

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

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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 (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

(1) Whereas by Directive 96/22/EC (4) the Council decided to maintain the prohibition on the use of certain substances having a hormonal or thyrostatic action, by extending it to beta-agonists having an anabolic effect;

(2) Whereas on 9 March 1995 the European Parliament pointed out, inter alia, that the Community urgently needed an effective and uniform monitoring system and asked the Member States to reinforce supervision and monitoring with regard to the use of illegal substances in meat;

(3) Whereas, by Directive 85/358/EEC (5), the Council adopted certain rules on the detection and monitoring of substances having a hormonal or thyrostatic action; whereas those rules should be extended to cover other substances which are used in stockfarming to promote growth and productivity in livestock or for therapeutic purposes and which may prove dangerous to the consumer on account of their residues;

(4) Whereas by Directive 86/469/EEC (6), the Council introduced certain rules on the monitoring of a certain number of residues of pharmacological substances and of environmental contaminants in farm animals and in the fresh meat obtained from such animals; whereas such monitoring should be extended to cover other animal species and all animal products for human consumption;

(5) Whereas Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (7) laid down in its Annexes limits for certain veterinary medicinal products;

(6) Whereas the Community legislation on monitoring residues in meat lacks clarity, giving rise to varying interpretations in the different Member States;

(7) Whereas there is a need to reinforce the controls carried out by and in the Member States;

(8) Whereas producers and others involved in the stockfarming industry should take greater responsibility in future for the quality and safety of meat for human consumption;

(9) Whereas the specific penalties in respect of stockfarmers not complying with Community legislation in particular prohibiting the use of certain hormonal and anabolic substances in stockfarming are to be incorporated in the separate provisions governing particular product groups;

(10) Whereas Article 4 of Directive 71/118/EEC (8) requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological action, their derivatives and other substances which may be transmitted to poultrymeat and which may make the consumption of fresh poultrymeat dangerous or harmful to human health;

(11) Whereas Directive 91/493/EEC (9) requires a monitoring system to be established by the Member States to detect contaminants present in the aquatic environment;

(12) Whereas Directive 92/46/EEC (10) provides that, by 30 June 1993 at the latest, national measures for the detection of residues in raw milk, heat-treated milk and milk-based products shall have been submitted to the Commission by the Member States, the residues to be detected being those in Part A, group III, and Part B, group II, of Annex I to Directive 86/469/EEC;

(13) Whereas Directive 89/437/EEC (11) requires Member States to ensure that checks are conducted to detect residues of substances having a pharmacological or hormonal action, antibiotics, pesticides, detergents and other substances harmful or likely to alter the organoleptic characteristics of egg products or make the consumption of such products dangerous or harmful to human health;

(14) Whereas Directive 92/45/EEC (12) requires Member States to extend their residue detection plans in order to make wild-game meat subject, where necessary, to sampling checks with a view to detecting the presence of contaminants from the environment and to include rabbits and farmed game in such monitoring;

(15) Whereas, if the illegal use of growth and productivity promoters in stockfarming is to be combated effectively in all Member States, action will have to be organized at Community level;

(16) Whereas systems of self-regulation by producer groups can play an important role in combating the illegal use of growth promoters; whereas it is essential for consumers that these systems adequately guarantee the absence of such promoters and whereas a general European approach is essential to safeguard and support self-regulation systems;

(17) Whereas, to that end, producer groups should be assisted in developing self-regulation systems to ensure that their meat is free of unauthorized substances or products;

(18) Whereas a certain number of provisions of Directives 86/469/EEC and 85/358/EEC and of Decisions 89/187/EEC (13) and 91/664/EEC (14) require clarification in the interests of the effective application of controls and residue detection in the Community; whereas, with a view to immediate and uniform application of the controls provided for, the present rules and amendments to them should be assembled in a single text repealing the aforesaid instruments,
HAS ADOPTED THIS DIRECTIVE:

CHAPTER I Scope and definitions

Article 1

This Directive lays down measures to monitor the substances and groups of residues listed in Annex I.

Article 2

For the purposes of this Directive, the definitions in Directive 96/22/EC shall apply. In addition:

- (a) 'unauthorized substances or products' shall mean substances or products the administering of which to animals is prohibited under Community legislation;
- (b) 'illegal treatment' shall mean the use of unauthorized substances or products or the use of substances or products authorized under Community legislation for purposes or under conditions other than those laid down in Community legislation or, where appropriate, in the various national legislations;
- (c) 'residue' shall mean a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health;
- (d) 'competent authority' shall mean the central authority of a Member State competent in veterinary matters or any authority to which such central authority has delegated such competence;
- (e) 'official sample' shall mean a sample taken by the competent authority which bears, for the purposes of examination of the residues or substances listed in Annex I, a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product;
- (f) 'approved laboratory' shall mean a laboratory approved by the competent authorities of a Member State for the purposes of examining an official sample in order to detect the presence of residues;
- (g) 'animal' shall mean the species covered by Directive 90/425/EEC (15);
- (h) 'batch of animals' shall mean a group of animals of the same species, in the same age range, reared on the same holding, at the same time and under the same conditions of rearing;
- (i) 'beta-agonist' shall mean a beta adrenoceptor agonist.

CHAPTER II Monitoring plans for the detection of residues or substances

Article 3

The production process of animals and primary products of animal origin shall be monitored in accordance with this Chapter for the purpose of detecting the presence of the residues and substances listed in Annex I in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water.

