Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2000/0132(COD)
Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists Amending Directive 96/22/EC 1993/1036(CNS) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		12/07/2000
		ELDR OLSSON Karl Erik	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		12/07/2000
		ELDR OLSSON Karl Erik	
	Former committee for opinion		
	ITRE Industry, External Trade, Research, Energy		13/09/2000
		V/ALE PIÉTRASANTA Yves	
	AGRI Agriculture and Rural Development		11/07/2000
		PPE-DE MÜLLER Emilia Franziska	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2524	22/07/2003
	Agriculture and Fisheries	2486	20/02/2003
	Agriculture and Fisheries	2476	16/12/2002
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events

24/05/2000	Legislative proposal published	COM(2000)0320	Summary
07/07/2000	Committee referral announced in Parliament, 1st reading		
09/01/2001	Vote in committee, 1st reading		Summary

09/01/2001	Committee report tabled for plenary, 1st reading	A5-0002/2001	
01/02/2001	Debate in Parliament		
01/02/2001	Decision by Parliament, 1st reading	T5-0051/2001	Summary
06/03/2001	Modified legislative proposal published	COM(2001)0131	Summary
20/02/2003	Council position published	14502/1/2002	Summary
13/03/2003	Committee referral announced in Parliament, 2nd reading		
22/05/2003	Vote in committee, 2nd reading		Summary
22/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0201/2003	
01/07/2003	Debate in Parliament		
02/07/2003	Decision by Parliament, 2nd reading	T5-0317/2003	Summary
22/07/2003	Act approved by Council, 2nd reading		
22/09/2003	Final act signed		
22/09/2003	End of procedure in Parliament		
14/10/2003	Final act published in Official Journal		

Technical information

Procedure reference	2000/0132(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 96/22/EC 1993/1036(CNS)
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/14406

Documentation gateway

Legislative proposal		COM(2000)0320 OJ C 337 28.11.2000, p. 0163 E	24/05/2000	EC	Summary
Economic and Social Committee: opinion, report		CES1213/2000 OJ C 014 16.01.2001, p. 0047	19/10/2000	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0002/2001	09/01/2001	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0051/2001 OJ C 267 21.09.2001, p. 0020-0053	01/02/2001	EP	Summary
Modified legislative proposal		COM(2001)0131 OJ C 180 26.06.2001, p. 0190 E	06/03/2001	EC	Summary
Council statement on its position		05193/2003	06/02/2003	CSL	

Council position		14502/1/2002 OJ C 090 15.04.2003, p. 0001-0008 E	20/02/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0285	07/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0201/2003	22/05/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0317/2003 OJ C 074 24.03.2004, p. 0100-0625 E	02/07/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2003)0489	11/08/2003	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2003/74
OJ L 262 14.10.2003, p. 0017-0021 Summary

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

PURPOSE : to amend Council directive 96/22/EC regarding the use in stockfarming of certain hormonal substances. CONTENT : in the light of an opinion of the Scientific Committee on Veterinary measures relating to Public Health (SCVPH), the Commission proposes definitively to ban the use of oestradiol 17 beta and its ester-like derivatives in farm animals and to only allow its adminisatration to non-farm animals for therapeutic purposes. The administration of five other hormonal substances for animal growth promotion purposes is prohibited by the above directive. These are testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. In the case of these five, the need for further information ahs been identified. Therefore, the Commission proposes to continue provisionally to apply the prohibition on these five hormones until more complete scientific information is made available. The use of some of these substances may, however, continue to be authorised for therapeutical purposes and zootechnical treatment under the conditions of Council directive 96/22/EC. In comparison to the present situation, this proposal has an impact on imports from third countries who legally use oestradiol 17 beta and its ester-like derivatives for therapeutical purposes or zootechnical treatment in farm animals. The Commission considers the presentation of this proposal represents another step towards the implementation of the European Community's international obligations, specifically in the World Trade Organisation.?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The committee adopted the report by Karl-Erik OLSSON (ELDR, S) approving the proposal under the codecision procedure subject to a number of amendments designed mainly to tighten up the text. The committee supported the Commission's decision to apply the precautionary principle and hence to ban the use of the hormones in question. Pending reliable scientific findings, consumer health should be respected at all times and effective monitoring systems introduced. The committee introduced a new clause stipulating that the Commission would review the monitoring and control systems for meat imports from third countries and ensure that they were completely compatible with the principle of consumer protection. ?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The European Parliament adopted the report by Mr Karl Erik Olsson (ELDR, S). Several amendments were adopted, one of which is designed to strengthen the monitoring of imports from third countries. (Please refer to the previous text).?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The amended proposal includes clarifications proposed by the European Parliament as regards wording in Article 1 (4) and Article 1 (7), in

particular to the effect that the Commission will take into account recent scientific data from any source when keeping the measures under review.?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The common position, adopted with the abstention of the United Kingdom, is based on a modified Commission proposal that already includes several amendments proposed by then European Parliament into account. As adopted by the Council by qualified majority, it does not alter the basic objectives of the proposed Directive: to protect consumer health and reach WTO compliance. There is no difference of opinion between the Council, the European Parliament and the Commission regarding the essential elements of the proposed directive and in particular on the need for maintaining a prohibition on the use of oestradiol 17 beta and its ester-like derivatives for growth promotion purposes and to introduce a temporary precautionary prohibition on the use of other hormones while additional scientific information, necessary for a fuller assessment of the risk, is gathered. In deciding such measures the Council has taken into account the latest scientific evidence and risk assessments, in particular the opinion of the SCVMPH of April 2002, together with other possible consequences, in particular environmental, of the large scale use of hormones in stock farming. The recitals of the proposed directive have been modified accordingly. Contrary to the Commission's proposal, the Council considered preferable to let the Parliament and the Council take future risk management decisions concerning the updates of the directive's provisions in the light of the new evidence which the Commission is required to gather taking into account recent scientific data from all possible sources and present to them. The Council, in agreement with the Commission and Parliament, has decided to maintain the use of certain of the substances, where this is strictly necessary, for therapeutic purposes or zootechnical treatment as this is not likely to constitute an unacceptable hazard for public health due to the nature and the limited duration of the treatments, the limited quantities administered and the strict conditions under which their administration can take place, laid down in Directive 96/22/EC in order to prevent any possible misuse. The Council has, however, considered appropriate, in the light of the existing information to limit as far as reasonably achievable the exposure to oestradiol 17 beta and only authorise those very few treatments (foetus maceration or mummification, pyometra in cattle and oestrus induction in cattle, horses, sheep or goats) for which no viable and effective alternatives seem presently to be available. Such treatments are not likely to present an unacceptable risk to public health, especially in the light of the new very stringent conditions required to be taken to avoid any possible abusive use. The Council has equally provided for a timely review of the provisions concerning treatments of farm animals with oestradiol 17 beta. Lastly, the Council feels that the fact that it has to a very large extent taken account of the European Parliament's position ought to lead to an early adoption of the Directive. There are also some statements added to this text, such as : - the Council and the Commission emphasise that the aim pursued in Article 11a is, in five years' time, to ban the use of oestradiol 17 beta or its ester-like derivatives for treating farm animals and replace it with equally effective substances; - the Commission undertakes to continue its efforts to establish Community-wide harmonised maximum levels for natural sex hormonesand validated methods of analysis, having due regard to physiological levels observed in farm animals.?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The Commission supports the common position adopted by the Council as the best compromise that could be reached and has made a relevant declaration during the Council of Agriculture of 16 December 2002. The Council and the Commission emphasise that the aim pursued in Article 11a is to ban in five years' time the use of oestradiol 17 beta and its ester-like derivatives for treating farm animals and replace it with equally effective substances.?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The committee adopted the report by Karl-Erik OLSSON (ELDR, S) amending the Council's common position under the 2nd reading of the codecision procedure. It voted to delete the article in the common position allowing for veterinary medicinal products containing oestradiol 17 beta to be administered to animals for certain treatments (Article 5a). MEPs argued that the precautionary principle should be applied to safeguard consumers' health in view of the dangerousness of this substance, which may be carcinogenic. However, they said that exceptions could be made for the treatment of non-farm animals, i.e. animals not used for food production. The committee also deleted the new article stipulating that the Commission should report to Council and Parliament within two years on the availability of alternative veterinary medical products which did not contain oestradial 17 beta. It pointed out that such alternatives were already available. ?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The European Parliament adopted some of the amendments in the report by Karl Erik OLSSEN (ELDR, Sweden). The amendments were designed to phase out the use of oestradiol 17 for oestrus induction over three years. However, the use of oestradiol for the treatment of certain conditions (foetus maceration or mummification or pyrometra in cattle) is maintained under strict conditions.?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

