duplication between requirements is being avoided insofar as the objectives protected by one legislative framework can be considered to be covered sufficiently by another legislative framework.

**ii. A more risk-based approach**

The *primary responsibility of operators* to ensure that the requirements of the Regulation are met, in line with the approach adopted in Community legislation on food and feed hygiene, is being reinforced. This should allow the competent authorities to focus resources on verifying compliance of operators with this obligation.

In particular regarding the manufacture of *products based on ABP without direct relevance to the safety of the (food and) feed chain* (other than those produced as feed to farmed animals or as organic fertilisers), operators are entrusted with increased responsibility for the placing on the market of safe products. Provided they use safe raw materials for the production, develop safe manufacturing processes or use ABP for end purposes which are on balance safe, ABP of all categories may be used. Further details regarding this option may be laid down by way of implementing rules.

New products, which have been proven to pose only limited risks, should be introduced into the *classification of ABP*. At the same time, the precautionary provision, whereby any ABP which are not expressly classified fall under Category 2 and may not be used in feed to farmed animals, should be maintained.

Current derogations regarding *the exceptional burial and burning on site* in cases of disease outbreaks should be clarified and extended to situations in which recovery operations in accordance with the general rules of the Regulation become practically very difficult, such as during natural disasters.

## 7. OTHER INFORMATION

### 7.1. Consistency with other policies and objectives of the Union

The proposal is consistent with other Community policies, in particular the policy on the protection of the environment and of public health in relation to the use of animal by-products in feed, cosmetics, medicinal products and, medical devices.

### 7.2. Budgetary implication

The proposal has no financial implications for the budget of the European Community.

### 7.3. Other

The proposal is in line with the Commission's Lisbon Strategy commitment to improve the acquis communautaire, addressing possible health risks by adequate measures, while enhancing competitiveness. It is also in line with the "Better Regulation" Programme of the Commission[3].

[3] Cf. COM (2006)689 final.

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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[4],

Having regard to the opinion of the European Economic and Social Committee[5],

Having regard to the opinion of the Committee of the Regions[6],

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

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 socio-economic situation of the farmers and of the industrial sectors concerned and on consumer confidence in the safety of products of animal origin. Disease outbreaks can 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, and in the course of the disposal of dead animals and of disease control measures. Regardless of their source, they pose a potential risk to animal and public health and the environment. This risk needs to be adequately controlled, either by channelling 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

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4 OJ C […], […], p. […].
5 OJ C […], […], p. […].
6 OJ C […], […], p. […].

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 to a large number of productive sectors. However, the use of those new technologies might pose health risks that must also be minimised.

(5) Community health rules on animal by-products should be laid down in a coherent and comprehensive framework for their collection, handling, processing, disposal or use.

(6) Those general rules should be proportionate to the risk to public and animal health which animal by-products pose at different stages of their handling along 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, intra-Community trade and importation of animal by-products, where appropriate.

(7) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[7] lays down Community rules applicable to animal by-products. Based on scientific advice, 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 in October 2005[8] 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

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7 OJ L, 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 1432/2007 (OJ L 320, 6.12.2007, p. 13).

8 COM (2005)521 final.

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 succeeded 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 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 (animal by-products "by law"). Those rules should, however, also apply to products which do comply with certain rules regarding their possible use 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, carcasses or parts of carcasses 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. Animal by-products from hunted game should only be subject to the provisions of this Regulation insofar as food hygiene legislation applies to the placing on the market of such game and involves operations carried out by game-handling establishments.

(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, except for material to which a disease risk is clearly attached.

(15) 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 should not be used in feed for farmed animals. In particular, the species listed in Annex I to Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals[9] should be regarded as pet animals.

(16) For the sake of consistency of Community legislation, the 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

[9] OJ L 146, 13.6.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 245/2007, (OJ L 73, 13.3.2007, p. 9).

transmissible spongiform encephalopathies[10] 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 [11] should be clarified.

(17) For the sake of consistency of Community legislation, the definition of aquatic animal in Article 3(1)(e) of 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[12] should be used in this Regulation.

(18) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste[13] 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.

(19) 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 disposal of animal by-products which may not be used, or which are not used for economic reasons. Member States should commit adequate resources for the necessary infrastructure for that purpose and they should ensure its smooth operation. 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.

(20) 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[14].

(21) 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 which have been approved in advance for such operations by the competent authority. This condition should apply in particular to rendering plants and other plants handling and processing untreated animal by-products. It should be permitted that animal by-products of more than one category are handled in the same establishment provided cross-contamination is prevented. It should further be permitted to amend these conditions if the amount of

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10 OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1275/2007, (OJ L 284, 30.10.2007, p. 8).

11 OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

12 OJ L 328, 24.11.2006, p.14.

13 OJ L 182, 16.7.1999, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

14 OJ L 62, 15.3.1993, p. 69. Directive as last amended by Commission Directive 2007/729/EC (OJ L 294, 13.11.2007, p. 26).

material for disposal and processing arises 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.

(22) In addition, such approvals should not be necessary for plants and establishments which process or handle certain safe materials, such as products processed to an extent that they no longer pose a risk to public and animal health. Such plants and establishments should be registered so as to permit official control of the flow of material and ensure their traceability. In particular, plants which have been approved or registered under Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[15] should only be required to be registered under this Regulation.

(23) Plants and establishments should be approved following the submission of information to the competent authority which demonstrates that the requirements for the infrastructure and operation of the plant or establishment in accordance with this Regulation will be met, so that any risks to public and animal health arising from the process used will be adequately contained. The competent authority should carry out checks to verify compliance with these requirements.

(24) Plants and establishments whose operations have already been approved in accordance with Community legislation on food and feed hygiene should not be required to be approved under this Regulation, as approvals under that Community legislation already take into account the objectives of this Regulation.

(25) Animal by-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 material posing a high risk should only be used for purposes outside the feed chain, the use of material posing a lower risk should be permitted under safe conditions.

(26) 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 materials 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 the EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of material for which risks are to be assessed. However, it should be clear that once materials 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.

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

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15 OJ L 35, 8.2.2005, p. 1.

(28) The use of certain substances and products is illegal 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[16] 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[17]. 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[18] 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.

(29) Manure and digestive tract content do not need to be disposed of, provided that proper treatment ensures that diseases are not transmitted during application to land. By-products from animals that die on farm and animals killed for the eradication of diseases except TSEs, should not be used in the feed chain. This restriction should also apply to imported animal by-products which are allowed into the Community, even though 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.

(30) 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.

(31) 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[19], namely Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[20] and Regulation (EC) No

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16 OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1353/2007 (OJ L 303, 21.11.2007, p. 6).

17 OJ L 125, 23.5.1996, p. 3. Directive as amended by Directive No 2003/74/EC of the European Parliament and the Council (OJ L 262, 14.10.2003, p. 17).

18 OJ L 125, 23.5.1996, p. 10. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).

19 OJ L 31, 1.2.2002. p. 1. Regulation as amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

20 OJ L 139, 30.4.2004, p. 1; corrected version OJ L 226, 25.6.2004, p. 3.

853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[21], 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 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. The respective basic obligation of such operators to ensure compliance with this Regulation 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.