Article 4

1. Member States shall assign the task of coordinating the implementation of the inspections provided for in this Chapter, which are carried out within their national territory, to a central public department or body.

2. The department or body referred to in paragraph 1 shall be responsible for:

- (a) drawing up the plan provided for in Article 5 to enable the competent departments to carry out the required inspections;

(b) coordinating the activities of the central and regional departments responsible for monitoring the various residues. Such coordination shall extend to all departments working to prevent the fraudulent use of substances or products on stock farms;

(c) collecting the data needed to evaluate the means used and the results obtained in carrying out the measures provided for in this Chapter;

(d) sending the Commission, by not later than 31 March of each year, the data and results referred to in (c), including the results of any surveys undertaken.

3. This Article shall not affect more specific rules applicable to the monitoring of animal nutrition.

Article 5

1. By 30 June 1997 at the latest, Member States shall submit a plan to the Commission setting out the national measures to be implemented during the initial year of the plan and subsequently any update of plans previously approved in accordance with Article 8 on the basis of the experience of the preceding year, or years by 31 March at the latest of the year of the update.

2. The plan provided for in paragraph 1 shall:

(a) provide for detection of groups of residues or substances according to type of animal, in accordance with Annex II;

(b) specify in particular the measures for detection of the presence of:

(i) the substances referred to in (a) in the animals, in the drinking water of the animals and in all places where the animals are bred or kept;

(ii) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products such as meat, milk, eggs and honey;

(c) comply with the sampling rules and levels laid down in Annexes III and IV.

Article 6

1. The plan must conform to the sampling levels and frequencies laid down in Annex IV. However, at the request of a Member State the Commission may, in accordance with the procedure provided for in Article 32, adjust the minimum control requirements laid down in Annex IV provided that it is clearly established that such adjustments increase the overall effectiveness of the plan in respect of the Member State concerned and in no way reduce its ability to identify residues of, or cases of illegal treatment with, substances listed in Annex I.

2. Re-examination of the groups of residues to be checked for in accordance with Annex II and determination of the sampling levels and frequencies covering the animals and products referred to in Article 3 and not already laid down in Annex IV shall take place in accordance with the procedure provided for in Article 33 and on the first occasion within a maximum of 18 months of the adoption of this Directive. In doing so, account shall be taken of experience gained under existing national measures and information forwarded to the Commission under existing Community requirements making such specific product groups subject to monitoring for residues.

Article 7

The initial plan shall take into account the specific situation of each Member State and specify in particular:

- legislation on the use of the substances listed in Annex I and, in particular, provisions on their prohibition or authorization, distribution and placing on the market and the rules governing their administration, in so far as such legislation is not harmonized.

- the infrastructure of the relevant departments (in particular, giving details of the type and size of the bodies involved in implementing the plans),

- a list of approved laboratories with details of their capacity for processing samples,

- national tolerances for authorized substances where no maximum Community residue levels have been set under Regulation (EEC) No 2377/90 and Directive 86/363/EEC (16),

- a list of the substances to be detected, methods of analysis, standards for interpreting the findings and, in the case of the substances listed in Annex I, the number of samples to be taken, giving reasons for this number,

- the number of official samples to be taken in relation to the number of animals of the species concerned slaughtered in preceding years in accordance with the sampling levels and frequencies laid down in Annex IV,

- details of the rules governing the collection of official samples, and in particular the rules concerning the particulars to appear on such official samples,
- the type of measures laid down by the competent authorities with regard to animals or products in which residues have been detected.

Article 8

1. The Commission shall examine the initial plans forwarded pursuant to Article 5 (1) to ascertain whether they conform to this Directive. The Commission may ask a Member State to modify or supplement these plans to make them conform.

Once the Commission has established their conformity, it shall submit the plans for approval in accordance with the procedure provided for in Article 33.

In order to take account of changes in the situation in a given Member State or in a region thereof, of the results of national surveys or of investigations carried out in the framework of Articles 16 and 17, the Commission may, at the request of the Member State concerned or on its own initiative, decide, in accordance with the procedure provided for in Article 32, to approve an amendment or addition to a plan previously approved pursuant to paragraph 2.

2. Annual amendments to the initial plans communicated by the Member States, in particular in the light of the results referred to in Article 4 (2) (d), shall be forwarded by the Commission to the other Member States once the Commission has established their conformity with this Directive.

Member States shall have 10 working days from receipt of those amendments in which to inform the Commission of any comments.

If there are no comments from Member States, the amendments to the plans shall be deemed to be approved.

The Commission shall inform the Member States of such approval immediately.

Where there are comments from Member States or where the Commission deems the update not to be in conformity or insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the procedure laid down in Article 33.

The provisions laid down in paragraph 3 and 4 shall apply to the updated plans.

3. Every six months, Member States shall inform the Commission and the other Member States within the Standing Veterinary Committee of the implementation of plans approved pursuant to paragraph 2 or of the development of the situation. Where necessary, paragraph 4 shall apply. By not later than 31 March each year, Member States shall forward to the Commission the results of their residue and substance detection plans and of their control measures.

Member States shall make public the outcome of the implementation of the plans.

The Commission shall inform Member States, within the Standing Veterinary Committee, of developments in the situation in the various regions of the Community.

