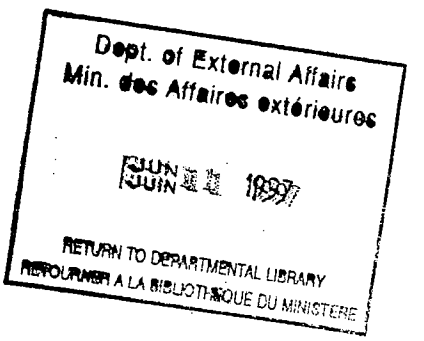
EUROPEAN COMMUNITIES - MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

FIRST SUBMISSION OF CANADA

Public Version



December 3, 1996

TABLE OF CONTENTS

PART I INTRODUCTION

1. Canada's complaint arises out of measures taken by the European Communities ("EC") which bar the importation of Canadian beef produced with certain growth promoting hormones. These EC measures nullify or impair the benefits accruing to Canada pursuant to the *Agreement Establishing the World Trade Organization* ("*WTO Agreement*") respecting market access for beef.[1]

2. The EC prohibits the importation of livestock and meat from livestock that have been treated with certain substances having a hormonal action. This prohibition applies to several substances and species, but Canada's complaint is confined to the prohibition with respect to six hormones that are used for the purposes of growth promotion in cattle. The six growth promoting hormones in question are oestradiol 17β, progesterone, testosterone, trenbolone acetate ("trenbolone"), zeranol and melengestrol acetate ("MGA").[2]

3. The *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*") allows WTO members, within prescribed limitations, to adopt measures to protect human, animal or plant life or health. The EC measures do not meet the prescribed limitations. The EC measures are not based on an appropriate risk assessment, and are more restrictive than required to meet their appropriate level of protection. Indeed these measures are far more restrictive than measures the EC has adopted to control the use of other substances used in animal husbandry that present a demonstrably greater risk to health than the six hormones at issue. The EC level of protection for growth promoting hormones is significantly higher than the EC level for antimicrobial growth promoters and other veterinary drugs, resulting in discrimination against Canadian beef imports and a disguised restriction on international trade.

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[1] *Uruguay Round Schedule LXXX - European Communities*, Part I Most Favoured-Nation Tariff, Section I - Agricultural Products, Section I A Tariffs and Section I B Tariff Quotas, as subsequently modified. Tariff items covered by the EC beef and veal regime are:

02011050; 02012015; 02012035; 02012055; 02012090; 02013000; 02021000; 02022010; 02022030; 02022050; 02022090; 02023010; 02023050; 02023090; 02061010; 02061091; 02061095; 02061099; 02062100; 02062210; 02062290; 02062910; 02062991; 02062999; 02102010; 02102090; 02109041; 02109049; 16025010; 16025090; 16029061; and 16029069.

[2] Oestradiol 17β, progesterone and testosterone are sex steroidal hormones produced by mammalian species, and hence will be referred to as the "natural hormones". Compounds that are chemically synthesized to mimic the effect of natural hormones are called xenobiotic hormones. Xenobiotic hormones include trenbolone and MGA. Zeranol is a non-steroidal xenobiotic compound that has a weak oestrogenic effect. For the purposes of this submission, these three compounds will be referred to as the "xenobiotic hormones". For a more complete discussion on hormones, see Part II, Section D below.

4. The impugned measures adopted by the EC constitute an unauthorized exception to the *SPS Agreement* in that they fail to take account properly of internationally accepted standards, guidelines and recommendations in the absence of scientific justification. The measures are being used, in part, as a means to control domestic production resulting in a disguised restriction on international trade.

5. In addition, the EC measures are either an import prohibition, in contravention of the *General Agreement on Tariffs and Trade 1994* ("*GATT 1994*"), or internal measures that discriminate in favour of EC cattle and beef products, and against like Canadian cattle and beef products, also contrary to *GATT 1994*.

6. It is Canada's position that under Article 3.8 of the *Understanding on the Rules and Procedures Governing the Settlement of Disputes* it is up to the EC to rebut Canada's *prima facie* case.

7. Canada will advance alternative arguments that the impugned measures also fail to meet obligations under the *Agreement on Technical Barriers to Trade* ("*TBT Agreement*") in the event it is found to be applicable.

A. PROCEDURAL HISTORY

8. On 28 June 1996, Canada requested consultations with the EC pursuant to Article XXII of the *GATT 1994*, Article 11 of the *SPS Agreement*, Article 14 of the *TBT Agreement*, and Article 19 of the *Agreement on Agriculture,* regarding certain measures prohibiting the importation of livestock and meat from livestock that have been treated with certain substances having a hormonal action.[3] The request alleged that these measures adversely affect the importation of livestock and meat from livestock, and as such the Government of Canada was of the view that the measures are inconsistent with EC obligations under the *SPS Agreement,* the *GATT 1994*, the *TBT Agreement*, and the *Agreement on Agriculture*.

9. Australia, the United States and New Zealand, requested to join the consultations.[4] The EC accepted the requests of Australia and New Zealand, but denied the request of the United States.

10. Consultations took place in Geneva on 25 July 1996, but failed to settle the dispute. Consequently, Canada placed a request for the establishment of a panel on the agenda of the

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[3] WT/DS48/1

[4] WT/DS48/2, WT/DS48/3, and WT/DS48/4.

27 September 1996 meeting of the Dispute Settlement Body ("DSB").[5] This Panel was established on 16 October 1996.

11. The terms of reference of this Panel are:

> To examine, in the light of the relevant provisions of the covered agreements cited by Canada in document WT/DS48/5, the matter referred to the DSB by Canada in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements.[6]

12. This is the second WTO Panel examining the EC measures. On 26 January 1996, the United States requested consultations with the EC on the same matter.[7] Due to Canada's substantial trade interest in the matter, Canada notified the consulting Members and the DSB that it desired to be joined in the consultations.[8] Canada's request was accepted by the EC on 19 March 1996.[9] Canada participated in the consultations that took place in Geneva on 27 March 1996.

13. The United States requested the establishment of a WTO Panel on 25 April 1996.[10] It was established on 20 May 1996 (the "USA-EC Panel"). Canada presented a third party submission to that Panel on 27 September 1996, which noted that Canada would also be requesting the establishment of a panel.

14. On 4 November 1996, the parties to this dispute agreed to a Panel composed of the same members as the USA-EC Panel.

B. THE EC MEASURES CHALLENGED BY CANADA

15. Canada challenges EC measures prohibiting the importation of livestock and meat from livestock that have been treated with six growth promoting hormones, *i.e.*, oestradiol 17β, progesterone, testosterone, trenbolone, zeranol and MGA ("EC measures"). As stated

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5 WT/DS48/5

6 WT/DS48/6

7 WT/DS26/1

8 WT/DS26/4

9 WT/DS26/5

10 WT/DS26/6

in Canada's request for the establishment of a panel, the EC measures at issue include, but are not limited to: Directive 88/146/EEC; the directives referenced in that Directive (72/462/EEC, 81/602/EEC, 81/851/EEC, 81/852/EEC, 85/358/EEC), the decisions referred to in Article 6(2) of Directive 88/146/EEC; the control programme referred to in Article 6(7) of Directive 88/146/EEC; the derogations referred to in Article 7 of Directive 88/146/EEC; and any amendments or modifications, including Directives 96/22/EC and 96/23/EC.[11]

16. The main aspects of the EC measures in dispute are the following:

(a) the EC has prohibited the administering of any one of the six growth promoting hormones at issue: oestradiol 17β, progesterone, testosterone, trenbolone, zeranol and MGA to any farm animal;

(b) the EC has prohibited the trade in farm animals to which any of the six hormones at issue have been administered as well as the trade in meat derived from those animals within the EC; and

(c) the EC has imposed an import prohibition on farm animals which have been treated with any of the six hormones at issue as well as on meat from those animals.

17. In spite of these prohibitions, the EC continues to allow oestradiol 17β, testosterone and progesterone to be administered to animals for therapeutic treatment and allows the trading of these animals as well as meat derived from them under certain conditions.

1. Directive 81/602/EEC

18. Council Directive 81/602/EEC[12] established a general prohibition on: administering to a farm animal any substances having a thyrostatic, oestrogenic, androgenic or gestagenic action; marketing or slaughtering an animal to which such a substance has been administered; and marketing or processing meat from an animal to which such a substance has been administered.[13] Farm animals are defined as "...domestic animals of the bovine species, swine, sheep, goats, solipeds and poultry, and wild animals of these species and wild

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[11] On 29 April 1996, the Council adopted Directive 96/22/EC (which will replace Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as from 1 July 1997) (Annex 1, Tab T).

[12] Directive 81/602/EEC (Annex 1, Tab A).

[13] *Ibid.*, Article 2

ruminants which have been raised on a holding."[14] The general prohibition of the administering of growth promoting hormones as well as the trading within the EC of meat produced with growth promoting hormones will be referred to as the *internal* ban on beef derived from hormone-treated livestock.

19. Directive 81/602/EEC provided two exceptions to the internal ban. An exception was provided for substances with an oestrogenic, androgenic or gestagenic action when they are used for therapeutic purposes and administered by a veterinarian.[15] An exception was also provided for five growth promoting hormones - oestradiol 17β, progesterone, testosterone, TBA and zeranol - when they were used for growth promoting purposes and their use was governed according to the individual regulatory schemes maintained by Member States. The latter exception was made pending an examination of the effects of these hormones on the health of consumers, and the adoption of a Community rule.[16] Member States were obliged

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[14] *Ibid.*, Article 1

[15] *Ibid.*, Article 4

[16] *Ibid.*, Article 2 sets out a general prohibition regarding hormones:

> Subject to Articles 4 and 5, Member States shall ensure that the following are prohibited:
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> (a) the administering to a farm animal, by any means whatsoever, of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action;
>
> (b) the placing on the market or slaughtering of farm animals to which the abovementioned substances have been administered;
>
> (c) the placing on the market of meat of the farm animals referred to in (b);
>
> (d) processing of the meat referred to in (c) and the placing on the market of meat products prepared from or with such meat.

However, Article 5 preserved the regulatory *status quo* in the Member States for the five growth promoting hormones:

> The Council, acting unanimously on a proposal from the Commission shall take a decision as soon as possible on the administering to farm animals of oestradiol 17/β, Progesterone, Testosterone, Trenbolone and Zeranol for fattening purposes.
>
> Pending adoption of this decision, the national regulations in force and the arrangements made by Member States concerning these substances shall continue to apply while complying with the general provisions of the Treaty and without prejudice to measures adopted in accordance with a Community procedure designed for their approximation.
>
> Member States may not authorize the use of new substances during this transitional period.

to apply their regulatory schemes to imports from third countries in a manner not more favourable than that applied to intra-Community trade.[17]

2. Directive 88/146/EEC

20. In 1985, the Council of Ministers of the European Economic Community ("Council") adopted Directive 85/649/EEC, modifying Directive 81/602/EEC to eliminate the exception for the five growth promoting hormones and impose a prohibition on the importation of hormone-treated livestock and meat. This Directive was challenged by the United Kingdom before the Court of Justice of the European Communities. The Court found that the Directive was null and void because the Council had not complied with essential procedural requirements in adopting the Directive.[18] However, the Council rectified the procedural error and readopted the measure as Directive 88/146/EEC.[19]

21. Directive 88/146/EEC eliminated the exception for the five growth promoting hormones.[20] The use of these and other substances may still be authorized for therapeutic reasons, but only under prescribed conditions; in particular, the substances must be injected by a veterinarian, and treated animals may not be slaughtered until a prescribed waiting period has expired.[21]

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[17] *Ibid.*, Article 6 states:

> Member States shall ensure that, pending adoption of relevant Community rules, their national provisions applying to products imported from third countries are not more favourable than those applying to intra-Community trade pursuant to this Directive.

[18] *United Kingdom v. Council,* Case 68/86, [1988] ECR 855

[19] Directive 88/146/EEC (Annex 1, Tab B).

[20] *Ibid.*, Article 2 removed this derogation, thereby imposing a prohibition on the use of these hormones for growth promoting purposes:

> Without prejudice to Article 4 of Directive 81/602/EEC, Member States may not authorize any derogation from Article 2 of the said Directive. However, the administering to farm animals for therapeutic purposes of oestradiol-17-β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application may be authorized.

[21] *Ibid.*, Article 3(b)

22. In addition to eliminating the exception, Directive 88/146/EEC imposes a prohibition on imports of livestock and meat from livestock that have been treated with substances having a thyrostatic, oestrogenic, androgenic or gestagenic action,[22] although derogations are permitted for meat from sources that meet specified criteria.[23] Thus Directive 88/146/EEC establishes an *import* ban.

3. Derogations

23. The Council established derogations from Directive 88/146/EEC in Directive 88/299/EEC, of 17 May 1988, "...on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC."[24]

24. Directive 88/299/EEC requires Member States to authorize trade in animals intended for reproduction and reproductive animals at the end of their career which, during their reproductive career, have undergone treatments specified in the Directive, as well as trade in meat of these animals.[25] The first of the two treatments specified in the directive is therapeutic treatment with oestradiol 17β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application;[26] the second is the synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos.[27] There are no derogations applicable to the three xenobiotic hormones at issue

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[22] *Ibid.*, Article 6(1) provides:

> Member states shall prohibit importation from third countries of animals and of meat from animals to which have been administered in any way whatsoever substances with a thyrostatic, oestrogenic, androgenic or gestagenic action.

[23] All such derogations must meet the criteria set out in Council Directive 88/299/EEC (Annex 1, Tab C).

[24] *Ibid.*

[25] *Ibid.*, Article 4

[26] *Ibid.*, Article 2, paragraph 1(a)

[27] *Ibid.*, Article 2, paragraph 1(b). These required derogations under Directive 88/299/EEC appear to supplement the authority that the EC had already provided to the Member States to grant exceptions. In particular, under Article 4 of Directive 81/602/EEC, Member States may authorize the administering to farm animals of certain substances with oestrogenic, androgenic or gestagenic action for therapeutic use, for synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos. Under Article 2 of Directive 88/146/EEC, Member States may permit "the administering to farm animals for therapeutic purposes of oestradiol-17-β, testosterone and progesterone and those derivatives which readily yield the parent

in this case.

C. EC REGULATION OF VETERINARY DRUGS

25. The EC measures must be considered in the context of the EC's regulation of veterinary drugs in general. It has been estimated that across the EC, there are in the range of 10,000 to 15,000 authorized veterinary medicinal products, and some 400 active substances authorized for use in those products.[28]

26. The EC regulates veterinary drugs under two schemes: products intended for therapeutic use or for the alteration of physiological function are regulated under Directives 81/851/EEC and 81/852/EEC and their amendments ("Veterinary Medicines Directives"),[29] whereas those added to feed for prophylaxis and growth promotion are regulated under Directive 70/524/EEC and its amendments ("Feed Additives Directives").[30]

27. There appear to be notable differences between the two schemes.[31] Veterinary drugs

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compound on hydrolysis after absorption at the site of application."

[28] Commission of the European Communities, *Distribution of Veterinary Medicines in the Single Market*, Consultation paper from the Services of the Commission (January 1993) p. 10 [hereinafter *Distribution of Veterinary Medicines in the Single Market*] (Annex 2, Tab A).

[29] Directive 81/851/EEC (Annex 1, Tab D), Directive 81/852/EEC (Annex 1, Tab E);

Directive 93/40/EEC (Annex 1, Tab F), amongst others, makes substantial amendments to the original Directives.

[30] Directive 70/524/EEC (Annex 1, Tab G)

Directives 84/587/EEC (Annex 1, Tab H), 93/113/EC (Annex 1, Tab I), 93/114/EC (Annex 1, Tab J), and 96/51/EC (Annex 1, Tab K), among others, contain substantial amendments. Directive 91/248/EC (Annex 1, Tab L) appears to contain the most recent consolidation of the annexes to the Feed Additives Directives.

[31] The scopes of the two regimes are mutually exclusive. Directive 81/851/EEC, *supra*, note 29, Article 1(4) provides:

> Additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs, as subsequently amended, where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive, shall not be considered as veterinary medicinal products for the purposes of this Directive.

See also, K.N. Woodward, "Maximum Residue Limits - the Impact of UK and EC Legislation" in P.C.

governed by the Veterinary Medicines Directives are subject to the authorization procedures and Maximum Residue Limit ("MRL") requirements set out in Regulation 2377/90/EEC and its amendments[32] ("MRLs Regulations") and to the residues monitoring requirements set out in Directives 86/469/EEC and 96/23/EC ("Residues Directives"). In contrast, veterinary drugs governed by the Feed Additives Directives do not appear to be subject to these provisions. These schemes are detailed below.

28. The three natural hormones at issue - oestradiol 17β, progesterone and testosterone - may only be used for therapeutic and zootechnical purposes. Their use is governed by the Veterinary Medicines Directives, and they are subject to the authorization procedures and MRL requirements set out in the MRLs Regulations, and the monitoring requirements set out in Directives 85/348/EEC and 96/23/EC.

1. Veterinary Medicines Directives

29. The Veterinary Medicines Directives lay down rules for marketing authorization and distribution of veterinary medicinal products. An application for authorization requires studies of toxicity, pharmacological properties, residues and their effects, and data on the emergence of resistant organisms in the case of products used for the prevention or treatment of infectious disease in animals. Directive 81/851/EEC established the Committee for Veterinary Medicinal Products to give opinions on whether a particular medicinal product complies with the Directive's requirements.

30. Member States are obliged to take regulatory measures to control the distribution of veterinary drugs in accordance with the Veterinary Medicines Directives. In implementation, there are divergent positions among Member States on whether some veterinary medicines for use in food animals should be available without prescription, or should be available subject to a prescription.[33] For example, anthelmintics (*e.g.*, ivermectin) are on prescription in France

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Garnsworthy & D.J.A. Cole, eds., *Recent Advances in Animal Nutrition* (Nottingham: Nottingham University Press, 1993) p. 165 [hereinafter "Maximum Residue Limits - the Impact of UK and EC Legislation"] (Annex 2, Tab B).

[32] Regulation 2377/90/EEC (Annex I, Tab P). There do not appear to have been amendments to the substantive provisions of Regulation 2377/90/EEC. However, the annexes to the Regulation have been amended several times. A recent consolidation was prepared by the VMD Residues Group: VMD Residues Group "Regulation 2377/90: Consolidated Annexes & Commission Regulation 2701/94 of 7 November 1994: Consolidating Text," (August 1995) [hereinafter "Regulation 2377/90: Consolidated Annexes"] (Annex 1, Tab Q).

[33] A.R.M. Kidd, *Distribution of Veterinary Medicines Within the European Community: Final Report prepared for DG III of the Commission of the European Communities* (September 1992) p. 25 [hereinafter *Distribution of Veterinary Medicines Within the European Community: Final Report*] (Annex 2, Tab D).

and Germany, but are non-prescription in a number of other Member States.[34] Similarly, the antibiotic Benzylpenicillin is available without prescription in Ireland.[35] Ectoparasiticides such as organophosphorus compounds, are available without prescription in several Member States.[36]

31. There are also divergent views on when it is necessary for a veterinarian to administer a prescribed drug.[37] EC Directives dictate that only a veterinarian can administer the three natural hormones. Yet, it appears that the EC does not extend that requirement to cover other drugs, such as general anaesthetics, narcotics or psychotropics.[38] In practice, farmers may be administering prescribed veterinary drugs without the veterinarian even seeing the

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See also A.R.M. Kidd, "Distribution of veterinary drugs within the European Union" *(1994) 8:2 Vet. Drug Reg. Newsletter* 35, pp. 35-38 (Annex 2, Tab C).

[34] *Ibid., Distribution of Veterinary Medicines Within the European Community: Final Report,* pp. 26-27 (Annex 2, Tab D).

[35] Ireland's *Animal Remedies (Control of Sale) Regulations*, 1985 (Ir.), S.I. 1985/258 (Annex 2, Tab I), states:

> Article 5. (1) Subject to paragraph (2) of this Regulation, the sale of any animal remedy to which these regulations apply is hereby prohibited save under licence of the Minister.
> Article 5. (2) Paragraph (1) of this Regulation shall not apply to any animal remedy which -
> (a) comprises or contains any substance specified in part III of the First Schedule to these Regulations, and
> (b) is marketed (whether by being packaged in a particular manner or otherwise) as an intramammary preparation for the prevention of mastitis in animals, and
> (c) is intended for use exclusively as such a preparation.

Benzylpenicillin appears in Part III of the First Schedule.

It would appear that Luxembourg also permits non-prescription use of antibiotics for control of mastitis. See *Distribution of Veterinary Medicines Within the European Community: Final Report, supra*, note 33, Table 4, p. 43 (Annex 2, Tab D).

[36] See *Distribution of Veterinary Medicines Within the European Community: Final Report, supra*, note 33, Table 6, p. 47 (Annex 2, Tab D).

