Basic information

2008/0110(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Health rules: animal by-products and derived products not intended for human consumption Repealing Regulation (EC) No 1774/2002 2000/0259(COD) Amended by 2013/0140(COD) Amended by 2013/0191(COD) Amended by 2016/0084(COD) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.01 Feedingstuffs, animal nutrition 3.10.08.05 Animal diseases 4.20 Public health 4.20.05 Health legislation and policy 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	SCHNELLHARDT Horst (PPE-DE)	14/07/2008

Committee for opinion	Rapporteur for opinion	Appointed
AGRI Agriculture and Rural Development	SMITH Alyn (Verts/ALE)	24/06/2008

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2959	2009-09-07

European Commission

Commission DG	Commissioner
Health and Food Safety	VASSILIOU Androulla

Key events

Date	Event	Reference	Summary
10/06/2008	Legislative proposal published	COM(2008)0345	Summary

19/06/2008	Committee referral announced in Parliament, 1st reading		
17/02/2009	Vote in committee, 1st reading		Summary
02/03/2009	Committee report tabled for plenary, 1st reading	A6-0087/2009	
24/04/2009	Decision by Parliament, 1st reading	T6-0323/2009	Summary
24/04/2009	Results of vote in Parliament		
24/04/2009	Debate in Parliament		
07/09/2009	Act adopted by Council after Parliament's 1st reading		
21/10/2009	Final act signed		
21/10/2009	End of procedure in Parliament		
14/11/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0110(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealing Regulation (EC) No 1774/2002 2000/0259(COD) Amended by 2013/0140(COD) Amended by 2013/0191(COD) Amended by 2016/0084(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 168-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/64097

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE418.148	09/01/2009	
Committee opinion	AGRI	PE414.308	22/01/2009	
Amendments tabled in committee		PE419.854	30/01/2009	
Committee report tabled for plenary, 1st reading/single reading		A6-0087/2009	02/03/2009	
Text adopted by Parliament, 1st reading/single reading		T6-0323/2009	24/04/2009	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03639/2009/LEX	21/10/2009	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0345	10/06/2008	Summary
Document attached to the procedure	SEC(2008)1994	10/06/2008	
Document attached to the procedure	SEC(2008)1995	10/06/2008	
Commission response to text adopted in plenary	SP(2009)3507	25/06/2009	
Follow-up document	COM(2024)0262	01/07/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1671/2008	22/10/2008	
EU	Follow-up document	32025R2016 OJ OJ L 09.10.2025	09/10/2025	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Regulation 2009/1069
OJ L 300 14.11.2009, p. 0001 Summary

Delegated acts

Reference	Subject
2023/2721(DEA)	Examination of delegated act

Health rules: animal by-products and derived products not intended for human consumption

2008/0110(COD) - 10/06/2008 - Legislative proposal

PURPOSE: to lay down health rules as regards animal by-products not intended for human consumption.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

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 was adopted. The Regulation, which has been applicable since 1 May 2003, consolidated and recast the various existing rules covering animal by-products (ABP).

The Commission presented a report in October 2005 reflecting the experience of all 25 Member States in applying the legislation. 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.

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

a) the basic framework of safeguards applicable to all ABP should be maintained;

b) the scope of the rules on ABP should be adjusted;

c) the interaction of the rules on ABP with other Community legislation should be clarified;

d) a more risk-based approach for the categorisation of ABP, as well as controls, should be introduced.

CONTENT: 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. 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:

1) Clarification

- anend 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.

2) A more risk-based approach

- theprimary 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.

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.

Health rules: animal by-products and derived products not intended for human consumption

2008/0110(COD) - 21/10/2009 - Final act

PURPOSE: to lay down health rules as regards animal by-products not intended for human consumption

LEGISLATIVE ACT: Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

CONTENT: the Council adopted this Regulation modernising the EU rules for animal by products, following a first reading agreement with the European Parliament. The new Regulation is aimed at introducing more risk-proportionate rules and at clarifying the rules on animal by-products, as well as their interaction with other EU legislation.

The Regulation lays down public health and animal health rules for animal by-products and derived products, in order to prevent and minimise risks to public and animal health arising from those products, and in particular to protect the safety of the food and feed chain .Animal by-products are products of animal origin which are not intended for human consumption. They arise mainly during the slaughter of animals for human consumption, during the production of products of animal origin such as dairy products, and in the course of the disposal of dead animals. Past crisis related to outbreaks of foot-and-mouth disease or the spread of bovine spongiform encephalopathy (BSE) have shown that the improper use of certain animal by-products pose a risk to public and animal health, the safety of the food and feed chain and consumer confidence. More than 15 million tonnes of animal by-products are produced in the EU every year.

