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

Official Journal L 224, 18/08/1990 pp. 0001 - 0008

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 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),
Whereas the use of veterinary medicinal products in food-producing animals may result in the presence of residues of foodstuffs obtained from treated animals;
Whereas as a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicines in foodstuffs at ever lower levels; whereas it is therefore necessary to establish maximum residue limits for pharmacologically active substances which are used in veterinary medicinal products in respect of all the various foodstuffs of animal origin, including meat, fish, milk, eggs and honey;
Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community;
Whereas the use of veterinary medicinal products plays an important part in agricultural production; whereas the establishment of maximum residue levels will facilitate the marketing of foodstuffs of animal origin;

Whereas the establishment of different maximum residue levels by Member States may hinder the free movement
of foodstuffs and of veterinary medicinal products themselves;
Whereas it is therefore necessary to lay down a procedure for the establishment of maximum residue levels of veterinary medicinal products by the Community, following a single scientific assessment of the highest possible quality;
Whereas the need for the establishment of maximum residue levels throughout the Community is recognized in the Community rules relating to trade in foodstuffs of animal origin;
Whereas provisions must be adopted with a view to the systematic establishment of maximum residue levels for new substances capable of pharmacological action intended for administration to food-producing animals;
Whereas arrangements must also be made for the establishment of maximum residue levels for substances which are currently used in veterinary medicines administered to food-producing animals; whereas, however, in view of the complexity of this matter and the large number of substances involved, long transitional arrangements are required;
Whereas, after scientific assessment by the Committee for Veterinary Medicinal Products, maximum residue levels must be adopted by a rapid procedure which ensures close cooperation between the Commission and the Member States through the Committee set up under Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (4), as last amended by Directive 87/20/EEC (5); whereas an urgent procedure is also required to ensure the swift review of any tolerance which might prove insufficient to protect public health;

Whereas medicinally induced immunological responses are usually indistinguishable from those which arise naturally, and do not affect consumers of food of animal origin;
Whereas the information necessary to assess the safety of residues should be presented in accordance with the principles laid down by Directive 81/852/EEC,
HAS ADOPTED THIS REGULATION:

Article 1
1. For the purposes of this Regulation, the following definitions shall apply:
(a) 'residues of veterinary medicinal products': means all pharmacologically active substances, whether active principles, excipients or degradation products, and their metabolites which remain in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered;
(b) 'maximum residue limit': means the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or mg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food.
It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects.
When establishing a maximum residue limit (MRL), consideration is also given to residues that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.
2. This Regulation shall not apply to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity used in immunological veterinary medicinal products.

Article 2
The list of pharmacologically active substances used in veterinary medicinal products in respect of which maximum residue limits have been established shall be contained in Annex I, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex I shall be adopted in accordance with the same procedure.

Article 3
Where, following an evaluation of a pharmacologically active substance used in veterinary medicinal products, it appears that it is not necessary for the protection of public health to establish a maximum residue limit, that substance shall be included in a list in Annex II, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex II shall be adopted in accordance with the same procedure.

Article 4
A provisional maximum residue limit may be established for a pharmacologically active substance used in veterinary medicinal products on the date of entry into force of this Regulation, provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard for the health of the consumer. A provisional maximum residue limit shall apply for a defined period of time, which shall not exceed five years. That period may

be extended once only in exceptional cases for a period not in excess of two years if that proves expedient for the completion of scientific studies in progress.
In exceptional circumstances, a provisional maximum residue limit may also be established for a pharmacologically active substance not previously used in veterinary medicinal products on the date of entry into force of this Regulation provided that there are no grounds for supposing that residues of the substance concerned at the limit proposed present a hazard for the health of the consumer.
The list of pharmacologically active substances used in veterinary medicinal products in respect of which provisional maximum residue limits have been established shall be contained in Annex III, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex III shall be adopted in accordance with the same procedure.

Article 5
Where it appears that a maximum residue limit cannot
be established in respect of a pharmacologically active substance used in veterinary medicinal products because residues of the substances concerned, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer, that substance shall be included in a list in Annex IV, which shall be adopted in accordance with the procedure laid down in Article 8. Except as provided for in Article 9, any amendments to Annex IV shall be adopted in accordance with the same procedure.
The administration of the substances listed in Annex IV to food-producing animals shall be prohibited throughout the Community.