(32) A system of own checks is necessary to ensure that within a plant or establishment, the requirements of this Regulation are fulfilled. The proper performance of own checks is also of indicative importance for checks carried out by the competent authority. Own checks should be carried out through a system based on the principles of hazard analysis and critical control points (HACCP) in plants processing animal by-products, such as rendering plants, in plants for the transformation of animal by-products into biogas or compost and in plants handling more than one category of animal by-products, such as plants storing raw material of two categories. Sampling of products to check compliance with Community standards such as microbiological criteria should not be compulsory for products which are to be incinerated, co-incinerated or disposed of on the same site, due to the fact that possible risks are being eliminated without the product being placed on the market.

(33) 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 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.

(34) 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[22]. Co-incineration of waste – either as a recovery or disposal operation – is subject to similar conditions regarding approval and operating as waste incineration, in particular as to air emission limit values, wastewater 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.

(35) The use of animal by-products or derived products as a fuel in the combustion process should be authorised and it is not 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.

(36) The coherence of Community legislation requires that material submitted to a detoxification process defined in accordance with Directive 2002/32/EC of the

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[21] OJ L 139, 30.4.2004, p. 26; corrected version OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

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

European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[23] may also be used for feeding purposes.

(37) 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 the Regulation (EC) No 1774/2002.

(38) Shells from shellfish from which the soft tissues or flesh have been removed, should be excluded from the scope of the Regulation. Due to the various practices regarding the removal of such soft tissue or flesh from shells in the Community, 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. Guides to good practice at Community or national level could assist in the dissemination of knowledge regarding proper conditions under which such use would be possible.

(39) 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 material, as referred to in Council Regulation (EC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs[24].

(40) 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. 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 the EFSA before such authorisation is granted, in order to ensure that an assessment of the risk reduction potential of the process is carried out.

(41) It is appropriate to clarify the requirements applicable to the placing on the market of animal by-products and derived products intended for feeding purposes and of organic fertilizers and soil improvers, so as to ensure the protection of the food and feed chain. Only Category 3 material should be used for feeding purposes. 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 proteineacous material, a component, such as an inorganic or an indigestible substance, should be added in order to prevent their direct use for feeding purposes.

(42) 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[25] lays down a general prohibition on the placing on the market and the importation and exportation of cat and dog fur and products containing such fur. However, that prohibition should

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[23] OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2006/77/EC (OJ L 271, 30.9.2006, p. 53).

[24] OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Commission Regulation (EC) No 1319/2007 (OJ L 293, 10.11.2007, p. 3).

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

not affect the obligation under this Regulation to dispose of animal by-products from cats and dogs, including fur.

(43) The promotion of science and research requires the use of animal by-products of all categories, sometimes in quantities below the scale of commercial exchanges. In order to facilitate the importation and use of such material, 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.

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

(45) Regulation (EC) No 1774/2002 allows for the feeding of Category 1 material to endangered species of necrophagous birds living in their natural habitat. 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.

(46) Burial and burning of unprocessed 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. The available rendering or incinerator capacity within a region or Member State could otherwise be a limiting factor in the control of a disease.

(47) The current derogation concerning burial and burning of unprocessed 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 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, 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.

(48) Establishments 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.

(49) 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 interruption of operations.

(50) The obligation of Member States to put in place a sufficient disposal infrastructure entails financial and other commitments. In order to ensure that Member States may control the quantity of material which may be introduced for disposal into their territory, the competent authority should authorise the dispatch of such material to its territory.

(51) 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 flow of material, the TRACES system introduced by Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system[26] should be used to provide information on the dispatch of all Category 1 and Category 2 material and derived products from rendering operations, and Category 3 processed animal protein.

(52) In order to facilitate the transportation 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 the Community territory are subject to veterinary checks in accordance with Council Directive 89/662/EC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[27].

(53) 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[28]. 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. It should also be prevented that animal by-products and derived products are exported with the objective to use them in a biogas or composting plant to third countries which are not members of the 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 in Article 37, the Commission shall fully respect in its decisions the Basel Convention on the control of transboundary movements of hazardous waste and their disposal, and the amendment to this Convention in Decision III/1 of the Conference of the Parties, as ratified by the European Community by Council Decisions 93/98/EEC[29] and 97/640/EC[30], respectively, and implemented by Regulation (EC) No 1013/2006.

(54) 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[31] 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.

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[26] OJ L 94, 31.3.2004, p. 63. Decision as last amended by Decision 2005/515/EC (OJ L 187, 19.7.2005, p. 29).

[27] OJ L 395, 30.12.1989, p. 13. Directive as last amended by Directive 2004/41/EC of the European Parliament and of the Council (OJ L 157, 30.4.2004, p.33; corrected version OJ L 195, 2.6.2004, p. 12).

[28] OJ L 190, 12.7.2006, p. 1.

[29] OJ L 39, 16.2.1993, p. 1. Corrigendum published at OJ L 74, 17.3.1994, p. 52.

[30] OJ L 272, 4.10.1997, p. 45.

[31] OJ L 226, 6.9.2000, p. 3. Decision as last amended by Council Decision 2001/573/EC (OJ L 203, 28.7.2001, p. 18).

(55) 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 of the European Parliament and 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[32].

(56) The importation 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.

(57) 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[33], 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[34], 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[35], 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[36], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[37] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[38]("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 these risks and safeguard measures in accordance with Regulation (EC) No 178/2002 should be possible.

(58) 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, insofar 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

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32 OJ L 165, 30.4.2004, corrected version OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

33 OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive (EC) No 2007/67/EC (OJ L 305, 23.11.2007, p. 22).

34 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

35 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

36 OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 2007/47/EC of the European Parliament and of the Council (OJ L 247, 21.9.2007, p. 21).

37 OJ L 169, 12.7.1993, p. 1. Directive as last amended by Directive 2007/47/EC of the European Parliament and of the Council (OJ L 247, 21.9.2007, p. 21).

38 OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

particular, Council Directive 76/768/EEC excludes Category 1 material and Category 2 material as part of the composition of a cosmetic product and obliges manufacturers to apply good manufacturing practices. Commission Directive 2003/32/EC of 23 April 2003[39] introduces detailed specifications with respect to medical devices manufactured utilising tissues of animal origin.

(59) 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.

(60) In order to ensure traceability, operators should indicate operations using such raw material derived from animals to the competent authority, so that intervention by the authorities responsible for the protection of public and animal health is possible, in the event of any failure to comply with the rules laid down in this Regulation.

(61) 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 ensure adequate risk control.

(62) Community rules may also provide that no requirements apply to the placing on the market of such products when it is justified due to the absence of risk, in particular when an end point in the manufacturing chain can be determined following which the resulting material no longer poses any significant risk.

(63) Under Regulation (EC) No 1774/2002, certain products, notably guano, certain hides to which particular forms of treatment such as tanning have been applied, and certain game trophies, have been exempted from the requirements of that Regulation. Similar exemptions should be provided for by implementing measures, such as in the case of oleochemical products. However, in order to maintain an adequate level of protection of the feed chain, operators handling Category 1 and Category 2 material for the manufacture of petfood should continue to be required to obtain approval.

