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**COUNCIL DIRECTIVE 95/53/EC**

**of 25 October 1995**

**fixing the principles governing the organization of official inspections in the field of animal nutrition**

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► <b><u>M2</u></b> Directive 2000/77/EC of the European Parliament and of the Council of 14 December 2000	L 333	81	29.12.2000

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**COUNCIL DIRECTIVE 95/53/EC**  
**of 25 October 1995**

**fixing the principles governing the organization of official inspections in the field of animal nutrition**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the European Parliament<sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

Whereas animal nutrition has become a very important aspect of Community agriculture;

Whereas fixing at Community level the principles governing the organization of official inspections in the field of animal nutrition helps safeguard animal health, human health and the environment, ensure the fairness of commercial transactions and protect the interests of consumers;

Whereas 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 foodstuff;

Whereas, in order to attain the desired objective, the rules laid down in this Directive must cover all products and substances used in animal nutrition in the Community; whereas inspections should therefore be organized to cover products imported into or released for free circulation in the Community;

Whereas the definition of 'competent authority' does not prevent Member States from delegating in whole or in part the responsibility of the authority for the purpose of carrying out official checks in the field of animal nutrition, provided that inspections continue to be carried out under their authority;

Whereas, to be effective, inspections must be carried out regularly; whereas they must not be restricted as to the subject, stage or moment at which they are carried out; whereas they must take the most suitable forms to ensure their effectiveness;

Whereas, in order to ensure that inspection procedures are not evaded, it is necessary to provide that Member States shall not exclude a product from appropriate inspection on the grounds that it is intended for export outside the Community;

Whereas products from third countries must be subject to random documentary and identity checks on entry into the Community territory;

Whereas provision should be made for Member States to have the possibility of designating entry points in order to ensure the efficient conduct of inspections of imported products, without prejudice to the provisions laid down in other relevant Community legislation, in particular Directives 90/675/EEC<sup>(4)</sup> and 92/118/EEC<sup>(5)</sup> concerning veterinary checks and animal health and public health requirements;

<sup>(1)</sup> OJ No C 313, 19. 11. 1993, p. 10.

<sup>(2)</sup> OJ No C 128, 9. 5. 1994, p. 97.

<sup>(3)</sup> OJ No C 127, 7. 5. 1994, p. 10.

<sup>(4)</sup> OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Regulation (EEC) No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13).

<sup>(5)</sup> OJ No L 62, 15. 3. 1993, p. 49. Directive as last amended by Commission Decision 94/723/EC (OJ No L 288, 9. 11. 1994, p. 48).

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Whereas principles should be laid down to govern the organization of and steps to be taken following the physical checks to be carried out by the competent authorities;

Whereas, as regards intra-Community trade, emphasis should be placed on the checks to be carried out at the place of origin; whereas, however, in the event of a presumption of irregularity, the check may, exceptionally, be carried out while the products are in transit or at the place of destination;

Whereas this solution requires greater confidence in the inspections carried out by the Member State of dispatch; whereas the Member State of dispatch must ensure that such checks are carried out in an appropriate fashion;

Whereas provision should be made for action to be taken where a check discloses that a consignment is irregular;

Whereas, for reasons of effectiveness, it is for the Member State of dispatch to ensure that the products comply with Community rules; whereas, in the event of infringements, the Commission must be able to take action, in cooperation with the Member States concerned, particularly by making on-the-spot visits and adopting measures appropriate to the situation;

Whereas, in accordance with Council Directive 70/373/EEC<sup>(1)</sup>, all methods of sampling and methods of analysis necessary for carrying out official checks on feedingstuffs should be adopted at Community level;

Whereas, although undertakings should not have the right to oppose inspections, their legitimate rights must nevertheless be preserved, in particular the right to manufacturing secrecy and the right of appeal;

Whereas the authorities responsible for inspections may differ from one Member State to another; whereas it is therefore desirable 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;

Whereas, although it is primarily for the Member States to lay down their inspection programmes, it is necessary, with a view to the proper functioning of the internal market, to arrange also for coordinated programmes at Community level;

Whereas the Commission should be entrusted with the task of adopting measures for applying this Directive,

HAS ADOPTED THIS DIRECTIVE:

#### CHAPTER I

### INTRODUCTORY PROVISIONS

#### *Article 1*

1. This Directive sets out the principles governing the organization of official inspections in the field of animal nutrition.
2. This Directive shall apply without prejudice to more specific Community rules, in particular Community customs rules and Community veterinary rules.

