Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (Text with EEA relevance)

REGULATION (EC) No 767/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 July 2009

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(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 Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

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

Having consulted the Committee of the Regions,

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

Whereas:

(1) 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 established the farm-to-fork approach designating feed as a sensitive stage at the beginning of the food chain. To ensure a high level of protection of public health is one of the fundamental objectives of this Regulation.

(2) The production of feed is an important end for European agricultural products, given that most of the materials used for the production of feed are agricultural products listed in Annex I to the Treaty. Furthermore, feed is of crucial significance for the 5 million livestock farmers in the Community because it represents the greatest expense.

(3) Feed may take the form of feed materials, compound feed, feed additives, premixtures or medicated feedingstuffs. The rules for the marketing of feed additives are set out

in Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[4] and for medicated feedingstuffs in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[5].

(4) The existing legislation on the circulation and use of feed materials and compound feed, which includes pet food, namely Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs[6], Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes[7] (dietetic feed), Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials[8] and Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[9] (bio-proteins), needs to be updated and replaced by a single regulation. In the interests of clarity, Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition[10] and Commission Directive 80/511/EEC of 2 May 1980 authorising, in certain cases, the marketing of compound feedingstuffs in unsealed packages or containers[11] should be repealed.

(5) As a consequence of the repeal of Directive 79/373/EEC by this Regulation, Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition[12] should also be repealed. Also, in view of the repeal of Directive 79/373/EEC, and given that this Regulation includes rules concerning the labelling of feed containing additives, Article 16 of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[13], which remained in force after the repeal of Directive 70/524/EEC by Regulation (EC) No 1831/2003, should be repealed.

(6) Unlike food, as defined in Regulation (EC) No 178/2002, the definition of feed does not include water. Furthermore, given that water is not marketed for animal nutrition purposes, this Regulation should not include conditions for water used in animal nutrition. It should, however, apply to feed administered in water. The use of water by feed businesses is covered by Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene[14], which stipulates that clean water should be used whenever necessary in order to prevent contamination that could prove hazardous and that water used in feed manufacture should be of suitable quality.

(7) Given the risk of contamination of the feed and food chain, it is appropriate that this Regulation apply to feed for both food and non-food producing animals, including wild animals.

(8) The responsibilities of the feed business operators laid down in Regulation (EC) No 178/2002 and Regulation (EC) No 183/2005 should apply, *mutatis mutandis*, in respect of feed for non-food producing animals.

(9) In order to enforce compliance with this Regulation, Member States should carry out official controls in accordance with 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[15]. Those controls should include not only the mandatory but also the voluntary labelling particulars. In order to allow control of the compositional data, acceptable tolerances for the labelled values should be determined.

(10) To manage feed safety risks, the list of materials whose placing on the market for animal nutrition purposes is prohibited, as currently provided for in Commission Decision 2004/217/EC[16], together with a list of materials whose placing on the market for animal nutrition purposes is restricted, should be included in an Annex to this Regulation. The existence of such an Annex should not, however, be interpreted to mean that all products not listed can, as such, be considered safe.

(11) The distinction between feed materials, feed additives, and other products such as veterinary drugs has implications for the conditions for the placing of such products on the market. Feed materials are primarily used to meet animals' needs, for example for energy, nutrients, minerals or dietary fibres. They are usually not chemically well-defined except for basic nutritional constituents. Effects which can be justified by scientific assessment and which are exclusive to feed additives or veterinary drugs should be excluded from the objective uses of feed materials. It is, therefore, appropriate to draw up non-binding guidelines for distinguishing between these kinds of products. In duly justified cases, the Commission should be empowered to clarify whether a product constitutes feed for the purposes of this Regulation.

(12) The definition of complementary feedingstuffs in Directive 79/373/EEC gave rise to application problems in various Member States. It is appropriate to clarify the distinction between complementary feedingstuffs and premixtures for the purposes of applying Regulation (EC) No 183/2005.

(13) In order to allow a uniform application of the legislation, feed materials and complementary feed should not contain additives above a certain level. However, highly concentrated feed, such as licking buckets containing minerals, may be used for direct feeding if the composition meets the particular nutritional purpose in respect of the relevant intended use. Conditions governing the use of such feed should appear on the labelling in order to ensure that the rules regarding the content of feed additives in the daily ration are complied with.

(14) Directive 82/471/EEC aims to improve the supply of feed used as direct and indirect protein sources in the Community. That Directive requires a pre-market authorisation procedure for all possible bio-proteins. However, only very few new authorisations have been granted to date and the shortage of protein-rich feed is still evident. Thus, the general pre-market authorisation requirement has proved to be prohibitive, and safety risks could be tackled instead by means of prohibiting risky products based on market surveillance. In cases where the outcome of the risk assessment of a bio-protein is negative, its circulation or use should be prohibited. Hence, the special requirement of a general pre-market authorisation procedure for bio-proteins should be abolished, with the consequence that the safety system for such products be the same as for all other feed materials. The existing restrictions or prohibition of certain bio-proteins should not be affected.