[37] *Ibid.*, p. 21

[38] *Distribution of Veterinary Medicines in the Single Market, supra,* note 28, p. 11 (Annex 2, Tab A).

animals being treated.[39]

2. Feed Additives Directives

32. The Feed Additives Directives govern the use of additives in feedingstuffs. Additives are substances or preparations used in animal nutrition in order, among other things, to improve animal production, in particular by affecting the gastro-intestinal flora or digestibility of feedingstuffs. Growth promoters such as ionophores (*e.g.*, monesin) and non-ionophore antibiotics (*e.g.*, avoparcin, carbadox, olaquindox) are used extensively as feed additives in all EC Member States.[40] Feed additives are incorporated into feedingstuffs for oral animal feeding. Substances used in accordance with the Feed Additives Directives are available without a veterinary prescription.[41]

33. It would appear that the substances governed by the Feed Additives Directives are not subject to the Residues Directives and the MRLs Directives.[42] Thus, it is questionable

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[39] In Germany, for example:

> The so-called "autobahn veterinarian" is perhaps the most widely known and practiced "grey market". Both practicing veterinarians but also veterinarians employed, in some cases by companies in the sector, engage in the supply of products to farmers without seeing the animals and, in some instances, they supply products by mail or, alternatively, mail prescriptions to pharmacists who then supply to farmers the requested products. In most cases it is very difficult to prove that animals were not inspected and in any event the grey market network appears to be very well organised with a well functioning warning system.

European Public Policy Advisers S.A., *The Distribution of Veterinary Medicinal Products in the Single Market of the European Community* (March 1993), p. 31. More generally, see pp. 25-38 (Annex 2, Tab E).

[40] See CEAS Consultants (Wye) Ltd. *et al.*, *The Impact on Animal Husbandry in the European Community of the Use of Growth Promoters: Final Report, vol. 1: Growth Promoters in Animal Feed* (February 1991), pp. 1-9 [hereinafter *The Impact on Animal Husbandry in the European Community of the Use of Growth Promoters*] (Annex 2, Tab F)

[41] *Distribution of Veterinary Medicines Within the European Community: Final Report, supra*, note 33, p. 25 (Annex 2, Tab D).

[42] K.N. Woodward & G. Shearer, "Antibiotic Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection" in H. Oka *et al.*, eds., *Chemical Analysis for Antibiotics Used in Agriculture* (Arlington, VA: AOAC International, 1995) c. 3, p. 56 (Annex 2, Tab G). It is noted, however, that two substances listed as feed additives have prescribed MRLs under the MRLs Regulations: spiramycin and tylosin. See "Regulation 2377/90: Consolidated Annexes," *supra*, note 32 (Annex 1, Tab Q).

whether residues in meat arising from the misuse or abuse of substances found in feed additives would be detected under the current EC regulatory scheme.

3. Residues Directives

34. Directive 86/469/EEC[43] lays down requirements for the examination of animals and fresh meat for the presence of veterinary drug residues. With respect to hormones, it supplements Directive 85/358/EEC[44] which sets out rules on the detection and monitoring of substances having a hormonal or thyrostatic action. EC countries are required to test for the presence of veterinary drug residues under a "National Plan". Community Reference Laboratories and National Laboratories provide surveillance testing of meat samples.[45] Where an examination of a sample reveals the presence of residues of prohibited substances or quantities of authorized substances exceeding the levels set by Community law or, in their absence, national levels, competent authorities must follow up with an investigation and appropriate measures.[46] These Directives do not appear to apply to substances governed by the Feed Additives Directives.[47]

35. As of 1 July 1997, these Directives will be repealed and replaced by Council Directive 96/23/EC,[48] which sets out measures to monitor listed substances and groups of residues. This Directive appears to broaden the scope of the repealed Directives "...to cover other substances which are used in stockfarming to promote growth and productivity in livestock or for therapeutic purposes and which may prove dangerous to the consumer on account of their residues."[49] It is not clear whether it will apply to substances governed by the Feed Additives Directives.

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[43] Directive 86/469/EEC (Annex 1, Tab M)

[44] Directive 85/358/EEC (Annex 1, Tab N)

[45] "Antibiotics Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection," *supra*, note 42, p. 57 (Annex 2, Tab G).

[46] Directive 86/469/EEC, *supra*, note 43, Article 9.

[47] "Antibiotic Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection," *supra*, note 42, p. 56 (Annex 2, Tab G).

[48] Directive 96/23/EC (Annex 1, Tab O)

[49] *Ibid.*, preamble.

4. MRLs Regulations

36. Regulation 2377/90/EEC[50] sets out a procedure for establishing MRLs of veterinary drugs in foodstuffs of animal origin. Under this Regulation, no new veterinary medicinal product may be authorized for use in EC Member States until a Community-wide MRL has been set, and MRLs for existing products must be established before 1997. It appears to apply only to veterinary medicinal products governed by the Veterinary Medicines Directives, and not to those governed by the Feed Additives Directives.[51]

37. All pharmacologically active substances considered must be entered into one of the annexes to the Regulation,[52] which are as follows:

I) substances for which MRLs have been fixed;
II) substances not subject to MRLs;
III) substances for which provisional MRLs have been fixed;
IV) substances for which no MRLs can be fixed.

38. Substances are included in Annex II where, "...following an evaluation... it appears that it is not necessary for the protection of public health to establish a maximum residue limit."[53] For substances contained in Annex III, a provisional MRL has been established for a defined period of time "...provided that there are no grounds for supposing that residues of the substance concerned at the level proposed present a hazard to the health of the consumer."[54] Substances are entered in Annex IV where it appears that a MRL cannot be established because residues of the substance, at whatever limit, in foodstuffs constitute a hazard to the health of the consumer. The administration of these substances are prohibited in the EC for use in food-producing species.[55]

39. Of the three natural hormones at issue in this dispute, only one appears to have been considered under this Regulation: oestradiol 17β is included in Annex II, so the EC has

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50 Directive 2377/90/EEC, *supra*, note 32.

51 "Antibiotic Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection," *supra*, note 42, p. 56 (Annex 2, Tab G).

52 "Regulation 2377/90: Consolidated Annexes," *supra*, note 32 (Annex 1, Tab Q).

53 Regulation 2377/90/EEC, *supra*, note 32, Article 3.

54 *Ibid.*, Article 4.

55 *Ibid.*, Article 5.

decided that it need not be subject to a MRL.[56] It is noteworthy that the EC has recently added two compounds to Annex II, namely ketoprofen and buserilin.[57]

40. Over the past five years, several substances were initially granted provisional MRLs and included in Annex III, but later moved to Annex IV, including nitrofurans[58] and chloramphenicol.[59]

5. Summary

41. The distinctions made between the regulatory schemes governing veterinary drugs on the one hand, and feed additives on the other, are anomalous.[60] As one EC scientist has commented:

> A recent meeting held in Asti in Italy considered the very question of the use of MRLs in relation to compounds covered by Directive 70/524/EEC and considered as feed additives in the Community. Indeed, the meeting was a joint meeting of DGIII and DGVI held under the auspices of the Scientific Committee on Animal Nutrition (SCAN). SCAN is the independent advisory body which comments on the safety of feed additives and it has seen certain benefits in following the MRL route in assuring consumer safety. Not least among these are the use of the MRL for establishing withdrawal periods for 70/524/EEC candidate compounds and for residues surveillance.
>
> This is important now as the JECFA system makes no distinction between veterinary medicines and medicinal feed additives and it recently assessed two drugs, carbadox and olaquindox, currently regulated in the Community under 70/524/EEC and so not subject to MRLs under 2377/90. In doing so it established an MRL for carbadox and identified further work on olaquindox. Hence, there is an urgent need for the EC to look at the MRL route for feed additive compounds before the JECFA system

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[56] Regulation 3059/94/EC amending Annexes I, II and III to Council Regulation 2377/90 (Annex 1, Tab R)

[57] Regulation 282/96/EC amending Annexes I, II and III of Regulation 2377/90/EEC (Annex 1, Tab S).

[58] Provisional MRL established by Regulation 675/92/EEC; moved to Annex IV by Regulation 2901/93/EEC. See "Regulation 2377/90: Consolidated Annexes," *supra*, note 32 (Annex 1, Tab Q).

[59] Provisional MRL established by Regulation 675/92; moved to Annex IV by Regulation 1430/94. See "Regulation 2377/90: Consolidated Annexes," *supra*, note 32 (Annex 1, Tab Q).

[60] "Antibiotic Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection," *supra*, note 42, p. 55 (Annex 2, Tab G).

> anticipates values with little corporate European input. This is important as the JECFA values are eventually introduced into the Codex Alimentarius system for international adoption and harmonisation.[61]

The scientist concluded:

> The EC and the international community, as well as national authorities, are engaged in the establishment of MRLs for veterinary drugs in food of animal origin. The basic inputs into these processes are the toxicology and residues data generated in support of the MRLs. In viewing MRLs within the Community, it seems only sensible to view medicines as one distinct group - rather than to see them, as is currently the case, largely as therapeutics and feed additives - and to establish MRLs for all. This would introduce some degree of harmonisation on this front with the JECFA/Codex Alimentarius system.[62]

42. The EC regulation of the six hormones at issue is also anomalous. In contrast to the prohibition imposed on the three xenobiotic hormones, some veterinary drugs such as ivermectin and benzylpenicillin are available over-the-counter without a prescription. Similarly, in comparison with the strict control maintained over the administration of the three natural hormones, many classes of prescription drugs may be administered by the farmer, in some instances without the veterinarian even seeing the animals being treated.

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[61] "Maximum Residue Limits - the Impact of UK and EC Legislation," *supra*, note 31, pp. 169-170 (Annex 2, Tab B).

[62] *Ibid.*

D. HISTORY OF THE EC MEASURES

1. Evolution of the Measures at Issue

43. The possibility of a ban on the use of growth promoting hormones first arose in late 1980 in response to a baby food scare in Italy. The food, containing veal of French origin, was found to have residues of the synthetic oestrogenic substance diethylstilboestrol (DES).[63] A judge ordered a ban on the sale of veal in Italy on health grounds and Italy closed its borders with France on the same grounds. The French public reasoned that what was bad for the health of the Italians was equally bad for the health of the French. The public outcry in Italy and France caused a collapse in the veal market and prompted calls for immediate action on hormones use in livestock farming. The French Ministry of Agriculture initially attempted to defend the producers, but was forced to retreat on the basis that the boycott of veal had been so successful that it was in the interests of producers to ban hormones entirely; this was seen to be the sole means of reestablishing consumption levels and reopening the lucrative Franco-Italian border.

44. Prior to 1981, there was no common EC policy on the use of growth promoting hormones. Belgium and Greece had never permitted the use of hormones for growth promoting purposes. Italy banned the use of hormones in 1961, Denmark in 1963 and Germany in 1977. France, Spain, the United Kingdom and the Netherlands permitted the use of the five growth promoting hormones (oestradiol 17β, progesterone, testosterone, trenbolone and zeranol) until the entry into force of Directive 88/146/EEC.

45. On 3 November 1980, the Commission of the European Communities ("Commission") presented to the Council a proposal to prohibit the use of substances with a hormonal, thyrostatic or anabolic action for the purposes of artificially accelerating the growth of livestock, while allowing the use of natural hormonal substances for therapeutic purposes.[64] In February 1981, the proposal was approved by the European Parliament.[65] The European

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[63] G.E. Lamming, "Anabolic Growth Promotants and the EEC" (Address given at the Technical Services Centre, Kingston, ACT, 29 April 1986) [unpublished] p. 4 (Annex 2, Tab H)

[64] Proposal for a Council Regulation concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals (Submitted by the Commission to the Council on 3 November 1980) 1980 O.J. (C 305) 2 (Annex 4, Tab A)

On 6 January 1981, the Commission put forward two further proposals for Regulations concerning surveillance for residues of prohibited substances and laying down conditions governing the possession, distribution and administration on hormonal substances: COM(80) 920 final and COM(80) 922 final.

[65] Resolution embodying the opinion of the European Parliament on the proposals from the Commission of the European Communities to the Council for

Community's Economic and Social Committee also welcomed the proposal, but encouraged the Commission to consider whether implants of certain hormonal substances for growth promoting purposes could be allowed, provided such substances were safe from a health point of view and did not impair the quality of the meat. The Committee also favoured the extension of the EC measures to third-country imports, but warned against the "danger of abusing this control system in order to create barriers to trade."[66]

46. What emerges clearly from the resolutions and proposals tabled at this time, is that the EC was motivated by four sets of concerns[67]: first, anxiety regarding the danger to human health occasioned by the illegal use of substances, such as DES; second, the pressure of public opinion which, under prevailing circumstances, did not distinguish between products or the conditions of their use; third, the economic consequences of a "sensationalist campaign",[68] which had resulted in the collapse of the veal market and a sharp decline in beef consumption throughout the Community; and fourth, the distortions in the conditions of competition among the Member States owing to dissimilar provisions and regulations governing the manufacture, distribution and use of substances.[69]

47. In a meeting of EC Agriculture Ministers in May 1981, there was agreement in principle that stilbenes and their derivatives, as well as substances with thyrostatic effect, should be banned. On other substances, specifically the five growth promoting hormones: oestradiol 17β, progesterone, testosterone, trenbolone and zeranol, a consensus emerged that a step-by-step approach should be adopted, based on scientific examination of harmful effects before decisions were taken.

I. a Regulation on the use of substances with a hormonal action and those having a thyrostatic action in domestic animals

II. a Regulation concerning the control and examination of animals and meat in the Community for the presence of residues of substances with oestrogenic, androgenic, gestagenic and thyrostatic effect

III. a Regulation laying down conditions for controlling the possession, distribution and administation to animals of certain substances with a hormonal action, 1981 O.J. (C 50) 89 (Annex 4, Tab B).

66 Opinion on the proposal for a Council Regulation concerning the use of substances with a hormonal action and those having a thyrostatic action in domestic animals, 1981 O.J. (C 138) 29 (Annex 4, Tab C).

67 See, J.B. Nielsen, Report drawn up on behalf of the Committee on Agriculture on the proposals from the Commission to the European Communities to the Council..., Eur. Parl. Doc. I-840/80 (1981) [hereinafter "Nielsen Report"] (Annex 4, Tab D).

68 *Ibid.*, Doc. 1-484/80

69 *Ibid.*, Doc. 1-523/80

48. Directive 81/602/EEC,[70] adopted by the Council on 31 July 1981, formally established a prohibition on certain substances having a hormonal action and of any substances having a thyrostatic action, but permitted the continuation of existing measures governing the five growth promoting hormones. The Directive also charged the Commission with the task of submitting to the Council a report on the experience acquired and scientific developments by 1 July 1984.

49. In 1981, the EC established an *ad hoc* Scientific Working Group on Anabolic Agents in Animal Production, chaired by professor G.E. Lamming, with the following terms of reference: "Does the use for fattening purposes in animals of the following substances: oestradiol 17β, testosterone, progesterone, trenbolone and zeranol present any harmful effects to health?"[71] In 1982, the group, composed of 22 scientists from the ten Member States, issued an interim report concluding that the use of the three natural hormones, oestradiol 17β, testosterone and progesterone in farm animals as growth promoters would not present any harmful effects to the consumer when used under the appropriate conditions.

50. In respect of trenbolone and zeranol, the group concluded that more information was required. Although the Scientific Working Group was suspended by the Commission before it had completed its terms of reference, it subsequently produced a second report in October 1987, stating that the levels of trenbolone and zeranol and their major metabolites found in edible tissue, following accepted husbandry practices, were substantially below the hormonally effective doses in animal test systems and therefore did not present a harmful effect to health.[72]

51. In an information memo released in June 1984, the Commission noted that it saw,

> ...no reason to oppose [the Scientific Working Group's 1982] findings, which are based on the latest scientific progress in the area of toxicity, including biological aspects. It also notes that the human organism itself daily produces quantities of natural hormones and that consumers are also regularly exposed to higher and widely variable levels of natural hormones in food from untreated animals.[73]

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[70] Directive 81/602/EEC, *supra*, note 12.

[71] Report of the Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production [hereinafter G.E. Lamming *et al.*, *Report of the Scientific Group on Anabolic Agents in Animal Production* (1982)] (Annex 4, Tab E).

[72] G.E. Lamming *et al.*, "Special Report: Scientific report on anabolic agents in animal production," *Veterinary Record* (October 24, 1987) 389 (Annex 4, Tab F)

[73] Annex 7, USA, USA/EC Panel.

52. On this basis the Commission, in consultation with the Scientific Veterinary Committee, the Scientific Committee for Animal Nutrition ("SCAN") and the Scientific Committee for Food, submitted a proposal for a Council Directive amending Directive 81/602/EEC. The proposal recommended that:

> Whereas, on scientific grounds, it appears that the use of oestradiol 17β, testosterone and progesterone, and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, would not present any harmful effects to the health of the consumer nor harm the consumer by altering the characteristics of meat when used under the appropriate conditions as growth promoters in farm animals; whereas, in consequence, Member States may authorize their use for fattening purposes....[74]

53. The proposal set out three conditions for the use of these hormones for growth promoting purposes: they could be administered only by implantation in a part of the animal which would be discarded at slaughter; treated animals had to be identified at the time of implantation; and the implants were to be administered by a veterinarian. The use of trenbolone and zeranol for growth promoting purposes was not permitted owing to insufficient data on the toxicology of these substances and their metabolites.[75]

54. The proposal would have allowed Member States to prohibit in their territory the marketing and use for growth promoting purposes of substances and products permitted by existing Community rules, but would not have allowed the raising of,

> ...any obstacle for human health reasons to the importation of animals and meat products from other Member States where such substances and products have been authorized in accordance with Community rules.[76]

55. The Commission's proposal was adamantly rejected by the Economic and Social Committee, to whom it had been referred by the Council on 6 July 1984.[77] The Committee called for the retention of the original Directive until such time as the Commission had fully considered the scientific evidence for which it had called. The Committee was particularly

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[74] COM(84) 295 *final*, p. 4 (Annex 4, Tab Y).

[75] *Ibid.*, pp. 5-6

[76] *Ibid., p. 5*

[77] Opinion on the proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (85/C 44/11) 1985 O.J. (C 44) 14 [hereinafter Opinion on the proposal for a Council Directive amending Directive 81/602/EEC] (Annex 4, Tab G).

concerned that the Commission's proposal would overturn what it saw to be the two central objectives of both the original Directive and the Commission's proposed Directive, which "...make the protection of the consumer's health and economic interests priority objectives."[78]

56. In rejecting the proposal to allow the use of the three natural hormones, the Committee clearly disregarded the findings of the Scientific Working Group. In support of its position, the Committee pointed to the fact, that "...on 30 September 1980 the Council undertook unanimously, under the pressure of public opinion, to prohibit the administering of all hormones...in livestock production."[79] The Committee also noted that, although consumer groups and workers had long been unequivocally opposed to the use of anabolics, neither farmers' organizations nor meat processors and traders had taken an official stand at the EC level on this issue.

57. Professor Lamming, in a presentation in 1986, was unequivocal in his assessment of the reasons behind the suspension of the Scientific Working Group and the rejection of the Commission proposal based on the Group's findings with respect to the three natural hormones.

> The British Minister has claimed, and rightly so, that [EC Agriculture Commissioner] Andriessen freely admits that the scientific background or scientific consideration were not taken into account. In other words it was purely a political decision and if you read the speeches that were made in the European Parliamentary debate they are mainly based on the fact the [sic] we have got such a surplus of beef and it costs a heck of a lot to store it, why should we authorize any techniques which are going to increase that productivity. The majority of European parliamentary members could see this as a prevention of an increased production of European beef and that probably motivated them more than the scientific background.[80]

58. The resolution of the European Parliament (February 1988), stated that "...the Community, with its directives banning hormones, has adopted consistent legislation both in terms of the necessary control of agricultural production and from the point of view of protecting the interests of consumers."[81]

59. Even among those who favour the ban, there is an acknowledgement that:

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[78] *Ibid.*, p. 14.

[79] *Ibid.*, p. 15.

[80] "Anabolic Growth Promotants and the EEC," *supra*, note 63, p. 11 (Annex 2, Tab H).

[81] Resolution on the ban on hormones, 1988 O.J. (C 68) 103 (Annex 4, Tab H).

> Cette interdiction générale n'est pas uniquement inspirée par un souci de protection de la santé du consommateur, mais aussi par des raisons économiques. Il n'y a en effet pas de pénurie de viande dans l'UE, bien au contraire. La politique agricole commune est la cause depuis 20 ans d'une surproduction de viande aussi massive que coûteuse. Des montagnes de viande de boeuf sont achetées par l'UE, stockées ensuite à grand frais dans les frigos de la Communauté pour être partiellement bradées par après sur des marchés étrangers (par exemple en Afrique de l'ouest ou l'on élimine ainsi les paysans locaux du marché.)[82]

60. The prohibition on the use of hormones for growth promoting purposes was formally adopted by the Council, on 7 March 1988, in Directive 88/146/EEC.[83] The preamble to this Directive sets out the rationales for the prohibition. These were: to harmonize the regulatory schemes of the Member States; remove competitive distortions and barriers to intra-Community trade; meet consumer anxieties and expectations; and bring about an increase in the consumption of meat products.[84] This was in keeping with the opinion of the Social and Economic Committee,[85] as well as the resolution of the Parliament of 11 October 1985.[86]

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[82] WD et RL, "Les hormones dans la viande" (1994) *Test-Achats magazine* 31, p. 32 (Annex 4, Tab I).

[83] Directive 88/146/EEC, *supra*, note 19.

[84] *Ibid.*, The relevant portions of the preamble state:

> Whereas the administration to farm animals of certain substances having a hormonal action is at present regulated in different ways in the Member States; whereas while their immediate effect on animals from the farmer's view is clear, assessments on their effect on human health vary and this is reflected in the variations governing their use; whereas this divergence distorts the conditions of competition in products that are the subject of common market organizations and is a serious barrier to intra-Community trade;
>
> Whereas these distortions of competition and barriers to trade must therefore be removed by ensuring that all consumers are able to buy the products in question under largely identical conditions of supply and that these products correspond to their anxieties and expectations in the best possible manner; whereas such a course of action is bound to bring about an increase in consumption of the product in question;

[85] Opinion on the proposal for a Council Directive amending Directive 81/602/EEC, *supra*, note 77(Annex 4, Tab G).