Article 6
1. In order to obtain the inclusion in Annex I, II, or III of a new pharmacologically active substance which is:
- intended for use in veterinary medicinal products for administration to food-producing animals, and
- intended to be placed on the market of one or more Member States which have not previously authorized the use of the substance concerned in food-producing animals,
the person responsible for marketing shall submit an application to the Commission. The application shall contain the information and particulars referred to in Annex V and shall comply with the principles laid down in Directive 81/852/EEC.
2. After verifying within a period of 30 days that the application is submitted in correct form, the Commission shall forthwith submit the application for examination by the Committee for Veterinary Medicinal Products set up under Article 16 of Directive 81/851/EEC. The Committee shall appoint one of its members to act as rapporteur and to undertake an initial evaluation of the application.
3. Within 120 days of referral of the application to the Committee for Veterinary Medicinal Products, and having regard to the observations formulated by the members of the Committee, the Commission shall prepare a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide the Committee with additional information for examination. The rapporteur shall update the evaluation report to take account of the additional information received.
4. Within 90 days of receipt of the additional information referred to in paragraph 3, the Commission shall prepare a draft of the measures to be taken, which shall forthwith be communicated to the Member States and the person responsible for marketing. Within a further 60 days, the person responsible for marketing may, at his request, provide oral or written explanations for consideration by the Committee for Veterinary Medicinal Products. The

Commission may, at the request of the applicant, extend this time limit.
5. Within a further 60 days the Commission shall submit the draft measures to the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, set up under Article 2b of Directive 81/852/EEC, for the application of the procedure laid down in Article 8.

Article 7
1. Paragraphs 2 to 6 shall apply in respect of pharmacologically active substances which are authorized for use in veterinary medicinal products on the date of entry into force of this Regulation.
2. After consulting the Committee on Veterinary Medicinal Products, the Commission shall publish a timetable for the consideration of these substances, including time limits for submission of the information referred to in Annex V.
The persons responsible for marketing the veterinary medicinal products concerned shall ensure that all relevant information is submitted to the Commission in accordance with the requirements of Annex V and in conformity with the principles laid down in Directive 81/852/EEC before expiry of the relevant time limits. The competent authorities of the Member States shall bring any other relevant information to the attention of the Commission.
3. After verifying within 30 days that the information is submitted in correct form, the Commission shall forthwith submit the information for examination to the Committee for Veterinary Medicinal Products, which shall deliver its opinion within a renewable period of 120 days. That Committee shall appoint one of its members to act as rapporteur and to undertake an evaluation of the information.
4. Having regard to the observations formulated by the members of the Committee for Veterinary Medicinal Products, the Commission shall prepare, within a maximum period of 30 days, a draft of the measures to be taken. If the information submitted by the person responsible for marketing is insufficient to enable such a draft to be prepared, that person will be requested to provide additional information, within a specified period, for examination by the Committee. The rapporteur shall update the evaluation report to take account of the additional information received.
5. The draft of the measures to be taken shall be communicated forthwith by the Commission to the Member States and those persons responsible for marketing who have submitted information to the Commission before expiry of the time limit established in accordance with paragraph 2. These persons may, at their request, provide oral or written explanations to the Committee for Veterinary Medicinal Products.
6. The Commission shall forthwith submit the draft measures to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products for the application of the procedure laid down in Article 8.

Article 8
1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.
2. The representative of the Commission shall submit a draft of the measures to be adopted to the Committee for Adaptation to Technical Progress. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.
3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b)
Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.
(c)
If, after a period of three months of the proposal being referred to it, the Council has not acted, the proposed measures shall be adopted by the Commission, unless the Council has voted against them by a simple majority.

Article 9
1. Where a Member State, as a result of new information or a reassessment of existing information, considers that the urgent amendment of a provision contained in Annexes I to IV is necessary in order to protect human or animal health, and therefore requires swift action to be taken, that Member State may temporarily suspend the operation of the provision concerned in its own territory. In that case, it shall immediately notify the other Member States and the Commission of the measures, attaching a statement of the reasons therefor.
2. The Commission shall as soon as possible examine the grounds given by the Member State concerned and, after consulting the Member States within the Committee for Veterinary Medicinal Products, it shall then deliver its opinion forthwith and take appropriate measures; the person responsible for marketing may be requested to provide the Committee with oral or written explanations. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council, acting by a qualified majority, may take a different decision within 30 days of the date on which the matter was referred to it.
3. If the Commission considers that it is necessary to amend the provision of Annex I to IV concerned in order to resolve the difficulties referred to in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 10 with a view to adopting those amendments; the Member State which has taken measures under paragraph 1 may maintain them until the Council or the Commission has taken a decision in accordance with the abovementioned procedure.