4. Each year, or whenever it deems it necessary on public health grounds, the Commission shall report to Member States within the Standing Veterinary Committee on the outcome of the checks and surveys referred to in paragraph 3, in particular on:

- the implementation of national plans,
- developments in the situation in the various regions of the Community.

5. The Commission shall send the European Parliament and the Council a communication each year on the results of action taken at regional, national or Community level, bearing in mind the report and Member States' comments on it.

CHAPTER III Self-monitoring and co-responsibility on the part of operators

Article 9

A. Member States shall ensure that:

1. any farms which place farm animals on the market and any natural or legal person engaged in trade in such animals register beforehand with the competent authorities and undertake to abide by the relevant Community and national rules, in particular the provisions laid down in Articles 5 and 12 of Directive 90/425/EEC;

2. the owners or persons in charge of the establishment of initial processing of primary products of animal origin take all necessary measures, in particular by carrying out their own checks, to

- (a) accept - whether by direct delivery or through an intermediary - only those animals for which the

producer is able to guarantee that withdrawal times have been observed;

(b) satisfy themselves that the farm animals or products brought into the establishment

(i) do not contain residue levels which exceed maximum permitted limits;

(ii) do not contain any trace of prohibited substances or products;

3. (a) the producers or persons in charge referred to in points 1 and 2 place on the market only:

(i) animals to which no unauthorized substances or products have been administered or which have not undergone illegal treatment within the meaning of this Directive;

(ii) animals in respect of which, where authorized products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed;

(iii) products derived from the animals referred to in (i) and (ii);

(b) where an animal is presented at a first-stage processing establishment by a natural or legal person other than the producer, the obligations laid down in (a) are incumbent on the latter.

B. For the purposes of applying point A, Member States shall ensure, without prejudice to compliance with the rules laid down in the Directives governing the placing on the market of the various products in question, that:

- the principle of quality monitoring of the production chain by the different parties involved is established in their legislation,

- the self-monitoring measures to be included in the specifications for trade marks or labels are stepped up.

They shall inform the Commission and the other Member States, at their request, of provisions laid down in this regard and in particular of provisions adopted for checks on point A (3) (a) (i) and (ii).

Article 10

Member States shall ensure that the terms of reference and responsibilities of veterinarians monitoring farms are extended to monitoring the rearing conditions and the forms of treatment referred to in this Directive.

Within this framework, the veterinarian shall enter in a register kept on the farm the date and nature of any treatment prescribed or administered, the identification of the animals treated and the corresponding withdrawal periods.

The stockfarmer shall enter in the register, which may be the register provided for in Directive 90/676/EEC (17), the date and nature of the treatment administered. He shall satisfy himself that withdrawal periods have been observed and keep the prescriptions to prove it for five years.

Stockfarmers and veterinarians shall be required to supply any information to the competent authority, at its request, and in particular supply information to the official veterinarian of the slaughterhouse, regarding a given farm's compliance with the requirements of this Directive.

CHAPTER IV Official control measures

Article 11

1. Without prejudice to the checks carried out in connection with implementation of the surveillance plans referred to in Article 5 or to the checks provided for in specific Directives, Member States may have official random checks conducted:

(a) during the manufacture of the substances included in Group A in Annex I and during their handling, storage, transport, distribution and sale or acquisition;

(b) at any point in the animal feedingstuffs production and distribution chain;

(c) throughout the production chain of animals and raw materials of animal origin covered by this Directive.

2. The checks provided for in paragraph 1 must be conducted with a view in particular to detecting the possession or presence of prohibited substances or products which it is intended to administer to animals for the purposes of fattening or illegal treatment.

3. Where fraud is suspected, and in the case of a positive result from any of the checks referred to in paragraph 1, Articles 16 to 19 and the measures provided for in Chapter V shall apply.

The checks provided for at the slaughterhouse or on the first sale of aquaculture animals and fishery products can be reduced to take account of the fact that the farm of origin or departure belongs to an epidemiological surveillance network or a quality monitoring system as referred to in the first indent of the first subparagraph of Article 9 (B).

Article 12

The checks provided for in this Directive must be carried out by the competent national authorities without prior notice.

The owner, the person empowered to dispose of the animals or their representative shall be obliged to facilitate pre-slaughter inspection operations, and in particular to assist the official veterinarian or the authorized staff in any manipulation judged necessary.

Article 13

The competent authority shall:

(a) where illegal treatment is suspected, ask the owner or person having charge of the animals or the veterinarian in charge of the farm to provide any documentation justifying the nature of the treatment;

(b) where this inquiry confirms illegal treatment or where unauthorized substances or products have been used, or where there are grounds for suspecting their use, conduct or have conducted:

- spot checks on animals on their farms of origin or departure, in particular with a view to detecting such use and in particular any traces of implants; these checks may include official sampling,
- checks to detect substances the use of which is prohibited or of unauthorized substances or products on the farms where the animals are being reared, kept or fattened (including holdings administratively connected with such farms) or on the animals' farms of origin or departure. Official samples of drinking water and feedingstuffs are necessary for that purpose.
- spot checks on animals' feedingstuffs on their farms of origin or departure, and on their drinking water or - for aquaculture animals - from the waters in which they are caught,
- the checks provided for in Article 11 (1) (a),
- any check required to clarify the origin of the unauthorized substances or products or that of the treated animals;

(c) where the maximum levels laid down by Community rules or, pending such legislation, the levels set by national legislation have been exceeded, carry out any measure or investigation which it may deem appropriate in relation to the finding in question.

