Amended proposal for a Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists [1]

(2001/C 180 E/15)

(Text with EEA relevance)

COM(2001) 131 final — 2000/0132(COD)

(Submitted by the Commission pursuant to Article 250(2) of the EC Treaty on 6 March 2001)

[1] OJ C 337 E, 28.11.2000, p. 163.

INITIAL PROPOSAL	AMENDED PROPOSAL
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	Unchanged
Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,	
Having regard to the proposal from the Commission,	
Having regard to the opinion of the Economic and Social Committee,	
Having regard to the opinion of the Committee of the Regions,	
Acting in accordance with the procedure laid down in Article 251 of the Treaty,	
Whereas:	
(1) Point (a) of Article 3 of Council Directive 96/22/EC [1] requires Member States to prohibit the administration to farm animals of substances having, *inter alia*, an oestrogenic, androgenic or gestagenic action. Administration of those substances to farm animals may only be authorised for therapeutic purposes or zootechnical treatment, in accordance with the provisions of Articles 4, 5 and 7 of the Directive.	
(2) Article 11(2) of Directive 96/22/EC requires Member States to prohibit the importation from third countries of farm or aquaculture animals to which substances or products referred to in point (a) of Article 3 have been administered, unless those products were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 of the Directive, as well as of meat or products obtained from animals the importation of which is prohibited under point (a) of Article 3 thereof.	

[1] OJ L 125, 23.5.1996, p. 3.

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(3) 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) [1] and the recommendations made in that respect by the WTO Dispute Settlement Body on 13 February 1998, the Commission immediately initiated a complementary risk assessment, in accordance with the requirements of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) [2], as interpreted by the Appellate Body in the *Hormones* case, of the six hormonal substances (oestradiol 17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) whose administration for animal growth promotion purposes is prohibited by Directive 96/22/EC.	
(4) In parallel, the Commission initiated and funded a number of specific scientific studies and research projects on these six hormones in order to obtain as much as possible of the missing scientific information, as identified in the interpretations and findings of the WTO panel and Appellate Body reports in the *Hormones* case. Moreover, the Commission addressed specific requests to the USA, Canada and other third countries, which authorise the use of these six hormones for animal growth promotion, and published an open call for documentation [3] requesting any interested party, including the industry, to provide any relevant and recent scientific data and information in their possession to be taken into account in the complementary risk assessment.	
(5) On 30 April 1999, as requested by the Commission, the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion concerning the assessment of potential adverse effects to human health from hormone residues in bovine meat and meat products [4]. The major conclusions of that opinion were, first, that, as concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and the epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones evaluated. Second, for the six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged and, of the various susceptible risk groups, prepubertal children is the group of greatest concern and, third, in view of the intrinsic properties of the hormones and taking into account epidemiological findings, 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.	

[1] WT/DS26/R/USA and WT/DS48/R/CAN (panel reports), and AB-1997-4 (Appellate Body report).

[2] OJ L 336, 23.12.1994, p. 40.

[3] OJ C 56, 26.2.1999, p. 17.

[4] Commission Document XXIV/B3/SC4 of 30 April 1999.

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(6) As regards, in particular, oestradiol 17β, the SCVPH assessment is that 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 and that the data currently available does not make it possible to give a quantitative estimate of the risk.	
(7) As regards the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate), the SCVPH assessment is that, in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers.	
(8) Subsequent to the opinion of the SCVPH of 30 April 1999, new and more recent scientific information was made available to the Commission from the United Kingdom's Veterinary Products Committee, in October 1999, the Committee on Veterinary Medicinal Products of the EC, in December 1999, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in February 2000, for some of the six hormones under consideration). All this latest scientific information was brought to the attention of the SCVPH, which reviewed it and, on 3 May 2000, concluded that it did not provide convincing data and arguments requiring revision of the conclusions drawn in its opinion of 30 April 1999.	
(9) As regards, in particular, oestradiol 17β, this substance can potentially be used in all farm animals and residue intake for all segments of the human population and in particular the susceptible groups at high risk can therefore be especially relevant. Avoiding such intake is important to safeguard human health. Moreover, the residues resulting from its use cannot be detected at present through the routine analytical methods available.	
(10) In accordance with the provisions of Articles 5.1 and 5.7 of the SPS Agreement, taking into account the results of the risk assessment and all other available pertinent information, it must be concluded that, in order to achieve the chosen level of health protection in the Community from the risks posed to human health by the consumption of residues found in meat derived from animals to which these hormones had been administered for growth promotion purposes, it is necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17β and to continue provisionally to apply the prohibition on the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate). The provisional prohibition of these five hormones should apply while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge on these substances, in accordance with Article 5.7 of the SPS Agreement.	

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(11) The use of certain of the above substances for therapeutic purposes or zootechnical treatment may, however, continue to be authorised under the strict conditions laid down in Directive 96/22/EC in order to prevent any misuse, save as regards oestradiol 17β and its ester-like derivatives whose administration may only be authorised for therapeutic treatment to non-farm animals, in view of the results of the risk assessment.

(12) In general, there are alternative treatments or strategies available to replace the use of oestradiol 17β for therapeutic or zootechnical purposes; the real need for oestradiol 17β for the treatment of specific limited conditions in individual animals will be identified by the Commission in association with competent authorities, with a view to developing appropriate alternative solutions before the entry into force of this Directive.

(13) In order to ensure effective implementation of Directive 96/22/EC, provision should be made for the adaptation of its Annexes and the substances contained therein, as appropriate.

(14) The measures necessary for the implementation of this Directive 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 [1].

(15) There is no other means that is reasonably available to the Community, taking into account technical and economic feasibility, to achieve the chosen level of health protection from the residues of these hormones in meat, and which is significantly less restrictive to international trade, and Directive 96/22/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/22/EC is amended as follows:

1. Articles 2 and 3 are replaced by the following:

'*Article 2*

Member States shall prohibit the placing on the market of the substances listed in Annex II for administering to animals, the meat and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4.

Article 3

Member States shall prohibit, for substances listed in Annex II, and shall provisionally prohibit, for substances listed in Annex III:

[1] OJ L 184, 17.7.1999, p. 23.

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(a) the administering of those substances to a farm or aquaculture animal, by any means whatsoever;	
(b) the holding, except under official control, of animals referred to in (a) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in Annex II and Annex III or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with Articles 4 or 5;	
(c) the placing on the market for human consumption of aquaculture animals to which substances referred to above have been administered and of processed products derived from such animals;	
(d) the placing on the market of meat of the animals referred to in (b);	
(e) the processing of the meat referred to in (d).'	
2. Article 4 is amended as follows:	
(a) In point 1, the words 'oestradiol 17β' are deleted.	
(b) The following paragraph is added:	
'Member States shall prohibit oestradiol 17β and its ester-like derivatives for use in growth promotion, for therapeutic purposes and zootechnical treatment except for therapeutic treatment under veterinary supervision of non-farm animals.'	
3. In Article 5, the first sentence of the first paragraph is replaced by the following:	
'Notwithstanding Article 3(a) and without prejudice to Article 2, Member States may authorise the administering to farm animals, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action which are authorised in accordance with Directives 81/851/EEC and 81/852/EEC.'	
4. In Article 7, paragraph 2 is replaced by the following:	
'Meat or products from animals to which substances having an oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action or beta-agonists have been administered in accordance with the dispensatory provisions of this Directive may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of Article 6 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.'	'Meat or products from animals to which substances having an oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action or beta-agonists have been administered in accordance with the dispensatory provisions of this Directive may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of Article 6 and in so far as the withdrawal period laid down for the product concerned was observed before the animals were slaughtered.'

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5. Article 8 is amended as follows:	Unchanged
(a) In point 1, the words 'Articles 2 and 3(a)' are replaced by 'Articles 2 and 3'.	
(b) In point 2(a), the words 'under Article 2' are replaced by 'under Articles 2 and 3'.	
6. Article 11 is amended as follows:	
(a) In paragraph 2(a)(i), the words 'point (a) of Article 2' are replaced by 'Annex II, List A'.	
(b) In paragraph 2(a)(ii), the words 'point (a) of Article 3' are replaced by 'Annex II, List B and Annex III'.	
(c) In paragraph 3, the words 'according to the procedure laid down in Article 33 of Council Directive 96/23/EC' are replaced by 'according to the procedure referred to in Article 11b(2)'.	
7. The following Articles 11a and 11b are added:	
'Article 11a	
1. Provisions in the Annexes may be amended and/or deleted in accordance with the procedure referred to in Article 11b(2).	
2. With regard to the substances listed in Annex III, the Community will seek additional information and keep the measures under regular review.	2. With regard to the substances listed in Annex III, the Community will seek additional information, taking into account recent scientific data from any source and keep the measures under regular review.
Article 11b	Unchanged
1. The Commission shall be assisted by the Standing Veterinary Committee instituted by Article 1 of Council Decision 68/361/EEC (*) (hereinafter referred to as "the Committee").	
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	
The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.	
(*) OJ L 255, 18.10.1968, p. 23.'	
8. The following Article 14a is added:	
'*Article 14a*	
The provisions laid down in this Directive with regard to oestradiol 17β shall not apply to farm animals for which it can be certified that, where oestradiol 17β has been administered to them for therapeutical purposes or zootechnical treatment, this administration has taken place before 1 July 2001.'	

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9. The Annex to Directive 96/22/EC becomes 'Annex I' and Annexes II and III in the Annex to this Directive are added.	
Article 2	
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2001 at the latest. They shall forthwith inform the Commission thereof.	
When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.	
Article 3	
This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.	
Article 4	
This Directive is addressed to the Member States.	
	ANNEX
'*ANNEX II*	Unchanged
List of prohibited substances:	
List A:	
— Thyrostatics,	
— Oestradiol 17β and its ester-like derivatives,	
— Stilbenes, stilbene derivatives, their salts and esters.	
List B:	
— Beta-agonists	
ANNEX III	
List of provisionally prohibited substances:	
Substances having oestrogenic (other than oestradiol 17β and its ester-like derivatives), androgenic or gestagenic action.	