[86] Resolution closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, 1985 O.J. (C 288) 158 (Annex 4, Tab J).

The Resolution states in part:

2. 1995 EC Scientific Conference

61. In response to sustained pressure by the United States, EC Agriculture Commissioner, Dr. Franz Fischler, convened a conference held in Brussels from 29 November to 1 December 1995, with a view to determining the safety of growth hormones from a scientific perspective. The conference was chaired by Sir John Maddox, Editor of *Nature*. In the December 1995 issue of *Nature*, he touched on two points that have been at the centre of the argument regarding the EC hormones legislation. He noted, first, that the conference had reconfirmed the scientific argument that these hormones "were not damaging to meat-eating consumers."[87] Second, his article highlighted the politicized nature of this debate within the EC and how that had been reflected in the composition and proceedings of the conference itself. Scientists were outnumbered by participants from bodies such as the European Parliament, the Economic and Social Committee and various lobby groups, all of which have been longtime advocates of the EC measures at issue. Moreover:

> ...the participants were also aware (they were reminded of that often enough) that decisions about the regulation of substances in the food chain may properly involve political, economic and even idiosyncratic considerations....One speaker complained that the pretence that it [is] possible to consider technical issues in isolation from broader issues is an abnegation of social responsibility....Another held that a bunch of scientists had no business telling the larger community how to conduct its affairs. The question of "Why are we talking about this issue when Europe has too much meat?" arose in several forms....[88]

62. The politicized nature, and thereby the questionable validity, of the conference was also commented on by Canadian scientists, one of whom had participated in the EC

> A. whereas protection of public health and the interests of the consumer are major concerns of the Community,
>
> I. whereas there is overproduction of meat and meat products in the European Community which adds considerably to the cost of the CAP,
>
> J. whereas the resultant uncertainty over the safety of these substances has had an adverse effect on consumer confidence,
>
> K. whereas the reactions of consumer organizations in the Member States have shown that those organizations reject the authorization of hormones in meat production,

87 J.Maddox, "Contention over growth promoters" (1995) 378 *Nature* 553 (Annex 4, Tab K).

88 *Ibid.*

conference, in a brief paper forwarded to the EC following publication of the proceedings.[89] Not only were scientists outnumbered by non-scientists but, as is noted in the "Report and Conclusions" of the proceedings, "...the final plenary session of the whole conference, apart from a brief statement of the principal conclusions by the chairman, was largely dedicated to statements by those not invited as scientist-participants."[90]

63. In addition, scientific participants were drawn largely from within the EC, with a small number of scientists from the U.S., Canada, Australia and New Zealand. Scientists directly employed by commercial companies with an interest in the sale of growth promoters were excluded from participating in the conference, despite the fact that these companies "hold much of the proprietary information that is required for review by national regulatory agencies and international bodies such as JECFA."[91] Finally, since the conference papers represented individual opinions, "[t]he scientific validity of these conference papers does not compare with the expert committee reviews and recommendations of JECFA, or with the regulatory review process in a registering country."[92] The extent to which world scientific opinion was reflected in the proceedings is, therefore, debatable.

64. This is in sharp contrast to the proceedings of the 1982 EEC Scientific Working Group chaired by Professor Lamming, who noted that:

> At every stage of the committee's deliberations, and I can repeat that we had unanimity on this particular approach, I checked with the relevant authorities like the committees in Britain that I referred to, with the FDA which took a similar approach, with the Food and Agriculture and WHO committees of the UN which had given consideration to these issues and all these committees arrived at the same scientific conclusion, that these materials are perfectly safe, so that there was world wide scientific unanimity in this particular approach.[93]

65. The level of non-scientific representation at the 1995 conference notwithstanding, the European Parliament adopted a resolution on 18 January 1996, in which it complained that:

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[89] J.D. MacNeil & M. Yong, *Canada's Comments on the EU Scientific Conference "Report and Conclusions"* (23 July 1996) (Annex 4, Tab L).

[90] Steering Committee, "Report and Conclusions," in *Scientific Conference on Growth Promotion in Meat Production* (Luxembourg: European Commission, 1996), p. 3.

[91] *Canada's Comments on the EU Scientific Conference "Report and Conclusions," supra*, note 89, p. 1 (Annex 4, Tab L).

[92] *Ibid.*

[93] "Anabolic Growth Promotants and the EEC," *supra*, note 63, p. 8 (Annex 2, Tab H).

> ...the conference concentrated principally on questions of a veterinary and scientific nature and either ignored or mentioned only in passing the effects of growth promoters in meat production on the health of animals, the composition and quality of meat, the concerns and expectations of consumers and the development of agricultural markets and structures.[94]

66. The resolution also notes regret:

> ...that too little attention was given to relevant questions underlying the EU's decision to ban hormones, such as the socio-economic and environmental impact and expectations of consumers, *i.e.*, the effects on meat quality, on the welfare of animals, and on agricultural structures and markets, particularly in the beef and milk sectors.[95]

67. Finally, it stressed the need for Commission action to be in conformity with the 1992 Common Agricultural Policy (CAP) reform.

68. At a meeting of EC Agriculture Ministers on 22 January, only the UK Minister argued for a decision based on scientific evidence. Commissioner Fischler, who had convened the Brussels scientific conference, announced that the EC would not be "contemplating lifting the ban...bearing in mind consumer trends."[96]

3. Misuse and Abuse of Substances

69. A serious problem confronting the EC, regulations and control measures notwithstanding, has been the persistence of illegal use of hormonal substances and beta-agonists. In his 1986 presentation on growth promoters and the EEC, Professor Lamming commented that: "It was our view then [*i.e.*, in 1982], and it still is, that if you produce an unnecessary ban, then unless you prohibit manufacture, distribution and sale for all purposes you are not likely to be able to control abuse."[97]

70. This view seems to have been borne out by the development of a black market for the manufacture and distribution of prohibited substances. According to a 1991 article in *The*

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[94] Resolution on the impact of the conclusions of the Commission's scientific conference on growth promoters in meat production (29 November to 1 December 1995) (Annex 4, Tab M).

[95] *Ibid.*

[96] "Ministers Back Hormones Ban" (1996) *EC-Update* (Annex 4, Tab N).

[97] "Anabolic Growth Promotants and the EEC," *supra*, note 63, p. 6 (Annex 2, Tab H).

European, Europe's black market in hormones boomed, following the 1988 ban.[98]

71. In the absence of legally-available, safe growth promoters, producers would appear to be resorting to the use of unapproved, illegal products, such as beta-agonists, that are recognized by the international scientific community to be unsafe for use in food-producing animals. More recently, an article detailing the incidence of fraud in respect of beta-agonists, stated that:

> En Europe, la fraude est internationale; la Hollande a dû interdire l'usage thérapeutique des β-agonistes contre la toux pour les veaux cars ils étaient tous asmathiques! Après les pays du Benelux, elle semble s'épanouir en Espagne et au Portugal....Selon Jaak Vandemeulebrouke et une association de consommateurs, Test-Aankoop, la majorité de la viande belge est traitée par des cocktails d'hormones ou des β-agonistes; les chiffres officiels eux, varient pour la Belgique et la Hollande, de 12 à 25%. [99]

72. A Committee established in October 1988 to examine the problem of quality in the meat sector noted with concern "the use of 'cocktails' of growth-promoting agents, and the increasing sophistication of the administering of prohibited substances."[100] A comprehensive survey undertaken among the Member States in 1990 confirmed that anabolic substances were generally available and in use.[101] In its communication to the Council and the European Parliament, the Commission acknowledged that:

> More sophisticated illegal products are under continual development, there is now widespread availability and mis-use of beta-agonists, the network for the distribution of illegal substances is well developed, and securing convictions through the courts is time-consuming and problematic.[102]

73. As a result, on 14 October 1993, the Commission put forward a proposal for a

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[98] L. Walker, "Drug Dealers Seek Fat Profits in Beef Farming," *The European* (April 26-28, 1991) (Annex 4, Tab O).

[99] M.-L. Moinet, "Les mobiles de la fraude," (1996) 941 *Science et Vie* 90, pp. 92-93 (Annex 4, Tab Z).

[100] Carlos Pimenta, *Report on the Findings of the Inquiry Committee, Part A: Recommendations and Conclusions*, European Parliament Committee of Inquiry into the Problem of Quality in the Meat Sector (21 March 1989) p. 11 [hereinafter *Committee of Inquiry into the Problem of Quality in the Meat Sector*] (Annex 4, Tab P).

[101] COM(93) 167 *final* (Annex 4, Tab Q).

[102] *Ibid.*, p. 4

Council Regulation extending the prohibition on the use of hormonal or thyrostatic substances to include beta-agonists.[103] Simultaneously, a complementary proposal was submitted regarding enhanced residue monitoring measures.[104]

74. The proposals, having been approved by the European Parliament as well as by the Economic and Social Committee, were adopted on 29 April 1996 as Directives 96/22/EC and 96/23/EC.[105]

E. EFFECT OF THE EC MEASURES ON CANADIAN EXPORTS

75. One of the considerations underlying the measures at issue was the elimination of distortions of competition within, and barriers to, intra-Community trade. The second recital of Directive 88/146/EEC notes:

> Whereas these distortions of competition and barriers to trade must therefore be removed by ensuring that all consumers are able to buy the products in question under largely identical conditions of supply and that these products correspond to their anxieties and expectations in the best possible manner; whereas such a course of action is bound to bring about an increase in consumption of the product in question....[106]

76. There is no doubt that, in respect of encouraging intra-Community trade, the EC measures have proven successful.[107] The price of this success, however, has been paid in no small part by exporters such as Canada, who were effectively eliminated from the EC market as a result of the hormones ban legislation.[108]

77. As a direct result of the implementation of the EC measures in January 1989, Canada's trade suffered a 72% decline in exports into the EC market. This dramatic decline

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[103] COM(93) 441 *final* (Annex 4, Tab R).

[104] COM(93) 441 *final* (Annex 4, Tab S).

[105] See Directive 96/22/EC, *supra*, note 11 and Directive 96/23/EC, *supra*, note 48.

[106] Directive 88/146/EEC, *supra*, note 19.

[107] The production- and export-related measures taken under the CAP, the Third Country Directive and the EC measures at issue all combined to encourage intra-Community trade and boost extra-EC exports, while effectively blocking market access for exporting countries such as Canada. See Table 6: EC Beef and Veal Supply Balance & Graph 2: EC Trade Figures: Meat and Livestock (Annex 4, Tab T).

[108] See Tables 1: Canadian Bovine Exports into the EC (Quantity), 1984-1987 and 2: Canadian Bovine Exports into the EC (Quantity), 1988-1995 & Graph 1: Canadian Exports into EC (Annex 4, Tab U).

was from a level that had already been severely impaired by the implementation of the Third Country Meat Directive in 1987, as a result of which the EC unilaterally abandoned the hitherto accepted practice of mutual recognition of national standards and insisted that all EC trading partners comply with EC standards. The EC measures at issue and the Third Country Meat Directive were both, moreover, applied more stringently and more precipitately to third countries than to EC Member States.[109]

78. In the case of the EC measures at issue, third countries were obliged perforce to meet the EC measures or cease exports into the EC. Internally, however, abuses have continued throughout the period of the ban. Consumer anxieties, far from being addressed by the EC measures, were exacerbated by persistent reports of illegal use of prohibited substances. The 1985 annual *Agricultural Report* stated that "[p]roblems on the domestic market were triggered by the detection of the illegal use of hormones and other prohibited substances. In the countries concerned (mainly the Federal Republic of Germany and the Netherlands) this resulted in falls in market prices for veal."[110] Evidently, the EC measures have failed to increase consumption.

79. A major problem confronting the EC has been an imbalance in production versus consumption.[111] According to a special report produced by the EC Court of Auditors,

> A look at the trend in consumption and production since 1980 reveals that Community production, which, admittedly, is cyclical, has always, even at the lowest point of the cycle, exceeded consumption. This structural imbalance, which has persisted over a decade, is growing worse. The surplus needing to be disposed of every year on the world market has, over the past ten years, represented on average about 6% of

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[109] The Third Country Meat Directive requires countries exporting to the EC to comply fully with EC standards. In contrast, Canada and many other countries require an exporting country to meet equivalent, albeit not necessarily identical, standards.

The Directive was applied to third country exporters sooner than to the Member States. In the case of Canada, the Directive was effective 1986, when a first list of establishments eligible to export under the EC Directive was drawn up. Even as late as 1991, however, most of the Mediterranean Member States (as well as France) had not been forced to comply with the standards of the Directive.

[110] Commission of the European Communities, *The Agricultural Situation in the Community: 1988 Report* (Brussels & Luxembourg, 1989) p. 44 (Annex 4, Tab 1).

[111] See Table 5: EC Beef and Veal Supply Balance (1980-1994) & Graph 3: EC Beef and Veal Supply Balance (Annex 4, Tab V).

Community production, which is tending to grow at slightly less than 0,5% a year.[112]

80. In 1992, the EC undertook to address some of these problems by launching a reform of the CAP. Among the objectives of the original CAP had been to increase agricultural productivity to achieve self-sufficiency in major products; the 1992 CAP reform was designed, in part, to reduce surpluses and production. Even so, the Court of Auditors opined that, in the beef and veal sector, "[i]n the long term, the structural surpluses will continue to be a problem, one which the 1992 CAP reform has failed to remedy in the slightest and whose extent is hardly likely to diminish either, unless corrective measures...are implemented."[113]

81. In the context of persistent over-production and declining consumption, there has been scant incentive within the EC to address the trade concerns of its trading partners. The impairment to Canada's trade must be assessed not only against the actual losses it suffered as a result of the EC measures, but against its increasing export potential, as evidenced by Canada's total exports since the 1980s.[114]

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[112] Court of Auditors, Special Report No 3/94 on the implementation of the intervention measures provided for by the organization of the market in beef and veal, together with the commission's replies, 1994 O.J. (C 356) 1, p. 11 (Annex 4, Tab W).

[113] *Ibid.*, p. 18.

[114] See Graph 4: Canada: bovine figures (Annex 4, Tab X).

PART II SCIENCE

A. INTRODUCTION

82. Science is key to this case; an understanding of how scientists evaluate risk is essential to an overall understanding of the safety of veterinary drugs used in animal husbandry. It is equally important to put into context the crucial role of the Codex Alimentarius Commission[115] ("Codex") in determining the safety of veterinary drugs used in food production. The *SPS Agreement* refers directly to the international standards, guidelines and recommendations established by Codex on questions dealing with the safety of food, including veterinary drug residues.[116]

83. There are two underlying circumstances which should be kept in mind when examining this case. The first is that the field of risk analysis[117] has evolved significantly over the past 20 years. This means that today's veterinary drugs have received a thorough safety evaluation before their use is permitted. To increase further the degree of safety of products used in animal husbandry, scientists are continually developing new and more sensitive testing procedures. Testing is part of an overall quality assurance regime to ensure that meat products are safe for the consumer. Secondly, it is noted that a range of veterinary drugs are commonly used in animal production and, as a result, drug residues are common in EC-produced beef.[118] Some of these residues present a greater risk to human health than

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[115] See Section C below for a detailed explanation of Codex, which is the international body, created in 1962, responsible for the execution of the Joint Standards Program of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO): both are specialized agencies of the United Nations.

[116] Annex A of the *SPS Agreement* provides that "*International standards, guidelines and recommendations*" relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice are those established by Codex.

[117] See Section B below for a description of risk analysis.

[118] The results of an enquiry on the control of residues in meat, hormones, beta-agonists and other substances, (Com (93) 167 *final*, *supra*, note 101, p. 2 (Annex 4, Tab Q)) showed that:

> a) anabolic substances (hormones and beta-agonists) were generally available leading to illegal use;
> b) antibiotic and sulphonamide residues were frequently found in meat, especially in the case of intensive livestock rearing systems (veal calves, young fattening bovines, and fattening pigs);
> c) other residues were detected occasionally (heavy metals including cadmium, pesticides, antiparasitic substances).

any residues from hormones could ever present.

84. The following section will review the internationally accepted principles of risk assessment as used by scientists in conducting safety evaluations of veterinary drugs. Subsequent sections describe the role of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") and Codex in setting food standards; the use of veterinary drugs in animal production; and the relative risks posed by a number of veterinary drugs commonly used in animal production in the EC.

B. RISK ANALYSIS

85. Risk analysis has been defined by Codex as meaning, "...a process consisting of three components: risk assessment, risk management, and risk communication."[119] At the end of the process, a sanitary measure may be put in place to control an identified health risk(s). The type of measure chosen relates to the severity of the risk and the least trade restrictive risk management option(s), as identified during the risk analysis process.

86. In its most recent draft, Codex has defined risk as, "...a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food."[120] Risk may be conceptualized as the expected proportion of a population who will develop a disease or die if exposed to a particular harmful agent.[121]

87. Codex acknowledges that hazards are present in food as a result of chemical contaminants (*e.g.*, pesticides and veterinary drug residues), microbiological contaminants, or naturally occurring substances (*e.g.*, toxins) found in food. These hazards present a risk to human health. Risk assessment, which is one component in the risk analysis process,

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[119] *Application of Risk Analysis to Food Standards Issues: Report of the Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13-17 March 1995* (Geneva: WHO, 1995) p.6 [hereinafter: *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation*] (Annex 3, Tab A). This is the most recent comprehensive international report on risk analysis. The Codex definitions for risk analysis, however, continue to evolve. In June 1996, Codex issued revised definitions for interim use. These definitions are found in: Codex Alimentarius Commission, "Terms and Definitions Used in Risk Analysis," Joint FAO/WHO Food Standards Programme, June 1996, p.2 [hereinafter "Terms and Definitions used in Risk Analysis"] (Annex 3, Tab B).

[120] *Ibid.*, "Terms and Definitions used in Risk Analysis."

[121] D. Waltner-Toews & S.A. McEwen, "Chemical residues in foods of animal origin: overview and risk assessment," in the Special Issue on "Human Health Risks from Chemical Contaminants in Foods of Animal Origin" (1994) 20 *Preventive Veterinary Medicine* 161, p. 163 (Annex 3, Tab C).

permits an objective evaluation of these hazards.

1. Risk Assessment

88. The *SPS Agreement* requires that a chosen sanitary measure be based on an appropriate risk assessment. Risk assessment is a process that recognizes the inherent uncertainties in conducting a scientific evaluation of the effects certain hazards pose to human health. Thus, the risk assessment process is designed to be conservative and requires extensive testing and analysis when evaluating potential human health hazards.

89. Risk assessment is a specific component of the risk analysis process. The risk assessment process, conducted by scientists, includes well defined procedures that have been described by Codex and JECFA[122]. In the most recent report of the Joint FAO/WHO Expert Consultation on the application of risk analysis to food standard issues, the risk assessment process is defined as having four components:

1. hazard identification
2. hazard characterization
3. exposure assessment
4. risk characterization[123]

90. Risk assessment systematically organizes scientific and technical information to answer specific questions about health risks. Risk assessment requires explicit recognition that there may be some uncertainties, owing either to limits in the data, or to alternative interpretations of the data.

91. The discussion that follows will deal with the four components of the risk assessment process outlined above.[124]

a. Hazard Identification

92. Hazard identification is the identification of biological, chemical and physical agents

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[122] See section C below for a detailed explanation of JECFA, the Joint (WHO/FAO) Expert Committee on Food Additives responsible for providing independent expert advice to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF).

[123] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation*, *supra*, note 119, p.6 (Annex 3, Tab A).

[124] *Ibid.*

capable of causing adverse health effects, and which may be present in a particular food or group of foods.[125]

93. In dealing with veterinary drug residues, the goal is to identify potential adverse health effects in humans associated with exposure to a veterinary drug. The qualitative likelihood of such effects occurring in exposed human populations, and the certainty or uncertainty associated with such effects, are evaluated using available data. These data may be derived from a number of sources, such as epidemiological studies or animal toxicological studies.[126] If there is any evidence of a hazard, then the hazard characterization process of the risk assessment is undertaken.

b. Hazard Characterization

94. Hazard Characterization is defined as the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, such as veterinary drugs, a dose-response assessment[127] is performed. In all cases, the chemicals being considered for hazard characterization are present at very low levels in foods, that is, parts per million ("ppm") or less. Therefore, to obtain adequate sensitivity in humans, animal toxicological studies must be conducted at very high levels, sometimes exceeding several thousand ppm's.[128] One of the main principles underlying all descriptive animal toxicity testing is that exposure of experimental animals to chemicals in high doses is a necessary and valid method of discovering possible hazards in humans. This principle is based on the quantal dose-response concept that the incidence of an effect in a population is greater as the dose, or exposure increases.

95. A safe level or Acceptable Daily Intake ("ADI") is derived from the experimental no observable effect level ("NOEL") or the no observed adverse effect level ("NOAEL") by applying an appropriate safety factor. To account for sensitivity variabilities between humans and animals, and dietary variabilities among humans, a safety factor is typically applied.

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[125] "Terms and Definitions used in Risk Analysis," *supra*, note 119 , p. 2 (Annex 3, Tab B).

[126] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p.13 (Annex 3, Tab A).

[127] Dose response assessment is, "...the determination of the relationship between the magnitude of exposure (dose) to a chemical, physical or biological agent and the severity and/or frequency of associated adverse health effects.": "Terms and Definitions used in Risk Analysis", *supra*, note 119, p. 2 (Annex 3, Tab B)

[128] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p. 15 (Annex 3, Tab A).