The main points of the Regulation are as follows:

- the concept of an **"end point"** in the manufacturing of animal by-products is introduced, after which the processed products are no longer subject to the animal by-products Regulation, as some potential risks have been eliminated for example by heat or chemical substances. Instead, the general rules on product safety apply. Under the current rules, almost all material from animals which does not enter the food chain, is subject to the rules on animal by-products;

- the distinction between foodstuffs and animal by-products is clarified by confirming that operators need to make an irreversible decision, if products are destined for purposes other than human consumption. This means that once a product has become an animal by-product, it must not re-enter the food chain;

- modification of the current classification 1 of animal by-products by Comitology procedure is permitted. In addition, certain animal by-products, which so far have been classified by default as category 2 material but which have been proven to pose no major risks, are reclassified as belonging to category 3, 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 classification by default as category 2 material is maintained for precautionary reasons;

- a registration obligation is introduced for operators who transport animal by-products, in order to strengthen traceability;

- the coherence between the Regulation on animal by-products and other EU legislation (for instance the legislation on food hygiene and waste) is improved by clarifying when the appropriate legislation applies. This removes unnecessary burdens for operators (for example, approvals of slaughterhouses and dairy plants under food and feed legislation are recognised).

The current classification scheme is maintained. This means that animal by-products of category 1 (injurious to health) and category 2 (unfit for human consumption) must not be placed on the market as food, whereas material of category 3 (which comply with certain rules regarding their possible use for human consumption) may be used for certain feeding purposes.

The basic principles of Regulation (EC) No 1774/2002 on animal by-products, however, remain unchanged. These include:

- the classification of animal by-products into three categories according to the degree of risk involved;
- the exclusion of animal by-products which are unfit for human consumption from the feed chain of farmed animals;
- the intra-species recycling ban (material derived from animals is not to be fed to animals of the species from which it is derived);
- the rule that only material from animals which have undergone veterinary inspection is to enter the feed chain for farmed animals;
- the ban on feeding of catering waste to farmed animals, in particular to pigs.

The technical details for the Regulation will be laid down in a separate legal act, to be adopted by comitology procedure. This implementing regulation will be prepared in the next year, so that it can enter into application simultaneously with the new basic regulation.

ENTRY INTO FORCE: 04/12/2009.

APPLICATION: from 04/03/2011.

Health rules: animal by-products and derived products not intended for human consumption

2008/0110(COD) - 24/04/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 391 votes to 3, with 4 abstentions, a legislative resolution modifying, under the first reading of the codecision procedure, the 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).

The amendments are the result of a compromise negotiated with the Council.

The main amendments are as follows:

Scope: the compromise clarifies that the Regulation shall apply to:

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- animal by-products and derived products which are excluded from human consumption under Community legislation; and
- the following products which pursuant to a decision by an operator are destined for purposes other than human consumption: (i) products of animal origin which may be destined for human consumption under Community legislation; (ii) raw materials for the production of products of animal origin.

Such decision shall be irreversible.

On the other hand, the Regulation **shall not apply** to the following animal by-products, inter alia:

- entire bodies or parts of wild animals, other than wild game, which are not suspected of being infected or affected with a disease communicable to humans or animals, except for aquatic animals landed for commercial purposes;
- entire bodies or parts of wild game which are not collected after killing, in accordance with good hunting practice, without prejudice to Regulation (EC) No 853/2004 laying down specific hygiene rules applicable to products of animal origin;
- raw pet food originating from retail shops, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot;
- raw pet food derived from animals which are slaughtered on the farm of origin for private domestic consumption;
- excrement and urine other than manure and non-mineralised guano.

Definitions: for the purposes of this Regulation, "animal by-products" means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen; "derived products" means products obtained from one or more treatments, transformations or steps of processing of animal by-products; "products of animal origin" means products of animal origin as defined in Regulation (EC) No 853/2004; "carcase" means carcase as defined in point 1(9) of Annex I to Regulation (EC) No 853/2004.

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

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

Members States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products. For that purpose, they shall maintain a system of official controls.

Member States shall also ensure that an adequate system is in place on their territory ensuring that animal by-products are: (i) collected, identified and transported without undue delay; and (ii) treated, used or disposed of in accordance with this Regulation.