Article 14

1. Each Member State shall designate at least one national reference laboratory. A given residue or residue group may not be assigned to more than one national reference laboratory.

However, until 31 December 2000, Member States may continue to entrust testing for the same residue or residue group to several national laboratories which they designated prior to the date of adoption of this Directive.

A list of such designated laboratories shall be drawn up in accordance with the procedure laid down in Article 33.

These laboratories shall be responsible for:

- coordinating the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned,
- assisting the competent authority in organizing the plan for monitoring residues,
- periodically organizing comparative tests for each residue or residue group assigned to them,
- ensuring that national laboratories observe the limits laid down,
- disseminating information supplied by Community reference laboratories,
- ensuring that their staff are able to take part in further training courses organized by the Commission or by Commission reference laboratories.

2. The Community reference laboratories shall be those designated in Chapter 1 of Annex V.

The powers and working conditions of the laboratories shall be as defined in Chapter 2 of Annex V.

Article 15

1. Official samples must be taken in accordance with Annexes III and IV in order to be examined in approved laboratories.

The detailed rules for the taking of official samples and the routine and reference methods to be employed for the analysis of such official samples shall be specified in accordance with the procedure laid down in Article 33.

Whenever an authorization is issued for the placing on the market of a veterinary medicinal product

intended for administration to a species the meat or product of which is intended for human consumption, the competent authorities shall forward the routine analysis methods as laid down in Article 5, second subparagraph, point 8 of Directive 81/851/EEC (18) and Article 7 of Regulation (EEC) No 2377/90 to the Community and national reference laboratories for detection of residues.

2. For Group A substances, all positive findings recorded following the application of a routine method instead of a reference method must be confirmed by an approved laboratory using the reference methods laid down in accordance with paragraph 1.

For all substances, if challenged on the basis of a contradictory analysis, those results must be confirmed by the national reference laboratory designated in accordance with Article 14 (1) for the substance or residue in question. Such confirmation must be carried out at the plaintiff's cost in the event of confirmation.

3. Where examination of an official sample reveals illegal treatment, Articles 16 to 19 shall apply, together with the measures laid down in Chapter V.

Where the examination reveals the presence of residues of authorized substances or contaminants exceeding the levels set by Community rules or, pending such legislation, the levels set by national legislation, Articles 18 and 19 shall apply.

Where the examination referred to in this paragraph covers animals or products of animal origin from another Member State, the competent authority of the Member State of origin shall apply Articles 16 (2), 17, 18 and 19 and the measures provided for in Chapter V to the farm or establishment of origin or departure, following the reasoned request of the competent authority having carried out the examination. Where the examination covers products or animals imported from a third country, the competent authority having carried out that examination shall refer the matter to the Commission, which shall take the measures provided for in Article 30.

Article 16

Member States shall ensure that, where positive results are obtained as described in Article 15:

1. the competent authority shall obtain without delay:

(a) all the information required to identify the animal and farm of origin or departure;

(b) full details of the examination and its result. If the controls carried out in a Member State demonstrate the need for an investigation or other action in one or more Member States or third countries, the Member State concerned shall inform the other Member States and the Commission. The Commission shall coordinate the appropriate measures taken in Member States where an investigation or other action proves necessary;

2. the appropriate authority shall carry out:

(a) an investigation on the farm of origin or departure, as appropriate, to determine the reasons for the presence of residues;

(b) in the case of illegal treatment, an investigation of the source or sources of the substances or products concerned at the stage of manufacture, handling, storage, transport, administration, distribution or sale, as appropriate;

(c) any other further investigations which the authority considers necessary;

3. animals from which samples have been taken are clearly identified. They may not in any circumstances leave the farm until the results of the checks are available.

Article 17

Where illegal treatment is established, the competent authority must ensure that the livestock concerned in the investigations referred to in point (b) of Article 13 is immediately placed under official control. It must furthermore ensure that all the animals concerned bear an official mark or identification and that, as a first step, an official sample is taken from a statistically representative sample, on internationally recognized scientific bases.

Article 18

1. Where there is evidence of residues of authorized substances or products of a level exceeding the maximum limit for residues, the competent authority shall carry out an investigation in the farm of origin or departure, as applicable, to determine why the above limit was exceeded.

In accordance with the results of that investigation, the competent authority shall take all necessary measures to safeguard public health which may include prohibiting animals from leaving the farm

concerned or products from leaving the farm or establishment concerned for a set period.

2. In the event of repeated infringements of maximum residue limits when animals are placed on the market by a farmer or products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and/or establishment in question must be carried out by the competent authorities for a period of at least six months, products or carcasses being impounded pending the results of analysis of the samples.

Any results showing that the maximum residue limit has been exceeded must lead to the carcasses or products concerned being declared unfit for human consumption.

Article 19

1. The costs of the investigations and checks referred to in Article 16 shall be borne by the owner or person having charge of the animals.

Where the investigation confirms that suspicion was justified, the costs of analyses carried out under Articles 17 and 18 shall be borne by the owner or person having charge of the animals.

2. Without prejudice to criminal or administrative penalties, the cost of destroying animals which have given a positive result or animals which have been deemed positive in accordance with Article 23 shall be borne by the owner of the animals without indemnity or compensation.

Article 20

1. Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (19) shall apply for the purposes of this Directive.

