

Proposal for a European Parliament and Council Directive amending Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition and Council Directive 1999/29/EC on undesirable substances and products in animal nutrition

(2000/C 274 E/04)

(Text with EEA relevance)

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(Submitted by the Commission on 21 March 2000)

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,

Having regard to the opinion of the Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

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

Whereas:

- (1) The safety of products destined for animal nutrition is of primary concern and it is necessary to ensure that products placed in the market for animal nutrition are safe. Council Directive 95/53/EC ⁽¹⁾ of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition contributes to the achievement of such objective. It is necessary to amend Directive 95/53 for the following reasons.
- (2) Council Directive 74/63/EEC ⁽²⁾ has been replaced by Council Directive 1999/29/EC ⁽³⁾ of 22 April 1999 on the undesirable substances and products in animal nutrition, therefore references to Directive 74/63/EEC shall be amended.
- (3) With reference to the circulation of products to be used in animal nutrition, it is necessary to harmonise the definitions for products to be used in animal nutrition with more recent Community legislation.
- (4) Serious dioxin contamination recently occurred twice in feed materials and feedingstuffs. The experience gained from these contaminations suggests that it is necessary

to improve the procedures both in taking protective measures and in exchanging information between Member States and the Commission in the event of the detection of non-conformity of products intended to be used in animal nutrition and in the event of immediate risk to public health, animal health or the environment.

- (5) The result of a Commission inspection carried out following dioxin contamination of feed and of the food chain identified operational deficiencies in the management of the dioxin crisis. In the light of the experience gained, it is necessary to introduce provisions requiring the Member States to have in place contingency plans to deal with emergencies in the animal feed sector. Such contingency plans are also necessary to collect properly the necessary information.
- (6) In case of a serious and immediate risk to animal health appearing in a Member State due to contamination of feed it is indispensable for the Commission to be able to take all the necessary precautionary measures to protect public and animal health. Therefore the Commission must have in particular the ability to suspend trade and exports from all or part of the Member State concerned and/or to establish special conditions for the relevant products or substances.
- (7) It is appropriate for the Commission to be able to take provisional protective measures, applicable at an early stage in the food chain, in particular in feed materials and feedingstuffs, in order to improve efficiency in reducing the spread of a hazard. This efficiency is also dependent on the uniform application throughout the Community of these provisional protective measures.
- (8) Directive 1999/29/EC establishes the maximum limits for certain undesirable substances and products whose presence cannot be totally excluded in a certain number of feed materials or feedingstuffs.
- (9) A system is established by Directive 1999/29/EC, at official inspection level, to enable the Member States to be informed by operators, at all stages of the feed producing chain, of cases of non-compliance with the above directive on undesirable products and substances. At present the obligation to inform the other Member States and the Commission is only required when a batch of feed materials or feedingstuffs, which is not in compliance with the directive, is likely to be sent to other Member States.

⁽¹⁾ OJ L 265, 8.11.1995, p. 17.

⁽²⁾ OJ L 38, 11.2.1974, p. 31 as last amended by Commission Directive 98/60/EC (OJ L 209, 25.7.1998, p. 50).

⁽³⁾ OJ L 115, 4.5.1999, p. 32.

- (10) It is necessary to incorporate such information system into Directive 95/53/EC so that it can be applied in future in all cases where a product endangers public health, animal health or the environment and for purposes of improving the inspection system as a whole.
- (11) It is not possible to list all potentially dangerous contaminations of biological or chemical origin, which may happen by accident or by illegal actions, and may affect products to be used in animal nutrition.
- (12) The risk of hazards originated by mislabelling or originating during handling, transport, storage or processing shall be considered.
- (13) To improve the effectiveness of the inspection system and the relevant inspection measures Member States must be obliged 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 lays down that Member States shall 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 these 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 for public health, animal health or the environment, relating to the circulation and use of products intended for animal nutrition, can be better analysed when provided in harmonised and standardised form; it is therefore appropriate to monitor the occurrence of certain cases of contamination or contamination occurring in certain products or practices which may lead to hazards.
- (15) The uniform and harmonised application of control programmes at Community level is essential to guarantee the safety of products to be used in animal nutrition and that the legal instrument of a decision provides better guarantees as regards its implementation than a recommendation, and that this has to be taken into account when setting coordinated control programmes.
- (16) Procedures have been established for the exchange of information in emergency situations under Council Directive 92/59/EEC⁽¹⁾ on general product safety, and taking into account that such procedures may be used for a matter of harmonisation and efficiency for the exchange of information in emergency related to animal nutrition,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/53/EC is amended as follows:

1. Article 2(1)(a) second indent is replaced by the following:

‘Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition.’

2. Article 2(1)(h) is replaced by the following:

“‘putting into circulation” (“circulation”): the holding of products to be used in 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.’

3. The following Article 4a is added after Article 4:

‘Article 4a

1. Member States shall set up national contingency operational plans to deal with emergencies relating to the detection of serious risks for public health, animal health or the environment from products for animal nutrition.

2. The Commission shall, in accordance with the procedure laid down in Article 23, set criteria for drawing up minimum requirements for the contingency plans by (October 2000). Such criteria may be amended taking into account the experience gained.

3. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendment required.

4. The efficiency of such contingency plans shall be verified by blind simulations, and on regular basis with particular reference when changes in the structure of the relevant control services takes place, and the plans shall be amended as necessary.’

4. The following Section 3a is added after Article 15:

‘Section 3a

Safeguard clause

Article 15a

1. Where a problem, due to a product to be used in animal nutrition, likely to pose a serious risk to human or animal health or to the environment appears or spreads on the territory of the European Union, the Commission, on its own initiative or at the request of a Member State, shall immediately, depending on the seriousness of the situation:

- suspend the putting into circulation within the Community and exports to third countries from all or part of the Member State(s) concerned and/or
- lay down special conditions for the putting into circulation in the Community and/or exports to third countries of products from all or part of the Member State(s) concerned.

⁽¹⁾ OJ L 228, 11.8.1992, p. 24.

2. The Commission shall notify the Council and Member States of any decision adopted in accordance with paragraph 1.

Except in emergencies, the Commission shall consult the Member States before taking the measures referred to in paragraph 1.

3. Any Member State may, within thirty days of such notification, refer the Commission's decision to the Council. The Council, acting by a qualified majority, may take a different decision within thirty days.

4. Where a Member State officially informs the Commission of the need to take protective measures and where the Commission has not acted in accordance with paragraph 1, that Member State may adopt temporary protective measures with regard to trade. Where a Member State adopts temporary protective measures, it shall inform the other Member States and the Commission. The Commission shall submit the question to the Standing Committee for Feedingstuffs within ten working days for its opinion in accordance with the procedure laid down in Article 23 with a view to the extension, amendment or repeal of the national temporary protective measures.'

5. The following Chapter 'III A' is added after Article 16:

'CHAPTER III A

INFORMATION SYSTEM FOR HAZARDS FROM FEED-INGSTUFFS

Article 16a

1. Member States shall prescribe that when an operator (importer, intermediaries, producer, etc.) or a person who, by virtue of his professional activities possess or has possessed or has had direct contact with a consignment of products to be used in animal nutrition, in its broader meaning, and has knowledge to the effect that:

- the consignment of products to be used for animal nutrition is contaminated by dangerous substances or products or organisms, or hazard may derive from mislabelling or from handling, transport, storage, or manufacturing;
- the consignment of feed materials does not comply with the provisions laid down in Directive 1999/29/EC;

and therefore is aware that such a consignment constitutes a serious risk for animal and/or public health or the environment, such a person or operator shall immediately inform the official authorities even if the destruction, withdrawal from the market or reprocessing of the consignment is envisaged.

2. In verifying the information received, the official authorities shall take the necessary measures to ensure that the consignment is not used in animal nutrition and in particular shall put the consignment under restriction and investigate immediately:

- the nature of the hazard and when necessary the level of the contamination;
- the possible origin of the contamination or of the hazard.

Member States shall ensure that the final destination of the contaminated consignment, including possible decontamination, reprocessing or destruction, cannot have harmful effects on public or animal health or on the environment.

3. Where it cannot be excluded that the contamination or the hazard could have been extended to the feed and food chain or occurred in other batches, the relevant authorities of the Member State shall immediately:

- trace and put under restriction any batch of the product deemed hazardous, including live animals fed with hazardous feed and products or by-products thereof ensuring coordination between the relevant control services with particular reference to avoid the hazardous products from being placed on the market and to the enforcement of recall procedures for the products already on the market;
- carry out a preliminary risk assessment on:
 - a) possible cross contamination with other products used or to be used in the feed chain;
 - b) possible recycling of hazardous products in the feed chain
- inform immediately the Commission with particular reference to sufficient information to trace and identify feed materials, live animals and products thereof and on safeguard measures envisaged or already taken, in order to enable the Commission to inform properly the other Member States.

Any Member state concerned shall inform the Commission of any follow up measure taken in respect of the notified hazards including information related to the end of the risk situation.

4. The Commission and the Member States shall operate this system for exchange of information in application of this directive with the same procedure applied for the rapid alert system established in Council Directive 92/59/EC on general product safety.'

6. Article 22 is amended as follows:

1. The following paragraph '2a' is added:

'Member States shall keep records of actions taken when operating in conformity with Article 16a(2) and include a summary of these actions in the annual report to the Commission.

When the frequency of a certain contamination or hazard deriving from a certain product to be used in animal nutrition increases, an interim report shall be provided, without delay, to the Commission.

The information contained in interim reports shall be discussed in the Standing Committee for Feedingstuffs in order to take the appropriate measures.

Annual reports and interim reports shall be provided in accordance with a model to be established in accordance with Article 23.'

2. The first sentence of paragraph 3 is modified as follows:

1. After the words '... Community level,' is inserted the following text: 'and a summary of the interim reports'.
2. The word 'recommendation' is replaced with 'decision'.

Article 2

Paragraphs 3 and 4 of Article 12 of Council Directive 1999/29/EC are repealed.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than (31 December 2000). They shall apply these provisions from (1 January 2001).

They shall forthwith inform the Commission thereof.

2. When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by the Member States.

3. Member States shall communicate to the Commission the text of the essential provisions of national law they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the twentieth day following its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.