(64) The dissemination and use of guides to good practice at Community and national level by the economic sectors concerned by the Regulation can serve as a useful tool to enhance knowledge about and develop suitable practical instruments for the application of this Regulation.

(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 objectives of the action to be taken 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,

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[39] OJ L 105, 26.4.2003, p. 18.

as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(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[40]. In order to improve coherence and clarity of Community legislation, the technical rules concerning specific operations involving animal by-products, which are currently laid down in the Annexes to Regulation (EC) No 1774/2002, as well as in implementing measures adopted on the basis of that Regulation[41], 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[42].

(69) In particular, the Commission should be empowered to adopt rules concerning the site and equipment of plants and establishments handling animal by-products, the handling and treatment of animal by-products, the categorisation of materials according to the risk arising from them to public and animal health, measures intended to ensure the traceability of animal by-products, derogations regarding the use and disposal of animal by-products, conditions for the placing on the market of animal by-products and derived products, conditions for the control for the dispatch of certain animal by-products and derived products between Member States and conditions for the import and transit of animal by-products and derived products. 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.

(70) 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.

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40 OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

41 Regulation (EC) No 811/2003 on intra-species recycling (OJ L 117, 13.5.2003, p. 14); Decision 2003/322/EC on the feeding of necrophagous birds (OJ L 117, 13.5.2003, p. 32; Decision as last amended by Decision 2005/830/EC (OJ L 311, 26.11.2005, p. 40); Decision 2003/324/EC on intra-species recycling for fur animals (OJ L 117, 13.5.2003, p. 37, Decision adapted by Decision 2004/434/EC, OJ L 189, 27.5.2004, p. 43); Regulation (EC) No 92/2005 on alternative methods of disposal or use (OJ L 19, 21.1.2005, p. 27; Regulation as last amended by Regulation (EC) No 1576/2007, OJ L 340, 22.12.2007, p. 89); Regulation (EC) No 181/2006 on organic fertilisers and soil improvers (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 No 2007/2006 on Category 3 intermediate products (OJ L 379, 28.12.2006, p. 98).

42 OJ L 275, 25.8.2004, p. 17.

HAVE ADOPTED THIS REGULATION:

# CHAPTER I
# COMMON PROVISIONS

## SECTION 1:
## SUBJECT-MATTER, SCOPE, DEFINITIONS, INFRASTRUCTURE

*Article 1*
*Subject-matter*

This Regulation lays down animal and public health rules for animal by-products and products derived thereof, in order:

(a) to prevent and minimise risks to animal and public health arising from those products; and

(b) to protect the safety of the food and feed chain.

*Article 2*
*Scope*

1. This Regulation shall apply to animal by-products and products derived thereof

   (a) which are excluded from human consumption under Community legislation; or

   (b) that may be destined for human consumption under Community legislation, but pursuant to a decision by an operator are destined for purposes other than human consumption.

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

(a) entire bodies or parts of wild animals:

(i) which are not suspected of being infected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes;

(ii) in the case of wild terrestrial animals, which are not collected after killing, in accordance with good hunting practice;

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

(c) oozytes, embryos and semen destined for breeding purposes;

(d) liquid milk, colostrum and products derived thereof which are obtained, kept, disposed of or used on the farm of origin;

(e) shells from shellfish with the soft tissue or flesh removed;

(f) catering waste, except if it

(i) originates from means of transport operating internationally;

(ii) is destined for feeding purposes;

(iii) is destined for use in a biogas plant, for composting or for the manufacture of derived products which are intended for use by way of alternative methods as referred to in Article 22(a); and

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

3. This Regulation shall not apply to the following derived products, subject to the special regime set out in Chapter VI:

(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.

4. 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 of dead animals or products of animal origin referred to in Articles 11, 12 and 13, including oozytes, embryos and semen;

(2) "animal" means any invertebrate or vertebrate animal (including fish, reptiles and amphibians);

(3) "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 of animal origin or for other farming purposes;

(b) equidae;

(4) "wild animal" means any animal not kept by humans;

(5) "pet animal" means any animal belonging to species normally nourished and kept by humans for purposes other than farming and listed in Annex I to Regulation (EC) No 998/2003;

(6) "aquatic animals" means aquatic animals as defined in Article 3(1)(e) of Directive 2006/88/EC;

(7) "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;

(8) "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;

(9) "transit" means a movement through the Community from a territory of a third country to a territory of a third country, other than by sea or by air;

(10) "export" means a movement from the Community to a third country;

(11) "producer" means any person who produces animal by-products or derived products;

(12) "operator" means any natural or legal person who has an animal by-product or derived product under their actual control, including the producer;

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

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

(15) "derived products" means any product obtained from one or more treatments, transformations or steps of processing of animal by-products;

(16) "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;

(17) "products of animal origin" means products obtained from animals and products obtained from such products, including live animals where they are prepared for such use;

(18) "manure" means any excrement and/or urine of farmed animals, with or without litter, or non-mineralised guano;

(19) "authorised landfill" means a landfill for which a permit has been issued in accordance with Directive 1999/31/EC;

(20) "approved plant" means a plant approved in accordance with this Regulation for a particular operation involving the handling of animal by-products, other than a fishing vessel;

(21) "establishment" means a place of manufacture of derived products which are regulated by other Community legislation;

(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, digestive tract content, compost and digestion residues;

(23) "remote area" means an area where the animal population is so small, and where disposal facilities 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" means food as defined in Article 2 of Regulation (EC) No 178/2002;

(25) "feed" means feed as defined in Article 3(4) of Regulation (EC) No 178/2002.

*Article 4*

*National infrastructures and systems for the collection and disposal of animal by-products*

1. Member States shall have an adequate infrastructure in place on their territory that ensures that animal by-products are

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

   (b) disposed of in accordance with this Regulation.

2. Member States shall

   (a) provide a system for the collection and disposal of animal by-products, which operates efficiently and which is monitored continuously by the competent authority;

   (b) commit adequate resources for the operation of such a system.

3. Member States may fulfil their obligations under this Article in cooperation with other Member States and third countries.

**SECTION 2: ANIMAL HEALTH RESTRICTIONS**

*Article 5*

*General animal health restrictions*

1. Without prejudice to Article 2(4), animal by-products and derived products shall not be dispatched from holdings, 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) set out in a list laid down by the Commission.

The measures referred to in point (b)(ii) 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 48(4).

2. Paragraph 1 shall not apply where animal by-products and derived products are dispatched under conditions to be adopted by the Commission 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 48(5).

## SECTION 3: APPROVAL OF PLANTS AND ESTABLISHMENTS

### *Article 6*
### *Plants and establishments requiring approval*

1. Plants and establishments handling animal by-products and derived products shall be approved by the competent authority.

Such approval shall specify for which of the following operations it is granted:

(a) the handling, storage or processing of animal by-products and derived products;

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

(c) the incineration of animal by-products;

(d) for the disposal or recovery of animal by-products or derived products, which are waste, in co-incineration plants;

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

(f) the handling or manufacture of petfood as referred to in the third subparagraph of Article 45.

