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EUROPEAN COMMUNITIES – MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

Communication from the European Communities

The following communication, dated 27 October 2003, from the Permanent Delegation of the European Commission to the Dispute Settlement Body, is circulated at the request of that delegation.

The EC initiated a complementary risk assessment of potential risks to human health from hormone residues in bovine meat and meat products, focusing in particular on the six hormonal substances (oestradiol 17ß, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) at issue in accordance with the requirements of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and in light of the relevant clarifications on risk assessment provided by the Appellate Body.

The risk assessment was submitted to the Commission by the independent Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) responsible for this issue in its Opinion of 30 April 1999.[1] It confirmed the case for a prohibition on the use of the hormones in question for growth promotion.

Subsequently, new and more recent scientific information, including on the hormones under consideration was reviewed by the Scientific Committee. The first review, adopted on 3 May 2000, concluded that there were no convincing data or arguments demanding revision of the opinion adopted in 1999. The second review, adopted on 10 April 2002, again confirmed the validity of this position.[2]

In light of such results of the risk assessment as are now available to it, the EC adopted Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 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 (see Annex I).

Following the EC's failure to comply within the prescribed timeframe with the recommendations and rulings of the DSB in the aforementioned case, the United States and Canada

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[1] *Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health: Assessment of potential risks to human health from hormone residues in bovine meat and meat products (30 April 1999)*, available on http://europa.eu.int/comm/food/fs/him/him_index_en.html.

[2] *Opinion on review of previous SCVPH opinions of 30 April 1999 and 3 May 2000 on the potential risks to human health from hormone residues in bovine meat and meat products (adopted on 10 April 2002)* and *Review of specific documents relating to the SCVPH opinion of 30 April 99 on the potential risks to human health from hormone residues in bovine meat and meat products (adopted on 3 May 2000)* also available on the internet at the address referred to in Footnote 1.

requested and obtained from the DSB the authorization to suspend concessions to the EC (WT/DS26/21 and WT/DS48/19). On the basis of such authorization, the US and Canada have suspended concessions to the EC equivalent to an amount of, respectively, 116 million US Dollars and 11.3 million Canadian Dollars. Such concessions are presently suspended.

This Directive was published in the Official Journal of the European Community on 14 October 2003 and entered into force on the same day.

With the publication and entry into force of this Directive, the EC considers that it has now fully implemented the recommendations and rulings of the DSB in the aforementioned dispute. As a consequence, the EC considers that the suspension of concessions to the EC by the United States and Canada in this dispute is no longer justified.

ANNEX I

**DIRECTIVE 2003/74/EC
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2003
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**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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[3],

Having regard to the opinion of the European Economic and Social Committee[4],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[5],

Whereas:

(1) Article 3(a)of Directive 96/22/EC[6] requires Member States to prohibit the administration to farm animals of substances having, inter alia ,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 provisions of Articles 4, 5 and 7 of that 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 Article 3(a)of that Directive have been administered, unless those products were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 thereof, as well as of meat or products obtained from animals the importation of which is prohibited.

(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)[7] and 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 Agreement on the application of sanitary and

[3] OJ C 337 E, 28.11.2000 and OJ C 180 E, 26.6.2001, p. 190.
[4] OJ C 14, 16.1.2001, p. 47.
[5] Opinion of the European Parliament of 1 February 2001 (OJ C 267, 21.9.2001,p.53),Council Common Position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 1) and Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal). Council Decision of 22 July 2003.
[6] OJ L 125, 23.5.1996, p. 3.
[7] WT/DS26/R/USA and WT/DS48/R/CAN (panel reports), and AB-1997-4 (appellate body report).

phytosanitary measures (WTO-GATT)[8] as interpreted by the appellate body in the Hormones case, of the six hormonal substances (oestradiol 17ß , 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[9] 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. 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. Secondly, 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 constitute 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.