Article 10
1. Where the procedure laid down in this Article is to be followed, the chairman shall, without delay, refer the matter to the Committee for Adaptation to Technical Progress of the Directives on Veterinary Medicinal Products either on his own initiative or at the request of a representative of a Member State.
2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of
the matter. It shall act by a qualified majority, the votes of
the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.
3. (a) The Commission shall adopt the measures envisaged, where they are in accordance with the opinion of the Committee.
(b)
Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.
(c)
If within 15 days of the proposals being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11
Any changes which are necessary to adapt Annex V to take account of scientific and technical progress shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

Article 12
As soon as possible after the amendment of Annexes I, II, III or IV, the Commission shall publish a summary of the assessment of the safety of the substances concerned by the Committee for Veterinary Medicinal Products. The confidential nature of any proprietary data shall be respected.

Article 13
Member States may not prohibit or impede the putting into circulation within their territories of foodstuffs of animal origin originating in other Member States on the grounds that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit provided for in Annex I or III, or if the substance concerned is listed in Annex II.

Article 14
With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III shall be prohibited within the Community, except in the case of clinical trials accepted by the competent authorities following notification or authorization in accordance with the legislation in force and which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

Article 15
This Regulation shall in no way prejudice the application of
Community legislation prohibiting the use in livestock farming of certain substances having a hormonal action.
Nothing in this Regulation shall prejudice the measures taken by Member States to prevent the unauthorized use of veterinary medicinal products.

Article 16
This Regulation shall enter into force on 1 January 1992.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Luxembourg, 26 June 1990.
For the Council
The President
M. O'KENNEDY

ANNEX I
List of pharmacologically active substances for which maximum residue levels have been fixed (List to be established in accordance with the procedure laid down in Article 8)

ANNEX II
List of substances not subject to maximum residue levels (List to be established in accordance with the procedure laid down in Article 8)

ANNEX III
List of pharmacologically active substances used in veterinary medicinal products for which maximum residue levels have been fixed (List to be established in accordance with the procedure laid down in Article 8)

ANNEX IV
Lists of pharmacologically active substances for which no maximum levels can be fixed (List to be established in accordance with the procedure laid down in Article 8)

ANNEX V
Information and particulars to be included in an application for the establishment of a maximum residue limit for a pharmacologically active substance used in veterinary medicinal products 1. Administrative particulars
1.1.
Name or corporate name and permanent address of the person responsible for placing the veterinary medicinal product(s) on the market.
1.2.
Name of the veterinary medicinal product(s).
1.3.
Qualitative and quantitative composition in terms of active principles, with mention of the international non-proprietary name recommended by the World Health Organization, where such name exists.
1.4.
Manufacturing authorization, if any.
1.5.
Marketing authorizations, if any.
1.6.
Summary of the characteristics of the veterinary medicinal product(s) prepared in accordance with Article 5a of Directive 81/851/EEC.
2.
Identity of substance
2.1.
International non-proprietary name.
2.2.
International Union of Pure and Applied Chemistry (IUPAC) name.
2.3.
Chemical Abstract Service (CAS) name.
2.4.
Classification:
- therapeutic
- pharmacological.
2.5.
Synonyms and abbreviations.
2.6.
Structural formula.
2.7.
Molecular formula.
2.8.
Molecular weight.
2.9.

Degree of impurity.
2.10.
Qualitative and quantitative composition of impurities.
2.11.
Description of physical properties:
- fusion point
- boiling point
- vapour pressure
- solubility in water and organic solvents expressed in g/l, with indication of temperature
- density
- spectra of refraction, rotation, etc.
3.
Toxicological studies
3.1.
Short-term toxicological studies.
3.2.
Long-term toxicological studies.
3.3.
Studies on reproduction.
3.4.
Studies on teratogenicity.
3.5.
Studies on mutagenicity.
3.6.
Studies for carcinogenicity.
3.7.
Studies of immunological effects.
3.8.
Studies of microbiological effects.
3.9.
Observations in humans.
3.10.
Other biological effects.
4.
Metabolic and residue studies
4.1.
Absorption, distribution, excretion and biotransformations.
4.2.
Determination of residues, including methods of residue analysis.
4.3.
Existing maximum permitted residue levels.
5.
Conclusions
5.1.
Level causing no toxicological effect.
5.2.
Estimate of temporary acceptable daily intake for man.
5.3.
Estimate of maximum residue levels in food with the specification of the residue concerned.
5.4.
Methods of routine analysis that may be used by the competent authorities for the detection of

residues.
5.5.
Further work or information:
- required
- desirable.
References
Experts report