

**Amended 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 <sup>(1)</sup>**

(2001/C 96 E/24)

(Text with EEA relevance)

COM(2000) 777 final — 2000/0068(COD)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 1 December 2000)

<sup>(1)</sup> OJ C 274 E, 26.9.2000, p. 28.

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INITIAL PROPOSAL

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 <sup>(1)</sup> 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 <sup>(2)</sup> has been replaced by Council Directive 1999/29/EC <sup>(3)</sup> of 22 April 1999 on the undesirable substances and products in animal nutrition, therefore references to Directive 74/63/EEC shall be amended.

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<sup>(1)</sup> OJ L 265, 8.11.1995, p. 17.

<sup>(2)</sup> 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).

<sup>(3)</sup> OJ L 115, 4.5.1999, p. 32.

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Unchanged

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- (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.

- (7) Serious dioxin contamination recently occurred twice in feed materials and feedingstuffs. The experience gained from these contamination suggests that it is necessary to improve the procedures taking protective measures and in exchanging information between Member States and the Commission in the event of 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.

- (8) 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.

- (9) 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.

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- (4) Rules must be laid down for the organization of official inspections of feedingstuffs in view of the very wide range of products used, the large volume of consignments of goods commercially traded, the integrated structure of the sector and, in particular, the need to ensure both the wholesomeness of the feedingstuff to be consumed by animals and the quality of the food.

- (5) As regards intra-Community trade, emphasis should be placed on the checks to be carried out at the place of origin; however, in the event of a presumption of irregularity, the check may be carried out while the products are in transit or at the place of destination.

- (6) The authorities responsible for inspections may differ from one Member State to another; it is therefore necessary to publish a list of the competent authorities in the field in each Member State, with an indication of the territories for which they are competent and the laboratories authorized to carry out analyses in connection with such inspections.

- (7) Serious dioxin contamination recently occurred twice in feed materials and feedingstuffs. The experience gained from these incidents suggests that it is necessary to improve the procedures for taking protective measures and exchanging information between Member States and the Commission in the event of detection of non-conformity of products intended to be used in animal nutrition and in the event of risk to public health, animal health or the environment.

Unchanged

- (9) In the event of a serious risk to human or animal health or the environment appearing in a Member State due to harmful feed it is indispensable for the Commission to be able to take all the necessary precautionary measures to protect public and animal health and the environment. 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.

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(10) 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.

(11) 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.

(12) 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.

(13) 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.

(14) it is not possible difficult to list all potentially dangerous contaminations of biological or chemical origin, which may happen by accident or by illegal actions, and may affect to be used in animal nutrition,

(15) The risk of hazards originated by mislabelling or originating during handling, transport, storage or processing shall be considered.

(16) 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.

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(10) It is necessary 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.

Unchanged

(14) Although it is difficult 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, it would be desirable, in the framework of current scientific knowledge, as in the case of the directive on undesirable substances and products, for a non-exhaustive list of biological and chemical contaminants to be established

Unchanged

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- (17) 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.
- (18) 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 regard its implementation than a recommendation, and that this has to be taken into account when setting coordinated control programmes.
- (19) Procedures have been established for the exchange of information in emergency situations under Council Directive 92/59/EEC<sup>(1)</sup> 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.

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- (19) Procedures have been established for the exchange of information in emergency situations under Council Directive 92/59/EEC<sup>(1)</sup> on general product safety, and taking into account that such procedures, may be used, after certain changes in the interest of harmonisation and efficiency for the exchange of information in emergency related to animal nutrition.
- (19a) The obligation on persons and operators to inform the official authorities when a batch of feed materials or feedingstuffs constitutes a serious risk for animal and/or human health and/or for the environment must not be seen as encouraging denunciation but basically as a means to enable the inspection services to take the necessary measures to withdraw a batch from circulation.
- (19b) Member States should provide that officials responsible for inspection are subject to professional confidentiality in respect of information which, if disclosed, would be likely to damage the activities of an undertaking. Protection of trade secrets must not, however, prevent publication of information which is in the public interest from an environmental and health protection point of view,

<sup>(1)</sup> OJ L 228, 11.8.1992, p. 24.

<sup>(1)</sup> OJ L 228, 11.8.1992, p. 24.

## INITIAL PROPOSAL

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.’