When data from long-term animal toxicity studies are available, a safety factor of 100 is generally applied. Larger safety factors, up to 1000, may be used in certain cases. This means that there is no significant risk if the chemical is ingested at or below the ADI and the likelihood of adverse health effects is notionally zero. The process of risk management may result in some countries choosing a different ADI value by applying a larger safety factor.[129]

i. Genotoxic and Non-Genotoxic Carcinogens

96. Traditionally, toxicologists have accepted the existence of thresholds for adverse effects with the exception of carcinogenicity. This is because genotoxic carcinogenic compounds have the ability to produce mutations in genetic material (DNA) leading to tumour formation. In recent years, however, it has been possible to discriminate between genotoxic carcinogens and non-genotoxic carcinogens. The latter are themselves not capable of producing mutations, although there may be an effect on cells that are already in the process of mutating.

97. Hazard characterization now distinguishes between genotoxic and non-genotoxic carcinogens.[130] In principle, non-genotoxic carcinogens may be regulated using a threshold approach, such as the NOEL-safety factor approach. Similarly, ADI is derived from an experimental NOEL or NOAEL, and by applying appropriate safety factors. This means that there is no significant risk if the chemical is ingested at or below the ADI, and the likelihood of adverse health effects is notionally zero.[131]

98. For genotoxic carcinogens, the NOEL-safety factor approach is generally not considered a suitable method for setting ADIs. Two approaches are available: 1) to ban the chemical from commercial use, or 2) to establish a level of risk that is sufficiently small to be deemed negligible or insignificant. For genotoxic carcinogens, in establishing a negligible level of risk, a quantitative risk assessment process is used.[132] This approach has been used to establish a MRL for Carbadox, which has a metabolite that is a known genotoxic carcinogen. Carbadox is permitted for use in the EC as a feed additive. The first approach,

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[129] *Ibid.*, p. 17

[130] Non-genotoxic carcinogens are referred to as "promoters"; that is, they do not cause cancer, but rather, they can act as promoters in cells that have already been damaged. Non-genotoxic carcinogens are not capable of producing mutations. In contrast, genotoxic carcinogens are "initiators", and can cause mutations of DNA resulting in tumours in humans or animals.

[131] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p. 17 (Annex 3, Tab A).

[132] *Ibid.*, p. 17

to ban the compound, has been adopted by several countries, including the EC, for nitrofurans, which are also known genotoxic carcinogens.

c. Exposure Assessment

99. Exposure Assessment is defined as the qualitative or quantitative evaluation of the likely intake of biological, chemical or physical agents via food, as well as exposures from other sources if relevant.[133] This is usually done by examining the dietary intake of foods and determining if the theoretical dietary intake is below the recommended ADIs.

d. Risk Characterization

100. Risk Characterization is the qualitative and/or quantitative estimation of the probability of occurrence, and severity, of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.[134] Risk characterization is performed by taking into consideration the results of the hazard identification, hazard characterization and exposure assessment.[135]

2. Risk Management

101. Risk Management has been defined by Codex as, "...the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures."[136]

102. It is the view of Codex that, "...risk assessment of chemical hazards in foods usually results in the selection of risk management options to ensure that foodborne risks to

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[133] "Terms and Definitions used in Risk Analysis," *supra*, note 119, p. 2 (Annex 3, Tab B).

[134] *Ibid.*, p. 2

[135] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p. 19 (Annex 3, Tab A).

[136] Codex Alimentarius Commission, *Risk Analysis: Definitions, Procedures and Principles*, Joint FAO/WHO Food Standards Programme, Codex Committee on General Principles - Twelfth Session, Paris, France, 25-28 November 1996 p. 18 [hereinafter *Risk Analysis: Definitions, Procedures and Principles*] (Annex 3, Tab D).

consumers are not appreciable ('notionally zero')."[137] The setting of MRLs is a risk management option that is commonly used in controlling the risks arising from chemical contaminants (*e.g.*, veterinary drugs) in foods.

103. The setting of MRLs, coupled with monitoring and testing programs, is an example of a comprehensive sanitary control measure that can be used to manage risk effectively.

3. Risk Communication

104. Risk Communication is defined by Codex as, "[t]he interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties."[138]

105. Risk communication must take place at all stages of the risk analysis process to ensure open, balanced and meaningful discourse between science experts, policy makers, farmers, industry, consumers and all other interested parties. Absence of timely communication at all stages may cause a lack of trust between the groups involved in the process. This may lead to a situation where perception of risks, rather than the actual risk involved, takes over the issue and leads to control measures far in excess of the actual risk involved.

106. Failure to communicate the actual risks, and failure to initiate a dialogue between all parties, may also lead to sensationalization of the issue. The popular media play an important role in this. The media tend to emphasize dramatic and negative aspects of issues, rather than presenting the actual facts. Once an issue enters this arena, and gains notoriety, meaningful discourse becomes difficult, as policy makers and politicians may not wish to fight public opinion, however misguided it may be.

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[137] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p. 31 (Annex 3, Tab A).

[138] *Risk Analysis: Definitions, Procedures and Principles, supra*, note 136, p. 16 (Annex 3, Tab D).

C. ROLE OF CODEX AND JECFA IN SETTING FOOD STANDARDS

1. What Is Codex?

107. With the active participation of member countries, Committees of Codex develop internationally accepted food standards that promote fair practices in food trade, while providing protection to the consumer.[139]

108. Membership in Codex is open to all members and associate members of the FAO and WHO.[140] Today, there are 152 members of Codex representing 97 % of the world's population. It is the view of Codex that the Member States of the EC play a very important role in the development of Codex standards.[141]

109. The members of Codex participate in, or chair, the various Codex Committees responsible for setting the food standards. Codex proposals and recommendations for food standards are made to the governments of its members, for implementation into national law.[142]

110. Codex has developed step-by-step procedures to ensure divergent views are discussed and adequate deliberations take place prior to the adoption of food standards. There are several opportunities throughout the development of a standard for members to express their views and concerns.

111. Codex develops standards by allocating the work to its various Committees. There are Committees dealing with specific commodities, and others dealing with specific issues or subject areas. On the advice of an *ad hoc* Joint FAO/WHO Expert Consultation convened in 1984 to discuss the need for special work in the area of veterinary drug residues, the Codex Commission established, within its structure, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). This Committee is responsible for examining the issue of

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[139] *Introducing Codex Alimentarius*, Prepared by the Secretariat of the Joint FAO/WHO Food Standards Programme (Rome: FAO, 1988), pp. 3-12 , p. 3 [hereinafter *Introducing Codex Alimentarius*] (Annex 3, Tab E).

[140] *Ibid.*, p. 5.

[141] *Ibid.*

[142] *Ibid.*

residues of veterinary drugs in foods.[143]

112. At its first session, the CCRVDF recommended that the JECFA provide it with independent scientific advice on veterinary drugs.

2. What Is JECFA?

113. The Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) is an expert group of scientists, having a broad range of expertise. JECFA examines complex scientific issues, in particular, those issues involving the review of the safety of veterinary drugs and food additives. Committee members are chosen for their scientific expertise and do not participate as representatives of their respective governments.

114. JECFA provides independent expert advice to the CCRVDF. One of the roles of JECFA is to establish principles for evaluating the safety of residues of veterinary drugs in foods, and to determine acceptable and safe levels for such residues when the drugs in question are administered to food-producing animals in accordance with good practice in the use of veterinary drugs.

3. JECFA Risk Assessment Process to Develop a Standard

115. For veterinary drugs, the risk analysis is normally initiated by the CCRVDF and a request to conduct a risk assessment is communicated to JECFA.

116. JECFA carries out toxicological evaluations of veterinary drugs, and estimates the amount of the compound that can be ingested daily over a lifetime without appreciable health risk (notionally zero risk), *i.e.*, an ADI. In setting an ADI, JECFA applies a safety factor to the NOEL, as determined in the most appropriate, usually most sensitive, animal species.[144]

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[143] The definition of veterinary drug residue adopted by the Codex includes both the parent substance administered to an animal and all the chemical compounds produced by the metabolic transformation of this substance which may be present in food derived from the treated animal. See Codex Alimentarius Commission, *Risk Assessment in the Codex Committee on Residues of Veterinary Drugs in Foods*, Joint FAO/WHO Food Standards Programme, Codex Committee on Residues of Veterinary Drugs in Food - Tenth Session, San José, Costa Rica, 29 October-1 November 1996, p. 2 [hereinafter: *Risk Assessments in the Codex Committee on Residues of Veterinary Drugs in Foods*] (Annex 3, Tab F).

[144] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultation, supra*, note 119, p. 8 (Annex 3, Tab A).

This corresponds to the hazard characterization step of the risk assessment.[145]

117. Occasionally JECFA considers that the use of an ADI in numerical terms is not appropriate, for example, when the estimated consumption of the compound in question is expected to be well below any numerical value that would ordinarily be assigned to it. Under such circumstances, JECFA uses the term "ADI not specified". JECFA defines this term to mean that, on the basis of available data, the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of JECFA, represent a hazard to health. The establishment of an ADI is deemed as "not necessary", and the establishment of a MRL will also be deemed as "not necessary".[146] The natural hormones are an example of a situation where JECFA determined that the daily consumption of each compound, resulting from its use as a growth promoter, would be well below exposure levels from other sources. As a result, no ADI or MRL was considered necessary.

118. JECFA also estimates potential intake of residues of veterinary drugs using standard assumptions about the consumption of edible animal products, such as meat and milk, and proposes MRLs that are consistent with Good Practice in the Use of Veterinary Drugs.[147] These estimates of potential intakes are compared with the ADIs. This is the risk characterization process.[148]

119. JECFA must unanimously consent to the report on the safety of the evaluated veterinary drugs prior to recommendations being made to the CCRVDF for ADIs and MRLs. Any MRLs proposed by JECFA are circulated to governments by the CCRVDF, the primary role of which is to recommend MRLs. Details of the scientific risk assessment are not discussed in depth at the CCRVDF, but risk management options may be considered in light of governments' comments.[149]

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[145] *Ibid.*, p. 10.

[146] *Ibid.*, p. 8.

[147] Good Practice in the use of veterinary drugs is defined as: "... the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions." Codex Alimentarius Commission, *Codex Alimentarius, vol. 3: Residues of Veterinary Drugs in Foods*, 2nd ed. (Rome: FAO, 1996) p. 75 [hereinafter *Residues of Veterinary Drugs in Foods*] (Annex 3, Tab G).

[148] *Application of Risk Analysis to Food Standards Issues: Report of the FAO/WHO Expert Consultations, supra*, note 119, p. 10 (Annex 3, Tab A).

[149] *Ibid.*

120. Following consideration of Codex members' comments, the CCRVDF accepts or modifies the JECFA recommendations for the ADIs and MRLs. Once passed through the CCRVDF, the standards are brought forward for approval by Codex for adoption at Step 8.

4. Adoption of a Codex Standard

121. Codex bases its food safety standards on four principles concerning the role of science. The four principles are:

i) The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

ii) When elaborating and deciding upon food standards the Codex Alimentarius Commission will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for promotion of fair practices in food trade.

iii) In this regard, it is noted that food labelling plays an important role in furthering both of these objectives.

iv) When the situation arises that members of the Codex Alimentarius Commission agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.[150]

122. Most commonly, the elaboration of a standard is an eight step process, although there are provisions for a shortened procedure. Draft standards do not advance through the eight step process unless there is a consensus of the appropriate scientific committee at each step. Throughout this process, members have numerous opportunities to comment on the standard prior to finalization and adoption at step 8.

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[150] These principles were adopted at the 21st session of the Codex Alimentarius Commission in July 1995: Codex Alimentarius Commission, *Report of the Twenty-First Session, Rome, 3-8 July 1995*, Joint FAO/WHO Food Standards Programme, Ref. No. ALINORM 95/37 1995 (Rome: FAO, 1995) pp. 5 and 61 (Annex 3, Tab H).

D. VETERINARY DRUGS

123. A veterinary drug is defined as "[a]ny substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behaviour."[151]

124. A large number of veterinary drugs are used in farm animals. These products can be categorized into a number of classes, including antimicrobials (*e.g.*, antibiotics), anthelmintics, pesticides, antiprotozoals (*e.g.*, coccidiostats) and hormones. The fate of these veterinary drugs within the animal body is highly variable. Some compounds are metabolized or eliminated quickly, while others, such as some antibiotics, are much more persistent.[152]

125. Under the MRLs Regulation, MRLs[153] are established for certain veterinary drugs,

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[151] *Residues of Veterinary Drugs in Foods*, *supra*, note 147, p. 77 (Annex 3, Tab G).

[152] A.R. Peters, "Residues of Veterinary Drugs in Animal Products" in W. Haresign and D.J.A. Cole, eds., *Recent Advances in Animal Nutrition*, (London: Butterworths, 1989) pp. 13-25, p. 14 (Annex 3, Tab 4).

[153] According to the MRLs Regulation, (Annex 1, Tab P) a MRL means:

> ...the maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or μg/kg on a fresh weight basis) which may be accepted by the Community to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technology aspects. When establishing a maximum residue limit (MRL), consideration is also given to residues that occur in food of plant origin and/or come from the environment. Furthermore, the MRL may be reduced to be consistent with food practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

Codex defines a MRL as:

> ...the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/k or mg/k on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs ant to the extent that practical analytical methods are available.

implying that there is an accepted level of risk in the use of each of these compounds. For other veterinary drugs, such as many of the antimicrobial growth promoters, MRLs do not appear to have been established under the MRLs Regulation, despite the fact that they pose some human health risks.

126. Hormones are only one type of veterinary drug used for growth promotion. Antimicrobial feed additives are also commonly used as growth promoters in a number of animal species, including cattle.

E. HORMONES

1. What Are Hormones?

127. Hormones are chemical messengers which bind to specific receptors in the target tissue, thereby initiating a series of biochemical events within the cell, resulting in increased protein synthesis. The chemical messengers can be divided into various classes, based on chemical structure, such as steroid, peptide, or simple chemical messengers.[154]

128. Sex steroidal hormones, such as oestradiol 17β, progesterone and testosterone, are naturally derived from cholesterol. These hormones produced in the body are called endogenous or natural hormones, while compounds that are chemically synthesized to mimic the effect of natural hormones are called xenobiotic hormones. Xenobiotic hormones include trenbolone and MGA. Zeranol is a non-steroidal xenobiotic compound that has a weak oestrogenic effect.

129. There are three natural hormones at issue in this case: oestradiol 17β, progesterone and testosterone. Trenbolone, zeranol and MGA are xenobiotics that mimic the biological activity of the natural hormones. Trenbolone mimics testosterone; zeranol mimics oestradiol 17β; and MGA mimics progesterone.

130. The hormones responsible for male characteristics are collectively known as androgens, and those responsible for female characteristics are known as oestrogens. Those hormones responsible for maintaining pregnancy are gestagens or progestogens. Androgens and oestrogens are referred to as "anabolic" agents, as they have an effect on general body metabolism by having a positive action on protein synthesis. For the purposes of growth

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Residues of Veterinary Drugs in Foods, supra, note 147, p. 76 (Annex 3, Tab G).

[154] G.C. Brander *et al.*, eds., *Veterinary Applied Pharmacology & Therapeutics*, 5th ed. (London: Bailliere Tindall, 1991), pp 279-290 at p. 279 [hereinafter *Veterinary Applied Pharmacology & Therapeutics*] (Annex 3, Tab I)

promotion, animals are administered those hormones in which they are deficient. Generally, for growth promotion purposes, males are given oestrogens and gestagens, and females are given androgens.[155]

131. The chemical structure of the principal natural sex steroids is identical in mammalian species. There are, however, variations in the natural levels found, depending on sex, age and physiological status of the individual or animals. It has, therefore, been concluded that natural hormones must be regarded as natural constituents of food of animal origin.[156]

132. In fact, naturally occurring hormones exist in a wide variety of food products at levels far higher than those found in beef derived from hormone-treated cattle. The amount of oestradiol 17β contained in 157 grams of such beef (average daily intake of beef), for example, is 2,380 parts per trillion (15 ppt). In human milk fed to babies, one finds 12,500 pg/500mL (25 ppt) of oestradiol 17β, and in soybean oil, the levels of oestradiol equivalents are 314,000,000 pg/157 g (200,000 ppt).[157] This demonstrates that human milk for babies has nearly twice the amount of oestradiol as beef derived from hormone-treated cattle. It also illustrates that the consumption of this substance from other dietary sources is far greater than the amount consumed in such beef.

133. Thus, it can be stated that the hormone load taken orally from other foodstuffs is far greater than that which occurs by the consumption of beef derived from hormone-treated cattle.[158]

134. The natural hormones are frequently used in human therapy. For example, progesterone is used in combination with oestradiol in oral contraceptives or for hormone replacement therapy of post menopausal women.[159] Oestradiol 17β is also used in a number

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[155] The main male androgen is testosterone. Trenbolone has an androgenic effect. The main female oestrogen is oestradiol 17β. Zeranol has a weak estrogenic effect. Progesterone has a catabolic effect in farm animals, and is used in combination with the female oestrogens to balance the estrogenic effect of oestradiol 17β, and to stimulate cell proliferation. MGA, also a gestagen, has an anabolic action in animals.

[156] B. Hoffman, "Natural occurrence of steroids hormones in food producing animals", *Anabolics in Animal Production: Public health aspects, analytical methods and regulation*, Symposium held at OIE, (Paris, 15-17 February 1983) p. 224 (Annex 3, Tab J).

[157] Ayerst, "The Facts About the Safety of Synovex Implants." (Annex 3, Tab K).

[158] "Anabolic Growth Promotants and the EEC," *supra*, note 63, p. 4 (Annex 2, Tab H).

[159] J.G. Hardman *et al.*, eds., *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 9th ed. (New York: McGraw-Hill), p. 1429 (Annex 3, Tab L).

of cosmetic skin preparations.[160]

135. Although humans are potentially exposed to exogenous amounts of hormones, such as oestradiol 17β, through the consumption of meat from hormone-treated cattle, it is an insignificant amount when compared to the normal human production of the chemical. It is reported that, "[t]he production rate in humans ranges between 6 micrograms/24 hours in prepubescent boys and 945 micrograms/24 hours in normal adult cycling females."[161] Therefore, the amount of hormone consumed through hormone-treated beef would be 2,500 times lower than natural production levels in prepubescent boys and up to 400,000 times lower than the natural production levels in normal adult cycling females.

2. How Are Hormones Used for Growth Promotion?

136. Of the six growth promoting hormones at issue in this case, five are administered as hormonal implants. The sixth hormone, MGA, is administered as a feed additive.

137. Hormonal implants are formulated as pellets with approved and fixed amounts of compound. These pellets are implanted in the middle third of the animal's ear. This allows for proper dosage and administration by producers. All implanted animals are visually inspected upon arrival at the slaughterhouse, and the ear portion of each carcass is discarded. This removes the chance that any portion of the implanted compound will enter the food chain.

138. Hormonal implants are designed to release the active ingredient into the bloodstream for a period of 100-200 days, depending on the particular implant.[162] Hormonal implants may be formulated as combinations of two hormones. This combining of hormones allows for a balancing of the hormonal effects, resulting in the optimal effects in animal production.

139. MGA is the only hormone not administered as an implant. MGA is an orally active progesterone hormone and is, therefore, premixed in a predetermined amount into feed. The premixing reduces the chance of improper use or administration. The feed is administered to the cattle in a controlled feedlot environment, and is withdrawn from the animals 48 hours prior to slaughter.

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[160] Technical Resources, Inc., *Seventh Annual Report on Carcinogens: Summary 1994* (Washington: U.S. Department. of Health and Human Services, Public Health Service, 1994) p. 196 (Annex 3, Tab M).

[161] *Ibid.*

[162] J. Pickering *et al.*, *Implants and Feed Additives for Beef Cattle* (Toronto: Ontario Ministry Of Agriculture and Food, July 1993) [hereinafter: *Fact Sheet: Implants and Feed Additives for Beef Cattle*] (Annex 3, Tab N).

3. Why Are Hormones Used in Animal Production?

a. Feedlot System of Production

140. Several countries, including Canada, raise animals in a pastoral situation and move the animals through to a feedlot for finishing prior to slaughter. In this type of animal production system, it is necessary to castrate bulls for the purposes of behavioral control. In a pastoral situation, intact bulls[163] cannot be allowed to run, particularly if there are heifers anywhere in the area. Moreover, where there are intact bulls, animals cannot be moved from herd to herd, or to a feedlot, because of behavioral problems.[164]

141. Other EC countries, such as Germany, Italy and Denmark, having intensive animal production systems, keep the animals indoors and confined. Thus, there is not the same need to castrate bulls for behavioral reasons and, consequently, no need to replace hormones that would have been lost through castration.[165]

142. The problem with castration of male animals is that the natural male hormones are lost. This results in the regression or loss of many skeletal muscles. Such regression can be reversed by replacing the lost male hormones in the form of an implant.[166] In some EC countries, hormones were previously used for this purpose.

143. In the case of MGA, the feed additive is used to improve feed utilisation and growth rate, and to suppress oestrus in intact heifers destined for slaughter. It is used predominantly in feedlot operations and serves a legitimate production need for these types of operations.

b. Growth Promotion

144. Besides serving the legitimate needs of the feedlot production system, hormones are used to increase feed efficiency and rate of gain, and to increase the quality of the meat. It is reported that:

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[163] Intact bulls are males that have not been castrated. Bulls that have been castrated are referred to as steers. Steers make up the larger percentage of animals raised for beef production purposes.