(6) As regards, in particular, the use of oestradiol 17ß ,with the aim of promoting growth, 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 do 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 on some of the six hormones under consideration 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 European Community (CVM), in December 1999,and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in February 2000. The CVM has noted in particular that oestradiol 17ß has a carcinogenic effect only after prolonged exposure and at levels which are considerably higher than those needed

[8] OJ L 336, 23.12.1994, p. 40.
[9] OJ C 56, 26.2.1999, p. 17.

for a physiological (oestrogenic) response. 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. The SCVPH confirmed in its opinion of 10 April 2002 the validity of its previous opinion, after revising it in the light of the most recent scientific data.

(9) As regards, in particular, oestradiol 17ß ,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. 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.

(10) Taking into account the results of the risk assessment and all other available pertinent information, it has to be concluded that, in order to achieve the chosen level of protection in the Community from the risks posed, in particular to human health, by the routine use of these hormones for growth promotion and the consumption of residues found in meat derived from animals to which these hormones have been administered for growth promotion, it is necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17ß and to continue provisionally to apply the prohibition to the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate). Furthermore, according to Article 7 of 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[10], 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 of these substances.

(11) However, the use of certain of the above substances, where this is necessary, for therapeutic purposes or zootechnical treatment may continue to be authorised as it is not likely to constitute a hazard for public health owing to the nature and the limited duration of the treatments, the limited quantities administered and the strict conditions laid down in Directive 96/22/EC in order to prevent any possible misuse.

(12) However, in the light of the existing information it is appropriate to limit as far the exposure to oestradiol 17ß and only authorise 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 17ß 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, it is appropriate to phase out the use of oestradiol 17ß for oestrus induction over a given period. It is also appropriate to maintain the possibility of authorising, under strict and verifiable conditions so as to prevent any possible misuse and any unacceptable risk for public health, its use for the treatment of certain conditions (foetus maceration or mummification and pyometra in cattle) which have serious consequences for animal health and welfare. It is necessary to review this possibility within a given time.

[10] OJ L 31, 1.2.2002, p.1.

(13) The proposed amendments to Directive 96/22/EC are necessary to achieve the chosen level of health protection from the residues in meat of farm animals treated with these hormones for growth promotion purposes, whilst respecting the general principles of food law set out in Regulation (EC) No 178/2002 and the international obligations of the Community. Moreover, there is no other means that is reasonably available at present, taking into account technical and economic feasibility, which is significantly less restrictive of trade and can achieve equally effectively the chosen level of health protection. In addition, minor drafting amendments are equally necessary in particular in view of the replacement of a number of Directives by 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[11],

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/22/EC is hereby amended as follows:

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

'*Article 2*

Member States shall prohibit:

(a) the placing on the market of the substances listed in Annex II, list A, for administering to animals of all species;

(b) the placing on the market of the substances listed in Annex II, list B, for administering to animals, the flesh and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4 and in Article 5a.

Article 3

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

(a) the administering of those substances to farm or aquaculture animals, by any means whatsoever;

(b) – the holding, except under official control, of animals referred to in point (a) on a farm, and

– the placing on the market or the slaughter for human consumption of farm 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, 5 or 5a;

[11] OJ L 311, 28.11.2001, p.1.

(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 from animals referred to in point (b);

(e) the processing of the meat referred to in (d).'

2. in Article 4, point 1, 'oestradiol 17ß' are deleted;

3. in Article 5, first paragraph, the first sentence 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 17ß and its ester-like derivatives), androgenic or gestagenic action which are authorised in accordance with 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 (*).

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(*) OJ L 311, 28.11.2001, p. 1.'

4. the following Article is added:

'*Article 5a*

1. Notwithstanding Article 3(a)and without prejudice to Articles 2 and 11a,Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17ß or its ester-like derivatives for:

– the treatment of foetus maceration or mummification in cattle, or

– the treatment of pyometra in cattle, in accordance with Directive 2001/82/EC.

