

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(80) 920 final

Brussels, 6th January 1981

PROPOSAL FOR A COUNCIL REGULATION (EEC)

concerning the control and examination of animals and meat in the Community
for the presence of residues of substances with
oestrogenic, androgenic, gestagenic and thyrostatic effect

(presented by the Commission to the Council)

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EXPLANATORY MEMORANDUM

On the 3 November 1980 the Commission submitted to the Council a Proposal for a Council Regulation concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals⁽¹⁾. In that Proposal are laid down the basic principles concerning the prohibition of use on animals of substances with oestrogenic, androgenic, gestagenic and thyrostatic effect. In addition the outlines for the essential controls of this ban are laid down.

The present Proposal concerns the second step of control, namely the monitoring of animals and meat for the presence of residues. To ensure uniform control in Member States it is provided for the application of random sampling either at the abattoir or holding of origin. Provision is made for the automatic adoption of an intensive sampling system and tracing of animals to their origin, if the basic monitoring system reveals residues in excess of the tolerance. The basic monitoring system may only be resumed after a period in which the intensive system has shown absence of animals with residues in excess of the tolerance.

The tolerances for the substances involved are set at the limit of detection of the methods available (i.e. zero). However for certain natural substances which may be authorised for therapeutic purposes it is necessary to confirm this finding by further examinations in order to take into account the natural levels of these substances which might be expected in the animal concerned.

Provision is made to modify the sampling system proposed by the Committee procedure in light of the experiences gained on a Community basis.

Provision is also made to ensure confiscation and destruction of animals and meat in appropriate circumstances, and concerning the costs for the monitoring systems and other sampling provided for in the Proposal.

A requirement is included to ensure that records of examinations and results obtained are presented on an annual basis.

(1) O.J. No C 305 of 22.11.1980, p. 2

PROPOSAL
for
COUNCIL REGULATION
concerning

the control and examination of animals and meat in the Community for the presence of residues of substances with oestrogenic, androgenic, gestagenic and thyrostatic effect.

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 the Council Regulation concerning the use of substances with a hormonal or thyrostatic action on domestic animals, and in particular Article 5 thereof,

Having regard to Council Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries as last amended by the Greek Act of Accession, and in particular Article 20 thereof,

Having regard to the proposal of the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,
Whereas Council Regulation has prohibited the use on domestic animals of substances with oestrogenic, androgenic and gestagenic effect and of substances with thyrostatic effect; whereas certain of these substances may be used for therapy;

Whereas Article 5 of the abovementioned Regulation foresees that meat and animals should be subject to a control for residues of these substances by means of common rules, in particular concerning frequency and tolerances;

Whereas Article 3 of Council Regulation has prohibited the putting into trade in the territory of the Community of domestic animals and of fresh meat, whatever their origin, containing residues in excess of the tolerance;

Whereas it is therefore necessary to apply a uniform control system which affects meat or animals marketed in the Community;

Whereas it is necessary to set up immediately the general outlines for frequency of sampling and for applicable tolerances; whereas these outlines may be adopted and supplemented, in particular to take account of scientific progress by a procedure which ensures close collaboration between the Member States and the Community;

Whereas fresh meat marketed in the Community must be inspected for residues on the basis of Community criteria; whereas the purpose of this inspection is to protect human health from actual or possible damage arising from the consumption of fresh meat containing residues; whereas animals should also be subjected, under certain conditions to a control ensuring that no substances have been illegally used;

Whereas the uniform implementation of these control measures may be ensured only if the methods of analysis and the measures to be taken on the basis of inspection findings are laid down in detail following a procedure which ensures a close collaboration between the Member States and the Commission;

Whereas tolerance values must be laid down for the individual residues;

Whereas a separate and specially developed method of examination is usually required to detect each kind of residue and whereas most of these methods are based on wholly differing principles so that there is little possibility of using some procedures simultaneously in analysis for several residues; whereas some methods of analysis can be applied only to certain animal tissues; whereas due account must be taken of the differences between animal tissues; whereas the inspection for residues should therefore, in the first instance, be based on random sampling;

Whereas the purpose of all measures taken in pursuance of this Regulation, in particular the suspension of slaughterings, must be to ensure that residue-free meat is produced in the Community in the first place; whereas meat found to contain residues should be destroyed;

Whereas it should be possible for owners of animals in respect of which the suspension of slaughtering is ordered on the basis of inspection findings to slaughter their animals before the expiry of the period suspension on condition that each of the animals is inspected for residues at the owner's cost; whereas, however, to ensure a strict observance of rules concerning the use of the relevant substances, any illegally treated animals should be confiscated and destroyed;

Whereas provision should be made for meeting the cost of inspections for residues;

Whereas the Member States should report to the Commission on their monitoring activities in order to provide a constant overall view of the residue inspections carried out in the Member States,

HAS ADOPTED THIS DIRECTIVE :

Article 1

1. This Regulation concerns the control and examination of animals and meat marketed in the Community for the presence of residues of substances with oestrogenic, androgenic and gestagenic effect, and substances with thyrostatic action.
2. This Regulation applies without prejudice to Article 24 of Directive 72/462/EEC.

Article 2

1. Definitions contained in Directives 64/433/EEC⁽¹⁾, 71/118/EEC⁽²⁾, 72/462/EEC⁽³⁾ and 77/99/EEC⁽⁴⁾ shall apply for the purposes of this Regulation.

2. For the purposes of this Regulation :

Residues are detectable quantities of substances mentioned in Article 1 or their metabolites in animals and meat.

Examination for residues. Examination of animals or meat for detectable quantities of residues.

Tolerance. The maximum permitted quantity of residue in animals and meat.

Animals. Means domestic animals of the following species, bovine, porcine, ovine, caprine, solipeds and poultry.

Article 3

1. Animals and meat marketed in the Community shall be subject to an examination for residues in accordance with this Regulation.
2. These examinations shall include the use of the methods of analysis established in application of Article 5, paragraph 4 of Regulation
3. The tolerances are those laid down in Annex II. These tolerances may be subsequently modified following the procedure laid down in Article 10.

(1) O.J. No 121 of 29.7.1964, p. 2012/64.

(2) O.J. No L 55 of 8.3.1971, p. 23.

(3) O.J. No L 302 of 31.12.1972, p. 7.

(4) O.J. No L 26 of 31.1.1977, p. 85.

Article 4

1. Without prejudice to Article 6 meat shall be examined for residues following sampling on a random basis at the slaughterhouses of production in conformity with the frequency laid down in Annex I. Each sample must be taken from a different animal.
Carcases, parts of carcasses or offals from which a sample is taken must be detained until the result of the examination is available. If examination reveals residues in excess of the tolerance this meat must be condemned and destroyed.
2. The number of samples to be taken in accordance with paragraph 1 may, in justified cases, be altered in accordance with the procedure laid down in Article 10.
3. In addition the official veterinarian responsible for the examination of meat at the slaughterhouse of production may, if he has information suggesting the presence of residues in the carcasses presented for examination, examine each carcass for the residue or residues in question.
4. Examinations under paragraph 3 shall not be counted against the number of random samples required in accordance with paragraphs 1 and 2.

Article 5

1. Where examination for residues pursuant to Article 4 and 6 shows that the tolerances laid down in Annex II have been exceeded the competent veterinary authorities shall be informed without delay of :
 - a) the species of animal, its age, sex and breed, together with all information needed to identify with certainty the holding from which the animal came, and
 - b) the result of the examination.

2. The competent veterinary authorities shall thereupon ensure that :
- a) the livestock on the farm of origin is investigated to ascertain the cause of the tolerance being exceeded,
 - b) herds or animals which, as a result of the investigation referred to in the first indent, may be assumed to contain the residue or residues in question are provided with official markings, and subject to appropriate examination,
 - c) if the examination provided for in paragraph 2 b) reveals the presence of residues of substances other than those authorised by Regulation the animal shall be confiscated and destroyed,
 - d) if the examination provided for in paragraph 2 b) reveals residues in excess of the tolerance for substances authorised by Council Regulation slaughter of the animals concerned for human consumption is prohibited until it may be assumed that the amount of residue present no longer exceeds the tolerance. This period can in no case be shorter than the delay period fixed for the substance in application of Article 6, paragraph 3 of Regulation However, when it is ascertained that the conditions for use of substances authorised for therapy in Council Regulation have not been respected the animals concerned shall be confiscated and destroyed,
 - e) during this period the animals must not be ceded to other parties.

3. By way of derogation from paragraph 2 d), animals whose slaughter is prohibited may be slaughtered before the end of the prohibition period if the owner informs the competent authority at least one week before the proposed slaughter date, stating the place of slaughter. 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.

4. The carcase of each animal whose slaughter is notified pursuant to paragraph 3 shall be officially examined for the residue or residues concerned and shall be detained until the result of the examination is known.

If the examination reveals residues in excess of the tolerance level the meat shall be confiscated and destroyed and the owner shall bear the full cost of the examination.

These examinations shall not, however, count as random sampling for the purposes of Article 4(1) and (2).

Article 6

A. In the case of substances with an oestrogenic, androgenic and gestagenic effect :

1. The sampling of meat provided for in Article 4 may be replaced by sampling of animals for residues at the slaughterhouse of production on a random basis in conformity with the frequency laid down in Annex I.

The animal or meat thereof from which the sample is taken must be detained until the result of the examination is available. If the examination reveals residues in excess of the tolerance level the animal or meat therefore must be confiscated and destroyed.