<sup>(1)</sup> OJ No L 170, 3. 8. 1970, p. 2. Directive as last amended by Regulation (EEC) No 3768/85 (OJ No L 362, 31. 12. 1985, p. 8).

**▼B***Article 2*

1. For the purposes of this Directive the following definitions shall apply:

(a) 'official inspection in the field of animal nutrition', hereinafter called 'inspection', means an inspection by the competent authorities to check compliance with the Community provisions laid down in:

- Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs<sup>(1)</sup>,
- Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs<sup>(2)</sup>,

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- Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC,

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- Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs<sup>(3)</sup>,
  - Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>(4)</sup>,
  - Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes<sup>(5)</sup>, and
  - any other rules in the field of animal nutrition in which provision is made for official inspections to be carried out in accordance with the provisions of this Directive;
- (b) 'documentary check' means verification of the documents accompanying a product or of any other information provided on the product;
- (c) 'identity check' means verification, by visual inspection only, for consistency between the documents, the labelling and the products;
- (d) 'physical check' means a check of the product itself, including, where appropriate, sampling and laboratory testing;
- (e) 'product' means feedingstuffs and all substances used in animal nutrition;
- (f) 'competent authority' means the Member State's authority responsible for carrying out official checks in the field of animal nutrition;
- (g) 'establishment' means any undertaking which produces or manufactures a product or which holds the product at an intermediate stage before marketing or which markets the products;
- (h) 'marketing' means the holding of products with a view to their sale or other forms of disposal to others, by way of gift or in return for payment, and also sale and other forms of disposal themselves.
2. The definitions given in the Community legislation relating to the field of animal nutrition shall apply where appropriate.

*Article 3*

1. Member States shall take all the necessary measures to ensure that inspections are carried out in accordance with this Directive.

<sup>(1)</sup> OJ No L 270, 14. 12. 1970. Directive as last amended by Commission Directive 94/77/EC (OJ No L 350, 31. 12. 1994, p. 113).

<sup>(2)</sup> OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Commission Directive 94/16/EC (OJ No L 104, 23. 4. 1994, p. 32).

<sup>(3)</sup> OJ No L 86, 6. 4. 1979, p. 30. Directive as last amended by Directive 93/74/EEC (OJ No L 237, 22. 9. 1993, p. 23).

<sup>(4)</sup> OJ No L 213, 21. 7. 1982, p. 8. Directive as last amended by Directive 93/74/EEC (OJ No L 237, 22. 9. 1993, p. 23).

<sup>(5)</sup> OJ No L 237, 22. 9. 1993, p. 23.

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2. Member States shall not exclude a product from appropriate inspection on the grounds that it is intended for export.

*Article 4*

1. Inspections shall be carried out:
  - (a) at regular intervals;
  - (b) where non-compliance is suspected;
  - (c) using means proportionate to the desired objective and particularly in the light of the risks and of experience gained.
2. Inspections shall cover all stages of production and manufacture, the intermediate stages prior to marketing, including importation, and the use of products.

The competent authority shall select the stage or stages most appropriate for the intended purpose of the inspection.

3. As a general rule, inspections shall be carried out without prior warning.
4. Inspections shall also cover uses prohibited in relation to animal nutrition.

