

COUNCIL AND EUROPEAN PARLIAMENT REGULATION ON THE PLACING ON THE MARKET AND THE USE OF ANIMAL FEED

NOTE ON THE MAIN PROVISIONS OF THE MEASURE

This descriptive note summarises the provisions of the new EC Regulation on the marketing and use of feed. It is intended for the use of all stakeholders, including feed business operators and enforcement personnel. This descriptive note should be read in conjunction with, not as a substitute for, the EC Regulation.

Introduction

1. The Regulation is part of the European Commission's modernisation and simplification programme and replaces five existing EC measures, as follows:

- Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs;
- Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition;
- Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes;
- Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials; and
- Commission Decision 2004/217/EC of 1 March 2004 adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited.

2. The labelling of additives or premixtures of additives used or sold without incorporation in a feedingstuff will remain outside the scope of the Regulation, as will the labelling of feed containing or produced from genetically modified organisms (GMOs). These two issues will continue to be controlled by two separate EC Regulations, namely Commission Regulation (EC) 1831/2003 of 22 September 2003 on additives for use in animal nutrition and Commission Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed. The existing controls on undesirable substances under Council Directive 2002/32/EC of 7 May 2002 will also remain outside the scope of the Regulation.

3. The text of the Regulation has been agreed between the Council and the European Parliament, and was adopted by the Council of Ministers on 22 June 2009. There will be a period of 12 months after its publication in the *Official Journal* of the European Union before it applies in Member States. As a Regulation, it will apply directly in all Member States, although it will be necessary to amend UK legislation to link its provisions to the powers available to enforcement officers and to provide for offences and penalties for breaches of the measure's provisions. The Food Standards Agency will be consulting separately on this.

The Provisions of the Regulation

4. Much of the Regulation reflects the requirements of the measures it will replace, although it has a number of provisions which are new and/or may have implications for feed businesses and enforcement authorities. The following Article-by-Article commentary identifies the measure's key elements.

Article 1 -- Objectives

5. The Regulation is intended to harmonise the marketing of feed, provide for feed safety and public health, ensure adequate information for the users of feed, and strengthen the Community market.

Article 2 -- Scope

6. This Article lists other EC feed-related measures which will continue to apply. It also states (in Article 2.3) that the Regulation excludes water, whether fed directly or incorporated in feed, although it will apply to feed which is intended to be administered in water.

Article 3 -- Definitions

7. This Article introduces a number of new definitions which apply for the purposes of the Regulation, in particular;

- "oral feeding of animals" (Article 3.2(b));
- "contaminated materials" (Article 3.2(p)); and
- "batch or lot" (Article 3.2(r)).

8. This Article also extends the definition of "food producing animal" so that it now includes animals such as horses and rabbits which may not customarily be consumed in the UK but are eaten in other EU Member States (Article 2.3(c) -- "any animal that is fed, bred or kept for the production of food for human consumption including animals that are not used for human consumption but that belong to a species that is normally used for human consumption in the Community").

9. "Labelling" will cover advertising as well as other information (Article 3.2(s)).

Article 4 -- Safety and Marketing Requirements

10. This Article requires that feed does not have an adverse effect on the environment or animal welfare, that it is fit for its intended purposes, that it is labelled, packaged and presented in accordance with the Regulation, and that it complies with the technical provisions set out in Annex I. It also extends the feed safety provisions of EC Regulation 178/2002 on the general principles of food law to feed for non-food producing animals (which includes pet food).

Article 5 -- Responsibilities and Obligations of Feed Businesses

11. This Article requires feed business operators, including those producing feed for non-food producing animals, to comply with the traceability and recall provisions

of EC Regulation 178/2002 on the general principles of food law and Article 4.1 of EC Regulation 183/2005 on feed hygiene.