[164] "Anabolic Growth promotants and the EEC,", *supra*, note 63, p. 2 (Annex 2, Tab H).

[165] *Ibid.*

[166] G. Michel and E.E. Baulieu, "The mode of action of anabolics" in, *Anabolics in Animal Production: Public health aspects, analytical methods and regulation*, Symposium held at OIE, (Paris, 15-17 February 1983) p. 53 (Annex 3, Tab J).

...steers show a tendency to gain weight more rapidly after anabolic use, thus creating the potential to slaughter at an earlier age, and a greater margin of profit to producers. For example, feedlot steers have approximately 12 % growth promotion and 9 % feed efficiency claims, while heifers' claims are approximately 10 % and 9 % respectively. Non-implanted steers would require 12 % more days on feed to reach the same slaughter weight as an implanted steer while consuming 9 % more feed. Additionally - and very significant to producers, the beef trade and consumers - is that the implanted animal has better carcass composition, with a greater lean-to-fat tissue ratio.[167]

4. Mode of Action of Hormones

145. As stated by an EC scientist:

To our present knowledge up to now distinctions between untreated animals and those treated with oestradiol-17β, testosterone or progesterone can only be made on a quantitative and not a qualitative basis. This statement is based on the fact that the three steroids mentioned above (oestradiol-17β, testosterone, progesterone) will enter the same metabolic pathways, regardless of whether they are of endogenous or exogenous origin.[168]

146. When applied exogenously, the natural hormones enter the same metabolic pathways as the endogenously produced molecules. Metabolism leads to a rapid inactivation and, hence, these compounds exhibit only little oral activity. As explained by an EC scientist, "...in all species investigated, metabolism of testosterone, progesterone, and oestradiol 17β leads to a biological deactivation (biotransformation), often referred to as 'catabolism of endogenous steroids'."[169] For cattle it has been shown that 60-90 % of the parental steroids and the biodeactivated metabolites are eliminated via the bile and faeces.

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[167] D.A. Franco & C.E. Adams, "Hormones," in L.M. Crawford & D.A. Franco, eds., *Animal Drugs and Human Health*, (Lancaster: Technomic Publishing Co., 1994), pp. 103-112, p. 109 (Annex 3, Tab P).

[168] R.J. Heitzman, ed., *Veterinary Drug Residues: Residues in food producing animals and their products: Reference Materials and Methods*, 2nd ed., (Oxford: Blackwell Scientific Publications, 1994), pp. 7/1-7/7, p. 7/5 [hereinafter *Veterinary Drug Residues: Residues in Food Producing Animals and their Products*] (Annex 3, Tab Q).

[169] B. Hoffmann & P. Evers, "Anabolic Agents with Sex Hormone-Like Activities: Problems of Residues," in A.G. Rico, ed., *Drug Residues in Animals* (Orlando: Academic Press, 1986) p. 116-119 (Annex 3, Tab S).

147. Natural hormones are rapidly inactivated in the target animals. Furthermore, residue studies have shown that any increases in the levels of oestradiol 17β and progesterone due to implants were exceedingly small, when compared to the increases of hormone residue levels seen in pregnant heifers.[170]

148. For the xenobiotic trenbolone, the mode of action is the same as that of testosterone, and trenbolone enters the same metabolic pathways as testosterone. Upon entering the circulation of the animal, trenbolone is readily hydrolysed to free 17β-OH-trenbolone. Approximately 80 % of this compound is eliminated via the bile and faeces.[171]

149. Zeranol has been described as a "...non-carcinogenic, nonteratogenic, and non-mutagenic,"[172] anabolic agent having an affinity for the oestrogen receptor. Scientists reported that, "...toxicity testing (acute, subacute, and chronic) in several species by various routes of administration reveals an extremely low toxicity...". [173] The metabolites of zeranol also exhibit low toxicity.

150. In the case of MGA, it has its most potent effect in cattle, the target species. From a relative potency among species standpoint, the biological activity of MGA in humans is over 200 times lower than for cattle (0.14 mg/k vs 0.0006 mg/k) as measured by block of the reproductive cycle. This difference in potency allows for relatively low doses of MGA to exert the desired positive biological effect in cattle, while ensuring that potential residues in cattle would have little probability of exerting a biological response in humans.[174]

5. The Safety of Approved Hormones

151. Hormones are used and regulated as veterinary drugs in several countries, including Canada, the U.S., Australia and New Zealand. Countries that have not yet approved the use

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[170] *Residues of some veterinary drugs in animals and foods*, Monographs prepared by the Thirty-Second Meeting of the Joint FAO/WHO Expert Committee on Food Additives, Rome, 15-23 June 1987, FAO Food and Nutrition Paper 41 (Rome: FAO, 1988), pp. 7-49, pp. 8-42 (Annex 3, Tab R).

[171] *Ibid.*, p. 131

[172] R.S. Baldwin, R.D. Williams & M.K. Terry, "Zeranol: A Review of the Metabolism, Toxicology, and Analytical Methods for Detection of Tissue Residues" (1983) 3 *Regulatory Toxicology and Pharmacology* 9, p. 9 (Annex 3, Tab T).

[173] *Ibid.*

[174] J. W. Lauderdale, Use of MGA (melengestrol acetate) in animal production in *Anabolics in Animal Production: Public health aspects, analytical methods and regulation*, Symposium held at OIE, (Paris, 15-17 February 1983) p.204 (Annex 3, Tab J).

of growth promoting hormones in animal production nevertheless accept meat derived from hormone-treated livestock from Canada and other countries. There are very few exceptions where such meat is banned. These include the Czech Republic and Slovenia, which have harmonized their veterinary policies with the EC to facilitate trade.

152. Beef derived from hormone-treated livestock is widely accepted as being safe. Numerous international studies and conferences have been conducted to examine and re-examine the safety of the use of these substances as growth promoting agents.

153. The most recent conference on the subject was hosted by the EC. As noted by Sir John Maddox, who chaired the 1995 Scientific Conference, the scientific facts are indisputable:

> What last week's conference decided is that there is now no reason to suppose that the use of the reproductive steroid hormones, sanctioned for more than 30 years in the United States, Canada, Australia and New Zealand, is damaging to meat-eating consumers, although there may still be room for doubt about the effects of these materials on the animals to which they are administered, notably in the possibility that they may affect behaviour.[175]

154. Other reports contribute to the body of scientific evidence supporting the safety of hormones. In 1995, Codex adopted standards for five growth promoting hormones. These standards were based on the recommendations of the CCRVDF, which had reviewed the risk assessments of JECFA, and consulted with Codex members, prior to making its recommendations for adoption of the standards.

155. In making its recommendations to the CCVDRF, JECFA conducted risk assessments for oestradiol 17β, progesterone and testosterone in 1981 and 1988. Zeranol and trenbolone were examined by JECFA in 1982, 1983 and 1988, with trenbolone being evaluated again in 1989.

156. JECFA reached its conclusions on these particular hormones after a comprehensive review of toxicological data from laboratory animals, including studies on biological activity, carcinogenicity, embryo developmental toxicity, mutagenicity and residues in animals. Use patterns and analytical methodology were also reviewed.

157. JECFA concluded that there was no need to set an ADI or MRL for the three natural hormones because the estimated consumption of the natural hormones was well below any numerical value that would ordinarily be assigned to it.

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[175] "Contention over growth promoters," *supra*, note 87 (Annex 4, Tab K).

158. For oestradiol 17β, JECFA wrote:

> ...the Committee considered an ADI unnecessary for a hormone that is produced endogenously in human beings and shows great variation in levels according to age and sex. The Committee concluded that residues arising from the use of oestradiol-17β, as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health."[176]

159. In the case of progesterone:

> ...the Committee deemed it unnecessary to set an ADI for a hormone that is produced endogenously in human beings and shows marked physiological variation in levels according to sex and age. The Committee concluded that residues arising from the use of progesterone as a growth promoter in accordance with good animal husbandry practices are unlikely to pose a hazard to human health.[177]

160. Finally, for testosterone it was concluded that:

> ...testosterone is normally produced in all mammalian species. When heifers are treated in accordance with good animal husbandry practice, the levels of residues in edible tissue may be increased by about two-fold, but these levels are extremely low when compared with the amounts of testosterone normally produced by human beings. Even in prepubertal girls, the amount of endogenous testosterone produced daily (32 μg) is almost a thousand times the amount of testosterone that would be ingested in a 500 g portion of meat [three times that average daily intake] derived from treated animals (40 ng). The Committee concluded that the amount of exogenous testosterone ingested in edible tissues from treated animals would not be capable of exerting a hormonal effect, and therefore any toxic effect, in human beings."[178]

161. Zeranol was evaluated, and toxicological data on mutagenicity, reproduction and teratogenicity studies were examined. The Committee concluded that the determination of a

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[176] *Evaluation of certain veterinary drug residues in food: Thirty-second Report of the Joint FAO/WHO Expert Committee on Food Additives*, Technical Report Series 763 (Geneva: WHO, 1988) p. 19 (Annex 3, Tab 1)

[177] *Ibid.*, p. 21

[178] *Ibid.*, p. 22

no hormonal effect level[179] would allow for the estimate of a safe exposure level. Based on the no hormonal effect level, ADIs and MRLs were established. The standard set for zeranol was an ADI of 0-0.5 μg/kg of body weight and an MRL of 10 μg/kg in bovine liver and 2 μg/kg in bovine muscle.

162. Trenbolone was again evaluated at the Thirty-Fourth JECFA meeting. It was decided that the evaluation of trenbolone and its metabolites would be based on their no hormonal effect level. Using a safety factor of 100, JECFA recommended ADIs and MRLs. The standard for trenbolone is an ADI of 0-0.02 μg/kg of body weight and a MRL of 10 μg/kg of α-trenbolone in bovine liver, and 2 μg/kg of β-trenbolone in bovine muscle. Conservative estimates using the daily intake values for edible tissues indicated that the ADI for trenbolone should not be exceeded at any time after the implantation of the drug, and that the maximum concentrations of residues occurring at 15-30 days after implantation are below the recommended MRLs. Concentrations would be even lower following the usual treatment time of 60 days.

163. These JECFA recommendations for the five growth promoting hormones were adopted by Codex in June of 1995.[180]

164. The review of veterinary drugs in Canada follows a stringent process that requires manufacturers to submit data on laboratory animal toxicity studies (*e.g.*, chronic toxicity studies, carcinogenicity studies, teratogenicity testing, mutagenicity studies) and pharmacology and residue studies (*e.g.*, metabolism studies, residue studies). A comprehensive review is conducted on all veterinary drugs to ensure compounds used in animal production meet human safety requirements.[181] Health Canada (Bureau of Veterinary

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[179] The concept a of no hormonal effect level is used in those cases where hormonal effects have the potential to cause tumours in the test species. The no hormonal effect level is the level at which the residue cannot express any hormonal action in the test species. At the no hormonal effect level, the compound would not be able to present a risk because the exposure is at levels below those required for detectable hormonal activity.

[180] ALINORM 91/31, Appendix IV and ALINORM 93/31, Appendix II, as adopted by the 21st Session of Codex, *supra*, note 150 (Annex 3, Tab H).

[181] The regulation of veterinary drugs in Canada is the responsibility of the Bureau of Veterinary Drugs of the Health Protection Branch, Health Canada, and is legislated under the Foods and Drugs Act and Regulations. The Bureau advises veterinarians, drug manufacturers, feed manufacturers, livestock producers, and the general public concerning the safety and recommended use of veterinary drugs in food producing animals. The Bureau is responsible for evaluating drugs to ensure that: 1) veterinary drugs are safe and effective, and 2) meat, milk, egg, fish and honey do not contain potentially harmful residues. In order to fulfil the mandate, the Human Safety Division carries out safety evaluation and human risk assessment of drugs intended for use in food-producing animals. Generally, three types of veterinary drug submissions are reviewed: new drug and supplemental new drug submissions;

Drugs) reviewed MGA and approved it for use in Canada in 1988. The U.S. Food and Drug administration has also reviewed the safety of MGA and has approved it for use since 1968.[182]

165. In 1983, the Office Internationale Epizootics (OIE) organized a meeting specifically to examine the use of anabolics in animal production. In the conference proceedings it is stated:

> Through recent progress in analytical methods, residues of anabolics in meat and in other edible animal products can now be detected at levels of parts per billion, or even at parts per trillion. This splendid advancement sheds a new light on anabolics. Now it is possible to distinguish between harmful and innocuous substances.[183]

166. Furthermore, the OIE conference proceedings concluded that:

> ...the myth that all anabolics are dangerous to human health is still very much alive in many countries. It must be discredited. There is common agreement with the proof presented at this meeting that the endogenous anabolics (natural hormones) such as 17 β-oestradiol, progesterone, and testosterone, when administered as implants in animals, are not hazardous to man.[184]

167. The scientific information in the OIE conference recognized that certain exogenous xenobiotic hormones were also permitted for use in some countries. Examples given were zeranol by the U.S. Food and Drug Administration, and trenbolone by the UK Ministry of Agriculture, Fisheries and Food. One of the conference's aims was to bring forth scientific information as a guide to those entrusted with making decisions on the safety of these xenobiotic compounds.[185]

168. In 1982, the *ad hoc* EEC Scientific Working Group concluded that the three natural

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experimental studies certificates; and emergency drug releases. Before a new veterinary drug can be marketed, the Food and Drugs Act and Regulations requires manufacturers to submit scientific data demonstrating that the drug is safe and effective when used according to the directions on the label. Manufacturers must provide complete details about how both the ingredients and the drug in dosage form are to be manufactured, packaged and tested. They must also demonstrate through laboratory studies and animal testing that the drug will be safe and effective for treating animals.

[182] First submission of the United States, public version, USA-EC Panel.

[183] P.N. Acha, "Foreword", in *Anabolics in Animal Production: Public health aspects, analytical methods and regulation*, Symposium held at OIE, (Paris, 15-17 February 1983) p. vi (Annex 3, Tab J).

[184] *Ibid.*, p. vii

[185] *Ibid.*

hormones, and their derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, would not present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals.[186] In 1987, this same group published its final report, completing the risk assessments on the five growth promoting hormones that were started six years earlier. The report, published in the *Veterinary Record* in October 1987, concluded that zeranol and trenbolone and their metabolites found as residues do not show significant genotoxic potential. Furthermore, the levels of trenbolone and zeranol and their major metabolites found in edible tissue, following accepted husbandry practices, are substantially below the hormonally effective dose in animal test systems and, therefore, do not present a harmful effect to human health.[187]

169. The FAO/WHO have likewise been examining the issue of anabolic agents in animal production for several years, and held conferences on the subject in 1973 and 1975. As a result of these deliberations, in 1981, the JECFA was convened by the FAO/WHO to review the use of hormones and discuss safety aspects.[188] This led to the extensive work and risk assessment reports that were published by JECFA in subsequent years (1981, 1982, 1983, 1988).

170. The use of hormones in food producing animals has been under intense international scrutiny for several years. No scientific review has ever concluded that there is a basis for banning the sale of meat derived from cattle treated with growth promoting hormones in accordance with good veterinary practices.

6. Detection and Control of Hormones

171. Codex has recommended an international code of practice for the control of the use of veterinary drugs.[189] The code sets out guidelines on the prescription, application (including withdrawal times), distribution and control of drugs used in the treatment of food-producing animals. The code of practice applies to all veterinary drugs, including hormones.

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[186] G.E. Lamming *et al.*, *Report of the Scientific group on Anabolic Agents in Animal Production,* (1982) *supra,* note 71, p. 27 (Annex 4, Tab E).

[187] G.E. Lamming *et al.*, "Special Report: Scientific report on anabolic agents in animal production," *supra,* note 72 (Annex 4, Tab F)

[188] A. Koulikovskii, Review of FAO/WHO activities in the field of anabolics used in animal production in *Anabolics in Animal Production: Public health aspects, analytical methods and regulation,* Symposium held at OIE, (Paris, 15-17 February 1983) pp. 489-495 (Annex 3, Tab J).

[189] *Residues of Veterinary Drugs in Foods*, *supra,* note 147, pp. 27-29 (Annex 3, Tab G).

172. Codex has also established guidelines for a regulatory programme for control of veterinary drug residues in foods.[190] This code recognizes that governments need regulatory control programmes to control against various health risks that could be present as a result of veterinary drug residues in animal food products. The safety of food can be ensured by controlling the risk of residues through the use of a systematic set of procedures, or residue control programmes. A control programme includes the establishment of a programme to evaluate the safety of veterinary drugs, as well as the establishment of an inspection, monitoring and surveillance programme to detect residues in food.

F. ANTIMICROBIAL FEED ADDITIVES

1. What Are Antimicrobial Feed Additives?

173. In modern animal husbandry, various drugs are used for improving animal production without a primary therapeutic objective. Better weight gain and/or feed efficiency are the main goals.[191] These veterinary drugs are called growth promoters. Two ways in which growth is manipulated is through the use of antimicrobial feed additives or through the use of growth promoting hormones.

174. Antimicrobial feed additives are antimicrobial compounds which change the population of microorganisms in the alimentary tract of healthy animals, resulting in improvement in animal performance, whereas hormones exert their effects as chemical messengers which bind to specific receptors.[192]

175. Antimicrobial feed additives improve feed conversion efficiency and hence growth rate.[193] Antimicrobial growth promoters, in general, increase growth rate by 5-10 % and feed conversion efficiency by 5-7 %.[194] There are a number of growth promoting antimicrobial compounds that are administered in the feed at low dose rates. These compounds can be sub-divided into categories of ionophore antibiotics (*e.g.*, monesin, lasalocid), non-ionophore

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[190] *Ibid.*, pp. 30-78

[191] P. Van Der Wal & P.L.M. Berende, "Effects of anabolic agents on food producing animals" in, *Anabolics in Animal Production: Public health aspects, analytical methods and regulation*, Symposium held at OIE, (Paris, 15-17 February 1983) p. 72 (Annex 3, Tab J).

[192] *Veterinary Applied Pharmacology & Therapeutics*, *supra*, note 154, p. 279 (Annex 3, Tab I)

[193] N.T. Crosby, *Determination of Veterinary Residues in Food*, Ellis Horwood Series in Food Science and Technology, pp. 33-36, p. 34 [hereinafter *Determination of Veterinary Residues in Food*] (Annex 3-O)

[194] *Veterinary Applied Pharmacology & Therapeutics*, *supra*, note 154, p. 290 (Annex 3, Tab I).

antibiotics (*e.g.*, carbadox, avoparcin) and gut active growth promoters (*e.g.*, probiotics, enzymes). The ionophore antibiotics alter digestion, whereas the non-ionophore antibiotics may favourably modify the quantity and quality of nutrients entering the body.[195]

176. Coccidiostats are another group of antimicrobial feed additives used for prophylaxis purposes. Coccidiosis is a highly contagious infection of an animal caused by parasitic microbial organisms (*i.e.*, protozoa) collectively known as coccidia. This disease affects mainly poultry, but also cattle, pigs, sheep and game birds.

177. As many of the antimicrobial feed additives are fed to the animals throughout their lives, except in those few cases where it is explicitly prohibited, it is possible that other veterinary drugs will be administered in combination, or at the same time as the feed additives are being administered.

2. Why Are Antimicrobial Feed Additives Used?

178. Antimicrobial agents are added to animal feeds for two purposes: 1) growth promotion, or 2) to cure or prevent outbreaks of disease. As written by a EC scientist, "[i]t has been estimated that approximately one-third of all UK feeding stuffs contain medicinal compounds licensed for inclusion without a veterinary prescription, whilst only 5 per cent of feeds contain medicaments for therapeutic use".[196] The remainder are used for prophylaxis purposes, that is, to prevent disease outbreaks, or for growth promoting purposes.[197]

G. RISKS ARISING FROM THE USE OF VETERINARY DRUGS

179. There is a degree of risk associated with the use of <u>all</u> veterinary drugs used for animal husbandry. An examination of examples of veterinary drugs used in animal production shows that hormones are as safe as, or safer than, other veterinary drugs commonly used for therapeutic or non-therapeutic purposes. Many of these veterinary drugs used for animal husbandry in the EC, such as anthelmintics, pesticides, and some antibiotics, are administered by producers without a veterinary prescription.[198]

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[195] P. Schmidely & M. Hadjipanayiotou, "Growth Promoters for Fattening Kids," in P. Morand-Fehr, ed., *Goat Nutrition* (Pudoc Wageningen, 1991) 184 at p. 184 (Annex 3, Tab U).

[196] *Determination of Veterinary Residues in Food, supra*, note , p.34 (Annex 3, Tab O).

[197] *Ibid.*

[198] See Part 1, Section C.

1. Risks Arising from the Use of Antimicrobial Feed Additives

a. Ionophores

i. Example - Monesin

180. Monesin is an ionophore. Ionophores have been defined as follows:

> An ionophore may be defined as an organic substance which binds a polar compound and acts as an ion transfer agent to facilitate movement of monovalent (*i.e.*, sodium and potassium) and divalent ions (*i.e.*, calcium) through cell membranes. The change in electrical charge in membranes influences transport of nutrients and metabolites across the cell membrane, but the exact mechanism by which ionophores improve growth performance in growing ruminants is not known."[199]

181. Monesin has a dual role both as a coccidiostat in poultry and as a growth promoter in cattle. Monesin affects the transfer of sodium and potassium ions through the cell membranes. To ensure minimal residues in meat, a three-day withdrawal period is recommended for poultry.

