II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 16 September 1986

concerning the examination of animals and fresh meat for the presence of residues

(86/469/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (1), as last amended by Regulation (EEC) No 3768/85 (2), and in particular Article 4 thereof,

Having regard to Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substance having a thyrostatic action (3),

Having regard to the proposals from the Commission (4),

Having regard to the opinions of the European Parliament (5),

Having regard to the opinions of the Economic and Social Committee (6),

Whereas Article 4 (2) of Directive 64/433/EEC lays down as regards examination of animals or meat for residues that the Council shall adopt :

— the detailed arrangements for controls,

— the tolerances for the substances referred to in the second subparagraph of Article 4 (1) (b) of that Directive,

— the frequency of sampling ;

Whereas, on 16 July 1985, the Council, by Directive 85/358/EEC supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (7), adopted certain rules of control with a view to guaranteeing the uniform application of Directive 81/602/EEC ; whereas supplementary measures would appear to be appropriate ;

Whereas the detailed arrangements for controls of animals and fresh meat for residues, for the frequency of sampling of animals or meat, for examination for residues, and for the establishment of maximum permitted limits of residues of substances having a pharmacological action and of the conversion products thereof and other substances transmitted to meat are regulated in a differing fashion in the Member States ; whereas the consequences of such residues for human health are assessed differently in such regulations ; whereas these differences lead to major obstacles in intra-Community trade and to a distortion in the conditions of competition between products that are the subject of common organizations of the market ;

Whereas it is therefore necessary to adopt a general solution concerning controls in the Community of farm animals and meat and meat products obtained therefrom for the presence of residues, whether these products are intended for the national market of Member States or intra-Community trade ;

Whereas it is desirable that Member States should draw up plans which take account of their situation ; whereas these plans must be approved and, if necessary, amended or amplified by means of a Community procedure ;

(1) OJ No 121, 29. 7. 1964, p. 2012/64.
(2) OJ No L 362, 31. 12. 1985, p. 8.
(3) OJ No L 222, 7. 8. 1981, p. 32.
(4) OJ No C 251, 1. 10. 1981, p. 7 and OJ No C 132, 31. 5. 1985, p. 5.
(5) OJ No C 267, 11. 10. 1982, p. 59 and OJ No C 120, 20. 5. 1986, p. 176.
(6) OJ No C 112, 3. 5. 1982, p. 5 and OJ No C 75, 3. 4. 1986, p. 1.
(7) OJ No L 191, 23. 7. 1985, p. 46.

Whereas it is appropriate to provide that sampling be carried out officially in the Member States in accordance with common criteria for the different groups of substances of concern; whereas it is appropriate that samples are subject to examination at officially authorized laboratories;

Whereas it is appropriate that the national reference laboratories designated in accordance with Article 4 (1) (b) of Directive 64/433/EEC should coordinate the standards and methods of analysis used in their respective territories; whereas it is appropriate that for each residue or group of residues of concern a Community laboratory should be designated for liaison with the national reference laboratories;

Whereas further details of the criteria of operation of laboratories should be established later;

Whereas, when an examination reveals the presence of residues, it is necessary that common control measures are taken to ascertain and eliminate the cause of the residue, and which ensure that meat showing residues which exceed the permitted level is excluded from consumption;

Whereas, in order to make it easier to implement the provisions envisaged, provision should be made for a procedure which establishes close cooperation between the Member States and the Commission within the Standing Veterinary Committee set up by Decision 68/361/EEC (1);

Whereas it is necessary to keep under review the details of the controls carried out in particular in terms of the results which are found;

Whereas it is necessary to provide for the amendment and, where necessary, supplementation of technical provisions concerning controls and frequency of sampling to take account of new knowledge and scientific and technical developments;

Whereas it is desirable that Community control measures be introduced to guarantee uniform application in all Member States of the provisions of this Directive;

Whereas provision should be made for a procedure designed to settle any conflict which might arise between Member States on the efficiency of the controls provided for by this Directive;

Whereas the adoption of a harmonized set of rules in the Community leads to the setting-up of arrangements for imports from third countries, offering equivalent guarantees; whereas, in this connection, Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (2) should be amended;

Whereas the decisions necessary to set up the arrangements for imports from third countries must be adopted both in the framework of Directive 72/462/EEC and that established by this Directive;

(1) OJ No L 255, 18. 10. 1968, p. 23.
(2) OJ No L 302, 31. 12. 1972, p. 28.