12. Article 5.2 requires that the individuals responsible for feed labelling provide competent authorities with the information necessary to verify the accuracy of the labelling declarations, including exact percentage ingredient information. Article 5.3 permits competent authorities to pass this information to feed purchasers where an urgent issue of animal or human health is concerned and where they consider that such information-sharing is justified, subject to existing Community provisions on intellectual property rights and (if appropriate) the purchaser being required to sign a statement of confidentiality.

Article 6 -- Restriction and Prohibition

13. This Article provides for the existing list of prohibited ingredients published as the Annex to Directive 2004/217 to become Annex III to this Regulation and allows for it to be extended in the light of emerging scientific evidence, notifications made under the Rapid Alert System for Food and Feed and the results of inspections under Regulation 882/2004 on official controls. The Article also introduces a provision for a new category of materials the future use of which may be restricted in some way.

Article 7 -- Characteristics of Types of Feed

14. This Article permits the Commission to adopt guidelines to distinguish between feed materials, feed additives and other products such as veterinary drugs. This provision has been introduced in response to previous queries about some products whose status was in doubt.

Article 8 -- Content of Feed Additives

15. There are no maximum permitted levels in current legislation for the additive content of complementary feeds and premixtures although, when these products are used in combination with other feeds, the maximum permitted levels for additives in complete feeds must be observed. The Regulation specifies that complementary feeds should not contain additives at levels of more than 100 times the maximum permitted levels in complete feeds. (For coccidiostats and histomonostats the factor is five times the maximum permitted levels of these additives in complete feeds.)

16. In many cases, products such as pastes, drenches and boluses (slow-release capsules) have levels of additives in excess of the 100 factor mentioned above. These "nutritional supplements" will be subject to the authorisation procedure which is to be introduced for dietetic feeds (i.e., feeds for particular nutritional purposes -- see Articles 9 and 10). Manufacturers of such products will be subject to approval under EC Regulation 183/2005 on feed hygiene.

Articles 9 and 10 -- Feed Intended for Particular Nutritional Purposes

17. There is currently no set procedure for the addition of new nutritional purposes to the existing list (the Annex to Directive 93/74). The Regulation will

introduce a formal procedure for the consideration of submissions for new nutritional purposes, which will require applicants to submit a dossier demonstrating that a specific feed meets an intended nutritional purpose and has no adverse effects on animal and human health, the environment and animal welfare.

Article 11 -- Principles for Labelling and Presentation

18. This Article repeats some of the existing requirements of Directives 79/373 and 96/25 regarding the labelling of feed -- for example, that purchasers should not be misled and that feed marketed in bulk should be accompanied by a document providing all the mandatory labelling requirements. The Article also introduces provisions specifying what labelling information must be provided when feed is offered for sale via distance selling (e.g. over the internet) and what may be omitted, although the information omitted when the feed is offered for sale in this manner is required to be provided to the purchaser no later than the time of delivery. Additional provisions, including the format to be used for the date and instructions for the use of complementary feed with levels of additives above those in finished feed are set out in Annex II.

19. Article 11.5 requires that discrepancies between the labelled analytical values (for protein, fibre, moisture, etc) and those found when the product is sampled must lie within the upper and lower limits of variation laid down in Annex IV to the Regulation. The number of declarations subject to such limits has been reduced, which has resulted in a tightening of some of them and prompted concerns from some Member States and stakeholders that some feeds may not be compliant. In response to these concerns, the Commission has given an undertaking that the limits will be subject to discussion and possible review in the Standing Committee on the Food Chain and Animal Health before the Regulation applies in Member States.

Article 12 -- Responsibility

20. This Article specifies responsibilities for the accuracy of feed labelling, and requires that labelling information is transmitted throughout the food chain to ensure its provision to the final users of the feed.