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

(a) a particular category referred to in Articles 11, 12 or 13 ; or

(b) more than one category referred to in Articles 11, 12 or 13, indicating if such operations are carried out

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

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

– a widespread outbreak of an epizootic disease; or

– other extraordinary and unforeseen circumstances .

*Article 7*
*Exemptions from the requirement for approval*

1. By way of derogation from Article 6(1), no approval shall be required for:

(a) operations covered by the approval or registration of plants and establishments approved or registered in accordance with:

(i) Regulation (EC) No 853/2004; or

(ii) Regulation (EC) No 183/2005;

(b) incineration plants and co-incineration plants which have a permit to operate in accordance with Directive 2000/76/EC;

(c) biogas and composting plants in which animal by-products or derived products are transformed in accordance with the standard parameters laid down pursuant to Article 9(c) ;

(d) without prejudice to Chapter VI, establishments manufacturing derived products referred to in Article 2(3);

(e) without prejudice to Chapter VI, operators who import, collect or channel animal by-products and derived products exclusively for the manufacture of the derived products referred to in Article 2(3);

(f) plants and establishments subject to Section 2 of Chapter VI, except plants referred to in Article 6(1)(f).

2. Plants and establishments exempt from approval in accordance with paragraph 1(a), (b) and (c) shall be registered by the competent authority upon application by the operator.

The application must contain the following information:

(a) the category of animal by-products used;

(b) the nature of the operations performed using animal by-products or derived products as starting material for which the application is made.

3. Detailed rules for application for registration as provided for in paragraph 2 may be adopted in accordance with the procedure referred to in Article 48(3).

*Article 8*
*Approval of plants*

1. The competent authority shall approve a plant provided that the operator submits together with his application, evidence that:

(a) it is designed and constructed in compliance with this Regulation and has in place adequate controls to prevent risks arising to public and animal health and which comply with any measures laid down in accordance with paragraph 3 for the site and equipment, in particular for the treatment of waste water arising from the premises by way of filtration;

(b) it handles animal by-products and, if required by this Regulation or by rules adopted in accordance with this Regulation, derived products in accordance with hygiene requirements laid down in accordance with Article 9;

(c) if required by measures adopted in accordance with paragraph 3, the operator has carried out a validation of the process to be used in the plant, in order to verify its capacity to prevent risks arising to public and animal health; and

(d) the operator has put in place a system of own checks in the plant as referred to in Article 17.

2. The plant shall only be approved following an on-site visit by the competent authority.

The competent authority may grant conditional approval if it appears that the plant meets all the requirements referred to in paragraph 1(a) and (b).

It shall grant full approval only if it appears from a new official control of the plant, carried out within three months of granting conditional approval, that the plant meets the other applicable requirements.

If clear progress has been made but the plant still does not meet all the applicable requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

3. Measures for the implementation of the validations to be carried out by the operator in accordance with paragraph 1(c) may be laid down in accordance with the procedure referred to in Article 48(3).

*Article 9*
*Implementing measures*

Measures for the implementation of this Section may be laid down by the Commission, on:

(a) the requirements applicable to the incineration, co-incineration and combustion of animal by-products and derived products as referred to in Article 6(1)(c), (d) and (e);

(b) conditions for the handling, processing or storage of animal by-products or derived products in the same plant or establishment:

  (i) where such operations are carried out separately;

  (ii) where such operations are carried out temporarily;

(c) standard transformation parameters for biogas and composting plants as referred to in Article 7(1)(c);

(d) the site and equipment of plants and establishments requiring approval on:

  (i) general hygiene requirements applicable within approved plants and establishments;

  (ii) technical requirements for the handling, treatment, transformation and processing of animal by-products or derived products within approved plants and establishments;

  (iii) standards for treatment of waste water arising from the premises by way of filtration, including the filter pore size and the requirement to use filters capable of effectively removing certain pathogenic agents from the waste water.

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 48(4).

**SECTION 4: CATEGORISATION**

*Article 10*
*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 11, 12 or 13.

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 in measures for the implementation of this Regulation adopted by the Commission.

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 48(4).

*Article 11*
*Category 1 material*

Category 1 material shall comprise the following animal by-products or any material containing such 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;

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

(d) animal material collected during the filtration of waste water required by Article 8(1)(a), when such water is or has been in contact with Category 1 material;

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

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

*Article 12*
*Category 2 material*

Category 2 material shall comprise the following animal by-products or any material containing such by-products:

(a) manure and digestive tract content;

(b) animal material collected during the filtration of waste water required by Article 8(1)(a), when such water is or has been in contact with Category 2 material;

(c) products of animal origin 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 potential presence of physical residues in those products;

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

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

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

(f) animals and parts of animals, other than those referred to in Article 11 or 13, that died other than by being slaughtered for human consumption or, in the case of game, that died other than by being killed for human consumption, including animals killed for disease control purposes, and foeti and embryos of ruminants and pigs and dead-in-shell chicken;

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

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

*Article 13*
*Category 3 material*

Category 3 material shall comprise the following animal by-products or any material containing such by-products:

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

(b) 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 from game killed for human consumption in accordance with Community legislation:

  (i) carcasses or 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 splittings thereof;

  (iv) feet, including the phalanges and the tarsus and metatarsus bones, of:

    – animals other than ruminants,

    – ruminants not requiring TSE testing,

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

  (v) horns;

  (vi) pig bristles;

  (vii) feathers;

(c) blood of animals which did not show any signs of disease communicable through that blood to humans or animals obtained from:

  (i) animals other than ruminants and ruminants not requiring TSE testing that have been slaughtered in a slaughterhouse, which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation; or

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

(d) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;

(e) products of animal origin, other than catering waste, which, after having been placed on the market for human consumption or for feeding to animals, are no longer intended for such consumption or such 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 arise;

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

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

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

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

(i) shells, other than the shells referred to in Article 2(2)(e),

(ii) the following originating from terrestrial animals:

– hatchery by-products,

– eggs,

– egg by-products;

(iii) day-old chicks.

(j) terrestrial invertebrates other than species pathogenic to humans or animals;

(k) dead animals and parts thereof of the zoological orders of *Rodentia* and *Lagomorpha*, except Category 1 material or Category 2 material as referred to in Article 12(a) to (g);

(l) 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 (c);

(m) catering waste other than as referred to in Article 11(e).

*Article 14*
*Changes of categories*

Articles 11, 12 and 13 may be amended by the Commission in order to take into account progress in science 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 and only changes of categorisation of such products may be made or additional animal by-products may be added to those lists.

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 48(4).

# CHAPTER II:
# OBLIGATIONS OF OPERATORS, OPERATION OF PLANTS AND ESTABLISHMENTS

## SECTION 1:
## GENERAL OBLIGATIONS OF OPERATORS

*Article 15*
*Collection, identification as regards category and transportation*

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 transportation by a commercial document and, when required by this Regulation or by a measure adopted in accordance with paragraph 5, 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 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 transportation shall include information on 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.

4. The following measures may be laid down in accordance with the procedure referred to in Article 48(3):

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

(b) models for health certificates and the conditions subject to which they are required to accompany animal by-products and derived products during transportation.