Whereas it is desirable to entrust the Commission with the task of taking certain measures for the application of this Directive; whereas, with this in mind, provision should be made for a procedure which establishes close and efficient cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall ensure that examination of animals, their excrement and body fluids and of tissues and fresh meat for the presence of residues is carried out in accordance with the requirements of this Directive or provisions to be added at a later date, in particular those which will be adopted in accordance with Article 16.

Article 2

The definitions given in Article 2 of Directive 64/433/EEC and, where necessary, those given in Article 1 of Directive 85/649/EEC (3) shall apply for the purposes of this Directive.

In addition:

(a) 'official sample' means a sample, taken by the competent authority, which bears, for the examination of the residue concerned, a reference to the species, the type, the amount and the method of collection and the identification of the origin of the animal and the meat; this sample is to be taken without prior warning;

(b) 'approved laboratory' means a laboratory approved by the competent authorities of a Member State to make an examination of an official sample in order to detect the presence of residues;

(c) 'residue' means residue of substances having a pharmacological action and of conversion products thereof and other substances transmitted to meat and which are likely to be dangerous to human health.

Article 3

Member States shall assign a central department or body to coordinate implementation of the inspections provided for in this Directive. In particular, that department or body shall be responsible for:

— drawing up the plans provided for in Article 4 enabling the competent departments to carry out the required inspections,

— coordinating the activities of regional departments responsible for carrying out inspections for different residues,

— collecting the results of those inspections and the data which must be sent to the Commission.

(3) OJ No L 382, 31. 12. 1985, p. 228.

Article 4

1. Member States shall submit to the Commission :

— by 31 May 1987, a plan setting out the national measures to be taken to achieve the stated objective of this Directive in respect of the substances referred to in Annex I, Group A, I and II,

— by 31 May 1988, a plan stating the measures relating to the examination for residues in substances from the other groups.

Both of these plans will have to take into account the specific situation of each Member State and specify *inter alia :*

— legislation on the use of substances, and in particular on their prohibition or authorization, distribution, placing on the market and rules for administration,

— the infrastructure of the services (in particular giving details of the authorities associated with the implementation of the plans, and the type and size of the bodies involved in such implementation),

— a list of approved laboratories indicating their capacity for processing samples,

— whether there is a total or partial ban on using the substances referred to in Annex I, Group A, in particular in the absence of Community regulations,

— a list of the substances investigated, the methods of analysis and standards for interpreting the findings,

— the number of official samples to be taken in conjunction with the number of animals slaughtered with regard to the species concerned during preceding years,

— a list of the substances referred to in Annex I, Group B, indicating the number of samples and the reasons for this number,

— details of the rules observed when official samples are collected, in particular the rules permitting the indication of the details specified in point (a) of the second paragraph of Article 2,

— the type of measures laid down by the competent authorities with regard to products in which the presence of residues has been detected.

2. The Commission shall examine the plans communicated in accordance with paragraph 1, in order to determine whether they conform to the provisions laid down in this Directive.

3. In accordance with the procedure provided for in Article 15, the Commission shall approve the plans referred to in paragraph 1. In accordance with the same procedure, the Commission may decide that the Member State concerned must amend or supplement the plan which it has submitted. The abovementioned decisions must be adopted by 30 September 1987 for plans relating to inspection for the substances referred to in Annex I, Group A, I and II and by 30 September 1988 for plans relating to inspection for the other residues.

4. At the request of the Member State concerned, and in order to take account of developments in the situation in that Member State or in one of its regions, the Commission may decide, in accordance with the procedure provided for in Article 14, to approve any amendment or addition to a plan previously approved pursuant to paragraph 3.

5. In accordance with the procedure provided for in Article 14, the Commission may decide that a Member State must amend or supplement a plan previously approved pursuant to paragraph 3 in order to take account of the developments in the situation in that State or of findings established under Articles 5, 11 and 12.