Article 13 -- Claims

21. Existing legislation lays down a number of general principles by which labelling must abide -- for example, that any additional claims relate to objective or quantifiable factors which can be substantiated, that claims to treat, prevent or cure a disease should not be made, and that a feed should not be marketed as dietetic unless the nutritional purpose appears in the list of intended uses. This Article extends and reinforces these principles by requiring that feed business operators provide enforcement authorities with scientific substantiation of any claims made when asked to do so. Purchasers will have the right to refer claims which they consider of doubtful accuracy to enforcement authorities. Where there are doubts about the substantiation of such claims, the issue may be referred to the Commission for a decision. However, substantiation will not be required for "generic" claims which are not based on a pharmacological or immunological action, e.g. for the role of vitamins.

Article 14-- Presentation of Labelling Particulars

22. This Article repeats the existing requirements that labelling be conspicuous, legible and indelible, and be in at least one of the languages of the Member State in which the feed is marketed.

Article 15 -- General Mandatory Labelling Requirements

23. Much of this Article repeats the requirements of existing legislation, including (where it is appropriate to do so) the approval number of the establishment of the person responsible for the labelling. This may be the number issued under EC Regulation 183/2005 on feed hygiene or according to EC Regulation 1774/2002 on animal by-products. Article 15(c) requires that an establishment which has numbers issued under both measures should use that given under EC Regulation 183/2005.

24. At present, only certain additives (e.g. copper, vitamins A, D and E, enzymes, and micro-organisms) are required to be declared on the labels of livestock feeds. Article 15(f) requires the labelling of all additives subject to a maximum inclusion rate. The exact declarations to be made, including their identification number, the added amount, and the functional group (e.g. preservatives) to which they belong, are laid down in Annex VI for feed for food-producing animals. Similar requirements are laid down in Annex VII for feed for non-food producing animals, although here manufacturers have the option to label only the functional group for additives used as preservatives, antioxidants and colourants.

Article 16 -- Specific Mandatory Labelling Requirements for Feed Materials

25. This Article repeats the requirements in existing legislation concerning the names and analytical declarations to be given on labels. Article 16.2 introduces a requirement that, where additives have been incorporated, the labelling specifies the intended species and gives instructions for use in those cases where the additives in question have not been authorised for all species or are subject to a maximum limit.

Article 17 -- Specific Mandatory Labelling Requirement for Compound Feed

26. This Article repeats most of the existing requirements for the labelling of compound feed, including the intended species, instructions for use, and best before dates. This Article also covers the disclosure of information to purchasers by competent authorities on grounds of urgency under Article 5 and the labelling of additives under Article 15.

27. Where a business markets a feed it has not manufactured, the label must give the business name and address of the feed manufacturer. Alternatively, either the approval number of the manufacturing establishment may be declared on the label or an identifying (registration) number issued under EC Regulation 183/2005 on feed hygiene or issued at the request of the manufacturer or importer of the feed.

28. The existing mandatory requirement to declare the ingredients of compound feed for farmed livestock by their percentage weight of inclusion, which was

introduced in 2002 following a number of feed safety incidents, will be deleted. The previous requirement to declare the names of the ingredients in descending order of weight, without percentages, will be restored. However, manufacturers will be required to provide percentage ingredient information to customers on request, subject to existing Community provisions on intellectual property rights and a tolerance of +/-15% for the declaration of each ingredient. The ingredients of pet food may continue to be declared by category.

29. On grounds of urgency relating to human and animal health or to the environment, enforcement authorities may provide purchasers with percentage ingredient information, subject to certain criteria (e.g. the signing of a confidentiality agreement).

30. A list of categories of feed materials for feed for non-food producing animals is to be drawn up.

Article 18 -- Additional Mandatory Labelling Requirements for Feed Intended for Particular Nutritional Purposes

31. This Article repeats the requirements in existing legislation for the labelling of dietetic feeds.

Article 19 -- Additional Mandatory Labelling Requirements for Pet Food

32. Pet food manufacturers will be required to provide contact details on their labels for purchasers who wish to obtain the names of the ingredients (but not their percentage weight of inclusion) where these have been declared by category, and of all the additives used over and above those required to be declared. Contact may be by telephone, e-mail, ordinary post or the internet, at the manufacturer's discretion.

