Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (Text with EEA relevance)

REGULATION (EC) No 183/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 January 2005

laying down requirements for feed hygiene

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2) and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Livestock production plays a very important part in the agricultural sector of the Community. Satisfactory results of this activity depend to a large extent on the use of safe and good quality feed.

(2) The pursuit of a high level of protection of human and animal health is one of the fundamental objectives of food law, as laid down in 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[(3)]. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of feed within the Community.

(3) Council Directive 95/69/EC[(4)] established the conditions and arrangements applicable to certain categories of establishments and intermediaries in the animal feed sector, to enable them to exercise their activities. Experience has shown that these conditions and arrangements constitute a sound basis for ensuring feed safety. That Directive also established conditions for the approval of establishments producing certain substances listed in Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(5)].

(4) Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries

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operating in the animal feed sector[(6)], established certain measures that included arrangements for imports from third countries.

(5) Experience has also shown that it is necessary to ensure that all feed businesses, including aquaculture, operate in conformity with harmonised safety requirements and that it is necessary to conduct a general review in order to take into account the need to ensure a higher level of protection of human and animal health, and of the environment.

(6) The principal objective of the new hygiene rules set out in this Regulation is to ensure a high level of consumer protection with regard to food and feed safety, taking particular account of the following principles:

(a) that primary responsibility for feed safety rests with the feed business operator;

(b) the need to ensure feed safety throughout the food chain, starting with primary production of feed, up to and including, the feeding of food-producing animals;

(c) the general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP), which, together with the application of good hygiene practice, should reinforce feed business operators' responsibility;

(d) that guides to good practice are a valuable instrument to help feed business operators at all levels of the feed chain comply with feed hygiene rules and with the application of HACCP principles;

(e) the establishment of microbiological criteria based on scientific risk criteria;

(f) the need to ensure that imported feed attains a standard that is at least equivalent to that of feed produced in the Community.

(7) In order to ensure the complete application of the registration and approval system to all the feed business operators and, consequently, to guarantee full traceability, it is appropriate to ensure that they only source and use feed from establishments which are registered and/or approved in accordance with this Regulation.

(8) An integrated approach is necessary to ensure feed safety from, and including, primary production of feed up to, and including, its placing on the market or export. The primary production of feed includes products which only undergo simple physical treatment such as cleaning, packaging, storage, natural drying or ensiling.

(9) In accordance with the principles of proportionality and subsidiarity, Community rules should not apply to certain cases of private domestic production of feed and feeding of certain animals, nor to the direct supply of small quantities of primary production of feed at local level, nor to the retailing of pet food.

(10) Feed hazards present at the level of primary production of feed should be identified and adequately controlled, to ensure that the objectives of this Regulation are met. The fundamental principles of this Regulation should therefore apply to farms which

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manufacture feed solely for the requirements of their own production, as well as to farms which place feed on the market. It should be taken into consideration that the risk is less if feed is produced and used for feeding animals only used for domestic consumption, or for animals which are not used for food production. The trade of small quantities of feed products at local level and the retailing of pet food shall have particular treatment in the framework of this Regulation.

(11) The application of HACCP principles to primary production of feed is the medium-term objective of European hygiene legislation. But guides to good practice should already be encouraging the use of appropriate hygiene requirements.

(12) Feed safety depends on a number of factors. Legislation should lay down minimum hygiene requirements. Official controls should be in place to check feed business operators' compliance. In addition, feed business operators should take measures or adopt procedures to achieve a high level of feed safety.

(13) HACCP principles can help feed business operators attain a higher standard of feed safety. HACCP principles should not be regarded as a method of self-regulation and do not replace official controls.

(14) The implementation of the HACCP principles requires the full cooperation and commitment of feed businesses' employees.