5. Measures for the implementation of this Article may be laid down by the Commission on:

(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 paragraph 2 and having regard to the low level of risk to public and animal health arising from certain derived products, transportation of derived products may take place without documents or certificates referred to in that paragraph;

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

(d) conditions to prevent risks to public and animal health arising during the collection and transportation of animal by-products, including conditions for the safe transportation 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 48(4).

*Article 16*
*Records*

1. Any person 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 manure has been granted in accordance with the second subparagraph of Article 15(2).

2. Measures for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 48(3), in particular on:

(a) the format of records to be kept;

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

## SECTION 2: OPERATION OF PLANTS AND ESTABLISHMENTS

*Article 17*
*Own checks of plants and establishments*

1. Operators shall put in place, implement and maintain a permanent procedure of own checks in order to monitor compliance with this Regulation.

2. Operators shall ensure that no material suspected or known not to comply with this Regulation leaves the plant, unless destined for disposal, before being reprocessed under the supervision of the competent authority and re-sampled officially in accordance with Articles 11 and 12 of Regulation (EC) No 882/2004.

3. Plants processing animal by-products, plants for the transformation of animal by-products into biogas and compost and plants handling more than one category of animal by-products shall develop the procedure referred to in paragraph 1 in accordance with the principles of the system of hazard analysis and critical control points (HACCP).

   Operators of such plants shall in particular:

   (a) identify and control the critical control points in the plants;

   (b) establish and implement methods for monitoring and checking critical control points;

   (c) where the product derived from the processing is not directly disposed of on the same site by incineration, co-incineration, combustion or by an alternative method of disposal authorised pursuant to Article 22(a), take representative samples to check compliance:

      (i) of each processed batch with the standards, in particular as regards processing methods and microbiological safety of the end product, which have been laid down in measures which have been adopted in accordance with paragraph 6 of this Article,

      (ii) with the maximum permitted levels of physical and chemical residues laid down in Community legislation;

   (d) record the results of the checks and tests referred to in points (b) and (c), as applicable, and keep them for a period of at least two years for presentation to the competent authorities;

   (e) put in place a system ensuring the traceability of each batch dispatched.

4. Where the results of a test on samples taken pursuant to paragraph 3(c) show non-compliance with applicable safety requirements, the operator of the plant shall, in addition to the requirements laid down in paragraph 2:

   (a) notify the competent authority immediately, providing full details on the nature of the sample and on the batch from which it was taken;

   (b) establish the causes of non-compliance;

   (c) increase the frequency of sampling and testing of production;

   (d) instigate appropriate decontamination and cleansing procedures within the plant.

5. Batches found not to be in compliance with applicable safety requirements following checks carried out in accordance with paragraph 3(c) shall be reprocessed or disposed of under the supervision of the competent authority.

6. Measures for the implementation of this Article may be adopted by the Commission, on:

   (a) own checks and the maintenance of the HACCP system;

   (b) requirements specifying the modalities of the actions to be taken by the operator in accordance with paragraphs 2 and 3, in particular as regards sampling methods and reference methods for microbiological analyses.

   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 48(4).

# CHAPTER III:
# DISPOSAL AND USE
# OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS

## SECTION 1:
## RESTRICTIONS ON USE

*Article 18*
*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 species 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;

(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. Implementing rules to ensure the uniform application of the prohibitions laid down in paragraph 1 may be laid down by the Commission, and measures permitting:

(a) the feeding with processed animal protein derived from bodies or parts of bodies of animals of the same species to fur animals, by way of derogation from paragraph 1(a); and

(b) the feeding of farmed animals with herbage from land to which organic fertilisers or soil improvers have been applied, provided that the grazing or cutting takes place after the lapse of a waiting period which ensures adequate control of risks to public and animal health, by derogation from 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 48(4).

## SECTION 2:
## DISPOSAL AND USE

*Article 19*
*Disposal and use of Category 1 material*

Category 1 material shall be

(a) disposed of as a waste in an approved or registered incineration plant:

(i) directly without prior processing; or

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

(b) in case the Category 1 material is a waste, disposed of or recovered in an approved or registered co-incineration plant;

(i) directly without prior processing; or

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

(c) in the case of Category 1 material other than material referred to in Article 11(a)(i) and (ii), disposed of by processing by pressure sterilisation in an approved plant, permanent marking of the resulting material and burial in an authorised landfill;

(d) in the case of Category 1 material referred to in Article 11(c), submitted to a detoxification process defined in accordance with Article 8(2) of Directive 2002/32/EC, and used in accordance with Article 21(c), (d) and (e);

(e) in the case of Category 1 material referred to in Article 11(e), disposed of by burial in an authorised landfill;

(f) used as a fuel for combustion; or

(g) used for the manufacture of derived products referred to in Chapter VI and placed on the market in accordance with the special regime set out in that Chapter.

*Article 20*
*Disposal and use of Category 2 material*

Category 2 material shall be:

(a) disposed of as a waste in an approved or registered incineration plant

(i) directly without prior processing; or

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

(b) in case the Category 2 material is a waste, disposed of or recovered in an approved or registered co-incineration plant

(i) directly without prior processing; or

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

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

(d) permanently marked following processing in an approved plant:

(i) in the case of resulting proteinaceous material, by pressure sterilisation, and used as an organic fertiliser or soil improver; or

(ii) in the case of rendered fats, by pressure sterilisation, if the competent authority so requires, and further processed into fat derivatives in an approved plant, for use in organic fertilisers or soil improvers;

(e) transformed in an approved or registered biogas or composting plant:

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

(ii) 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, 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 colostrums, 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 or composted in an approved or registered plant;

(h) used as a fuel for combustion; or

(i) used for the manufacture of derived products referred to in Chapter VI and placed on the market in accordance with the special regime set out in that Chapter.

*Article 21*
*Disposal and use of Category 3 material*

Category 3 material shall be:

(a) disposed of as a waste in an approved or registered incineration plant, with or without prior processing;

(b) in case the Category 3 material is a waste, disposed of or recovered in an approved or registered co-incineration plant, with or without prior processing;

(c) processed in an approved plant, except in the case of material which has changed through decomposition, contamination or spoilage so as to present an unacceptable risk to public or animal health, and used:

(i) as feed material for farmed animals or for the feeding to farmed animals other than fur animals, and placed on the market in accordance with Article 24, except in the case of material referred to in Article 13(l) and (m);

(ii) for the feeding to fur animals; or

(iii) for the manufacture of organic fertilisers or soil improvers, which shall be placed on the market in accordance with Article 25.

(d) transformed in an approved or registered biogas or composting plant;

(e) in the case of material originating from aquatic animals, ensiled or composted in an approved or registered plant;

(f) in the case of shells other than the shells referred to in Article 2(2)(e), used under conditions which prevent risks arising to public and animal health;

(g) used as a fuel for combustion; or

(h) used for the manufacture of derived products referred to in Chapter VI and placed on the market in accordance with the special regime set out in that Chapter.