2. Where a Member State considers that, in another Member State, the controls 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 carried out in accordance with point 2 of Article 16, 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 those 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 an on-the-spot inspection.

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

If the Member States involved in a dispute 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 instruct one or more experts to deliver an opinion.

Pending that opinion, the Member State of destination may carry out checks on products coming from the establishment(s) or holding(s) to which the dispute relates and, if the result is positive, take measures similar to those provided for in Article 7 (1) (b) of Directive 89/662/EEC (20).

In the light of the experts' opinion, appropriate measures may be taken in accordance with the procedure provided for in Article 32.

Those measures may be reviewed in accordance with the same procedure, in the light of a new expert opinion delivered within 15 days.

Article 21

1. To the extent necessary to ensure uniform application of this Directive, and in cooperation with the competent authorities of the Member States, the Commission's veterinary experts may verify on the spot that the plans and the system for checking the plans by the competent authorities have been uniformly implemented. A Member State within whose territory a verification 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 verifications carried out.

The Member State concerned shall take the measures necessary to take account of the results of these verifications and shall notify the Commission of the measures taken. Where the Commission considers that the measures taken are insufficient, it shall, after consultation with the Member State in question and having regard to the measures necessary to safeguard public health, take appropriate measures in accordance with the procedure laid down in Article 32.

2. The general rules for implementing this Article, especially as regards the frequency and method of

carrying out the verifications referred to in the first subparagraph of paragraph 1 (including cooperation with the competent authorities), shall be determined in accordance with the procedure laid down in Article 33.

CHAPTER V Measures to be taken in the event of infringement

Article 22

Where unauthorized substances or products or substances listed in Group A and Group B (1) and (2) of Annex I are discovered in the possession of non-authorized persons, those unauthorized substances or products must be placed under official control until appropriate measures are taken by the competent authority, without prejudice to the possible imposition of penalties on the offender(s).

Article 23

1. During the period in which animals are impounded as provided for in Article 17, animals from the farm in question may not leave the farm of origin or be handed over to any other person except under official control. The competent authority shall take appropriate precautionary measures in accordance with the nature of the substance or substances identified.

2. After sampling has been carried out in accordance with Article 17, if there is confirmation of a case of illegal treatment, the animal or animals found to be positive shall be slaughtered immediately on the spot or taken immediately to the designated slaughterhouse or to the knacker's yard under cover of an official veterinary certificate in order to be slaughtered there. Animals so slaughtered shall be sent to a high-risk processing plant as defined by Directive 90/667/EEC (21).

In addition, samples must be taken at the farm's expense from the entire batch of animals belonging to the farm at which checks were carried out and which may be suspect.

3. However, if half or more of the samples taken by representative sampling in accordance with Article 17 are positive, the farmer may be left a choice between a check on all the animals present on the farm which may be suspect, or slaughter of these animals.

4. For a further period of at least 12 months, the farm(s) belonging to the same owner shall be subject to more stringent checks for the residues in question. Where an organized system of self-monitoring has been set up, this facility shall be withdrawn from the farmer for that period.

5. In view of the infringement recorded, the farms or establishments supplying the holding concerned shall be subject to checks in addition to those provided for in Article 11 (1) to determine the origin of the substance in question. The same shall apply to all farms and establishments in the same supply chain of animals and animal feed as the farm of origin or departure.

Article 24

The official veterinarian of a slaughterhouse must:

1. if he suspects or has evidence that the animals concerned have been subjected to illegal treatment or that unauthorized substances or products have been administered to them:

(a) arrange for the animals to be slaughtered separately from other batches of animals arriving at the slaughterhouse;

(b) impound the carcasses and offal and carry out all sampling procedures necessary to detect the substances in question;

(c) if positive results are obtained, send the meat and offal to a high-risk processing plant as defined by Directive 90/667/EEC, without indemnity or compensation.

In that event, Articles 20 to 23 shall apply;

2. if he suspects or has evidence that the animals concerned have been subjected to an authorized treatment but that the withdrawal periods have not been complied with, postpone slaughter of the animals until he can be satisfied that the quantity of residues does not exceed the permitted levels.

This period may in no circumstances be less than the withdrawal period laid down in point (b) of Article 6 (2) of Directive 96/22/EC for the substances in question, or than the withdrawal periods provided for in the marketing authorization.

However, in an emergency or where required for the well-being of the animals, or if the infrastructure or equipment of the slaughterhouse is such that slaughter cannot be deferred, the animals may be slaughtered before the end of the ban or postponement period. The meat and offal shall be impounded pending the outcome of the official checks carried out by the slaughterhouse's official veterinarian. Only meat and

offal containing a quantity of residues not exceeding the permitted levels shall be used for human consumption;

3. declare unfit for human consumption carcasses and products in which the residue level exceeds the levels authorized by Community or national regulations.

Article 25

Without prejudice to criminal penalties, where the holding, use or manufacture of unauthorized substances or products in a manufacturing establishment is confirmed, any authorizations or official approval arrangements enjoyed by the establishment concerned shall be suspended for a period during which the establishment shall be subjected to more stringent checks.

In the case of a repeated offence, such authorizations or approval arrangements shall be permanently withdrawn.

Article 26

Rights of appeal allowed by national legislation in force in the Member States against decisions taken by the competent authorities under Articles 23 and 24 shall not be affected by this Directive.

