Procedure file

Basic information

CNS - Consultation procedure Regulation	1996/0279(CNS)	Procedure completed
Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.60.04.04 Food safety		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Consumer Protection	PSE COLLINS Kenneth D.	22/01/1997
	Committee for opinion	Rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Environment	1990	03/03/1997

Key events

19/11/1996	Legislative proposal published	COM(1996)0584	Summary
15/01/1997	Committee referral announced in Parliament		
05/02/1997	Vote in committee		Summary
05/02/1997	Committee report tabled for plenary, 1st reading/single reading	A4-0035/1997	
19/02/1997	Debate in Parliament		Summary
20/02/1997	Decision by Parliament	T4-0055/1997	Summary
03/03/1997	Act adopted by Council after consultation of Parliament		
03/03/1997	End of procedure in Parliament		
07/03/1997	Final act published in Official Journal		

Technical information

Procedure reference	1996/0279(CNS)

Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 163; EC before Amsterdam E 043
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/08533

Documentation gateway

Legislative proposal		COM(1996)0584 OJ C 381 17.12.1996, p. 0009	19/11/1996	EC	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0035/1997 OJ C 085 17.03.1997, p. 0005	05/02/1997	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0055/1997 OJ C 085 17.03.1997, p. 0100-0127	20/02/1997	EP	Summary
Economic and Social Committee: opinion, report		CES0233/1997 OJ C 133 28.04.1997, p. 0027	26/02/1997	ESC	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 1997/434
OJ L 067 07.03.1997, p. 0001 Summary

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

OBJECTIVE : to amend Regulation 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. SUBSTANCE : the amendments proposed by the Commission aim essentially to: - adapt Regulation (EEC) No 2377/90 by conferring on the European Agency for the evaluation of medicinal products the task of dealing with applications for the establishment, amendment and extension of maximum residue limits and by aligning the decision-making process with respect to the authorization and supervision of medicinal products for veterinary use with that introduced by Regulation (EEC) No 2309/93; - enable the Community to fulfil its obligations under the Agreement on the application of sanitary and phytosanitary measures which emerged from the Uruguay Round, an agreement approved by the Community by Council Decision 94/800/EC; - extend until 1 January 1999 the deadline for reviewing old substances, in order to allow the continuation of their scientific evaluation in the best possible conditions. ?

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

According to committee chairman Mr Ken COLLINS (PSE, UK), the Commission proposal on residues of veterinary medicinal products in foods of animal origin was worthy of "Mickey Mouse". The Commission representative had irritated MEPs by advising them not to play "sorcerer's apprentice" by dividing the proposal under examination and only dealing with one part, thereby provoking a chain reaction which they would be powerless to stop. But Mr COLLINS, as rapporteur, replied that it was the Commission who was playing "sorcerer's apprentice" by squeezing two completely different matters into a single document and crying urgency on a proposal which it had only transmitted three weeks previously. The proposal in question was for a Council regulation amending Regulation (EEC) No 2377/90 on the establishment of maximum residue limits of veterinary medicinal products in foods of animal origin. Refusing to allow itself to be "bewitched", the Committee on Consumer Protection had unanimously decided, within the framework of the consultation procedure, to accept one part of the proposal and reject the other. It therefore approved, with reservations, the section extending the deadline for setting maximum residue limits of veterinary medicinal products previously authorized in foods of animal origin by two years (to 1 January 1999) in order to be able to complete the enormous volume of evaluation work needed. However, it rejected the part of the proposal seeking to authorize provisional residue limits in foods from animals which had undergone clinical trials. With no such limits, it would be impossible to use these animals to manufacture food after 1 January 1997. The Committee on Consumer Protection refused to allow the Commission to slip this part of the proposal through unnoticed together with the first part without giving Parliament time to examine it in detail. If the Commission refused to withdraw the section on clinical trials, Parliament would still have the facility to refer the entire text to the parliamentary committee.?

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

Following the contacts announced the day before, Mr Collins said that a revised motion for a resolution had been accepted by the political groups. This text provided for a vote on Amendment No 8 only which related to Article 14 of the proposal.

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

In adopting the report by Mr Ken COLLINS (PSE, UK) on the amendment of Regulation 2377/90/EEC establishing maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, Parliament adopted only Amendment 8 to this proposal. This amendment which does not concern the substance of the proposal states that if the potentially most dangerous substances such as pyrazolone derivates, nitromidazoles, arsanilic acid and phenylbutazone are not assessed before 31 December 1997 they will be prohibited within the Community from 1 January 1998. ?

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

The Committee notes that the amendments in question concern various procedural aspects and deadlines. Each will be considered in detail. Given the urgency as a result of the legal void which has been created, the Committee has adopted an opinion on the procedural aspects and deadlines contained in the proposal, and will return to the substantial issues raised subsequently as soon as the Commission formulates new proposals. The need to update the procedure The Committee considers that the proposed amendments to Articles 7, 8, 10 and 12 are appropriate to the new legal framework for medicinal products and the Community's international obligations. The need to extend the deadline for the review of substances already in use Given the rate at which substances already in use are being examined, and the fact that over 200 remain to be dealt with, the Committee is obliged to approve the extension laid down in the first and second paragraph of Article 14. The Committee does not, however, consider two years to be sufficient, given the time required for in-depth examination, which is essential to consumer and animal health protection and if the practice of repeated extensions is not to continue. This is partly on the basis of the data gathered by the European Agency for the Evaluation of Medicinal Products. The Committee proposes that the deadline be set definitively for 1 January 2000, with no possibility of extension. Establishment of maximum residue limits for substances undergoing clinical trials Since the Committee considers that consumer protection is already provided at national level by the rules under Directive 93/40/EEC and by the good clinical practices laid down in Directive 92/18/EEC, it does not believe that establishing a provisional MRL will enhance consumer safety. Consequently, the Committee does not accept the addition of a new Article 4(a) or of the third paragraph of Article 14, and calls upon the Commission to draft a new proposal reflecting the CVMP guidelines so as to reconcile consumer safety with the need to avoid the destruction of animals used for trials wherever possible. ?

Foodstuffs of animal origin: maximum residue limits of veterinary medicinal products

OBJECTIVE: to defer the revision of the old substances in order to allow the Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin to continue on a sound scientific basis. COMMUNITY MEASURE: Council Regulation 434/97/EEC amending Regulation 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products of animal origin. SUBSTANCE: the regulation defers the deadline for the evaluation of substances the use of which was authorized on 1 January 1997 and in respect of which documented applications for the establishment of maximum residue limits have been lodged with the Commission or with the European Agency for the Evaluation of Medicinal Products before 1 January 1996: - until 1 January 1998 in the case of products derived from pyrasolidon, nitroimidazoles, arsanilic acid and phenylbutazone; - until 1 January 2000 in the case of other substances. The Agency shall publish the list of these substances before 7 June 1997. ENTRY INTO FORCE: 07/03/1997. The regulation is applicable from 1 January 1997. ?