182. Ionophores such as monesin are capable of disturbing biological membranes and affecting action potentials, which presumably accounts for their high toxicity. Additionally, there are high variations in species toxicity. Workers involved in monesin production or feed compounding have reported adverse reactions, such as, headaches, nausea, nosebleeds and skin rashes.[200]

183. Monesin is administered by producers in the EC as a feed additive. The use of monesin is governed by the Feed Additives Directive. It would appear that no MRL or safety limit is established for this compound under the MRLs Regulation[201]

b. Non-ionophore Antibiotics

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[199] European Commission - Directorate-General VI, Agriculture, *Scientific conference on growth promotion in meat production: Proceedings*, (Luxembourg: Office for Official Publications of the European Communities, 1996) p. 45.

[200] J. Weissinger, "Miscellaneous Growth Promotants," in L.M. Crawford & D.A. Franco, eds., *Animal Drugs and Human Health* (Lancaster: Technomic Publishing Co., 1994) c. 8, p. 117 (Annex 3, Tab V)

[201] See Part I, Section C

i. Example - Carbadox

184. Carbadox is a widely available antimicrobial synthetic compound used as a growth promoter in pigs. Carbadox is both mutagenic and carcinogenic in animals. Concern has also been expressed about the safety of any residues to the consumer, but evidence suggests that these residues, when present, are devoid of carcinogenic and mutagenic activity, and any risk is likely to be to the workers handling the drugs.[202]

185. In 1990, at its thirty-sixth meeting, JECFA evaluated carbadox. Because of the genotoxic and carcinogenic nature of carbadox and some of its metabolites, JECFA was not able to establish an ADI. JECFA was able to complete a qualitative risk assessment, however, and concluded that residues resulting from the use of carbadox in pigs were acceptable, provided that MRLs were not exceeded. JECFA recommended MRLs of 0.03 mg/kg in liver and 0.005 mg/kg in muscle of pig, based on the levels of, and expressed as, quinoxaline-2-carboxylic acid.[203] Codex adopted the JECFA recommendations for carbadox as Codex standards.[204]

186. In a study commissioned by the EC, and concluded in 1991, it was reported that, "carbadox shows mutagenic effects in short time tests and in long term experiments and carcinogenic effects on rat-liver that could not be reproduced in experiments with primates. According to today's standards, a NEL [no effect level] cannot be derived nor can a ADI."[205]

187. Carbadox is administered by producers in the EC as a feed additive. The use of Carbadox is governed by the Feed Additives Directive. It would appear that no MRL or safety limit has been established for this compound under the MRLs Regulation.[206]

ii. Example - Olaquindox

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202 "Antibiotics Use in Animal Production in the European Union - Regulation and Current Methods for Residue Detection," *supra*, note 42, p. 54 (Annex 2, Tab G).

203 *Evaluation of certain veterinary drug residues in food: Thirty-sixth Report of the Joint FAO/WHO Expert Committee on Food Additives*, Technical Report Series 799 (Geneva: WHO, 1990), pp. 45-50., [hereinafter *Thirty-Sixth Report*] (Annex 3, Tab 3)

204 *Residues of Veterinary Drugs in Foods*, *supra*, note 147, p. 5 (Annex 3, Tab G).

205 *The Impact of Animal Husbandry in the European Community of the Use of Growth Promoters*, *supra*, note 40, p. 138 (Annex 2, Tab F).

206 See Part I, Section C

188. Olaquindox is an antimicrobial feed additive used as a growth promoter in pigs. This compound was most recently evaluated by the JECFA in 1994. In the report of that meeting it is written that:

> The Committee [JECFA] also concluded that, because of the genotoxic potential of the parent compound and the absence of specific toxicity studies on the metabolites, it was still unable to allocate an ADI. However, it noted that the parent drug was absent in muscle at the proposed withdrawal time and that the toxicity of the metabolites could be partially evaluated on the basis of toxicity studies in experimental animals because the metabolites are similar to those in the target species. The Committee extended the temporary acceptance of residues resulting from the use of olaquindox in pigs in accordance with good practice in the use of veterinary drugs.[207]

189. In a 1991 study commissioned by the EC, in the section describing the public safety aspects of this compound it was reported that:

> For Olaquindox a NEL of 1 mg/kg has been determined. Without withdrawal time the residue concentration are above the ADI value. Data concerning kinetics of excretion and practical experience indicate that a withdrawal time of 4 weeks and its use only up to 4 months of age respectively are sufficient to exclude risks for human health.[208]

190. The study goes on to conclude:

> Considering the residues [of the 11 antimicrobial growth promoters studied], all growth permitters approved seem to show a high level of safety, except carbadox and olaquindox. .... The quinoxalines and olaquindox deserve special attention concerning the safety aspects because they are nearly completely absorbed in the gut and are proven to be mutagenic. Carbadox is also carcinogenic. Therefore, a safety evaluation should be extended to the target animal as well as to human beings.[209]

191. Olaquindox is administered by EC producers as a feed additive. The use of olaquindox is governed by the Feed Additives Directive. It would appear that no MRL or

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[207] *Evaluation of certain veterinary drug residues in food: Forty-second Report of the Joint FAO/WHO Expert Committee on Food Additives*, Technical Report Series 851 (Geneva: WHO, 1995) p. 19 (Annex 3, Tab 5)

[208] *The Impact of Animal Husbandry in the European Community of the Use of Growth Promoters, supra*, note 40, p. 139 (Annex 2, Tab F).

[209] *Ibid.*, pp. 140-141

safety limit has been established for this compound under the MRLs Regulation.[210]

iii. Example - Avoparcin

192. There is a body of scientific evidence suggesting that avoparcin presents serious risks to human health, through the development of antibiotic-resistant bacteria. The use of this type of antibiotic at sub-therapeutic levels for growth promoting purposes, may result in resistant strains of bacteria in animals. These resistant strains have the potential to enter the human food chain causing food borne illness. Other risks include transferring antibiotic resistance to other human-disease-causing organisms, thus rendering the traditional therapy of human diseases ineffective.[211]

193. The EC has examined this issue in detail. Recently, animal nutrition experts were asked to react to a report by SCAN, which recommended further research into the effects of avoparcin, even though there is evidence of a human health risk. As reported in a recent issue of Agra-Europe, "...evidence had been presented to SCAN by Denmark and Germany

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[210] See Part I, Section C

[211] As noted by J. Davies, ("Bacteria on the rampage," *Nature*, vol. 383 (19 September 1996) 219) (Annex 3, Tab W):

> Avoparcin is chemically related to vancomycin (although its name disguises the fact.). In Denmark in 1993, 22 kg of vancomycin were employed in human therapy, while animal use consumed 19,000 kg of avoparcin - inadvertently breaking European Community rules, which state that no agents used in humans and none that cause cross-resistance can be used in animal feed additives. Not surprisingly, resistance to vancomycin sharing the same biochemical mechanisms as that found in humans isolates is now common in farm animals.
>
> Avoparcin was also used in Germany, where vancomycin-resistant enterococci are now widespread and can be detected on supermarket meat products (W.Witte, Robert Goch Inst.). Use of avoparcin is now prohibited in Germany and Denmark, but a powerful lobby is trying to dissuade the European Community from taking general preventative action.

Other difficulties associated with the increase in antibiotic resistant bacteria is an inability to treat human infectious diseases. As reported by S. Kingman ("Resistance a European Problem, Too," *Science*, vol. 264 (15 April 1994) 363-365 (Annex 3, Tab 6)) the rising level of antibiotic resistance is a real cause for concern, and reports from around Europe show that severe problems already exist in some countries:

> The emergence of vancomycin-resistant Enterococci is worrisome because these bacteria are themselves a significant cause of hospital infections. But even more alarming is the possibility that Enterococci will spread vancomycin resistance to other genera of bacteria. Researchers think this will eventually happen because bacteria are very adept at exchanging their antibiotic resistance genes.

that the use of avoparcin in animal feed could cause a resistance to antibiotics in humans but SCAN found that the two countries' evidence was insufficient proof of a link between the additive and increased antibiotic resistance."[212] As a result, avoparcin is still permitted for use in the EC, with the exception of those countries that have implemented a national ban.

194. The scientific community has raised doubts about the safety of avoparcin, particularly with respect to the detrimental effects that the continued use of this drug could have for human therapy and development of pathogenic microbial-resistant strains that could appear in the food chain. Despite scientific opinion that there is an actual risk, the EC has delayed taking a decision on this issue. As reported in Agra-Europe, the reason for the delay in action by the EC is that, "...[Commissioner Fischler] faces considerable difficulty in drawing up a proposal which could be approved by a qualified majority...."[213]

195. Avoparcin is administered by producers as a feed additive, and can be used without veterinary supervision. It is governed by the Feed Additives Directive and, therefore, it would appear that no MRL or safety limit has been established for this compound under the MRLs Regulation. [214]

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[212] "Opposition to avoparcin in EU growing," *Agra Europe* (25 October 1996) E/4 (Annex 3, Tab Y).

[213] *Ibid.*

[214] See Part I, Section C

2. Risks Arising from the Use of Therapeutic Agents

a. Antibiotics

i. Example - Benzylpenicillin

196. Benzylpenicillin is one of the most widely used antibiotics in both animals and humans. It is primarily used to control mastitis in dairy cows and for treating infections of the urinary tract, gastrointestinal system and respiratory tract. Benzylpenicillin is also administered as a feed additive to pigs to control streptococcal meningitis, and is included as an additive in the drinking-water of poultry.[215]

197. This drug was evaluated by JECFA in 1990. The Committee concluded that allergic reactions in humans was the determining factor in the safety evaluation of residues of Benzylpenicillin.

> Among the adverse reactions which had been reported in people consuming food containing Benzylpenicillin residues, hypersensitivity reactions were the most common. The overall prevalence of allergy to penicillin, taking into account various reports of allergic reactions in different populations and using a variety of test procedures, was estimated to be 3-10 %. [216]

198. JECFA set MRLs for meat at 0.05 mg/kg and an MRL of 0.004 mg/kg for milk.[217] Codex adopted at step 8 the JECFA recommendations as Codex standards.[218] The EC has also set final MRLs for milk and meat that are the same as the JECFA and Codex recommendations.[219]

199. To ensure that the MRLs are attained, proper dosage of the animal is essential. Exceeding the MRLs could result in severe allergic reaction in 3-10 % of the population. Although proper dose-level is critical to the safety of meat or milk products, it is noted that Benzylpencillin is sold without prescription and administered directly by the farmer in certain

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[215] *Thirty-Sixth Report*, *supra*, note 203, p. 35 (Annex 3, Tab 3).

[216] *Ibid.*, pp. 37-38

[217] *Ibid.*

[218] *Residues of Veterinary Drugs in Foods*, *supra*, note 147, p. 4 (Annex 3, Tab G)

[219] R.J. Heitzman, ed., *Agriculture - Veterinary Drug Residues - Residues in food-producing animals and their products: Reference materials and methods* (Luxembourg: Office for Official Publications of the European Communities, 1992), pp. 1-7, p. 4 (Annex 5, Tab E).

Member States.[220]

b. Anti-adrenergics

i. Example - Carazolol

200. Carazolol was reviewed by JECFA in 1994 at its forty-third meeting. Carazolol is a non-specific β-adrenoceptor-blocking agent, primarily used in pigs to prevent sudden death due to stress during transportation. The drug has also been used in cattle for the same reasons. Due to the purpose of this drug, it is usually administered to the animals just prior to being loaded for shipment to a slaughter facility.

201. In the JECFA report it is noted that:

> The Committee [JECFA] recognized that humans with chronic bronchitis or asthma are highly sensitive to the effects of carazolol. It also recognized that this subgroup forms a substantial part of the general population and that adequate allowance should be made for variations between individuals.[221]

202. The JECFA established an ADI of 0-0.1 μg/kg of body weight and established MRLs of 5 μg/kg in muscle and fat/skin, and 25 μg/kg in liver and kidney. It should, however, be noted that the JECFA recommendations have not yet passed through the eight step Codex process and are, therefore, subject to change, based on comments from countries.

203. Concerning the use of this drug, the JECFA report provided a cautionary note to regulators by stating:

> The Committee recommended that registration authorities should pay particular attention to the potential risk of residues of carazolol in tissue at the injection site. Considering the potential risk, the Committee concluded that the use of carazolol in pigs to reduce stress during transportation to slaughter is inconsistent with the safe use of veterinary drugs in food producing animals.[222] (emphasis added).

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[220] See Part 1, Section C.

[221] *Evaluation of Certain Veterinary Drug Residues in Food: Forty-third report of the Joint FAO/WHO Expert Committee on Food Additives* (Geneva: WHO) Section 3, "Comments on residues of specific veterinary drugs," 3.1 "β-Adrenoceptor-blocking agent." p. 6 (Annex 3, Tab X).

[222] *Ibid.*, p. 8

204. In June 1995, the EC revised their provisional MRLs and set final MRLs for use of this drug in porcine species; it is permitted for use on pigs in the EC.[223]

c. Anthelmintics

i. Example - Ivermectin

205. Ivermectin is an antiparasitic agent. It was evaluated by JECFA in 1990, at the thirty-sixth meeting, and again in 1993, at the fortieth meeting. Ivermectin is a mixture of two homologous compounds. While the compound is very effective in dealing with parasites, the mode of action in parasites has remained elusive, and the mechanisms of the toxic action of ivermectin in mammalian species have not been elucidated.[224]

206. Acute toxicity studies were carried out in a number of animal species. The typical signs of acute toxicity of ivermectin were attributed to its effects on the central nervous system. Effects were most severe in mice, where death occurred from approximately one hour to six days after dosing. Developmental toxicity was also investigated, with the results indicating that teratogenic effects (cleft palates, clubbed fore paws) were produced at dose levels similar to those causing severe toxic effects in pregnant animals.[225] A conservative ADI of 0-0.02 μg/kg of body weight was established. Upon further study in 1993, it was concluded that the compound was a developmental toxicant rather than an overt teratogen and the ADI was revised to 0-1 μg/kg of body weight, and MRLs were set for liver and fat in cattle, sheep and pigs.[226] Codex has adopted the JECFA recommendations for ivermectin as Codex standards.[227]

207. Ivermectin is approved for use in the EC, and an MRL in the target tissues of liver and fat has been set for the bovine and porcine species. It is available for use by producers without a veterinarian prescription in some EC Member States.[228]

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[223] Regulation 1442/95/EC (Annex 1, Tab U)

[224] *Thirty-sixth Report*, *supra*, note 215, p. 23 (Annex 3, Tab 3)

[225] *Ibid.*, pp. 27 & 28

[226] *Ibid.*, p. 30

[227] *Residues of Veterinary Drugs in Foods*, *supra*, note 147, p. 10 (Annex 3, Tab G).

[228] See Part I, Section C

d. Pesticides

208. In veterinary medicine, a pesticide is a compound which is active against parasites that live on the skin of animals or which spend part of their lives in the animal's body (*e.g.*, warble fly larvae). In their larval stage, these parasitic organisms known as ectoparasites, may migrate through the tissue of the host, or burrow into and live in the superficial skin layers. To counter ectoparasites, therefore, it is important to have a compound that can destroy the parasites at every stage of their life cycle, including the larval stage. A range of applications modes for the pesticides are available to treat the animals, such as dips, sprays, dusts, feed additives, or subcutaneous injections.

i. Example - Organophosphourous Compounds

209. Due to environmental concerns, the organophosphourous compounds have now replaced most of the organochloride compounds for use as pesticides. Unfortunately, the organophosphourous compounds are more toxic to man than the organochlorides, although they are rapidly metabolized and excreted. Compounds such as diazionon are used in the EC.[229]

H. RELATIVE RISK OF VARIOUS VETERINARY DRUGS

210. The use of agricultural production aids, such as veterinary drugs, presents a risk, albeit minuscule, to the consumer.

211. The United States Department of Agriculture (USDA) has developed a method to determine the relative risk of various agricultural production aids such as veterinary drugs, naturally occurring toxins, and pesticides. The USDA's Compound Evaluations System ("CES"), developed in 1983, has guided a number of countries in the development of their residue monitoring programmes. This allows for testing to be targeted at those compounds that are more likely to present a health risk to the consumer.

212. The first step in the CES process is to determine if a given compound can produce a residue in food. Next, the likelihood of a health hazard is rated A to D or Z. The highest health hazard compounds are scored A and the lowest receive a D. Those compounds for which insufficient information is available to conduct a toxicologic or pharmacologic evaluation, receive a rating of Z. Finally, each compound is assigned a rating to evaluate the probability of exposure to the consumer. The categories range from 1, meaning a high probability of exposure, to 4, which is negligible probability of exposure. Category Z

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[229] Regulation 1442/95/EC establishes a MRL for diazinon, *supra*, note 223 (Annex 1, Tab U)

designates a substance with insufficient information available to estimate the probability of exposure to humans.[230]

213. The CES can be used to rank compounds based on their relative risk. The compounds presenting the highest risk to human health would score A1, and the compounds with the lowest risk to human health would be those compounds with a score of D4. Compounds of unknown hazard or exposure risk would receive a Z rating.

214. The natural hormones are not ranked by the CES system as they do not leave detectable residues in food, and do not present any risk to human health.

215. The following is an example of some of the various veterinary drugs and their relative ranking:[231]

Xenobiotic Hormones

Trenbolone	C-4
Zeranol	C-2
MGA	B-4

Antimicrobial Feed Additives

Carbadox	A-3
Olaquindox	(Not permitted for use in Canada)
Avoparcin	(Not permitted for use in Canada)
Monesin	B-3

Therapeutic Veterinary Drugs

Carazolol	(Not permitted for use in Canada)
Penicillin	A-2
Ivermectin	B-1

216. This illustrates that the natural and xenobiotic hormones are safer than several veterinary drugs commonly used for animal production in the EC.

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[230] *Compound Evaluation and Analytical Capability: National Residue Program Plan 1993* (Washington: U.S. Department of Agriculture, Food Safety and Inspection Service), pp. 1.3-1.7 (Annex 3, Tab Z).

[231] *Compound Evaluation and Residue Information 1994* (Washington: U.S. Department of Agriculture, Food Safety and Inspection Service), pp. 2.3-2.5 (Annex 3, Tab Z).

PART III LEGAL ARGUMENT

A. SUMMARY AND SEQUENCE OF LEGAL ARGUMENT

217. It is Canada's position that

i) the EC measures are contrary to the *SPS Agreement*, and in particular Articles 2, 3 and 5 thereof;

ii) the EC measures are contrary to the *GATT 1994*, and in particular Article III or XI thereof;

iii) in the alternative, if the EC measures are not sanitary measures within the terms of the *SPS Agreement*, then they are technical regulations and are contrary to the *TBT Agreement*, and in particular Article 2 thereof.

218. Canada also holds that the application of the EC measures otherwise nullifies or impairs the benefits accruing to Canada pursuant to the *WTO Agreement*.

219. The *SPS Agreement*, *GATT 1994* and the *TBT Agreement* are agreements of equal status, contained in Annex 1A of the *WTO Agreement* (see Article II of the *WTO Agreement*).

220. Since the *SPS Agreement* contains rules that are more detailed and more precise than those of the *GATT 1994*, it is appropriate to examine first the application of the *SPS Agreement* to the EC measures, followed by the *GATT 1994*.

221. The scope of the *SPS Agreement* and the *TBT Agreement* are mutually exclusive.[232] Canada submits that the EC measures are governed by the *SPS Agreement*. Therefore, arguments with respect to the *SPS Agreement* are canvassed first. This is followed by arguments pertaining to the *GATT 1994*. Arguments with respect to the *TBT Agreement* are made in the alternative, in case the Panel decides that the EC measures are not governed by

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[232] Article 1.1 of the *SPS Agreement* provides that the Agreement "...applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade." The term "sanitary and phytosanitary measure" is defined in Annex A of the *SPS Agreement*. Article 1.5 of the *TBT Agreement* states:

> The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Thus, the scope of the *SPS Agreement* is mutually exclusive with the scope of the *TBT Agreement*.

the *SPS Agreement*. Finally, arguments are made with respect to non-violation nullification and impairment under the *WTO Agreement*.

B. APPLICABLE PRINCIPLES OF INTERNATIONAL LAW

222. The *SPS* and *TBT Agreements*, in respect of which submissions will be made in this document, have not been interpreted before in Panel reports that have been adopted by the Dispute Settlement Body. Therefore, before analyzing the texts of the Agreements concerned, it is appropriate to refer to the *Vienna Convention on the Law of Treaties* ("*Vienna Convention*"), which sets out the applicable rules of treaty interpretation.[233]

223. The rights and obligations of the WTO Members under the different Agreements must be interpreted having regard to the *Vienna Convention*, and in particular Articles 31 and 32. It was confirmed by the Appellate Body of the WTO in its reports on *United States - Standards for Reformulated and Conventional Gasoline* ("*Reformulated Gasoline*") and *Japan - Taxes on Alcoholic Beverages* ("*Japanese Liquor Tax*") that these provisions are part of customary international law.[234]

224. According to Article 31, paragraph 1, of the *Vienna Convention*, a treaty must be interpreted "...in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." In this regard, the Appellate Body, in *Japanese Liquor Tax*, stated the following:

> Article 31 of the *Vienna Convention* provides that the words of the treaty form the foundation for the interpretive process: "interpretation must be based above all upon the text of the treaty". The provisions of the treaty are to be given their ordinary meaning in their context. The object and purpose of the treaty are also to be taken into account in determining the meaning of its provisions.[235]

225. Good faith requires *inter alia* that where a treaty is open to more than one interpretation, only one of which enables the treaty to have appropriate effects, the

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[233] Canada Treaty Series 1980 No. 37; 1155 U.N.T.S. 331 (Annex 5, Tab A)

[234] See Report of the Appellate Body, *United States - Standards for Reformulated and Conventional Gasoline* (WT/DS2/AB/R), at page 18; and Report of the Appellate Body, *Japan - Taxes on Alcoholic Beverages* (WT/DS8/AB/R; WT/DS10/AB/R;WT/DS11/AB/R), at page 10

[235] *Ibid.*, at pages 11 and 12 (footnotes omitted)

interpretation that gives the treaty its full effect should be adopted.[236] The principle of effectiveness (*ut res magis valeat quam pereat*) is a long-standing rule of treaty interpretation. It has been endorsed by the Appellate Body and requires that an international agreement should be interpreted so as to give meaning and effect to all the terms of the treaty.[237]

226. In Canada's view it is clear that on the basis of these principles the EC measures are inconsistent with the EC's obligations under the *WTO Agreement,* as discussed further below.