Article 5

1. Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

A Member State within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member State concerned of the results of the investigation.

The Member State concerned shall take any measures which may prove necessary to take account of the results of the investigation. If the Member State does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of Article 4 (5).

2. The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down in accordance with the procedure set out in Article 15.

Article 6

Member States shall ensure that during examination for the presence of residues :

— the minimum frequencies for inspections, as laid down in Annex II, are complied with.

However :

(i) Luxembourg shall be authorized to inspect 0,01 and 0,2 % of animals instead of a random statistical frequency of 300 and 700 official samples respectively.

(ii) In the case of the substances referred to in Annex I, Group A, I and II :

— for the initial stage Denmark shall be authorized to carry out inspections using 750 official samples,

— until the total ban on the use of anabolic substances in production for the national market is extended, the United Kingdom shall be authorized to inspect only 0,15 % of animals slaughtered in slaughterhouses approved and inspected in accordance with Articles 8 (1) and 9 of Directive 64/433/EEC, the rest of the bovine population being officially sampled annually at a frequency which gives 99,9 % assurance that in the absence of positive findings, the proportion of the bovine fattening population liable to contain residues will be less than 1 %,

— the inspections are applied in accordance with the procedures to be specified in the plan which will be approved, amended or supplemented pursuant to Article 4.

Article 7

1. The following shall be inserted in Article 3 (2) of Directive 72/462/EEC :

'(f) that country's legislation on the use of substances, in particular legislation concerning the prohibition or authorization of substances, their distribution, release on to the market and their rules covering administration and inspection ;'.

2. Admission to, or retention on, the list referred to in Article 3 of Directive 72/462/EEC shall be subject to the submission, by the third country concerned, of a plan giving details of the guarantees afforded by the said country for the checking of residues.

The effect of these guarantees must be at least equivalent to that resulting from the guarantees provided for by this Directive.

In accordance with the procedure provided for in Article 14, the Commission shall approve the plans in question. Likewise in accordance with this procedure, guarantees alternative to these resulting from the application of this Directive may be allowed.

Decisions to be taken in this context must be adopted :

(i) not later than 31 December 1987 as regards the substances referred to in Annex I, Group A, I and II ;

(ii) not later than 31 December 1988 as regards the substances referred to in Annex I, Group A, III and Group B, I and II.

3. Where no decision within the meaning of paragraph 2 is taken with regard to a given third country by the said dates, entry of that country on the list referred to in Article 3 of Directive 72/462/EEC shall be suspended in accordance with the procedure provided for in Article 14.

4. Compliance by the competent authorities of third countries with the execution of the plans shall be verified when the inspections referred to in Article 5 of Directive 72/462/EEC are carried out.

Article 8

1. Member States shall seek to ensure, when implementing this Directive, that :

(a) official samples are taken from animals, their excrement and body fluids and from tissues and fresh meat for examination at approved laboratories for residues in accordance with Annex II ;

(b) the national reference laboratories designated in accordance with Article 4 (1) (b) of Directive 64/433/EEC coordinate standards and methods of analysis for each residue or group of residues concerned, including the arrangement of periodic comparative tests of split samples by approved laboratories, and compliance with the limits laid down.

2. The Council, acting by a qualified majority on a proposal from the Commission, shall designate for each residue or group of residues a Community reference laboratory which shall be responsible for coordinating inspections, to be selected from among the various national reference laboratories, and shall determine, according to the needs of this Directive, the powers and conditions of operation of those reference laboratories.

3. The analysis of samples referred to in paragraph 1 must be carried out in accordance with methods which are applied by the Member States and have been submitted to the Commission under their inspection plans.

All positive findings must, if challenged, be confirmed by a laboratory officially approved for that purpose by the competent authorities, using the reference methods established pursuant to Article 4 (1) (b) of Directive 64/433/EEC.

Article 9

1. Where an examination of an official sample taken in accordance with Annex II reveals the presence of residues of prohibited substances or quantities of authorized substances exceeding the levels set by Community law or, in their absence, national levels permitted on 16 September 1986 the competent authorities shall seek to ensure that it obtains without delay :

(a) all information, to be established according to the procedure laid down in Article 15, needed to identify the animal and the farm of origin ;

(b) the result of the examination.