(15) HACCP principles in feed production should take into account the principles contained in the Codex Alimentarius, but should allow sufficient flexibility in all situations. In certain feed business, it is not possible to identify critical control points and, in some cases, good practices can replace the monitoring of critical control points. Similarly, the requirement to establish 'critical limits', as set out in the Codex Alimentarius, does not require a numerical limit to be fixed in every case. The requirement to retain documents as set out in the same Code needs to be flexible to avoid undue burdens for very small businesses. It should be ensured that operations carried out by a feed business at the level of primary production of feed, including associated operations, as well as the mixing of feed with complementary feedingstuffs for the exclusive requirements of its own holding, are not obliged to follow the HACCP principles.

(16) Flexibility is also necessary to accommodate the needs of feed businesses situated in regions suffering from special geographical constraints or related to structural requirements. But such flexibility should not compromise feed hygiene objectives. Provision should be made for discussion within the Standing Committee on the Food Chain and Animal Health, where appropriate.

(17) A system of registration and approval by the competent authority of the Member State of all feed businesses is appropriate to ensure traceability from manufacturer to final user and to facilitate the implementation of effective official controls. The existing systems for collection of data concerning feed businesses may be used by the competent authority of the Member States to start up and implement the system provided for in this Regulation.

(18) It is appropriate that an approval system for feed businesses be maintained for activities which can present a higher risk in the manufacture of feed. Provision should be made

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for procedures to extend the current scope of the approval system provided for in Directive 95/69/EC.

(19) In order to be approved or registered, feed businesses should meet several conditions relevant to their operations, concerning facilities, equipment, personnel, production, quality control, storage and documentation, in order to ensure both feed safety and product traceability. Provision should be made for these conditions to be varied, to ensure that they are appropriate to the various types of feed business. Member States should be allowed to grant conditional approval of establishments, if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. However, it is also appropriate to set a maximum length of time for such conditional approval.

(20) Provision should be made for temporarily suspending, amending or revoking the registration or approval, where establishments change or cease their activities or no longer fulfil the conditions applicable to their activity.

(21) The traceability of feed and feed ingredients throughout the feed chain is an essential element in ensuring feed safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of feed and feed ingredients and provides a procedure for the adoption of implementing rules applicable to specific sectors.

(22) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. The characteristics of feed production and the complexity of the feed distribution chain mean that it is difficult to withdraw feed from the market. The costs of rectifying the economic damage along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator whose activity causes economic damage in the feed sector is held financially responsible. However, establishing a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all feed business operators may not be feasible or appropriate. The Commission should therefore consider this issue in greater depth, taking into account provisions in existing legislation with regard to liability in other spheres, as well as existing systems and practices amongst the Member States. To this end, the Commission should present a report, accompanied where appropriate by legislative proposals.

(23) Feed imported into the Community must satisfy the general requirements laid down in Regulation (EC) No 178/2002 and the import conditions laid down in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[7]. In order to avoid trade disruptions it is appropriate that, pending the completion of the implementing measures, imports continue to be authorised under the conditions laid down in Directive 98/51/EC.

(24) Community products exported to third countries have to satisfy the general requirements laid down in Regulation (EC) No 178/2002.

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(25) It is appropriate to broaden the scope of the rapid alert system for food and feed laid down by Regulation (EC) No 178/2002 to include risks to animal health or the environment from feed used for animals not kept for food production.

(26) Community legislation on feed hygiene has to be underpinned by scientific advice. To this end, the European Food Safety Authority should be consulted whenever necessary.

(27) To take account of technical and scientific progress, there should be close and effective cooperation between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

(28) This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the Codex Alimentarius.

(29) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties have to be effective, proportionate and dissuasive.

(30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(8)].

(31) It is appropriate to provide for a deferred date of application of the Regulation, in order to allow the feed businesses affected by it time to adapt.

(32) For the above reasons, Directives 95/69/EC and 98/51/EC should be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down:

(a) general rules on feed hygiene;

(b) conditions and arrangements ensuring traceability of feed;

(c) conditions and arrangements for registration and approval of establishments.

Article 2

Scope

1 This Regulation shall apply to: