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

2000/0132(COD) - 22/09/2003 - Final act

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.