*Article 22*
*Derogations*

By way of derogation to Articles 19, 20 and 21, animal by-products may be:

(a) disposed of or used in an approved plant, in accordance with alternative methods which have been approved in accordance with Article 29(1) to (9);

(b) used for research and other specific purposes in accordance with Article 26;

(c) in the case of animal by-products referred to in Article 27, used for special feeding purposes in accordance with that Article;

(d) in the case of animal by-products referred to in Article 28, disposed of in accordance with that Article;

(e) in the case of Category 2 and Category 3 material and if authorised by the competent authority:

(i) used for the preparation and application to land of bio-dynamic preparations as referred to in point 2.3 of Part A of Annex I to Regulation (EC) No 2092/91;

(ii) used for the feeding to pet animals;

(f) in the case of Category 3 material referred to in Article 13(f) and other animal by-products which are removed in the course of surgical intervention on live animals, if authorised by the competent authority, disposed of on farm.

*Article 23*
*Implementing measures*

1. Measures for the implementation of this Section may be laid down by the Commission, on:

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

   (b) parameters for the transformation of animal by-products into biogas or compost;

   (c) ensilage of material originating from aquatic animals;

   (d) permanent marking of animal by-products;

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

   (f) the use of certain animal by-products as feed material for farmed animals or for the feeding to farmed animals;

   (g) the level of risk to public or animal health with respect to certain material which is considered as unacceptable as referred to in Article 21(c).

   Those measures designed to amend non essential elements of this Section, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 48(4).

2. Pending the adoption of rules in accordance with points (b) and (c) of the first subparagraph of paragraph 1, Member States may adopt or maintain national rules for the transformation of animal by-products referred to in Article 13(m) and for the ensilage of material originating from aquatic animals.

**SECTION 3: PLACING ON THE MARKET**

*Article 24*
*Placing animal by-products on the market for feeding purposes*

1. Animal by-products destined for feeding to farmed animals or derived products for use as feed material for farmed animals may only be placed on the market if:

(a) they are or are derived from Category 3 material; however, in the case of material destined for feeding to farmed animals other than fur animals, they are, or are derived from, Category 3 material other than material referred to in Article 13(l) and (m);

(b) they have been collected, processed or transformed, 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 Section 2 and any measures which have been laid down in accordance with paragraph 2 of this Article;

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

2. Measures for the implementation of this Article may be laid down by the Commission on:

(a) public and animal health conditions for the collection, processing and treatment of animal by-products and derived products referred to in paragraph 1;

(b) conditions aimed at ensuring traceability and preventing cross-contamination which apply to the destination of material fit for human consumption to feeding purposes or to use as feed 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 48(4).

*Article 25*

*Placing on the market and use of organic fertilisers and soil improvers*

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 of Section 2 and any measures which have been laid down in accordance with paragraph 2;

(c) in the case of organic fertilisers and soil improvers derived from proteineacous material, they have been mixed with a component excluding the subsequent use of the mixture for feeding purposes; and

(d) they come from approved or registered plants or establishments, as applicable.

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. Measures for the implementation of this Article may be laid down by the Commission on:

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

(b) components 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 substances or 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.

Those measures designed to amend non essential elements of this Section, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 48(4).

## SECTION 4: DEROGATIONS REGARDING THE USE AND DISPOSAL OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS

### *Article 26*
### *Derogations regarding the use of animal by-products for research and other specific purposes*

1. The competent authority may, by way of derogation from Sections 1 and 2, authorise the use of animal by-products and derived products for exhibitions, 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;

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

2. Operators of plants and establishments performing operations with respect to Category 1 and Category 2 material and users performing such operations in accordance with paragraph 1 shall be registered by the competent authority upon submission of the following information on:

(a) the category of animal by-products used;

(b) the nature of the operations performed for which an application for registration is made using animal by-products or derived products as starting material.

3. Measures for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 48(3) as regards the submission of information, including a standard form.

4. 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 importation and use of the animal by-products and derived products referred to in paragraph 1 may be adopted by the Commission. Such conditions may include requirements regarding the storage, packaging, identification, transportation 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 48(4).

*Article 27*
*Derogations regarding the collection and use of animal by-products for special feeding purposes*

1. The competent authority may, by way of derogation from Sections 1 and 2, authorise, under conditions which ensure the control of risks to public and animal health, the collection and use of:

(a) 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;

(b) Category 3 material for the feeding to:

(i) zoo animals;

(ii) circus animals;

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

(iv) fur animals;

(v) wild animals the meat of which is not destined for human consumption;

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

(vii) maggots for fishing bait.

2. The competent authority may authorise, by way of derogation from Sections 1 and 2, and in accordance with conditions laid down pursuant to paragraph 3 of this Article, the feeding of the Category 1 material referred to in Article 11(b)(ii) to zoo animals and to endangered or protected species of necrophagous birds living in their natural habitat.

3. Measures for the implementation of this Article may be adopted by the Commission on the conditions under which:

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

(b) the feeding of Category 1 material as referred to in paragraph 2 may be authorised, including:

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

(ii) the measures which are necessary to ensure that access of other species to the material fed is being prevented.

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 48(4).

*Article 28*
*Derogations regarding the disposal of animal by-products*

1. The competent authority may, by way of derogation from Sections 1 and 2, authorise the disposal:

(a) by burial of dead pet animals;

(b) of Category 1 material referred to in Article 11(a)(v) and 11(b)(ii), Category 2 material and Category 3 material in remote areas by burning or burial on site or by other means under official supervision which prevent the transmission of risks to public and animal health;

(c) by burning or burial on site or by other means under official supervision preventing the transmission of risks to public and animal health of Category 1 material referred to in Article 11(b)(ii), Category 2 material, and Category 3 material 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 present risks to the health and safety of the personnel carrying out the collection or where access would necessitate the use of disproportionate means of recovery;

(d) by means other than burning or burial on site, under official supervision, of Category 2 and Category 3 materials which do not pose a risk to public and animal health and which arise at the premises of operators handling no more than a volume of such animal by-products arising per week, which is set in accordance with point (c) of the first subparagraph of paragraph 4, 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 11(a)(i) in the event of an outbreak of a notifiable disease listed in accordance with point (d) of the first subparagraph of paragraph 4, 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 would lead, in case of a widespread outbreak of an epizootic disease, to a lack of capacity at such plants.

2. The size of the remote areas in a particular Member State referred to in paragraph 1(b) may not exceed a percentage of the size of the surface of its land territory.

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;

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

4. Measures for the implementation of this Article may be adopted by the Commission on:

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

(b) the maximum percentage of the territory 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);

(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 48(4).

## SECTION 5: ALTERNATIVE METHODS FOR THE USE AND DISPOSAL OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS

### *Article 29*
### *Approval of alternative methods for use or disposal*

1. The procedure for approval 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 application to the competent authority of the Member State where they intend to use the alternative method.

3. 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.

   The competent authority shall communicate applications from Member States and interested parties, together with a report on its evaluation to the European Food Safety Authority (hereinafter referred to as "the Authority") and to the Commission.

4. The Commission shall communicate applications, together with a report on its evaluation to the Authority.

5. The Authority shall assess, within six months following receipt of a complete application, whether the method submitted ensures that risks to public or animal health are reduced to a degree which is at least equivalent to the processing methods laid down in accordance with Article 23(1)(a) and issue an opinion on the submitted application.

