Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance)

REGULATION (EC) No 470/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the procedure referred to in Article 251 of the Treaty[(2)],

Whereas:

(1) As a result of scientific and technical progress it is possible to detect the presence of residues of veterinary medicinal products in foodstuffs at ever lower levels.

(2) In order to protect public health, maximum residue limits should be established in accordance with generally recognised principles of safety assessment, taking into account toxicological risks, environmental contamination, as well as the microbiological and pharmacological effects of residues. Account should also be taken of other scientific assessments of the safety of substances concerned which may have been undertaken by international organisations or scientific bodies established within the Community.

(3) This Regulation directly concerns public health and is relevant to the functioning of the internal market in products of animal origin included in Annex I to the Treaty. It is therefore necessary to establish maximum residue limits for pharmacologically active substances in respect of various foodstuffs of animal origin, including meat, fish, milk, eggs and honey.

Changes to legislation: *There are outstanding changes not yet made to Regulation (EC) No 470/2009 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) 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[(3)] introduced Community procedures to evaluate the safety of residues of pharmacologically active substances in accordance with human food safety requirements. A pharmacologically active substance may be used in food-producing animals only if evaluated favourably. Maximum residue limits are established for such substances where they are considered necessary for the protection of human health.

(5) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products[(4)] provides that veterinary medicinal products may be authorised or used in food-producing animals only if pharmacologically active substances contained therein have been assessed as safe according to Regulation (EEC) No 2377/90. Moreover that Directive contains rules concerning the documentation of use, re-designation (off label use), prescription and distribution of veterinary medicinal products intended for use in food-producing animals.

(6) In the light of the European Parliament's resolution of 3 May 2001[(5)] on the availability of veterinary medicinal products, the Commission's public consultation undertaken in 2004 and its assessment of the experience gained, it has proved necessary to modify the procedures for setting maximum residue limits while maintaining the overall system for setting such limits.

(7) Maximum residue limits are the points of reference for the establishment, in accordance with Directive 2001/82/EC, of withdrawal periods in marketing authorisations for veterinary medicinal products to be used in food-producing animals as well as for the control of residues in food of animal origin in the Member States and at border inspection posts.

(8) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of β-agonists[(6)] prohibits the use of certain substances for specific purposes in food-producing animals. This Regulation should apply without prejudice to any Community legislation prohibiting the use in food-producing animals of certain substances having a hormonal action.

(9) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(7)] lays down specific rules for substances not resulting from intentional administration. Those substances should not be subject to legislation on maximum residue limits.

(10) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(8)] lays down the framework for food legislation at Community level and provides for definitions in that area. It is appropriate that those definitions apply for the purposes of legislation on maximum residue limits.

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(11) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[(9)] lays down general rules for the control of food in the Community and provides for definitions in that area. It is appropriate that those rules and definitions apply for the purposes of legislation on maximum residue limits. Priority should be given to the detection of the illegal use of substances and part of the samples should be selected according to a risk-based approach.

(12) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(10)] entrusts the European Medicines Agency (the Agency) with the task of advising on the maximum residue limits for veterinary medicinal products which may be accepted in food of animal origin.

(13) Maximum residue limits should be set for pharmacologically active substances used or intended to be used in veterinary medicinal products placed on the market in the Community.

(14) It appears from the public consultation and from the fact that only a small number of veterinary medicinal products for food-producing animals have been authorised in recent years that Regulation (EEC) No 2377/90 has resulted in such medicinal products being less readily available.

(15) In order to ensure animal health and welfare, it is necessary that veterinary medicinal products are available to treat specific disease conditions. Furthermore, the lack of availability of appropriate veterinary medicinal products for a specific treatment for a specific species may contribute to the misuse or illegal use of substances.

(16) The system established by Regulation (EEC) No 2377/90 should therefore be modified with a view to increasing the availability of veterinary medicinal products for food-producing animals. In order to serve that objective, provision should be made for the systematic consideration by the Agency of the use of a maximum residue limit established for one species or foodstuff for another species or another foodstuff. In this respect, the adequacy of the safety factors already inherent in the system should be taken into account in order to ensure that food safety and animal welfare are not compromised.

(17) It is recognised that, in certain cases, scientific risk assessments alone cannot provide all the information on which risk management decisions should be based and that other factors relevant to the matter under consideration should legitimately be taken into account, including the technological aspects of food production and the feasibility of controls. The Agency should therefore provide an opinion consisting of a scientific risk assessment and risk management recommendations on residues of pharmacologically active substances.