Where the results of the controls carried out in one Member State indicate the need for investigation or action in one or more other Member States or in one or more third countries, the Member State concerned shall inform the other Member States and the Commission thereof.

Member States in which an investigation or action proves to be necessary shall take the appropriate measures.

2. The competent authorities shall thereupon ensure that :

(a) an investigation is carried out at the farm of origin to determine the reasons for the presence of residues ;

(b) an investigation of the source or sources of the substances concerned is carried out as necessary at the levels of manufacture, handling, storage, transport, administration, distribution or sale.

3. The competent authorities shall also ensure that :

(a) the herd or animals at the farm of origin and herds which, as a result of the investigations referred to in paragraph 2 may be regarded as containing the residues in question, bear an official marking and are subjected to appropriate examinations ;

(b) if the examination reveals the presence of prohibited substances, the animals may not be placed on the market for human or animal consumption ;

(c) if the conditions of use of an authorized substance have not been respected and, in particular, if the examination reveals the presence of residues of authorized substances above the permitted levels referred to in paragraph 1, the slaughter of animals for human consumption is prohibited until it can be ensured that the amount of residue no longer exceeds the permissible levels. This period may under no circumstances be shorter than the waiting period prescribed for the substances in question ;

(d) during the period of examination, the animals are disposed of to other persons only subject to the control of the official veterinarian.

4. By way of derogation from paragraph 3 (c), animals whose slaughter is prohibited may be slaughtered before the end of the prohibition period if the competent authority has been informed before the envisaged slaughter date, and the place of slaughter has been indicated to it. The officially marked animals must be accompanied to the place of slaughter by an official veterinary certificate containing the information required under paragraph 1 (a).

The meat of each animal whose slaughter is notified pursuant to the first subparagraph shall be officially sampled for the residue concerned and shall be detained until the result of the examination is known.

Meat in which the presence of residues is confirmed must be excluded from human consumption.

5. The competent authorities shall also ensure that the production establishment or animal holdings in the same region or locality supplying the establishment are subject to additional monitoring for the substance concerned.

6. For the effective application of this Directive, a Member State may require that, within its own territory, a register be kept, in particular, on the farm, at the slaughterhouse or at markets.

Article 10

Without prejudice to Article 4, the competent authority may — where there is suspicion that residues are present — subject the animals of the species concerned or the fresh meat in question to examinations to establish the presence of such residues in its national production.

Article 11

1. Where a Member State considers that, in another Member State, the checks provided for in this Directive are not being, or have ceased to be, carried out, it shall inform the competent central authority of that State accordingly. Following an investigation in accordance with Article 9 (2), that authority shall take all necessary measures and shall, at the earliest opportunity, notify the competent central authority of the first Member State of the decisions taken and the reasons for such decisions.

If the first Member State fears that such measures are not being taken or are inadequate, it shall, together with the Member State which has been challenged, seek ways and means of remedying the situation ; if appropriate, this may involve a visit.

Member States shall inform the Commission of disputes and of solutions arrived at.

If the Member States involved are unable to reach agreement, one of them shall bring the matter to the notice of the Commission within a reasonable period of time and the latter shall entrust one or more experts with delivering an opinion.

Pending the experts' conclusions, the Member States of destination may carry out checks on products coming from the establishment or establishments or from a holding or holdings challenged by the dispute and, if the result is positive, take measures similar to those provided for in Article 10 (4) of Directive 64/433/EEC.

In the light of the experts' opinion, appropriate measures may be taken in accordance with the procedure provided for in Article 15.

These measures may be reviewed in accordance with the same procedure should the experts deliver a new opinion within a period of 15 days.

2. The general rules for the application of this Article shall be adopted in accordance with the procedure set out in Article 15.

Article 12

Every year the Member States shall inform the Commission and the other Member States of the implementation of the plans approved in accordance with Article 4. In the light of that information, Article 4 (5) may be invoked.

Within the Standing Veterinary Committee the Commission will inform the Member States periodically — and at all events whenever it sees fit on public health grounds — of the development of the situation in the various regions of the Community.