## CHAPTER II

**IMPORTS FROM THIRD COUNTRIES***Article 5*

Notwithstanding Article 4 (1), Member States shall take all the necessary steps to ensure that when products are introduced into the customs territory of the Community they are subjected by the competent authorities to a documentary check of each batch and to random identity checks in order to verify:

- their nature,
- their origin,
- their geographical destination,

so as to determine the customs procedure applicable to them.

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Where appropriate, detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 23.

**▼B***Article 6*

For the purpose of the checks provided for in Article 5, Member States may designate particular entry points in their territory for the various types of products.

To the same end they may require notice to be given to them of arrival of products at a particular entry point.

*Article 7*

Member States shall ensure the conformity of products by means of random physical checks before they are marketed.

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Where appropriate, detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 23.

**▼B***Article 8*

1. Where the checks show that products do not meet the requirements of the rules, the Member State shall prohibit their entry or marketing and order their redispach out of Community territory; it shall immediately

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inform the Commission and the other Member States that it has rejected the products, indicating the infringements found.

2. Notwithstanding paragraph 1, Member States may authorize the carrying out, under the conditions laid down by the competent authority, of one of the following operations:

- bringing the products into line with the requirements within a deadline to be determined, or
- decontamination where appropriate, or
- processing in any other suitable manner, or
- use for other purposes, or
- destruction of the products.

Member States shall ensure that the operations listed in the first subparagraph do not give rise to any adverse effects on human and animal health or on the environment.

3. The costs incurred in the measures taken in accordance with paragraphs 1 and 2 shall be borne by the authorization holder or his representative.

*Article 9*

1. Where products are not marketed in the territory of the Member State which carries out the checks referred to in Article 5 and, where appropriate, a physical check, that Member State shall provide the person concerned with a document indicating the type of check carried out and its outcome. Commercial documents shall contain a reference to this document.

However, the right of the Member State of destination to carry out random checks on products shall not be affected.

2. A standard document and, where appropriate, detailed rules for the application of paragraph 1 shall be adopted in accordance with the procedure laid down in Article 23 before the 30 April 1998.

**▼M2***Article 9a*

1. Where a problem likely to pose a serious risk to human or animal health or the environment appears or spreads on the territory of a third country, the Commission, on its own initiative or at the request of a Member State, shall immediately depending on the gravity of the situation take the following measures, in accordance with the procedure laid down in Article 23a:

- suspend imports of products from all or part of the third country concerned or from one or more specific production establishments and, where appropriate, any third country of transit and/or
- lay down special conditions for products intended for import from all or part of the third country concerned.

2. However, in emergencies, the Commission may provisionally adopt the measures referred to in paragraph 1 after informing the Member States. It shall submit the matter to the Standing Committee for Feedingstuffs within ten working days for its opinion, in accordance with the procedure laid down in Article 23a, with a view to the extension, amendment or repeal of those measures. For such time as the measures adopted by the Commission have not been replaced by another legal act, they shall continue to apply.

3. 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 imports. Where a Member State adopts temporary protective measures, it shall immediately inform the other Member States and the Commission. The Commission shall submit the matter to the Standing Committee for Feedingstuffs within ten working days in accordance with the procedure laid down in Article

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23 with a view to the extension, amendment or repeal of the national temporary protective measures.

*Article 9b*

1. Where necessary, on-the-spot inspections may be carried out by Commission and Member State experts in third countries to verify whether guarantees, offered by those countries, regarding the conditions for the production and putting into circulation of products can be considered as at least equivalent to those required in the Community.
2. The inspections referred to in paragraph 1 shall be carried out on behalf of the Community, which shall bear the costs thereof.
3. The Commission shall inform the Member States of the results of the inspections referred to in paragraph 1.
4. Where necessary, detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 23.

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## CHAPTER III

**TRADE WITHIN THE COMMUNITY***Article 10*

Member States shall take all necessary measures to ensure that products intended for dispatch to another Member State are inspected with the same care as those intended to be marketed in their own territory.