2. Notwithstanding Article 3(a)and without prejudice to Article 2,Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17ß or its ester-like derivatives for oestrus induction in cattle, horses, sheep or goats until 14 October 2006,in accordance with Directive 2001/82/EC.

3. The treatment must be carried out by the veterinarian himself or herself on farm animals which have been clearly identified. This treatment must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be that provided for in Directive 2001/82/EC:

– the type of product administered,

– the nature of the treatment,

– the date of treatment,

– the identity of the animals treated,

– the date of expiry of the withdrawal period.

The register must be made available to the competent authority at its request.

Stockfarmers shall be prohibited from holding on their farms veterinary medicinal products containing oestradiol 17ß or its ester-like derivatives.'

5. Article 6(1) is replaced by the following:

'1. Hormonal products and beta-agonists the administration of which to farm animals is authorised in accordance with Articles 4, 5 or 5a must meet the requirements of Directive 2001/82/EC.'

6. Article 7(1), first subparagraph, is replaced by the following:

'1. For the purpose of trade, Member States may authorise the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in Articles 4, 5 or 5a and may authorise the affixing of the Community stamp to meat from such animals where the conditions laid down in Articles 4, 5 or 5a and the withdrawal periods provided for in the authorisation to place on the market are complied with.'

7. Article 8 is amended as follows:

(a) point 1 is replaced by the following:

'1. at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in Articles 2 and 3,their possession is restricted to the persons authorised by national legislation in accordance with Article 68 of Directive 2001/82/EC.'

(b) in point 2(a),'Article 2 'is replaced by 'Articles 2 and 3 ';

(c) in point 2(d),'in Articles 4 and 5 'is replaced by 'in Articles 4,5 and 5a ';

(d) footnote 2 is deleted and footnote 3 becomes footnote 2;

8. Article 11(2)(a)is amended as follows:

(a) in point (i),'point (a)of Article 2 'is replaced by 'Annex II, List A,';

(b) point (ii)is replaced by the following:

'(ii) to which substances referred to in Annex II, List B, and Annex III have been administered, unless those substances were administered in compliance with the provisions and requirements laid down in Articles 4,5,5a and 7 and the withdrawal periods allowed in international recommendations have been observed;'

9. the following Article is added:

'*Article 11a*

The Commission shall present within two years from 14 October 2003 to the European Parliament and to the Council, a report on the availability of alternative veterinary medicinal products to those containing oestradiol 17ß or its ester-like derivatives for the treatment of foetus maceration or mummification in cattle, and for the treatment of pyometra in cattle, and present to them the following year any necessary proposals intending to replace these substances in due time.

Likewise, with regard to the substances listed in Annex III, the Commission shall seek additional information, taking into account recent scientific data from all possible sources, and keep the measures applied under regular review with a view to timely presentation to the European Parliament and to the Council of any necessary proposals.'

10. the following Article is added:

'*Article 14a*

Notwithstanding Articles 3 and 5a,and without prejudice to Article 2,farm animals for which it can be certified that they have been administered oestradiol 17ß or its ester-like derivatives for therapeutic or zootechnical purposes prior to 14 October 2004 shall be subject to the same provisions as those laid down for the substances authorised in accordance with Article 4(1)as regards therapeutic use and Article 5 as regards zootechnical use.'

11. all references to 'Directive 81/851/EEC' and 'Directive 81/852/EEC' are construed as references to 'Directive 2001/82/EC';

12. the Annex to Directive 96/22/EC become 'Annex I', and Annexes II and III in the Annex to this Directive are added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 14 October 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 September 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	R: BUTTIGLIONE

ANNEX

'*ANNEX II*

List of prohibited substances:

List A:

– thyrostatic substances
– stilbenes, stilbene derivatives, their salts and esters

List B:

– oestradiol 17ß and its ester-like derivatives
– beta-agonists

ANNEX III

List of provisionally prohibited substances:

substances having oestrogenic (other than oestradiol 17ß and its ester-like derivatives), androgenic or gestagenic action.'