C. THE EC MEASURES ARE CONTRARY TO THE SPS AGREEMENT

227. Canada submits that the EC measures are contrary to Articles 2, 3 and 5 of the *SPS Agreement.*

1. General Principles of Interpretation

228. The *SPS Agreement* must be interpreted in the light of its object and purpose. The preamble to the Agreement is an important source of guidance in this respect.

229. The preamble states the desire of the WTO Members to establish "...a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade". The *SPS Agreement* fulfils this objective: it is a stand-alone agreement, setting out a complete code governing the establishment and use of sanitary and phytosanitary measures.

230. The preamble also states the desire of the Members to "...further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant

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[236] Sir I. Sinclair, *The Vienna Convention of the Law of Treaties*, 2d ed. (Manchester: Manchester University Press, 1984) at p. 118 (Annex 5, Tab B)

[237] The principle of effectiveness was endorsed by the Appellate Body in *Reformulated Gasoline*, *supra*, note 234, at p. 24, and again in *Japanese Liquor Tax*, *supra*, note 234, at p. 12, as follows:

> One of the corollaries of the 'general rule of interpretation' in the *Vienna Convention* is that interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.

international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health". Article 3 of the Agreement meets this goal, requiring Members to base their sanitary or phytosanitary measures on international standards, guidelines or recommendations where they exist, unless a Member can show that its measure must deviate from an international direction to meet a chosen, higher level of protection and that it is otherwise consistent with the Agreement.

231. The final preambular paragraph states an additional desire to "...elaborate rules for the application of the provisions of *GATT 1994* which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)." Article 2(4) provides that sanitary or phytosanitary measures that conform to the disciplines of the *SPS Agreement* are presumed to be in accordance with the relevant provisions of *GATT 1994*, and in particular Article XX(b).

232. The *SPS Agreement* must also be interpreted in accordance with the ordinary meaning to be given to the terms of the treaty. As the first substantive provision of the Agreement, Article 2 by its own terms is said to establish the "Basic Rights and Obligations" of WTO Members.[238] The successive provisions of the Agreement set out more specific rights and obligations, illustrative of the fundamental rights and obligations set out in Article 2.

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[238] Article 2 is entitled "*Basic Rights and Obligations*". It provides:

> 1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
>
> 2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
>
> 3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
>
> 4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

233. For example, the requirements set out in Article 5 that SPS measures must be based on a risk assessment and that the assessment must take into account available scientific evidence,[239] are rational extensions of the basic obligations in Article 2(2) to ensure that SPS measures are based on scientific principles and not maintained without scientific evidence.

234. Similarly, Article 5(6) gives precision to the obligation in Article 2(2) that a Member must ensure that any SPS measure is applied only to the extent necessary to protect human, animal or plant life or health. In effect, Article 5(6) sets out how a Member is to meet this basic requirement of Article 2(2).[240]

235. Likewise, Article 3(2)[241] provides a prescription for satisfying the presumption of consistency with *GATT 1994* in Article 2(4).

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[239] Paragraphs 1 and 2 of Article 5 state:

> 1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
>
> 2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

[240] Article 5(6) and its footnote state:

> Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.*
>
> *For the purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary and phytosanitary protection and is significantly less restrictive to trade.

[241] Article 3(2) provides:

> 2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

2. Basic Concepts

236. Annex A of the *SPS Agreement* defines two concepts that are integral to the application of the Agreement to this case. The first concept is "risk assessment". For the purposes of this dispute, the *SPS Agreement* defines this term to mean, "...the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or feedstuffs."[242] Reducing this definition to its components, risk is the *potential* for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or feedstuffs. Assessment is the *evaluation* of that potential.[243] Under the *SPS Agreement*, a sanitary measure must be based upon an appropriate risk assessment.[244] As detailed below, the EC measures do not meet this requirement.[245]

237. The second concept is the "appropriate level of sanitary and phytosanitary protection". The *SPS Agreement* defines this as the "...level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."[246] The concept is also referred to as the "acceptable level of risk". The choice of an appropriate level of SPS protection is central to the risk management phase of risk analysis.[247] The *SPS Agreement* imposes a discipline on the right of a Member to choose the level of sanitary or phytosanitary protection it deems appropriate: arbitrary or unjustifiable distinctions in the levels considered appropriate in different situations must be avoided if they result in discrimination or a disguised restriction on international trade.[248] In addition, the *SPS Agreement* restricts what measure a Member applies to achieve

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242 Annex A

243 See Part II, Section B.1 for a discussion of risk assessment in Codex.

244 Annex A, paragraph 4.

245 See Part III, Section A.4.a

246 Annex A

247 The requirement to base an SPS measure on a risk assessment is set out in Article 5(5); see Section A.4.a below.

248 This limit on the right of a Member to choose an "appropriate level of SPS protection" is set out in Article 5(5); see Section A.4.b below.

the appropriate level of sanitary or phytosanitary protection.[249] As demonstrated below, the EC measures fail to meet these disciplines.[250]

238. It is appropriate to consider the more specific rights and obligations of Articles 5 and 3 before turning to the fundamental rights and obligations set out in Article 2.

3. The EC measures are governed by the *SPS Agreement*

239. Article 1 of the *SPS Agreement* provides, in part:

> This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade.

240. The EC measures have had a profound and direct effect on Canadian beef exports to the EC.[251] Thus, there is no question that the EC measures directly affect international trade. The issue here is whether the EC measures are sanitary measures within the terms of the *SPS Agreement*.

241. Annex A of the Agreement defines a sanitary or phytosanitary measure to mean, in part, any measure applied "...to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-carrying organisms in foods, beverages or feedstuffs." Contaminants include veterinary drug residues.

242. [

] The preambles to Directive 81/602/EEC[252] and Directive 88/146/EEC[253] suggest

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[249] The limits placed on the measure chosen to meet the "appropriate level of SPS protection" are set out in Article 5(6); see Section A.4.c below.

[250] See Sections A.4.a; A.4.b; and A.4.c below

[251] See Part I, Section E

[252] The preamble to Directive 81/602/EEC states, in part (Annex 1, Tab A):

> Whereas, due to the residues that they leave in meat, certain substances with a thyrostatic, oestrogenic, androgenic or gestagenic action may be dangerous for consumers; whereas these substances may also affect the quality of meat;
>
> Whereas, moreover, the harmless or harmful effects of the use of Oestradiol 17ß, Progesterone,

that one purpose of the measures was to address a concern for human health arising from the presence of hormone residues in meat. On this characterization, Canada submits that the EC measures are subject to the disciplines of the *SPS Agreement*.

243. Canada notes, however, that a resolution of the European Parliament, an opinion of the Economic and Social Committee, and the Directives themselves, ascribe several additional purposes to the EC measures which are not contemplated or sanctioned by the *SPS Agreement*, such as harmonizing the regulatory schemes of the Member States, thereby removing competitive distortions and barriers to intra-Community trade, meeting consumer anxieties and expectations, and bringing about an increase in the consumption of meat products.[254] As shown below, a consequence of these additional motives is that the EC measures are more trade restrictive than necessary to protect human life and health.

4. The EC measures are contrary to Article 5 in at least three respects

a. The EC measures are not based on an appropriate risk assessment

244. Article 5 of the *SPS Agreement* sets out the obligation of Members to ensure that SPS measures are based on a risk assessment. Article 5, paragraphs 1 and 2 state:

> 1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
>
> 2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling

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> Testosterone, Trenbolone and Zeranol still have to be examined in detail; whereas, pending the adoption of a decision relating to these substances, the current measures governing them should be maintained as a precautionary measure with due regard for the general provisions of the Treaty;

[253] The preamble to Directive 88/146/EEC states, in part (Annex 1, Tab B):

> Whereas the administration to farm animals of certain substances having a hormonal action is at present regulated in different ways in the Member States; whereas while their immediate effect on animals from the farmer's point of view is clear, assessments of their effect on human health vary and this is reflected in the regulations governing their use; whereas this divergence distorts the conditions of competition in products that are the subject of common market organizations and is a serious barrier to intra-Community trade.

[254] See Part I, Sections D and E.

and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

245. The essence of this obligation is that when a Member devises and maintains a sanitary or phytosanitary measure to attain an appropriate level of sanitary or phytosanitary protection, the measure must be based on a risk assessment. In this case, the risk assessment would be an evaluation of the potential for adverse effects on human health arising from the presence of hormone residues in meat.

246. Canada has been unable to find any evidence of the EC having undertaken an appropriate assessment of the risk to human life or health arising from the presence of residues in beef from the six hormones in question. [

] The terms of reference for the Scientific Working Group were to examine whether the use of oestradiol 17β, testosterone, progesterone, trenbolone and zeranol presented any harmful effect to health.[255] In its first report, the Working Group, chaired by Professor Lamming, concluded:

> 5.1 The Scientific Group is of the opinion that the use of oestradiol-17β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, would not present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals.
>
> 5.2 Evaluation of the data on "trenbolone" and "zeranol" revealed that some data on the hormonal non-effect level and the toxicology of these compounds and their metabolites are still missing.
>
> 5.3 The Scientific Working Group considers it necessary that additional information be provided before a final conclusion can be given on trenbolone and zeranol.[256]

247. The Scientific Working Group was suspended before it could render a final report on zeranol and trenbolone.[257] Thus, the work of the Scientific Working Group could at best be

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[255] Part I, Section D

[256] Report of the Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production, at p. 12 (Annex 4, Tab E)

[257] See Part I, Section D

considered a risk assessment only of the three natural hormones.[258] In the absence of a final report, the EC does not appear to have based its prohibition on the use of zeranol or trenbolone on any risk assessment. Indeed, having discontinued the work of the Scientific Working Group before it could complete its report on these two substances, it would be disingenuous of the EC to state now that the level of scientific knowledge on these substances is uncertain. Moreover, it would appear that the EC has never conducted a risk assessment of MGA.

248. [

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249. Thus, the EC prohibition on zeranol, trenbolone and MGA is still not based on a risk assessment of those hormones, and the requirements of Article 5(1) have not been met for the EC measures. Moreover, even if the Panel considers that the first report of the Scientific Working Group constitutes a risk assessment for the three natural hormones, that risk assessment concluded that these hormones would *not* present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals. Thus, as Professor Lamming, the Chairman of the Scientific Working Group, has asserted, the EC measures could not be based on that risk assessment.[259]

250. Canada submits, therefore, that the EC measures are not based on an appropriate risk assessment and are contrary to Article 5(1).

b. The level of sanitary protection for growth promoting hormones is significantly higher than the level for antimicrobial growth promoters and other veterinary drugs, resulting in discrimination and a disguised restriction on international trade

251. The appropriate level of sanitary or phytosanitary protection is the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure.[260]

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[258] The members of the group subsequently published an assessment of zeranol and trenbolone: see G.E. Lamming *et al.*, "Special Report: Scientific report on anabolic agents in animal production," *Veterinary Record* (October 24, 1987) 389 (Annex 4, Tab F)

[259] G.E. Lamming, "Anabolic Growth Promotants and the EEC" (Address given at the Technical Services Centre, Kingston, ACT, 29 April 1986) [unpublished], p. 11 (Annex 2, Tab H). See Part I, Section D.

[260] *SPS Agreement*, Annex A, paragraph 5.

However, Article 5(5)[261] of the
SPS Agreement limits this choice of an appropriate level of protection: arbitrary and unjustifiable distinctions in the level of protection considered appropriate in different situations must not result in discrimination, or a disguised restriction on international trade.[262]

252. [

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However, examination of EC measures governing the use of other growth promoters and veterinary drugs reveals that a significantly lower level of protection is considered appropriate for the risks to human health posed by those substances.

253. There is a degree of risk associated with the use of all veterinary drugs administered for animal husbandry purposes.[263] The six hormones in question are as safe as, or safer than, growth promoters commonly used in the EC. Moreover, they are demonstrably safer than veterinary drugs that are commonly used in the EC.

254. Antimicrobial growth promoters, distributed by producers as feed additives to livestock, pose some degree of risk to human health. As a group, they pose no less a risk to human health than that posed by the six growth promoting hormones. Three antimicrobial growth promoters authorized for use in the EC are particularly noteworthy, however. Carbadox is known to be both mutagenic and carcinogenic. JECFA recommended MRLs for carbadox, although it was not able to establish an ADI. Olaquindox is mutagenic; JECFA has been unable to allocate an ADI and is still studying the substance. There is scientific evidence indicating that the use of avoparcin as a feed additive presents a serious risk to human health because it may lead to the development of vancomycin-resistant strains of

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[261] Article 5(5) provides:

> 5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

[262] See J.J. Barcelo, "Product Standards to Protect the Local Environment - the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement", (1994) 27 *Cornell Int'l L.J.* 755 at pp.765-66 (Annex 5, Tab C)

[263] Part II, Section G

bacteria.[264]

255. The measures governing the use of feed additives are substantially less restrictive than the complete ban on the use of the six growth promoting hormones for growth promotion purposes. Growth promoters and coccidiostats regulated under the Feed Additives Directives can be administered by producers without the supervision of veterinarians, and do not appear to be subject to the authorization procedures and MRL requirements set out in the MRLs Regulation or the residues monitoring requirements established under Residues Directives. Given that these substances pose no less a risk than that posed by the six growth promoting hormones, it follows that these less restrictive measures cannot possibly attain the same level of protection that purportedly lies behind the prohibition on the use of the six growth promoting hormones. Indeed, this would be the case even if these substances were subject to MRL requirements and residue monitoring requirements. It is apparent that the EC's level of sanitary protection for growth promoting hormones is significantly higher than the level for antimicrobial growth promoters.

256. In addition, many veterinary drugs used for therapeutic purposes and governed by the Veterinary Medicines Directives pose demonstrably greater risks to human health when compared to the six growth promoting hormones.[265] While veterinary drugs are subject to the authorization procedures and MRL requirements of the MRLs Regulation and the residues monitoring requirements of Residues Directives, under the laws of EC Member States some of these substances, such as benzylpenicillin and ivermectin, may be administered by farmers without prescription or the supervision of a veterinarian. Indeed, farmers may be administering prescribed veterinary drugs without the veterinarian even seeing the animals being treated.[266] Once again, it follows that these less restrictive measures cannot possibly attain the same level of protection that purportedly lies behind the prohibition on the use of the six growth promoting hormones. It is apparent that the EC's level of sanitary protection for growth promoting hormones is significantly higher than the level for other veterinary drugs commonly used in the EC.

257. These marked distinctions in levels of protection are arbitrary and unjustifiable, and

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[264] See Part II, Sections G and H

[265] For example, in contrast to veterinary drugs with fixed MRLs under Annex I of Directive 2377/90/EEC, or *provisional* MRLs under Annex III, oestradiol 17β was placed in Annex II as a substance for which *no* MRL was necessary (Regulation 3059/94/EC). Carazolol, on the other hand, poses a significant risk to humans with chronic bronchitis or asthma and has assigned a MRL (Annex 1, Tab P). See Part II, Sections G and H.

[266] See Part I, Section C.

result in discrimination and a disguised restriction on international trade.[267] Canadian beef from cattle treated with the six growth promoting hormones poses no greater a risk to EC consumers than EC beef treated with anti-microbial growth promoters or other veterinary drugs. The prohibition on imports of beef from cattle treated with the six growth promoting hormones discriminates against Canadian beef imports, and constitutes an unwarranted restriction in this trade in the guise of a sanitary measure.

258. It is Canada's position, therefore, that the EC measures are contrary to Article 5(5).

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[267] J.J. Barcelo, *supra*, note 262, at pp. 765-66 (Annex 5, Tab C) provides a useful example:

> A party must "avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade." The meaning of this language is not immediately apparent, but on its face it could provide a ground for a more searching scrutiny of a party's S&P provisions than any of the other three requirements thus far discussed. We should note, however, that the "arbitrary distinctions" language is tied to the proviso "if such distinctions result in discrimination or a disguised restriction on international trade." That proviso helps to clarify the kind of case envisioned. A good example is the well known German Beer case in EU law decided by the European Court of Justice in 1987.
>
> In the German Beer case, Germany allowed beer to be sold in Germany and labelled "bier" only if it was made from malted barley, hops, yeast, and water. No additives at all were allowed. Most German beer has been made in this manner since the sixteenth century. Beer in other EU countries, however, is frequently made from rice and other cereals. In the case of these beers, additives are needed for technical reasons to produce the beer. The German rule therefore prevented much of the beer made in other EU countries from being imported and sold in Germany as "bier". Germany tried to justify the rule in part on the ground that Germans consume large quantities of beer and that the additives in general would pose a human health risk. The European Court of Justice rejected this argument, however, for one very striking reason: *for all beverages, other than beer, German law specifically allowed some of the very additives that were banned completely in beer.* Thus, the arbitrariness of these distinctions appeared to convince the ECJ that the German regulation was essentially a form of disguised protectionism designed to protect German beer producers from non-German competitors.
>
> Suppose, for example, that the toxicity of pesticides Y and Z are indistinguishable. Suppose further that the United States adopts a rule calling for zero pesticide Z residue on apples. The U.S. provision might run into trouble if, for example, pesticide Z were traditionally used in Canada, pesticide Y in the United States, and the zero pesticide rule applied only to pesticide Z.
>
> Admittedly, judgments could differ about the application of this "arbitrary distinctions" standard. But in its defense, how else could one deal with a situation such as that presented by the German Beer case, apparently a case of disguised protectionism? There is a risk of an inappropriate panel decision under the standard. Without it, however, there would be a loophole through which very large amounts of disguised protection could be driven.

c. The EC measures are more trade restrictive than required to achieve their appropriate level of sanitary protection

259. Article 5(6) prescribes how a Member must ensure that any sanitary measure is applied only to the extent necessary to protect human, animal or plant life or health. In effect, Article 5(6) sets out how a Member is to meet this basic requirement of Article 2(2):

> Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.*

A footnote to the paragraph provides:

> *For the purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary and phytosanitary protection and is significantly less restrictive to trade.

260. It is clear that under the Feed Additives Directives, the EC maintains regulatory control over antimicrobial growth promoters that is significantly less restrictive to trade than the complete ban on the use for growth promotion of the six growth promoting hormones. There is no technical or economic reason why a similar scheme could not reasonably be extended to the six growth promoting hormones.

261. It is Canada's position that the EC measures are more trade restrictive than necessary to achieve the level of sanitary protection achieved by the Feed Additives Directives, and therefore the EC measures are contrary to Article 5(6).