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

   After consulting the applicant, the Authority shall lay down a period within which that information may be provided to it and inform the Commission of the additional period needed.

7. Where applicants submit additional information on their own initiative, they shall send it to the Authority.

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

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

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

10. A standard format for applications for alternative methods may be adopted in accordance with the procedure referred to in Article 48(2).

11. The following measures may be adopted by the Commission:

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

(b) measures 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 48(4).

# CHAPTER IV:
# OFFICIAL CONTROLS

*Article 30*
*Official controls*

1. The competent authority shall at regular intervals carry out official controls and supervision at approved or registered plants and establishments and at premises for which information has been provided in accordance with Article 40(3).

2. The competent authority shall take into account adherence to Community and national guides to good practice, when carrying out its official controls.

*Article 31*
*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

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

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

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

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

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

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

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

– for reasons relating to the infrastructure of the 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 plant or establishment before the operator may apply for re-approval.

2. The competent authority shall temporarily or permanently prohibit a registered plant, establishment or user or an operator of premises on which information has been provided in accordance with Article 40(3), from carrying out operations under this Regulation, as appropriate, following receipt of information indicating

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

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

*Article 32*

*Lists of approved or registered plants, establishments and users*

1. Each Member State shall draw up a list of plants, establishments and users which have been approved or registered in accordance with this Regulation and of establishments on which information has been provided in accordance with Article 40(3) within its territory.

It shall assign an official number to each approved or registered plant, establishment or user, and to each operator on which information has been provided in accordance with Article 40(3) which identifies the plant, establishment, user 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 plant, establishment, user or operator under other Community legislation.

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

Member States shall keep the lists of approved plants or registered plants and the lists of operators upon which information has been provided up-to-date 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 procedure referred to in Article 48(3), in particular on:

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

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

*Article 33*

*Controls for dispatch of animal by-products to other Member States*

1. Where an operator intends to dispatch Category 1 material, Category 2 material or meat and bone meal or animal fat derived from Category 1 material to another Member State, the competent authority of the Member State of destination shall decide upon application by the operator:

(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 material or derived products have not undergone pressure sterilisation, it must undergo such treatment; or

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

Operators shall inform the competent authority of the place of origin prior to the intended dispatch of a consignment.

2. The competent authority of the place of origin shall inform the competent authority of the place of destination, by means of the TRACES system in accordance with Decision 2004/292/EC, of the dispatch of each consignment sent to other Member States, of

(a) material or derived products referred to in paragraph 1;

(b) meat and bone meal and animal fat derived from Category 2 material;

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

When informed of the dispatch, the competent authority of the place of destination shall inform the competent authority of the place of origin of the arrival of each consignment by means of the TRACES system.

3. Animal by-products, meat and bone meal and animal fat referred to in paragraph 1 of this Article shall be conveyed directly to the plant of destination, which must have been approved or registered in accordance with Articles 6, 7 and 8 or, in the case of manure, to the farm where the application to land is to take place in accordance with an authorisation issued by the competent authority.

4. 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 means of transport which have been sealed in the Member State of origin and shall be accompanied by a health certificate.

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

5. By way of derogation from paragraphs 1 to 4, animal by-products or derived products referred to therein which have been mixed or contaminated with any of the 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.

6. Measures for the implementation of this Article may be adopted by the Commission on:

(a) supplementary conditions for the dispatch of animal by-products or derived products referred to in paragraph 3;

(b) models for the health certificates which have to accompany consignments sent in accordance with paragraph 4.

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 48(4).

7. Derogations from paragraphs 1 to 4 may be granted by the Commission with respect to 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.

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 48(4).

*Article 34*
*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 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 procedure referred to in Article 48(3), in particular on the procedure for the cooperation with national authorities.

# CHAPTER V:
# IMPORT, TRANSIT AND EXPORT

*Article 35*
*Import and transit of animal by-products*

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

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

(b) conditions recognised by the Commission 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 derived products referred to in Chapter VI or material for their manufacture, in accordance with the special regime set out in that Chapter.

The measures provided for in point (b), 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 48(4).

2. By way of derogation from paragraph 1, the importation 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 of the 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 thereof, which are not intended for the manufacture of derived products referred to in Chapter VI, shall only take place provided that rules for their importation have been adopted in accordance with Article 36(a);

(d) animal by-products and derived products destined for the purposes referred to in Article 26(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 26(4).

3. In case of the importation and transit of Category 3 material and products derived thereof, the relevant requirements as referred to in point (a) of the first subparagraph of paragraph 1 shall be adopted by the Commission.

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 plants or establishments approved or registered by the competent authority of the third country of origin and listed by that authority for that purpose;

(c) shall be accompanied during transportation to the point of entry into the Community where the veterinary checks take place by documentation such as a commercial document, a declaration or a health certificate which correspond to a model laid down in accordance with Article 36(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 48(4).

Pending the adoption by the Commission of the requirements referred to in point (a) and point (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 procedure referred to in Article 48(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 or contagious 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 or contagious animal diseases in force in the third country and their implementation, including rules on imports from other third countries.

The lists of plants and establishments referred to in paragraph 3 must be kept up-to-date and communicated to the Commission and the Member States and made available to the public.

*Article 36*
*Implementing measures*

Measures for the implementation of Article 35 may be adopted by the Commission on:

(a) conditions for the importation and transit of Category 1 and Category 2 material and for products derived thereof;

(b) restrictions regarding public or animal health applicable to imported Category 3 material or products derived thereof which may

  (i) be laid down by reference to Community lists of third countries or parts of third countries drawn up in accordance with Article 35(4) or for other public or animal health purposes;

  (ii) exclude animal by-products or derived products manufactured in certain establishments from importation or transit in order to protect public or animal health;

(c) conditions for the manufacture of animal by-products or derived products in plants or establishments in third countries; such conditions may include the modalities for controls of such plants or establishments by the competent authority concerned and may exempt certain plants or establishments handling animal by-products or derived products from approval or registration as referred to in Article 35(3)(b);

(d) models for health certificates which shall accompany consignments and state 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 48(4).

*Article 37*
*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 for use in a biogas or composting plant to third countries which are not members of the OECD shall be prohibited.

3. Category 1 material, Category 2 material and products derived thereof shall only be exported for purposes other than those referred to in paragraphs 1 and 2 provided that rules for their export have been adopted by the Commission.

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 48(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 thereof 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 of the waste listed as hazardous in Decision 2000/532/EC shall take place only subject to the requirements of Regulation (EC) No 1013/2006.

*Article 38*

*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 35(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 VI
# SPECIAL REGIME

## SECTION 1: DERIVED PRODUCTS REGULATED BY CERTAIN OTHER COMMUNITY LEGISLATION

*Article 39*

*Placing on the market of derived products regulated by other Community legislation*

1. The placing on the market of the derived products referred to in Article 2(3) shall not be subject to Chapters II, III and IV.

However, in the case of derived products

(a) referred to in Article 2(3)(a), (b), (c) and (d), those Chapters shall apply where the Community legislation referred to in Article 2(3) does not provide for conditions controlling potential risks to animal health in accordance with the objectives of this Regulation;

(b) referred to in Article 2(3)(e) and (f), those Chapters shall apply where the Community legislation referred to in Article 2(3) does not provide for conditions controlling potential risks to public and animal health in accordance with the objectives of this Regulation.

2. Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency measures shall apply *mutatis mutandis*

(a) to the derived products referred to in Article 2(3)(a), (b), (c) and (d) of this Regulation, in the case of risks to animal health;

(b) to the derived products referred to in Article 2(3)(e) and (f) of this Regulation, in the case of risks to public and animal health.

*Article 40*

*Manufacture of derived products regulated by other Community legislation*

1. The importation, collection and channelling of animal by-products and derived products destined for establishments for the manufacture of the derived products referred to in Article 2(3) and the manufacture of those derived products shall be carried out in accordance with the Community legislation referred to in that paragraph.

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

2. However, this Regulation shall apply where the Community legislation referred to in Article 2(3) does not provide for conditions controlling potential risks to public and animal health in accordance with the objectives of this Regulation.

3. Operators referred to in Article 7(1)(e) shall provide the following information to the competent authority responsible for official controls in accordance with this Regulation:

(a) the category of animal by-products and derived products used;

(b) the operations using animal by-products or derived products as starting material which are being performed in the establishment.

4. Measures may be adopted in accordance with the procedure referred to in Article 48(3) for the implementation of this Article as regards the transmission of the information referred to in paragraph 3 of this Article.

## SECTION 2: PLACING ON THE MARKET OF OTHER DERIVED PRODUCTS

### *Article 41*
### *Placing on the market of other derived products outside the feed chain*

1. Operators may place on the market derived products, other than the products referred to in Article 2(3), provided:

   (a) those products are

      (i) not intended for use as feed material 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 42;

      (ii) safe treatment in accordance with Article 43, 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 44 where safe treatment does not ensure sufficient control.

2. Operators may also place the derived products referred to in paragraph 1 on the market without restrictions, subject to determination by the Commission of an end point in the manufacturing chain in accordance with Article 46(2)(a), when such products no longer pose any significant risk to public or animal health.

### *Article 42*
### *Safe sourcing*

1. Safe sourcing shall include the use of the material:

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

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

(c) which has been imported into the Community and channelled from the point of first entry to the manufacturing establishment under conditions which exclude risks arising 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.

The operator shall also transport consignments of material from the point of collection to the manufacturing establishment or, in the case of a point of collection in a third country, to the point of first entry into the Community.

The consignments shall be accompanied by a health certificate corresponding to a model laid down in accordance with Article 46(1)(a).

*Article 43*
*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 such material used and from other substances arising from the manufacturing process.

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

*Article 44*
*Safe end uses*

Safe end uses shall include uses of derived products:

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

(b) which 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 45*
*Registration of operators*

Operators shall be registered by the competent authority where they:

(a) handle material used in accordance with Article 41(1) and Article 42;

(b) treat material used in accordance with Article 41(1) and Article 43; or

(c) place derived products on the market in accordance with Article 41(1) and Article 44(b).

Registration shall take place upon receipt by the competent authority of the information referred to in Article 7(2).

However, operators handling animal by-products other than Category 3 material, or products derived thereof for the manufacture of petfood shall be approved in accordance with Articles 6, 7 and 8.

*Article 46*
*Implementing measures*

1. Measures for the implementation of Articles 42 and 45 may be adopted in accordance with the procedure referred to in Article 48(3), on:

   (a) models for health certificates which must accompany consignments in accordance with the fourth subparagraph of Article 42(2);

   (b) a harmonised form for the transmission of information in order to obtain registration as referred to in Article 45.

2. Measures for the implementation of this Section may be adopted by the Commission, on:

   (a) conditions which determine an end point in the manufacturing chain following which no public or animal health requirements apply to the placing on the market;

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

   (c) documentation as referred to in the second subparagraph of Article 42(2);

   (d) parameters for the manufacturing process as referred to in the first subparagraph of Article 43, in particular as regards the application of physical or chemical treatments to the material used;

   (e) testing requirements applicable to the end product;

   (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 48(4).

# CHAPTER VII
# GENERAL AND FINAL PROVISIONS

*Article 47*
*National legislation*

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

*Article 48*
*Committee*

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, hereinafter referred to as "the Committee".

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, Articles 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, Articles 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.

*Article 49*
*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 […] at the latest and shall notify it without delay of any subsequent amendment affecting them.

*Article 50*
*Repeal*

Regulation (EC) No 1774/2002 is repealed with effect from [the date of application of this Regulation].

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 51*
*Transitional measure*

Plants, establishments and users approved or registered in accordance with Regulation (EC) No 1774/2002 before [the date of application of this Regulation] shall be deemed to be approved or registered, as required, in accordance with this Regulation.

*Article 52*
*Entry into force*

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

This Regulation shall apply from [the first day of the month, fifteen months after the date of its entry into force].

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

Done at Brussels,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |

**ANNEX**

CORRELATION TABLE

| Regulation (EC) No 1774/2002 | This Regulation |
|---|---|
| Art. 1 | Art. 1, 2 |
| Art. 2 | Art. 3 |
| Art. 3(1) | ./. |
| Art. 3(2) | Art. 35(3), fourth subparagraph |
| Art. 3(3) | Art. 4 |
| Art. 4(1) | Art. 11 |
| Art. 4(2) | Art. 19, 22, 23 |
| Art. 4(3) | Art. 6(1)(a) |
| Art. 4(4) | Art. 35(2)(c), 37(3), 37(5)(a) |
| Art. 5(1) | Art. 12 |
| Art. 5(2) | Art. 20, 22, 23 |
| Art. 5(3) | Art. 6(1)(a) |
| Art. 5(4) | Art. 35(2)(c), 37(3) |
| Art. 6(1) | Art. 13 |
| Art. 6(2) | Art. 21, 22, 23 |
| Art. 6(3) | Art. 6(1)(a) |
| Art. 7 | Art. 15 |
| Art. 8 | Art. 33 |
| Art. 9 | Art. 16 |
| Art. 10, 11, 12, 13, 14, 15, 17, 18 | Art. 6, 7, 8, 9 |
| Art. 16 | Art. 5 |
| Art. 19 | Art. 24 |

| | |
|---|---|
| Art. 20(1) | Art. 41 |
| Art. 20(2) | Art. 25 |
| Art. 20(3) | Art. 41 |
| Art. 21 | ./. |
| Art. 22 | Art. 18 |
| Art. 23 | Art. 26, 27 |
| Art. 24 | Art. 28 |
| Art. 25 | Art. 17 |
| Art. 26 | Art. 30, 31, 32 |
| Art. 27 | Art. 34 |
| Art. 28 | Art. 35(1)(a), (c) |
| Art. 29 | Art. 35, 36 |
| Art. 30 | Art. 35(1)(b) |
| Art. 31 | Art. 38(1) |
| Art. 32 | ./. |
| Art. 33 | Art. 48 |
| Art. 34 | ./. |
| Art. 35 | Art. 47, 23(2) |
| Art. 36 | ./. |
| Art. 37 | Art. 50 |
| Art. 38 | Art. 52 |