Member States may fulfil their obligations in cooperation with other Member States or third countries.

Starting point: the starting point is the precise moment in the life cycle of animal by-products following which, the requirements of this Regulation should apply. Once a product has become an animal by-product, it should normally not re-enter the food chain.

However, special circumstances apply for the handling of certain raw materials, such as hides, handled in establishments or plants integrated at the same time into the food chain and the animal by-products manufacturing chain. In those cases, the necessary measures should be taken by means of segregation to mitigate potential risks for the food and feed chain which can arise from cross-contamination. For other establishments, risk-based conditions should be determined to prevent cross contamination in particular through separation between the two chains.

End point: for reasons of legal certainty and proper control of potential risks, an end point in the manufacturing chain should be determined for products without direct relevance for the safety of the feed chain. For certain products regulated under other Community legislation, such an end point should be determined at the stage of manufacturing. Products which have reached this end point should be exempt from controls under this Regulation. In particular, products beyond the end point should be allowed to be placed on the market without restriction under this Regulation and may be handled and transported by operators which have not been approved or registered in accordance with this Regulation.

However, it should be possible to modify such an end point, particularly in the case of new emerging risks.

Approved establishments or plants: operations with animal by-products which give rise to a considerable degree of risk to public and animal health should only be carried out in establishments or plants which have been approved in advance for such operations by the competent authority. This condition should apply in particular to processing plants and other establishments or plants which handle or store animal by-products with a direct relevance for the safety of the feed chain.

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

Establishments and plants which have been approved or registered under hygiene legislation should be under the obligation to comply with the requirements of this Regulation and subject to official controls carried out for the purposes of verifying compliance with the requirements of this Regulation.

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

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

Traceability: the respective basic obligation of 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. Established systems ensuring traceability for products exclusively circulating on national level by other means should continue to operate, if they provide equivalent information. Every effort should be made to promote the use of electronic and other means of documentation which do not involve paper records, as long as they ensure full traceability.

Own checks: a system of own checks is necessary to ensure that within an establishment or plant, the requirements of this Regulation are fulfilled. During official controls, the competent authorities should take into account the performance of own checks.

In certain establishments or plants own checks should be carried out through a system based on the principles of hazard analysis and critical control points (HACCP). The principles of HACCP should be based on the experience with their implementation under Community legislation on food and feed hygiene. In this respect, national guides to good practice could serve as a useful tool to facilitate the practical implementation of the HACCP principles, and of other aspects of this Regulation.

Placing on the market of animal by-products and derived products intended for feeding purposes and of organic fertilisers and soil improvers: in order to ensure the protection of the food and feed chain, the text clarifies the requirements on these points. Only Category 3 material should be used for feeding farmed animals other than fur animals.

Fertilisers produced on the basis of animal by-products may affect the safety of the feed and food chain. Where they have been manufactured from meat-and-bone meal of Category 2 or from processed animal protein, a component, such as an inorganic or an indigestible substance, should be added in order to prevent their direct use for feeding purposes. Such mixing should not be required if the composition or packaging of products, in particular of products destined for use by the final consumer, excludes the misuse of the product for feeding purposes. When determining the components, different circumstances regarding climate and soil and the objective for the use of particular fertilisers should be taken into account.

Official controls: the possible courses of action which the competent authority can take when carrying out official controls should be specified in order to ensure legal certainty, in particular regarding the suspension or permanent prohibition of operations or the imposition of conditions to ensure the proper application of this Regulation.

These official controls should be carried out in the framework of multi-annual control plans under Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Powers of the Commission (comitology): the Commission shall be empowered to adopt:

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

The Commission shall also be empowered to adopt more specific rules concerning:

- collection and transport of animal by-products;
- the infrastructure, equipment and hygiene requirements for plants and establishments handling animal by-products;
- the conditions and technical requirements for the handling of animal by-products, including the evidence to be presented for the purpose of validation of such treatment;
- conditions for the placing on the market of animal by-products and derived products;
- requirements related to safe sourcing, safe treatment and safe end uses;
- conditions for the import, transit and export of animal by-products and derived products;
- detailed arrangements for implementing official controls including rules concerning the reference methods for microbiological analyses as well as conditions for the control of the dispatch of certain animal by-products and derived products between Member States.

These measures shall be adopted in accordance with the regulatory procedure with scrutiny.