

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:

- 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.

Member States shall monitor and verify that the relevant requirements of this Regulation are fulfilled by operators along the entire chain of animal by-products and derived products. 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.