The Commission supports the compromise proposal presented at the EP Plenary on 1 July 2003 as it meets the main objectives (to protect

consumer health and to reach compliance with the requirements of the World Trade Organisation).?

Stockfarming: prohibition of certain substances with hormonal or thyrostatic action, of beta-agonists

PURPOSE : to prohibit certain substances in stock farming. LEGISLATIVE ACT : Directive 2003/74/EC of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of beta-agonists. CONTENT : Directive 96/22/EC requires Member States to prohibit the administration to farm animals of substances having an oestrogenic, androgenic or gestagenic action. Nevertheless administration of those substances to farm animals may be authorised but only if they are used for therapeutic purposes or zootechnical treatment, in accordance with the Directive. Directive 96/22/EC also requires Member States to prohibit the importation from third countries of farm animals to which the substances have been administered, except in certain specified circumstances. In the light of the results of a dispute settlement case brought before the World Trade Organisation (WTO) by the United States of America and by Canada (the Hormones case) and recommendations made in that respect by the WTO Dispute Settlement Body on 13 February 1998, the Commission immediately initiated a complementary risk assessment of the six hormonal substances (oestradiol 17 beta, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) whose administration for animal growth promotion purposes is prohibited by Directive 96/22/EC. The conclusions of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) indicate that a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones evaluated. Furthermore, for the six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged. Prepubertal children constitute the group of greatest concern. Finally, no threshold levels and, therefore, no acceptable daily intake (ADI) can be established for any of the six hormones evaluated when they are administered to bovine animals for growth promotion purposes. - With regard to the use of oestradiol 17 beta, a substantial body of recent evidence suggests that it has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects. It can potentially be used in all farm animals and residue intake for all segments of the human population. The avoidance of such intake is of absolute importance to safeguard human health. Furthermore, the routine use of the above substances for animal growth promotion purposes is likely to lead to increased concentration of those substances in the environment. - As regards the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate), the SCVPH assessment is that the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers. This Directive therefore maintains the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17 beta and continues provisionally to apply the prohibition to the other five hormones. However, the use of certain of these substances for therapeutic purposes or zootechnical treatment may continue to be authorised as it is not likely to constitute a hazard forpublic health owing to the nature and the limited duration of the treatments. The exposure to oestradiol 17 beta is limited to those treatments for which no viable effective alternatives exist. In general, there are alternative treatments or strategies available to replace most of the uses of oestradiol 17 beta for therapeutic or zootechnical purposes. Nonetheless, studies appear to show that at present no viable effective alternatives exist in all the Member States for certain treatments which are currently authorised. In order to allow for the necessary adjustments and in particular for the authorisation or the mutual recognition of the pharmaceutical products needed, the Directive phases out the use of oestradiol 17 beta for oestrus induction over three years (until 14/10/06.) The Directive also maintains the possibility of authorising its use for the treatment of foetus maceration or mummification and pyometra in cattle which have serious consequences for animal health and welfare. The Commission must present a review of this by 14/10/05. DATE FOR TRANSPOSITION : 14/10/04. ENTRY INTO FORCE : 14/10/03.?