## Section 1

**Checks at source***Article 11*

1. Member States shall ensure that the competent authority carries out checks on establishments in order to satisfy itself that they meet their obligations under Community rules and that products intended to be marketed comply with Community requirements.
2. Where there are grounds for suspecting that requirements are not being met, the competent authority shall carry out the necessary checks and, if the suspicion is confirmed, take the appropriate measures.

## Section 2

**Control at destination***Article 12*

1. The competent authority of the Member State of destination may, at places of destination, check the compliance of products with the provisions of Article 2 (1) (a) by means of non-discriminatory random checks.
2. However, where the competent authority of the Member State of transit or the Member State of destination has information leading it to suspect an infringement, checks may also be carried out during the transport of products in its territory.

*Article 13*

1. If, during a check carried out at the place of destination of a consignment or during transport, a Member State establishes the non-compliance of the products with the provisions of Article 2 (1) (a), it shall take the appropriate measures and formally require the consignor, the consignee or any other person entitled to carry out, under the

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conditions laid down by the competent authority, one of the following operations:

- bringing of the products into compliance within a deadline to be determined, or
- decontamination where appropriate, or
- processing in any other suitable manner, or
- use for other purposes, or
- redispach to the country of origin, after informing the competent authority of the country of the establishment of origin, or
- destruction of the products.

2. The costs incurred in the measures taken in accordance with paragraph 1 shall be borne by the consignor or any other person entitled, including where appropriate the consignee.

## Section 3

**Cooperation in the event of infringements***Article 14*

In the event of the destruction, use for other purposes, redispach to the country of origin or decontamination 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.

If the Member State of destination fears that such measures are inadequate, the two Member States shall together seek ways and means of remedying the situation; if appropriate this may involve a joint on-the-spot inspection.

Where the checks carried out in accordance with Article 12 show repeated irregularities, the Member State of destination shall inform the Commission and the other Member States.

*Article 15*

1. At the request of the Member State of destination or on its own initiative, taking into account the nature of the infringements established, the Commission may:

- send representatives, in cooperation with the Member State concerned, to the establishment in question,
- request the Member State of dispatch to intensify its checks on the products of the establishment concerned.

2. The Commission shall inform the Member States concerned of its findings.

Pending the Commission's findings, the Member State of dispatch must, if so requested by the Member State of destination, intensify checks on products coming from the establishment in question.

The Member State of destination may, for its part, intensify checks on products coming from the same establishment.

3. The Commission may review the situation within the Committee referred to in Article 23. It may adopt the necessary decisions, including those relating to intra-Community movements of products, in accordance with the procedure laid down in the same Article.



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## Section 4

**Inspections on holdings***Article 16*

Member States shall ensure that the competent authority has access to places where agricultural production is carried on and where the products are manufactured or used in order to carry out the prescribed checks.

## CHAPTER IV

**▼M2****GENERAL PROVISIONS AND INSPECTIONS****▼B***Article 17*

1. Member States shall ensure that inspections are carried out in such a way that delays in the delivery of products are minimized and that inspections do not result in unjustified obstacles to the marketing thereof.
2. Member States shall provide that officials responsible for inspection are subject to professional confidentiality.

**▼M2***Article 17a*

1. Without prejudice to Article 15, and insofar as necessary for the uniform application of the requirements of this Directive, Commission and Member State experts may carry out on-the-spot inspections, in cooperation with the competent national 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.
3. The outcome of the inspections made shall be discussed with the competent authority of the Member State concerned before a final report is drawn up and circulated.

The Commission shall inform the Member States and the European Parliament of the results of inspections carried out.

4. Where the Commission or a Member State considers that the results of an inspection justify it, these shall be examined in the Standing Committee for Feedingstuffs. The Commission shall adopt any necessary decisions in accordance with the procedure laid down in Article 23.
5. The Commission shall monitor the situation and amend or repeal the decisions referred to in paragraph 4 in accordance with the procedure laid down in Article 23.
6. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 23.