3. 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.’

4. 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 a regular basis, with particular reference when changes in the structure of the relevant control services take place, and the plans shall be amended as necessary.’

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Unchanged

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

‘“establishment”: means any undertaking which produces or manufactures a product intended for animal nutrition or which holds the product at an intermediate stage before marketing or which markets the products;’

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

‘“putting into circulation” (“circulation”): the holding of any type 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.’

Unchanged

5. Article 13(1), second indent, is replaced by the following:

‘— rendering the products harmless where appropriate, or’

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7. 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.

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.

6. Article 14, first paragraph, is replaced by the following:

'In the event of the destruction, use for other purposes, redispach to the country of origin or rendering harmless of the products as provided for in Article 13(1), the Member State of destination shall contact the Member State of dispatch without delay. In other cases, the Member State of destination may contact the Member State of dispatch. The Member State of dispatch shall take all necessary measures and notify the Member State of destination of the nature and outcome of the checks carried out, the decisions taken and the reasons for such decisions.'

Unchanged

- suspend the putting into circulation within the Community, exports to third countries and prohibit the feeding to animals of products from all or part of the Member State(s) concerned or

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

- require the Member State(s) concerned to ensure that the products are recalled where appropriate.

Unchanged

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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.'

8. The following Chapter IIIA 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 possesses 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; products or organisms, or may be hazardous as a result of mislabelling or by virtue of its handling, transport, storage or manufacture.

— 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:

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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 the use or putting into circulation of products. Where a Member State adopts temporary protective measures, it shall immediately 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 Commission shall inform the European Parliament of the measures taken.'

Unchanged

— the consignment of products to be used for animal nutrition contains 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 Directives 1999/29/EC, 70/524/EEC, 82/471/EEC and 96/25/EC <sup>(1)</sup>.

Unchanged

<sup>(1)</sup> OJ L 125, 23.5.1996, p. 35.

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- 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 such as 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 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 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.

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

Member States shall ensure that the final destination of the harmful consignment, including possible processes of rendering it harmless such as decontamination, reprocessing or destruction, cannot have harmful effects on public or animal health or on the environment.

Unchanged

- trace and put under restriction any batch of the product deemed harmful, including live animals fed with hazardous feed and products or by-products thereof ensuring coordination between the relevant control services with particular reference to prevent the harmful products from being placed on the market and to the enforcement of recall procedures for the products already on the market;

Unchanged

b) possible recycling of harmful products in the feed chain

- inform immediately the Commission providing in particular sufficient information to trace and identify products intended for use in animal nutrition, live animals and products thereof and details on any 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 immediately of any follow up measure taken in respect of the notified hazards including information related to the end of the risk situation.



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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.'

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Unchanged

9. Article 17(2) is replaced by the following:

'2. Member States shall provide that officials responsible for inspection are subject to professional confidentiality in respect of information which, if disclosed, might be assumed to prejudice the activities of an undertaking. Such protection of trade secrets may not prevent publication of information which is of public interest from an environmental and health protection point of view.'

10. The following Article 17a is added after Article 17:

*'Article 17a*

1. Without prejudice to Article 15, Commission and Member State experts may carry out on-the-spot inspections with the cooperation of the national competent authorities to verify that the provisions of this Directive, and in particular Articles 4, 5, 7, 11 and 12, are being applied.

The Commission shall appoint Member State experts on a proposal from the Member States.

2. The Member State on whose territory an inspection is carried out shall afford the Commission and Member State experts full assistance to carry out their duties. After informing the Member State concerned and in full collaboration with the competent authorities, an inspection of an establishment may be carried out without giving the operators prior notice.

The Commission shall inform the Member State and the European Parliament of the results of inspections carried out, and shall publish an inspection report.'

11. Article 22 is amended as follows:

Unchanged

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.

'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. An annual report shall be drawn up by the Commission on the basis of the annual reports from the Member States and shall be presented to the European Parliament.

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.

Unchanged

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

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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'.

12. Recitals 3, 11, 17 of Council Directive 95/53/EC are deleted.

## AMENDED PROPOSAL

2. Paragraph 3 is modified as follows:

Unchanged

*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. They shall apply these provisions from.

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.

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than (30 June 2001). They shall apply these provisions from (1 July 2001).

Unchanged

*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.

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