(15) The provisions of Directive 93/74/EEC implemented by Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes[17] have proved to be working well. The list of intended uses thus established should, therefore, be maintained and provision should be made in this Regulation for its updating. In particular, the European Food Safety Authority should be consulted on the efficacy and the safety of such feed when, on the basis of available scientific and technological information, there are reasons to believe that the use of the feed in question may not meet the particular intended nutritional purpose or may have adverse effects on animal health, human health, the environment or animal welfare.

(16) Scientific substantiation should be the main factor to be taken into account for the purpose of making claims in respect of feed, and feed business operators making such claims should be able to substantiate them. A claim may be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(17) Labelling serves enforcement, traceability and control purposes. In addition, labelling should provide the necessary information to purchasers to enable them to make the optimal choice for their needs, and it should be consistent, coherent, transparent and understandable. As purchasers, in particular livestock farmers, make their choices not only at the point of sale where they can inspect the packaging of the feed, the requirements concerning information provided on the labelling must apply, not only to the labels which appear on the products, but also to other kinds of communication between the vendor and the purchaser. Furthermore, those principles should apply also to the presentation and the advertising of feed.

(18) Mandatory and voluntary information is provided on labelling. The mandatory information should combine general labelling requirements and specific requirements for feed materials or compound feed respectively, and additional requirements in the case of dietetic feed, contaminated material and pet food.

(19) The present situation with respect to chemical impurities resulting from the manufacturing process of feed materials and from processing aids is not satisfactory. In order to ensure a high level of feed safety, and thus a high level of protection of public health, and in order to improve transparency, provisions should be adopted laying down acceptable levels of such chemical impurities in accordance with good practice as referred to in Regulation (EC) No 183/2005.

(20) The principle that only certain feed additives have to be labelled once they are used in feed materials and compound feed is working well. However, the categorisation resulting from Regulation (EC) No 1831/2003 needs to be updated and modernised, due also to the fact that pet owners, in particular, might be confused by some additive labelling.

(21) As a consequence of the bovine spongiform encephalopathy (BSE) and the dioxin crises, the obligation to indicate the percentage by weight of all feed materials incorporated in compound feed was introduced in 2002 by Directive 2002/2/EC of

the European Parliament and of the Council of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs[(18)], at the initiative of the European Parliament. Furthermore, the level of food and feed safety has been significantly improved as a result of Regulation (EC) No 178/2002 and Regulation (EC) No 183/2005 and their implementing measures, in particular as a result of the focus put on the responsibility placed on feed and food business operators, the improved traceability system, the introduction of the hazard analysis and critical control points (HACCP) principle in feed businesses and the creation of guides to good hygiene practice in feed businesses. In light of these positive achievements, mirrored in the notifications to the Rapid Alert System for Food and Feed (RASFF), the obligation to indicate the percentage by weight of all feed materials incorporated in compound feed on the labelling is no longer necessary for the purpose of ensuring a high level of feed safety and thus a high level of protection of public health. The exact percentages may, however, be provided on a voluntary basis for the purpose of providing adequate information to purchasers. Furthermore, given that the competent authorities have access to information on the exact percentages by weight of all feed materials incorporated in compound feed, they should be able, on the ground of any urgency relating to human or animal health or to the environment, and in accordance with Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights[(19)], to provide further information to purchasers.

(22) To ensure proper information for, and to avoid misleading, the purchaser, the exact percentage by weight should, however, be required in those cases where the feed material in question is emphasised on the labelling of a compound feed.

(23) The indication of the feed materials incorporated in compound feed in descending order of weight already provides important information on compositional data. In certain areas where the producer is not obliged to label particulars, the purchaser should be able to request additional information. In such cases, a margin of +/– 15 % of the declared value should be maintained.

(24) The intellectual property rights of producers should be protected. For the enforcement of such intellectual property rights, Directive 2004/48/EC should apply. It should also be acknowledged that the quantitative composition of compound feed, unlike the names of feed materials contained therein, can, under certain conditions, be considered confidential information to be protected.

(25) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[(20)] does not apply to the labelling of feed with excessive levels of undesirable substances. Provisions should therefore be laid down in order to ensure adequate labelling and proper implementation of the dilution ban provided for in Article 5 of that Directive, until such contaminated materials have been detoxified by a detoxification establishment, approved in accordance with Article 10(2) or (3) of Regulation (EC) No 183/2005, or until they have been cleaned.

(26) Derogations from the general labelling requirements should be provided for in so far as the application of such requirements is not necessary to protect human or animal