Article 20 -- Mandatory Labelling Requirements for Non-Compliant Feed

33. Feed which contains levels of undesirable substances above those permitted under Directive 2002/32 on undesirable substances must be labelled to indicate that it is intended to be cleaned or detoxified prior to use. This will help close a potential loophole in the existing legislation which could allow contaminated feed to be diverted back into the feed chain without undergoing such processing. The labelling declarations are laid down in Annex VIII. Provision is made for the future amendment of this Annex in line with developing standards.

Article 21 -- Derogations

34. Most of the derogations set out in the existing legislation are carried forward into the Regulation unchanged, with the exception of the blanket derogation in Directive 96/25 for the provision of certain analytical declarations for by-products of agro-industrial processing the moisture content of which exceeds 50%. However, this Article also provides for the omission of certain analytical information and other declarations on condition that the purchasers state in writing before each transaction that they do not require it.

Article 22 -- Voluntary Labelling

35. This Article allows for the provision of additional information over and above the statutory declarations, with any conditions relating to this to be laid down in the Community Codes of good labelling practice established under Article 25.

Article 23 -- Packaging

36. This Article repeats some of the existing derogations for the labelling of feed materials and compound feed. However, some of the derogations available under existing legislation have been removed -- for example, it will no longer be possible to market pelleted feedingstuffs and molassed feedingstuffs consisting of less than three feed materials in bulk or unsealed containers (unless covered by one of the other derogations, for example deliveries direct from producer to user).

Article 24 -- Community Catalogue of Feed Materials

37. The names and descriptions and certain labelling requirements for the most commonly used feed materials are currently listed in the Annex to Directive 96/25. This Annex will be replaced by a Community Catalogue of feed materials, which will be subject to amendment and extension by the feed industry in consultation with Member States, the European Food Safety Authority (EFSA) and feed users. The first version of the Catalogue is to be adopted no later than six months after the entry into force of the Regulation (as specified in Article 33), and is to include the materials in both the Annex to Directive 96/25 and those remaining in the Annex to Directive 82/471. Adoption of the Catalogue will be subject to the agreement of the Commission and Member States. The Catalogue will be voluntary, but where it is used all relevant provisions have to be complied with.

38. In addition to the Community Catalogue, the European feed industry will be required to maintain and publish a register listing the names of feed materials which have not yet been included in the Catalogue. The intention is that a person placing a feed material on the market for the first time must notify the European feed industry in order that it can be listed in the register.

39. Pet food may still be labelled by categories of ingredient, although the existing list of categories is to be reviewed (see Article 17.4).

Article 25 -- Community Codes of Good Labelling Practice

40. Supplementing the mandatory labelling requirements, there will be Community Codes of good labelling practice to cover claims made under Article 13, general labelling particulars under Article 14, and voluntary labelling declarations under Article 22. It is envisaged that there will be two Codes: one for compound feed for food-producing animals (which may include a section for feed for fur-producing animals) and one for pet food. As with the Community Catalogue of feed materials, these Codes will be drawn up by the feed industry in consultation with Member States, the EFSA and feed users. However, no timetable is given for the development of these Codes.

Article 26 -- Establishment of the Codes and Amendments to the Community Catalogue and the Community Codes

41. This Article lays down the procedures for the amendment of the Catalogue and the Codes. It also specifies, in Article 26.3, that (within two years of the application of the Regulation) the Commission should introduce maximum permitted levels for the presence of chemical impurities (such as processing aids) in feed. Paragraph 1 of Annex I specifies that these maximum levels should be laid down in the Catalogue to be drawn up under Article 24. Provision is also made for setting levels of botanical purity and moisture.

Article 27 -- Implementing Measures

42. This Article allows for the amendment of the Annexes and "non-essential elements" of the Regulation in the light of scientific and technical developments.