2. The number of samples to be taken in accordance with paragraph I may, in justified cases, be altered in accordance with the procedure laid down in Article 9/

3. In addition the official veterinarian responsible for the examination at the slaughterhouse may, if he has information suggesting the presence of residues in the animal presented for examination, examine each animal for the residue or residues in question.

4. Examinations under paragraph 3 shall not be counted against the number of random samples required in accordance with paragraphs 1 and 2.

B. It may be decided, following the procedure laid down in Article 10 that the sampling at the slaughterhouse referred to in part A, may be replaced by sampling at the holding of origin on a random basis in conformity with the frequency laid down in Annex I.

Article 7

The Member States shall inform the Commission by means of a summary annual report, not later than 31 March of the year following that to which the report refers, of the examinations for residues carried out under this Regulation, of the results of the examinations and of the measures taken using the form set out in Annex III to this Regulation. The Commission shall inform the Member States of the result of these communications.

Article 8

With the exception of the costs of the examination under Article 5(4) all costs incurred during the examination for residues provided for by Article 4 shall be apportioned among the total number of animals slaughtered and shall be borne by the owners thereof.

Article 9

1. Where the procedure laid down in this Article is to be followed, the Chairman shall without delay refer the matter, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called the "Committee"), set up by the Council Decision of 15 October 1968.
2. Within the Committee, the votes of Member States shall be weighted as provided in Article 148(2) of the Treaty. The Chairman shall not vote.
3. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within a period to be determined by the Chairman in keeping with the urgency of the question submitted for examination. Opinions shall be delivered by a majority of 45 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority. If, within three months from the date which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

Article 10

1. Where the procedure laid down in this Article is to be followed, the Chairman shall without delay refer the matter, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter called the "Committee") set up by the Council Decision of 15 October 1968.
2. Within the Committee, the votes of Member States shall be weighted as provided in Article 148(2) of the Treaty. The Chairman shall not vote.
3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 45 votes.
4. The Commission shall adopt the measures and shall apply them immediately where they are in accordance with the opinion of the Committee. Where they are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority. If, within fifteen days from the date on which the proposal was submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately.

Article 11

This Regulation shall enter into force on the ... 1981.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

FREQUENCY OF SAMPLING

1. (a) Basic monitoring system for substances with oestrogenic, gestagenic and androgenic action.

Three hundred samples shall be taken during each period of 12 months for each of the following categories :

- cattle over 12 months,
- pigs,
- sheep and goats,
- horses
- poultry

in the case of cattle under 12 months the number of samples shall be doubled.

For each of the categories of animals involved samples for testing shall be chosen by random number generation in respect of :

- the slaughterhouses in the national territory from which the samples are taken,
- the number of animals to be sampled, and
- the moment in time for sampling.

- (b) Basic monitoring system for substances with thyrostatic action.

Three hundred samples shall be taken during each period of 12 months for cattle over 12 months, following the provisions of the last sentence of paragraph 1.(a).

2. Intensive monitoring system

Following the detection of one or more findings exceeding the tolerance during the basic sampling system, the frequency of sampling of the total of slaughtered animals shall be increased as follows during a period of 2 months within the territory of a Member State.

- (a) For substances with oestrogenic, gestagenic and androgenic action,

- 2% of cattle under 12 months,
- .5% of all other species.

(b) for substances with thyrostaatic action:

- 2% of all cattle over 12 months,

following the provisions of the last sentence of paragraph 1.(c).

Intensive sampling periods shall be maintained until for a 2 month period no samples are found with residues exceeding the tolerances.

Following an intensive sampling period of 2 months during which no findings exceeding the tolerance for residues and species concerned have been found, a new period of the basic monitoring system shall start.

ANNEX II

TOLERANCES

1. For endogenous hormones with oestrogenic, gestagenic or androgenic effect :

When residues of substances which are identical to endogenous hormones are found in an animal and the levels found in the animal examined exceed considerably the level which is normally found in an animal of the same type and condition the official veterinarian must confirm this finding by additional examinations. These examinations in particular shall include examinations for pathological, anatomical alterations and in justified cases examination of animals at the holding of origin.

The tolerance is exceeded where the official veterinarian confirms that the substance in question has been administered to the animal or the conditions of use have not been observed.

2. For all other substances the level of detection by the methods laid down in accordance with Article 3.2.

ANNEX III

REPORT ON INSPECTIONS FOR RESIDUES IN FRESH MEAT

Member State : _____

Year under review : _____

Number of animals slaughtered	Cattle over 12 months	Cattle under 12 months	Pigs	Horses	Small ruminants
a) Number of samples examined b) Number of samples which showed that tolerances were exceeded					
on examination for : a) <u>Oestrogens</u> b)					
a) <u>Thyrostatics</u> b)					
a) b)					
a) b)					
a) b)					
a) b)					
a) b)					