**▼B***Article 18*

1. Where products are sampled for the purpose of analysis, Member States shall adopt the provisions necessary:
  - to ensure that those subject to checks are entitled to a second opinion,
  - to ensure that officially sealed reference samples are preserved.

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2. Member States shall draw up a list of laboratories responsible for carrying out analyses; they shall ensure that such laboratories are designated on account of their capabilities.

3. Member States shall ensure that sampling and analysis are carried out in accordance with Community rules.

However, in the absence of Community rules and methods, Member States shall take all necessary steps to satisfy themselves that inspections are carried out:

- in accordance with standards recognized by international bodies,
- in the absence of such standards, in accordance with scientifically recognized national rules which comply with the general principles of the Treaty.

4. Detailed rules for the application of this Article may be adopted in accordance with the procedure laid down in Article 23.

*Article 19*

Each Member State shall take the measures required to ensure that all the provisions of this Directive are applied in full. Penalties must be laid down for the event of a failure to comply with those measures. Such penalties shall be effective, shall be commensurate with their purpose and shall have an adequate deterrent effect.

*Article 20*

Rights of appeal existing under the laws in force in the Member States against decisions by the competent authorities shall not be affected by this Directive.

Decisions taken by the competent authority where an infringement has been found and the reasons for such decisions must be notified to the operator concerned by such decisions or his representative.

If the operator concerned or his representative so requests, the said decisions and reasons must be communicated to him in writing with details of the rights of appeal which are available to him under the law in force in the Member State performing the checks and of the procedure and time limits applicable.

*Article 21*

Each Member State shall communicate to the Commission one year after this Directive enters into force:

- the competent authority or authorities, their geographical coverage and their sphere of competence,
- the laboratory or laboratories referred to in Article 18 (2),
- where appropriate, the list of entry points referred to in Article 6.

This information, together with subsequent amendments, shall be published in the 'C' series of the *Official Journal of the European Communities*.

*Article 22*

1. By 1 October 1998 at the latest, Member States shall draw up programmes setting out the national measures to be taken to achieve the aim of this Directive.

These programmes must take into account the specific situation of each Member State and specify the type and frequency of the inspections, which must be performed regularly.

2. Before 1 April each year and before 1 April 2000 for the first time, the Member States shall transmit to the Commission all relevant information concerning the implementation of the programmes referred to in paragraph 1 during the previous year, specifying:

- the criteria used in drawing up the programmes,
- the number and type of inspections carried out,

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- the results of the inspections, in particular the number and type of infringements found,
- action taken where infringements have been found.

3. Before 1 October each year and before 1 October 2000 for the first time, the Commission shall submit an overall summary report on the results of inspections carried out at Community level, together with a proposal for a recommendation concerning a coordinated inspection programme for the following year, for adoption in accordance with the procedure under Article 23. This recommendation may be amended at a later date as required by the implementation of the coordinated programme.

The coordinated programme shall indicate, in particular, the priority criteria to be followed for its implementation.

The information provided for in paragraph 2 shall contain a separate section specifically concerning implementation of the coordinated programme.

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4. Without prejudice to paragraphs 1, 2 and 3, where the protection of human or animal health or the environment requires the prompt introduction of limited, specific, coordinated programmes of inspections at Community level, the Commission shall take the necessary measures in accordance with the procedure laid down in Article 23.

These programmes shall in particular serve in situations provoked by a specific incident.

*Article 23*

1. The Commission shall be assisted by the Standing Committee for Feedingstuffs (hereinafter referred to as 'the Committee').

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be 3 months.

3. The Committee shall adopt its rules of procedure.

*Article 23a*

1. The Commission shall be assisted by the Standing Committee for Feedingstuffs (hereinafter referred to as 'the Committee').

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be 15 days.

3. The Committee shall adopt its rules of procedure.

**▼B***Article 24*

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 April 1998. They shall forthwith inform the Commission thereof.

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

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the area covered by this Directive.

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*Article 25*

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

*Article 26*

This Directive is addressed to the Member States.