Article 27

Without prejudice to criminal penalties, or penalties imposed by professional bodies, appropriate administrative measures must be taken against any person where he is responsible, as the case may be, for the transfer or administering of prohibited substances or products or for the administering of authorized substances or products for purposes other than those laid down in the current legislation.

Article 28

Any failure to cooperate with the competent authority and any obstruction by slaughterhouse personnel or the slaughterhouse supervisor or, in the case of a private enterprise, by the slaughterhouse owner or owners, or by the owner of the animals or person having charge of them, during inspection and sampling as required for the implementation of national plans for monitoring residues and during the investigations and checks provided for in this Regulation, shall result in appropriate criminal and/or administrative penalties being imposed by the competent national authorities.

If it is proven that a slaughterhouse owner or supervisor is helping to conceal the illegal use of prohibited substances, the Member State shall deny the guilty party any opportunity of receiving or applying for Community aid for a period of 12 months.

CHAPTER VI Imports from third countries

Article 29

1. Inclusion and retention on the lists of third countries provided for in Community legislation from which Member States are authorized to import animals and animal products covered by this Directive shall be subject to submission by the third country concerned of a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I. This plan must be updated at the request of the Commission, particularly when the checks referred to in paragraph 3 render it necessary.

The provisions of Article 8 concerning time limits for submission and updating of plans shall apply for plans to be submitted by third countries.

The guarantees must have an effect at least equivalent to those provided for in this Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive and meet the requirements of Article 11 (2) of Directive 96/22/EC.

The Commission shall approve the plan in accordance with the procedure laid down in Article 33. Under the same procedure, guarantees alternative to those resulting from the implementation of this Regulation may be accepted.

2. Where the requirements of paragraph 1 are not complied with, inclusion of a third country on the lists of third countries laid down by Community legislation or as a result of the benefit of pre-listing may be suspended in accordance with the procedure laid down in Article 33, at the request of a Member State or by the Commission on its own initiative.

3. Compliance with the requirements of and adherence to the guarantees offered by the plans submitted

by third countries shall be verified by means of the checks referred to in Article 5 of Directive 72/462/EEC (22) and the checks provided for in Directives 90/675/EEC (23) and 91/496/EEC (24).

4. Member States shall inform the Commission each year of the results of residue checks carried out on animals and animal products imported from third countries, in accordance with Directives 90/675/EEC and 91/496/EEC.

Article 30

1. Where the checks provided by Directives 90/675/EEC and 91/496/EEC reveal the use of unauthorized products or substances for the treatment of the animals in a given batch - batch within the meaning of Article 2 (2) (e) of Directive 91/496/EEC - or the presence of such products or substances in all or part of a batch originating in the same establishment, the competent authority shall take the following measures in respect of the animals and products involved in such use:

- it shall inform the Commission of the nature of the products used and the batch concerned; the Commission shall forthwith inform all frontier posts,
- the Member States shall carry out more stringent checks on all batches of animals or products from the same source. In particular, the next 10 batches from the same source must be impounded - and a deposit lodged against inspection costs - at the frontier inspection post for a check on residues by taking a representative sample of each batch or of the part of the batch.

Where such additional checks demonstrate the presence of unauthorized substances or products or of residues of such substances or products:

- (i) the batch or the part of the batch concerned must be returned to the country of origin at the expense of the consignor or his agent with a clear indication on the certificate of the reasons for rejecting the batch;
- (ii) depending on the nature of the infringement found and the risk associated with such an infringement, it must be left to the consignor to decide whether to send back the batch or part of the batch concerned, to destroy it or to use it for other purposes authorized by Community legislation, without indemnity or compensation;

- the Commission shall be informed of the outcome of the more stringent checks and on the basis of this information shall make all necessary investigations, to identify the reasons for and origins of the infringements found.

2. Where the checks provided for by Directive 90/675/EEC reveal that the maximum residue limits have been exceeded, use shall be made of the checks referred to in the second indent of paragraph 1.

3. If, in cases involving third countries which have concluded equivalence agreements with the Community, the Commission, after making enquiries of the competent authorities of the third countries concerned, concludes that they have failed to fulfil their obligations and the guarantees given by the plans referred to in Article 29 (1), it shall cease to allow that country, under the procedure laid down in Article 32, to benefit from the said agreements for the animals and products in question until the third country in question has made good its shortcomings. The suspension shall be revoked under the same procedure. If necessary, in order to re-establish the benefit afforded by the said agreements, a Community deputation including experts from the Member States shall visit the country concerned, at that country's expense, in order to verify that such measures have been taken.

CHAPTER VII General provisions

Article 31

The Council, acting on a proposal from the Commission, shall amend Directive 85/73/EEC (25) before 1 July 1997 in order to provide for the charging of a fee to cover monitoring carried out pursuant to this Directive.

Pending that decision by the Council, Member States shall be authorized to charge national fees to cover the actual costs of such monitoring.

Article 32

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC (26), by its Chairman, either on his own initiative or at the request of a Member State.

2. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those matters within a time limit which the Chairman may set according to the

urgency of the matter submitted. Opinions shall be delivered by a majority of 62 votes.

3. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.

(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, 15 days after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 33

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee, by its Chairman, either on his own initiative or at the request of a Member State.

2. The Commission representative shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on those matters within a time limit which the Chairman may set according to the urgency of the matter submitted. Opinions shall be delivered by a majority of 62 votes.