(18) Detailed rules on the format and content of applications for the establishment of maximum residue limits and on methodological principles of risk assessment and of risk

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management recommendations are necessary for the smooth functioning of the whole framework of maximum residue limits.

(19) Besides veterinary medicinal products, other products which are not subject to specific legislation on residues, such as biocidal products, are used in animal husbandry. These biocidal products are defined in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[(11)]. Furthermore, veterinary medicinal products not having a marketing authorisation in the Community may be authorised in countries outside the Community. That may be because in other regions different diseases or target species are more prevalent or because companies have chosen not to market a product in the Community. The fact that a product is not authorised in the Community does not necessarily indicate that its use is unsafe. For the pharmacologically active substances of such products, the Commission should be enabled to set a maximum residue limit for food, following an opinion by the Agency, in accordance with the principles set for pharmacologically active substances intended for use in veterinary medicinal products. It is also necessary to amend Regulation (EC) No 726/2004 to include, within the tasks of the Agency, advising on the maximum levels of residues of active substances in biocidal products.

(20) Under the system established by Directive 98/8/EC, operators having placed or seeking to place biocidal products on the market are obliged to pay charges for the evaluations carried out pursuant to different procedures associated with that Directive. This Regulation provides that the Agency is to carry out evaluations related to the establishment of the maximum residue limit for pharmacologically active substances intended to be used in biocidal products. As a consequence, this Regulation should clarify how those evaluations are financed, in order to take due account of fees already collected for evaluations carried out, or to be carried out, under that Directive.

(21) The Community contributes, in the context of the Codex Alimentarius, to the development of international standards on maximum residue limits, while ensuring that the high level of protection of human health maintained in the Community is not reduced. The Community should therefore take over without a further risk assessment those Codex Alimentarius maximum residue limits it has supported in the relevant Codex Alimentarius Commission meetings. Consistency between international standards and Community legislation on residue limits in food will thereby be further enhanced.

(22) Foodstuffs are subject to controls on residues of pharmacologically active substances in accordance with Regulation (EC) No 882/2004. Even if residue limits are not set for such substances pursuant to this Regulation, residues of such substances might occur due to environmental contamination or the occurrence of a natural metabolite in the animal. Laboratory methods are capable of finding such residues at ever lower levels. Such residues have caused different control practices in Member States.

(23) Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries[(12)] requires that each consignment imported from a third country is subject to veterinary controls, and Commission Decision 2005/34/EC[(13)] lays down harmonised

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standards for the testing for certain residues in products of animal origin imported from third countries. It is appropriate to extend the provisions of Decision 2005/34/EC to all products of animal origin placed on the Community market.

(24) A number of pharmacologically active substances are prohibited or currently not authorised under Regulation (EC) No 2377/90, Directive 96/22/EC or Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(14)]. The residues of pharmacologically active substances in products of animal origin arising, in particular, from illegal use or from environmental contamination should be carefully controlled and monitored in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products[(15)], regardless of the origin of the product.

(25) It is appropriate for the Community to provide for procedures to set reference points for action at concentrations of the residues for which laboratory analysis is technically feasible in order to facilitate intra-Community trade and imports, without undermining a high level of protection of human health in the Community. However, the setting of reference points for action should in no way serve as a pretext for condoning the illegal use of prohibited or non-authorised substances to treat food-producing animals. Therefore, any residues of those substances in food of animal origin should be considered undesirable.

(26) It is also appropriate for the Community to establish a harmonised approach for situations where Member States find evidence of a recurrent problem, since such a finding could suggest a pattern of misuse of a particular substance or a disregard for guarantees provided by third countries concerning the production of food intended for import into the Community. Member States should notify the Commission of recurring problems, and appropriate follow-up measures should be taken.

(27) The current legislation on maximum residue limits should be simplified by placing together in one single Commission regulation all decisions classifying pharmacologically active substances as regards residues.

(28) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(16)].

(29) In particular, the Commission should be empowered to adopt methodological principles for the risk assessment and risk management recommendations regarding the establishment of maximum residue limits, rules on the conditions for extrapolation, measures setting reference points for action, including measures reviewing those reference points, as well as methodological principles and scientific methods for the establishment of reference points for action. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.