DIRECTIVE 2001/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 July 2001

amending Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition and Directives 70/524/EEC, 96/25/EC and 1999/29/EC on animal nutrition

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) The safety of products destined for animal nutrition is of primary concern and it is necessary to ensure that products put into circulation in the Community for the purposes of animal nutrition are safe. Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition [4] contributes to the achievement of that objective.

(2) Council Directive 74/63/EEC has been repealed by Article 16 of Council Directive 1999/29/EC of 22 April 1999 on undesirable substances and products in animal nutrition [5]. Therefore, references to Directive 74/63/EEC have to be amended pursuant to the Table in Annex IV to Directive 1999/29/EC.

(3) As regards the reference to the circulation of products to be used in animal nutrition, it is necessary to harmonise the definitions used by Directives 70/524/EEC [6], 95/53/EC and 96/25/EC [7] in the animal nutrition sector.

(4) Serious dioxin contamination recently occurred twice in products to be used in animal nutrition. Taking into account the experience gained from these incidents, it is necessary to improve the procedures applicable to cases where a product for animal nutrition poses a serious risk to human or animal health or to the environment or where certain infringements of Directive 1999/29/EC are detected. The aim is in this way to improve the management of risks which would preclude the level of protection of human or animal health and of the environment provided for in the Community Regulation on animal nutrition while not trivialising those special procedures by systematically applying them to minor problems.

(5) A Commission inspection carried out following dioxin contamination of the feed and food chain revealed that Member States had had difficulty in managing such an unusual crisis. In the light of the experience gained, and in order to ensure that serious risks involving a product for animal nutrition are managed with equivalent guarantees of efficiency throughout the Community, it is necessary to introduce provisions requiring the Members States to have in place contingency operational plans to deal with emergencies in the animal nutrition sector.

(6) Where a serious risk to human or animal health or to the environment arises in a Member State due to products for animal nutrition, and where that risk cannot be contained satisfactorily by the Member State(s) concerned, it is indispensable for the Commission to be able to take all the necessary precautionary measures and to have in particular the authority to suspend trade in, and exports of, products for animal nutrition from all or part of the Member State concerned or to establish special conditions for the relevant products or substances.

(7) Directive 1999/29/EC establishes the maximum permitted levels for certain undesirable substances and products in feed materials and feeding stuffs.

(8) A system has already been established to enable the Member States to be informed by operators, at all stages of the feed producing chain, of certain cases of non compliance with the rules on undesirable products and substances. In view of both the experience gained and the similar arrangements provided for in the Community rules on general product safety, that system should be improved and extended to render it applicable to all

[1] OJ C 274 E, 26.9.2000, p. 28 and OJ C 96 E, 27.3.2001, p. 279.
[2] OJ C 367, 20.12.2000, p. 11.
[3] Opinion of the European Parliament of 4 October 2000 (not yet published in the Official Journal), Council Common Position of 12 February 2001 (OJ C 93, 23.3.2001, p. 1) and Decision of the European Parliament of 15 May 2001 (not yet published in the Official Journal). Council Decision of 19 June 2001.
[4] OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2000/77/EC of the European Parliament and of the Council (OJ L 333, 29.12.2000, p. 81).
[5] OJ L 115, 4.5.1999, p. 32.
[6] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs (OJ L 270, 14.12.1970, p. 1). Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).
[7] Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials (OJ L 125, 23.5.1996, p. 35). Directive as last amended by Directive 2000/16/EC of the European Parliament and of the Council (OJ L 105, 3.5.2000, p. 36).

cases where an operator finds that a product for animal nutrition poses a serious risk to human or animal health or to the environment.

(9) At present there is an obligation to inform the other Member States and the Commission when a consignment of feed materials or feeding stuffs which is not in compliance with the maximum levels for undesirable substances or products is likely to be sent to other Member States.

(10) It is necessary to incorporate this rapid information exchange system into Directive 95/53/EC and set standard procedures for its operation, so that it can be applied in future in all cases where a product endangers human health, animal health or the environment and for the purpose of improving the inspection system as a whole. For reasons of simplicity and efficiency, the system should also apply where a Member State refuses a product from a third country when checking it upon importation. These standard procedures could, subject to certain amendments, be the same as those laid down for exchanging information in emergencies pursuant to Council Directive 92/59/EEC of 29 June 1992 on general product safety ([1]).

(11) It is not possible to list all potentially dangerous contaminations of biological or chemical origin, which may happen by accident or by illegal action, and may affect a product to be used in animal nutrition.

(12) The risk of hazards deriving from mislabeling or from handling, transport, storage or processing should be taken into consideration.

(13) To improve the efficiency of the inspection system and the relevant inspection measures, where there is a suspicion of contamination posing a serious risk to human health, animal health or to the environment, Member States should be required to verify the nature and extent of the contamination and to make every effort to identify its origin in order to detect any other possible contamination.

(14) Directive 95/53/EC requires Member States to submit to the Commission information on the results of inspections carried out each year, before 1 April 2000 for the first time. It is also laid down that those reports will be used by the Commission to prepare and submit an overall summary report on inspections carried out at Community level together with a proposal for a coordinated inspection programme for the following year. Information concerning contamination affecting the safety of a product to be used in animal nutrition shall be considered by the Member States and the Commission in fixing the priorities for annual coordinated inspection programmes. All the information gathered on risks to human health, animal health or to the environment, relating to the circulation and use of products for animal nutrition, can be better analysed when provided in harmonised and standardised form.

(15) Taking into account the foregoing, Directives 95/53/EC, 70/524/EEC, 96/25/EC and 1999/29/EC should be amended,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Council Directive 95/53/EC is amended as follows:

1. Article 2(1) is amended as follows:

   (a) in point (a), the second indent shall be replaced by the following:

   '— Council Directive 1999/29/EC of 22 April 1999 on undesirable substances and products in animal nutrition (*).

   (*) OJ L 115, 4.5.1999, p. 32.'

   (b) point (e) shall be replaced by the following:

   '(e) "product intended for animal nutrition" or "product": animal feed or any substance used in animal nutrition;'

   (c) point (h) shall be replaced by the following:

   '(h) "putting into circulation" or "circulation": the holding of any product intended for animal nutrition for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves.';

2. the following Article shall be added after Article 4:

'*Article 4a*

1. Member States shall draw up contingency operational plans setting out measures to be implemented without delay where a product for animal nutrition has been found to pose a serious risk to human health, animal health or to the environment and specifying powers and responsibilities as well as channels for transmitting information. Member States shall review these plans as appropriate, particularly in the light of changes in the organisation of the inspection services and of the experience gained, including that gained in any simulation exercises.

2. Member States shall forward to the Commission the contingency operational plans drawn up by them and also any amendments thereto.

([1]) OJ L 228, 11.8.1992, p. 24.