3. (a) The Commission shall adopt the measures and implement them immediately where they are in accordance with the opinion of the Committee.

(b) Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal concerning the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, three months after the proposals were submitted to it, the Council has not adopted any measures, the Commission shall adopt the measures proposed and implement them immediately unless the Council has rejected those measures by a simple majority.

Article 34

Without prejudice to Article 6 (2), Annexes I, III, IV and V may be amended or supplemented by the Council acting by a qualified majority on a proposal from the Commission.

In particular, the aforementioned Annexes may be amended within three years of the date of adoption of this Directive, with a view to risk assessment of the following factors:

- potential toxicity of residues in foodstuffs of animal origin,
- likelihood of residues occurring in foodstuffs of animal origin.

Article 35

The Council, acting by a qualified majority on a proposal from the Commission, may adopt transitional measures required for the implementation of the arrangements laid down by this Directive.

Article 36

1. Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC are hereby repealed as from 1 July 1997.

2. The following are also repealed as from the said date:

(a) Article 4 (3) of Directive 71/118/EEC;

(b) Article 5 (3) and (4) of Directive 89/437/EEC;

(c) the last subparagraph of point II.3.B of Chapter V of the Annex to Directive 91/493/EEC;

(d) Article 11 (1) of Directive 92/45/EEC;

(e) Article 15 (1) of Directive 92/46/EEC.

3. References to Directives and Decisions which have been repealed shall be deemed to be references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 37

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997.

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 texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 38

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

Article 39

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1996.

For the Council

The President

W. LUCHETTI

ANNEX I

GROUP A - Substances having anabolic effect and unauthorized substances

- (1) Stilbenes, stilbene derivatives, and their salts and esters
- (2) Antithyroid agents
- (3) Steroids
- (4) Resorcylic acid lactones including zeranol
- (5) Beta-agonists
- (6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B - Veterinary drugs (1) and contaminants

- (1) Antibacterial substances, including sulphonamides, quinolones
- (2) Other veterinary drugs
 - (a) Anthelmintics
 - (b) Anticoccidials, including nitroimidazoles
 - (c) Carbamates and pyrethroids
 - (d) Sedatives
 - (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
 - (f) Other pharmacologically active substances
- (3) Other substances and environmental contaminants
 - (a) Organochlorine compounds including PcBs
 - (b) Organophosphorus compounds
 - (d) Chemical elements
 - (d) Mycotoxins
 - (e) Dyes
 - (f) Others
- (1) Including unlicensed substances which could be used for veterinary purposes.

ANNEX II

TABLE missing

ANNEX III

SAMPLING STRATEGY

1. The residue control plan is aimed at surveying and revealing the reasons for residue hazards in foods of animal origin on farms, slaughterhouses, dairies, fish processing plants, and egg collecting and packing stations.

Official samples are to be taken in accordance with the relevant chapter of Annex IV.

Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. The Member States must take all the precautions necessary to ensure that the element of surprise in the checks is constantly maintained.

2. For Group A substances, surveillance should be aimed at detecting the illegal administration of prohibited substances and the abusive administration of approved substances, respectively. The emphasis of such sampling must be concentrated according to the relevant chapter of Annex IV.

The samples must be targeted taking account of the following minimum criteria: sex, age, species, fattening system, all available background information, and all evidence of misuse or abuse of substances of this group.

The details of these criteria will be laid down in the Commission Decision provided for in Article 15 (1).

3. For Group B substances, surveillance should be aimed particularly at controlling the compliance with MRLs for residues of veterinary medicinal products fixed in Annexes I and III to Regulation (EEC) No 2377/90, and the maximum levels of pesticides fixed in Annex III to Directive 86/363/EEC, and monitoring the concentration of environmental contaminants.

Unless random sampling can be justified by Member States when presenting their national plans to the Commission, all the samples shall be targeted according to criteria laid down in the Commission Decision provided for in Article 15 (1).

ANNEX IV

SAMPLING LEVELS AND FREQUENCY

The purpose of this Annex is to define the minimum number of animals from which the samples must be taken.

Each sample can be analysed for detecting the presence of one or more substances.

CHAPTER 1 Bovine, porcine, ovine, caprine and equine animals

1. Bovine animals

The minimum number of animals to be controlled each year for all kinds of residues and substances must at least equal 0,4 % of bovine animals slaughtered the previous year, with the following breakdown:

Group A: 0,25 % divided as follows:

- one half of the samples are to be taken from live animals on the holding;

(by derogation, 25 % of samples analysed for the research of Group A 5 substances can be taken from appropriate material (feedingstuffs, drinking water, etc.))

- one half of the samples are to be taken at the slaughterhouse.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance must be allocated according to the experience and background information of the Member State.

Group B: 0,15 %

30 % of the samples must be checked for Group B 1 substances.

30 % of the samples must be checked for Group B 2 substances.

10 % of the samples must be checked for Group B 3 substances.

The balance must be allocated according to the situation of the Member State.

2. Porcine animals

The minimum number of animals to be checked each year for all kinds of residues and substances must at least equal 0,05 % of the pigs slaughtered the previous year, with the following breakdown:

Group A: 0,02 %

In those Member States which carry out their sampling of animals at the slaughterhouse, in addition analysis of drinking water, feedingstuffs, faeces, or all other appropriate parameters must be undertaken at farm level. In that case, the minimum number of farms to be visited annually must represent at least one farm per 100 000 pigs slaughtered the previous year.