Article 28 -- Committee Procedure

43. This Article specifies the procedures to be used when making the amendments envisaged under Article 27.

Article 29 -- Amendment to EC Regulation 1831/2003

44. This Article makes minor amendments to Article 16 of EC Feed Additives Regulation, which concerns the labelling of additives in premixtures. At present, a range of information for each of the additives in a premixture is required to be labelled, some of which -- such as the date of manufacture and the batch number -- will be of minimal use to purchasers. The amendment deletes the requirement to provide this information on premixture labels.

Article 30 -- Repeal

45. This Article lists all the existing measures to be revoked, including Directive 82/471 on "certain products" which requires new bio-proteins to undergo a pre-market safety assessment based on a dossier submitted by an applicant before they could be used in feed. As stated in recital 28, this procedure will be abolished and bio-proteins in future regarded as feed materials, to be controlled by post-marketing surveillance. Any bio-proteins which previously failed the dossier assessment procedures required by Directive 82/471 will be added to the list of prohibited ingredients in Annex III.

46. The complete list of measures to be repealed is as follows:

- Article 16 of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs;
- Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs;
- Commission Directive 80/511/EEC of 2 May 1980 authorising, in certain cases, the marketing of compound feedingstuffs in unsealed packages or containers;

- Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ("bio-proteins");
- Council Directive 83/228/EEC on the fixing of guidelines for the assessment of certain products used in animal nutrition;
- Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes;
- Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition;
- Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials; and
- Commission Decision 2004/217/EC of 1 March 2004 adopting a list of materials whose circulation or use for animal nutrition purposes is prohibited

Article 31 -- Penalties

47. This requires Member States to lay down "effective, proportionate and dissuasive" penalties for breaches of the Regulation's requirements. These will be set out in the new national legislation which will provide for the enforcement of the Regulation.

Article 32 -- Transitional Measures

48. Article 32.1 permits feed labelled in accordance with existing legislation to remain on the market until stocks are exhausted. Article 32.2 permits "nutritional supplements" (such as boluses, pastes and drenches) which have been legally placed on the market to continue to be marketed after the Regulation applies provided that an application for their authorisation has been submitted under Article 8 before the date of the Regulation's application in Member States.

49. Paragraph 1 of Annex I requires that feed materials be free from chemical impurities resulting from their manufacturing process and from processing aids unless a specified maximum permitted level has been set. Article 32.3 permits feed materials to be marketed according to the conditions set out in Part A Title II of the Annex to Directive 96/25 until these levels are agreed. However, this derogation will last no longer than three years after the date of the Regulation's application.

50. Article 32.4 permits the adoption by comitology of other transitional measures, including the labelling of feed in accordance with the provisions of the Regulation prior to its application in Member States.

Article 33 -- Entry into Force

50. This Article specifies that the Regulation will enter into force twenty days after its publication in the *Official Journal of the European Union* and apply in all Member States twelve months after the date of publication.

The Annexes to the Regulation

51. The provisions set out in the Annexes to the Regulation have been referred to previously in this document, but for completeness their content is summarised as follows:

- Annex I -- various technical provisions, including those on chemical impurities, ash levels and moisture content;
- Annex II -- general labelling provisions, including date formats and the labelling of complementary feed with levels of additives above the maximum permitted in complete feeds;
- Annex III -- lists of prohibited and restricted ingredients;
- Annex IV -- limits of variation;
- Annex V -- compulsory analytical declarations for feed materials;
- Annex VI -- labelling requirements for feed for food-producing animals, including the required additive declarations;
- Annex VII -- labelling requirements for feed for non-food producing animals, including the required additive declarations; and
- Annex VIII -- labelling requirements for contaminated feed to be sent for detoxification or other cleaning.

52. A table showing the correlation between the various provisions of the Regulation and those of the EC measures it will replace is provided at Annex IX.

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