Each sub-group in Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,03 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be

allocated according to the situation of the Member State.

3. Sheep and goats

The minimum number of animals to be checked for all kind of residues and substances must at least equal 0,05 % of sheep and goats over three months of age slaughtered the previous year, with the following breakdown:

Group A: 0,01 %

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 0,04 %

The same breakdown per sub-group as for bovine animals has to be respected. The balance will be allocated according to the experience of the Member State.

4. Equine animals

The number of samples is to be determined by each Member State in relation to the problems identified.

CHAPTER 2 Broiler chickens, spent hens, turkeys, other poultry

A sample consists of one or more animals depending on the requirements of the analytical methods.

For each category of poultry considered (broiler chickens, spent hens, turkeys, and other poultry), the minimum number of samples to be taken each year must at least equal one per 200 tonnes of annual production (deadweight), with a minimum of 100 samples for each group of substances if the annual production of the category of birds considered is over 5 000 tonnes.

The following breakdown must be respected:

Group A: 50 % of the total samples

The equivalent of one fifth of these samples must be taken at farm level.

Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.

The balance will be allocated according to the experience and background information of the Member State.

Group B: 50 % of the total samples,

30 % must be checked for Group B 1 substances,

30 % must be checked for Group B 2 substances,

10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the Member State.

CHAPTER 3 Aquaculture products

1. Finfish farming products

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

Member States must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought and the samples selected for analysis should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples:

all the samples must be taken at farm level, on fish at all stages of farming (1), including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples:

the sampling should be carried out:

- (a) preferably at the farm, on fish ready to be placed on the market for consumption;
- (b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

2. Other aquaculture products

When Member States have reason to believe that veterinary medicine or chemicals are being applied to the other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production as additional samples to those taken for finfish farming products.

- (1) For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

ANNEX V

Chapter 1

The following laboratories shall be designated Community reference laboratories for the detection of residues of certain substances:

- (a) For the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d)
Rijksinstituut voor Volksgezondheid en Milieuhygiëne (RIVM)

A. van Leeuwenhoeklaan, 9
NL-3720 BA Bilthoven

- (b) For the residues listed in Annex I, Group B 1 and B 3 (e) and carbadox residues and olaquinoxid residues

Laboratoires des médicaments vétérinaires (CNEVA-LMV)
La Haute Marche, Javene
F-35135-Fougères

- (c) For the residues listed in Annex I, Group A 5 and Group B 2 (a), (b), (e)
Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinärmedizin (BGVV)
Diedersdorfer Weg, 1

D-12277-Berlin

- (d) For the residues listed in Annex I, Group B 2 (c) and Group B 3 (a), (b), (c):

Istituto Superiore di Sanità
Viale Regina Elena, 299
I-00161-Roma

The compounds included in Group A 6, B 2 (f) and B 3 (f) are allocated to the designated Community reference laboratories, according to their pharmacological action.

Chapter 2

The powers and operating conditions of the Community reference laboratories for the detection of residues in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water shall be as follows:

- 1. The functions of Community reference laboratories shall be:

- (a) to promote and coordinate research into new analytical methods and to inform national reference laboratories of advances in analytical methods and equipment;

- (b) to help the national reference laboratories (NRLs) for residues to implement an appropriate quality assurance scheme system based on good laboratory practice (GLP) principles and EN 45 000 criteria;

- (c) to approve validated methods as reference methods, to be integrated into a collection of methods;

- (d) to provide the national reference laboratories with the routine analytical methods accepted during the MRL procedure;

- (e) to provide national reference laboratories with details of analytical methods and the comparative tests to be conducted, and to inform them of the results of the tests;

- (f) to provide national reference laboratories, at their request, with technical advice on the analysis of the substances for which they have been designated the Community reference laboratory;

(g) to organize comparative tests for the benefit of the national reference laboratories, the frequency of which shall be determined in agreement with the Commission. Consequently, the Community reference laboratories shall distribute blank samples and samples containing known amounts of analyte to be analysed;

(h) to identify residues and determine their concentration in cases where the results of an analysis give rise to a disagreement between Member States;

(i) to conduct initial and further training courses for the benefit of analysts from national laboratories;

(j) to provide the Commission services, including the standards, measurements and testing programme, with technical and scientific assistance;

(k) to compile a report on each year's work and transmit it to the Commission;

(l) to liaise, in the field of analytical methods and equipment, with the national reference laboratories designated by third countries in the plans to be submitted in accordance with Article 11 of this Directive.

2. In order to perform the functions specified in paragraph 1, Community reference laboratories must satisfy the following minimum requirements:

(a) have been designated as a national reference laboratory in a Member State;

(b) have suitable qualified staff who are adequately trained in analytical methods used for the residues for which they have been designated the Community reference laboratory;

(c) possess the equipment and substances needed to carry out the analysis for which they are responsible;

(d) have an adequate administrative infrastructure;

(e) have sufficient data-processing capacity to produce statistics based on their findings and to enable rapid communication of those statistics and other information to national reference laboratories and the Commission;

(f) ensure that their staff respect the confidential nature of certain issues, results or communications;

(g) have sufficient knowledge of international standards and practices;

(h) have available an up-to-date list of certified reference material and reference material held by the Institute for Reference Material and Methods, and an up-to-date list of manufacturers and vendors of that material.

ANNEX VI

>TABLE missing