5. Contrary to Article 3, the EC measures are not based on the relevant international standards, guidelines, or recommendations, and do not meet the requirements for derogations from this obligation

262. As noted above, other provisions of the *SPS Agreement* elaborate the basic rights and obligations set out in Article 2. Article 3 details the rights and obligations of Members with respect to harmonization. Article 3(1) provides:

> To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international

standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

a. The EC measures are not based on the relevant Codex Standards

263. For food safety, the standards, guidelines and recommendations established by the Codex apply.[268] In the present case, Codex has adopted MRLs for trenbolone and zeranol, but did not set MRLs for oestradiol, testosterone and progesterone because the estimated consumption of the natural hormones was well below any numerical value that would ordinarily be assigned to it.[269]

264. Article 3(1) compels the EC to base[270] its sanitary measures on these international standards, except as otherwise provided for in the *SPS Agreement*. A summary of the MRLs allocated by the EC Committee on Veterinary Medicinal Products[271] acknowledges that the EC measures are based on MRLs of zero on zeranol and trenbolone, and are not based on the Codex MRLs.[272]

265. Although MRLs are not sanitary measures in and of themselves, full acceptance of the Codex MRLs for residues of veterinary drugs in food dictates that distribution of food conforming with the MRLs will not be hindered by legal provisions.[273] Since the EC

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[268] *SPS Agreement*, Annex A, paragraph 3(a)

[269] See Part II, section E.5

[270] "**base** *v.t.* (usu. foll. by *on*, *upon*) found or establish (*a theory based on speculation; his opinion was soundly based*)": R.E. Allen, ed., *The Concise Oxford Dictionary of Current English*, 8th ed. (Oxford: Clarendon Press), pp. 89-90 (Annex 5, Tab D)

[271] R.J. Heitzman, ed., *Agriculture - Veterinary Drug Residues - Residues in food-producing animals and their products: Reference materials and methods* (Luxembourg: Office for Official Publications of the European Communities, 1992) at p. 4 (Annex 5, Tab E)

[272] To comply with Regulation 2377/90/EEC, the EC must determine whether MRLs are necessary for the three natural hormones. The EC has determined that oestradiol 17β does not require an MRL (Regulation 3059/94/EC) but does not appear to have determined whether MRLs are necessary for the other two natural hormones (Annex 1, Tab P)

[273] Paragraph 6.A.(i) *General Principles of the Codex Alimentarius*, in Codex Alimentarius Commission, *Procedural Manual*, 9th ed. (Rome: Secretariat of the Joint FAO/WHO Food Standards Programme, 1995), p. 45 (Annex 5, Tab F) states:

> (i) Full Acceptance

measures prohibit the distribution of beef treated with these products for growth promoting purposes, it is clear that the EC has not accepted these MRLs and has not based its measures on them.

b. The EC measures do not meet the requirements for derogations from this obligation

266. Article 3(3) provides an exception to the obligation to base SPS measures on international standards. Article 3(3) states:

> Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.* Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

A footnote to this paragraph provides:

> *For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

267. Thus, the EC may justify its measures under Article 3.3 if:

a) the measures result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the Codex standards; and

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Full acceptance of a Codex maximum limit for residues of pesticides or veterinary drugs in foods means that the country concerned will ensure, within its territorial jurisdiction, that a food, whether home-produced or imported, to which the Codex maximum limit applies, will comply with that limit. It also means that the distribution of a food conforming with the Codex maximum limit will not be hindered by any legal or administrative provisions in the country concerned which relate to matters covered by the Codex maximum limit.

b1) there is a scientific justification; or

b2) it is a consequence of the level of sanitary or phytosanitary protection the EC determined to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5; and

c) the measures are not inconsistent with any other provision of the *SPS Agreement.*

268. The EC measures fail to meet these requirements for derogations from the obligation in Article 3(1) in four ways.

269. First, with respect to the three natural hormones, the EC measures fail to provide a higher level of protection than would be achieved by measures based on the Codex standards. Since the levels of natural hormones in beef derived from untreated livestock vary widely, depending upon the sex, age and fertility cycle of an animal, the levels of these hormones in beef derived from hormone-treated livestock are well within these levels of natural variation.[274] Since the EC does not regulate the exposure of consumers to higher levels of these hormones occurring in the meat of untreated animals, the EC measures fail to achieve any purported higher level of protection. Indeed, the EC does not regulate the exposure of consumers to far higher levels of natural hormones occurring in a variety of foods.

270. Second, there does not appear to be a scientific justification for a higher level of protection. An examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement reveals that the six hormones in question do not present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals.

271. Third, as shown above, since the level of protection determined to be appropriate by the EC was *not* in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5, the EC measures cannot be a valid consequence of that level.

272. Fourth, as shown above, the EC measures are inconsistent with Article 5 of the *SPS Agreement.*

273. Canada submits, therefore, that the EC measures are contrary to Article 3.

6. The EC measures are contrary to the obligations set out in Article 2

[274] See Part II, Section E

274. The *SPS Agreement* sets out the "Basic Rights" of WTO Members in Article 2, paragraphs 1 and 4, and the "Basic Obligations" in paragraphs 2 and 3.

a. The EC measures are not applied only to the extent necessary to protect human life or health, and are maintained without sufficient scientific evidence

275. Article 2(2) sets out three conditions:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

276. The EC measures are applied well beyond the extent deemed necessary by the EC to protect human life and health from comparable risks posed by antimicrobial growth promoters in feed additives, and the demonstrably greater risks posed by some veterinary drugs used for therapeutic purposes. Consequently, the EC measures are not applied only to the extent necessary to protect human life or health.

277. In addition, the EC measures are maintained without sufficient scientific evidence, since study after study confirms that the six hormones in question are safe for use in growth promotion.[275]

278. Thus, it is Canada's position that the EC measures are contrary to Article 2(2).

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[275] See Part II, Section E

b. The EC measures arbitrarily and unjustifiably discriminate between the EC and WTO Members that permit the use of hormones as growth promoters, and are applied in a manner that constitutes a disguised restriction on trade

279. Article 2(3) is based on the requirements of the chapeau of *GATT 1994* Article XX, clarifying that the point of comparison for "where identical or similar conditions prevail" includes the territory of the Member taking the measure. It states:

> Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

280. In *Reformulated Gasoline*,[276] the WTO Appellate Body reviewed the chapeau to *GATT 1994* Article XX. Given the close relationship between the text of the chapeau and the obligation in Article 2(3), Canada submits that the Appellate Body's interpretation of the requirement that a measure shall "...not be applied in a manner which would constitute a disguised restriction on international trade..." is relevant to the present case. The WTO Appellate Body found:

> "Arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction" on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that "disguised restriction" includes disguised discrimination in international trade. It is equally clear that concealed or unannounced restriction or discrimination in international trade does not exhaust the meaning of "disguised restriction". We consider that "disguised restriction", whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX.[277]

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[276] WT/DS2/AB/R, April 29, 1996, adopted May 20, 1996.

[277] *Ibid.*, p. 25

281. Applying this to the present case, a protectionist measure in the guise of a sanitary measure formally within the terms of the *SPS Agreement*, is the essence of a disguised restriction on international trade.

282. One indication that a measure has been taken for a purpose other than the purpose stated is that the measure is more restrictive than necessary. In the present case, the EC measures have been shown to be far more restrictive than is necessary to achieve the level of protection achieved by comparable controls over the use of antimicrobial growth promoters and other veterinary drugs.

283. This is not surprising. As the relevant Directives, Resolution of the European Parliament and opinion of the Economic and Social Committee demonstrate, there are several additional purposes to the EC measures which are not contemplated or sanctioned by the *SPS Agreement*, such as harmonizing the regulatory schemes of the Member States thereby removing competitive distortions and barriers to intra-Community trade, meeting consumer anxieties and expectations, and bringing about an increase in the consumption of meat products.[278]

284. What these sources did not acknowledge was that in harmonizing their regulations on the most restrictive Member State regulations, the EC virtually eliminated all imports of beef from countries that permit the use of growth promoting hormones, such as Canada.[279] This result, however, has been perceived by many observers, both in Europe and abroad.[280]

285. Canada submits that the EC measures are more restrictive than necessary to meet a legitimate *SPS Agreement* objective, namely to protect human life or health. The EC measures are applied in a manner that controls domestic production and effectively limits foreign competition, constituting a disguised restriction on international trade.

7. The EC measures exceed the limited right to take SPS measures and cannot be presumed to be in accordance with *GATT 1994*

286. Article 2(1) sets out a limited right to take sanitary or phytosanitary measures:

> Members have the right to take sanitary and phytosanitary measures necessary for the

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[278] See Part I, Sections D and E.

[279] See Part I, Section E.

[280] See Part I, Section D.

> protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

287. Since the EC measures are inconsistent with Articles 5, 3, and 2, the EC has clearly exceeded this limited right.

288. Article 2(4) confirms one role of the *SPS Agreement* as an elaboration of the rules for the application of *GATT 1994* which relate to the use of sanitary or phytosanitary measures, and in particular the provisions of Article XX(b):

> Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

289. Since the EC measures do not conform to the provisions of the *SPS Agreement*, they cannot be presumed to be in accordance with the provisions of *GATT 1994* which relate to the use of sanitary measures, and in particular Article XX(b).

D. THE EC MEASURES ARE CONTRARY TO THE *GATT 1994*

290. Canada submits that the EC measures contravene Article III or XI of the *GATT 1994*.

291. There is a threshold question under the *GATT 1994* whether this matter is governed by Article III, by virtue of the Interpretive Note *Ad* Article III, or by Article XI.[281]

292. Canada is of the view that this matter would be more appropriately addressed under Article III than Article XI. Therefore, it will make submissions in respect of Article III; thereafter it will present arguments based on Article XI in the alternative.

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[281] The Note *Ad* Article III provides: "Any internal tax or other internal charge, or any law, regulation or requirement of the kind referred to in paragraph 1 which applies to an imported product and to the like domestic product and is collected or enforced in the case of the imported product at the time or point of importation, is nevertheless to be regarded as an internal tax or other internal charge, or a law, regulation or requirement of the kind referred to in paragraph 1, and is accordingly subject to the provisions of Article III."

1. The EC measures do not provide national treatment, in contravention of Article III

293. Paragraph 1 of Article III of the *GATT 1994* is its most general part. The text provides as follows:

> The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production. (emphasis added)

294. The Appellate Body, in its recent decision in *Japanese Liquor Tax*[282] commented on the relationship between Article III:1 and the other paragraphs of Article III as follows:

> Article III:1 of the GATT articulates a general principle that internal measures should not be applied so as to afford protection to domestic production. This general principle informs the rest of Article III.[283]

295. In the present case the most relevant part of Article III is paragraph 4; the text is as follows:

> The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use...

296. The report of the Appellate Body in *Japanese Liquor Tax* cited with approval the 1970 Working Party Report on "Border Tax Adjustments" as setting out the "...basic approach for interpreting 'like or similar products' generally in the various provisions of the GATT 1947."[284] The following passage of the report of the Working Party was quoted by the Appellate Body:

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[282] *Japan - Taxes on Alcoholic Beverages* (AB-1996-2; WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R; October 4, 1996)

[283] *Ibid.*, p. 18

[284] *Ibid.*, p. 20

> ..... the interpretation of the terms should be examined on a case-by-case basis. This would allow a fair assessment in each case of the different elements that constitute a 'similar' product. Some criteria were suggested for determining, on a case-by-case basis, whether a product is 'similar': the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature and quality. ...[285]

297. The Appellate Body, in the same case, further commented on the tests to determine what constitutes a "like product", in particular in the context of Article III:2:

> No one approach to exercising judgement will be appropriate for all cases. The criteria in *Border Tax Adjustments* should be examined, but there can be no one precise and absolute definition of what is "like". The concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the *WTO Agreement* are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is encountered as well as by the context and circumstances that prevail in any given case to which that provision may apply. We believe that, in the context of Article III:2, first sentence of the GATT 1994, the accordion of "likeness" is meant to be narrowly squeezed.[286]

298. Applying the flexible approach of the 1970 Working Party Report on "Border Tax Adjustments", different indicia of likeness have been invoked by various GATT 1947 Panels, *e.g.* tariff classification[287], end-uses[288] or physical characteristics of the product.[289] The EC does not differentiate in its tariff classification between beef produced with growth promoting hormones, antimicrobial growth promoters or any other veterinary drugs, and beef produced

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[285] Report of the Working Party on *Border Tax Adjustments*, L/3464, adopted on 2 December 1970, BISD 18S/97, 102, para. 18.

[286] Appellate Body, *Japan - Taxes on Alcoholic Beverages* (AB-1996-2), at page 21

[287] For example, see the 1978 Panel Report on *EEC - Animal Feed Proteins*, BISD 25S/49, 63, paras. 5.47-5.49

[288] For example, see the 1987 Panel Report on *United States - Taxes on Petroleum and Certain Imported Substances*, BISD 34S/136, 154-155, para. 5.1.1

[289] For example, see the 1992 panel report on *United States - Measures Affecting Alcoholic and Malt Beverages*, which held that low alcohol beer and high alcohol beer were like products, BISD 39S/206, 293-294, para. 5.71-5.74.

without. Similarly, in the EC meat-grading system no such differentiation is made.[290]

299. In *Japanese Liquor Tax*, the Appellate Body ruled, agreeing with the Panel, that the term "like products" in the first sentence of Article III:2 should be construed narrowly.[291] The rule of Article III:4 of the GATT 1994 is less specific than the rules of Article III:2. Therefore, the "likeness" test of Article III:4 of the GATT 1994 was probably intended to be less stringent than that of Article III:2. Even applying the more stringent test of Article III:2 Canada submits that its beef is a like product when compared with European beef.

300. In the present context, it should be emphasized that "likeness" is not the same as "being identical". The burden is not on Canada to prove that beef produced with growth promoting hormones is the same as other beef. Rather, Canada must prove that beef produced with growth promoting hormones is sufficiently similar to EC beef, *i.e.* beef containing residues of antimicrobial growth promoters and other veterinary drugs, to establish that a national treatment violation has occurred. In this context, it is useful to refer to an EC document entitled "Communication from the Commission to the Council and to the European Parliament on control of residues in meat - Hormones - Beta-Agonists - Other Substances", of 21 April 1993, which stated as follows:

> The results of the enquiry [on residues in meat, initiated by the Commission, following a request of the European Parliament] showed that
>
> - anabolic substances (hormones and beta-agonists) were generally available, leading to illegal use.
>
> - antibiotic and sulphonamide residues were frequently found in meat, especially in the case of intensive livestock rearing systems (veal calves, young fattening bovines, and fattening pigs);
>
> - other residues were detected occasionally (heavy metals including cadmium, pesticides, antiparasitic substances).
>
> ..... (emphasis added)[292]

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[290] Regulations 1208/81/EEC , 2930/81/EEC and 1026/91/EEC (Annex 5, Tab G)

[291] WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, at pages 19 and 20

[292] Communication from the Commission to the Council and to the European Parliament on Control of Residues in Meat - Hormones - Beta-Agonists - Other Substances COM(93) 167 final, para. 5 (Annex 4, Tab Q)

301. The physical characteristics of beef produced from animals treated with growth promoting hormones are indistinguishable for the consumer from beef produced without the use of growth promoting hormones. As was demonstrated above in paragraph 144, the use of growth promoting hormones results in beef of higher quality because the animals concerned have better carcass composition, with a greater lean-to-fat tissue ratio. This was confirmed in a Communication from the Commission to the Council and to the European Parliament on control of residues in meat, of 1993.[293]

302. Chemical analysis of the beef may be able to identify beef produced from animals treated with growth promoting hormones in certain instances. However, a document commissioned and published by the Commission admitted that this is virtually impossible with regard to oestradiol 17β, testosterone and progesterone.[294] The report commented as follows in this regard:

> To our present knowledge up to now distinctions between untreated animals and those treated with oestradiol-17β, testosterone and progesterone can only be made on a quantitative and not a qualitative basis. This statement is based on the fact that the three steroids mentioned above (oestradiol-17β, testosterone and progesterone) will enter the same metabolic pathways, regardless of whether they are of endogenous or exogenous origin. Thus treated animals can only be identified if their tissue levels significantly exceed those of untreated animals; if such a situation is detected it further has to be verified that the particular animal showing this levels [sic] was clinically sound and that no reproductive problems, such as cystic ovaries or tumours of sex hormone producing organs had been present at slaughter. (emphasis added)[295]

303. Thus a document published by the Commission conceded that beef produced with oestradiol 17β, testosterone or progesterone is indistinguishable from beef produced without these growth promoting hormones, unless the dosage administered is extraordinarily high.

304. A 1987 Monograph issued by the Joint FAO/WHO Expert Committee on Food

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[293] *Ibid.*, para. 23 (Annex 4, Tab Q)

[294] R.J. Heitzman, ed., *Veterinary Drug Residues: Residues in food producing animals and their products: Reference Materials and Methods*, 2nd ed., (Oxford: Blackwell Scientific Publications, 1994)(Annex 3, Tab Q)

[295] *Ibid.*, at p. 7/5 (Annex 3, Tab Q)

Additives confirmed the above conclusion in respect of progesterone.[296]

305. The difficulty of distinguishing beef produced with the three natural growth promoting hormones from other beef was also confirmed in a 1994 article by Dr. Stephen F. Sundlof in the Journal of Agromedicine:

> Despite public apprehensions concerning the use of these hormones [estradiol, progesterone and testosterone], numerous scientific studies have demonstrated that, when these drugs are used in accordance with good husbandry practices, concentrations of the hormones in meat remain within the normal physiological range that has been established for untreated cattle of the same age and sex. Because the rate of hormone release from the implant is slow and the half-life of these endogenous hormones extremely short (10 min), no preslaughter withdrawal time is necessary to protect the public health. Although hormone concentrations may be slightly greater in treated vs. untreated cattle, meat from treated animals contains progesterone, estradiol and testosterone at concentrations well within the physiologic range for untreated cattle.
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> Despite the small increase in estradiol, progesterone and testosterone in meat from treated animals, the concentrations of these hormones are far less than those naturally

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[296] *Residues of some veterinary drugs in animals and foods*, Monographs prepared by the Thirty-Second Meeting of the Joint FAO/WHO Expert Committee on Food Additives, Rome, 15-23 June 1987, FAO Food and Nutrition Paper 41 (Rome: FAO, 1988) at page 22 (Annex 3, Tab R):

> As with other endogenous steroid hormones, residue levels of progesterone in tissues are very low. Progesterone levels were measured in tissues from treated steers using a radio-immunoassay technique sensitive at the low ng/kg level, and were found to be about 0.4 μg/kg in muscle, liver and kidney and 3.5 μg/kg in fat; these levels can be compared with normal levels of approximately 0.2 μg/kg in muscle, liver and kidney and approximately 2.5 μg/kg in fat from untreated animals.
>
> Progesterone, like oestradiol-17β and testosterone, occurs naturally in mammals, and is normally present in the dairy products and the tissues of untreated animals. In the edible tissues of animals treated with progesterone in combination with oestradiol-17β, residue levels are up to twice as high as in the tissue of untreated animals. However, the levels of progesterone found in the meat from animals treated with implants according to good animal husbandry practice are extremely low when compared to the amounts of endogenous progesterone produced daily in human beings. The daily production rate of progesterone in humans is given in Table VII. (Farber and Arcos, 1983). Even in prepubertal boys, the 300 ng additional progesterone derived from a 500 g portion of meat from treated animals is considerably less than the amount of endogenous progesterone produced daily. In addition, for those animal classes studied, the progesterone residue levels in treated animals fell well within the normal range of levels found in untreated bovine animals of different types and ages.

> found in meat from sexually mature animals. Concentrations of estradiol in muscle from cattle in late pregnancy is 3 to 80 times greater than those found in the muscle of estradiol-treated heifers. Similarly, the concentration of progesterone in muscle from pregnant cattle is more than 20 times that which occurs in progesterone -treated steers, and muscle from mature bulls contains approximately 8 times the concentration of testosterone found in testosterone-treated heifers. .....[297]

306. All this goes to show that it is very difficult, if not impossible, to distinguish, even through chemical analysis, between beef produced with natural growth promoting hormones and beef produced without; and that these differences in production methods do not result in products that are "unlike" beef produced in the EC.

307. In any event, the EC continues to permit the use of oestradiol 17β, progesterone and testosterone for therapeutic purposes and has not prohibited the sale and consumption of the beef derived from animals treated with these hormones. This reinforces the point that it is difficult, if not impossible, to distinguish in the EC between beef from cattle that have been treated with these hormones and those that have not.

308. Given that beef is widely available in the EC market that contains residues of antimicrobial growth promoters and other veterinary drugs, it would not be appropriate, in determining the "likeness" of Canadian and EC beef, to limit the comparison of beef produced with growth promoting hormones to beef from cattle that were raised without the use of antimicrobial growth promoters and other veterinary drugs.

309. It has been shown in Part II that the use of antimicrobial growth promoters and other veterinary drugs in the EC results in the presence of residues in beef sold there. The presence of antibiotic and sulphonamide residues as well as other residues in meat was confirmed in a 1993 Communication from the EC Commission to the EC Council and to the European Parliament.[298] The EC itself, in its grading system of beef, does not distinguish between beef produced with and without growth hormones, or between beef with residues of antimicrobial growth promoters and other veterinary drugs and without.[299]

310. Canada submits that given the other residues present in beef produced in the EC, Canadian beef produced with the six growth promoting hormones at issue is a "like product"

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[297] S.F. Sundlof, "Human Health Risks Associated with Drug Residues in Animal-Derived Foods" (1994) 1:2 *Journal of Agromedicine* 5 at pp. 12-13 (Annex 5, Tab H)

[298] See para. 300, *supra*

[299] *Supra*, note 290

within the meaning of Article III:4 of the *GATT 1994* as compared to beef produced in the EC; and that Canadian beef has been accorded treatment that is less favourable than EC beef, in contravention of Article III:4 of the *GATT 1994*.

2. In the alternative, the EC import prohibition infringes Article XI

311. Canada makes the following submissions, in respect of Article XI of *GATT 1994* in the alternative, *i.e.* they should only be considered by the Panel if it decides that Article III of *GATT 1994* does not apply in this case.

312. Article XI of *GATT 1994* sets out the obligations of Members with respect to the general elimination of quantitative restrictions. Article XI:1 provides:

> No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

313. Article XI:2 provides for limited exceptions to this general prohibition, none of which are applicable here. Thus the EC is prohibited from banning the import of beef produced with growth hormones and has infringed Article XI of the *GATT 1994*.

3. Article XX does not justify the inconsistent EC measures

314. It is Canada's position that Article XX of the *GATT 1994* does not justify the infringement demonstrated above of Article III or Article XI. Canada will not comment further on Article XX, unless the EC invokes it as a defence.

E. IN THE ALTERNATIVE, THE EC MEASURES ARE CONTRARY TO THE *TBT AGREEMENT*

1. The *TBT Agreement* arguments are made in the alternative

315. Canada has submitted that the EC measures at issue are governed by the *SPS Agreement*. Therefore, the following submissions in respect of the *TBT* are made in the alternative, in case the Panel decides that the matters at issue are not governed by the *SPS Agreement*.

316. The *TBT Agreement* does not apply to sanitary measures. Article 1.5 of the *TBT Agreement* provides that:

> The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

2. The EC measures are "technical regulations" under the *TBT Agreement*

317. If the EC measures are not characterized as "sanitary and phytosanitary measures", then they fall within the disciplines of the *TBT Agreement* as "technical regulations".[300]

3. The EC measures are inconsistent with Articles 2.1 and 2.2 of the *TBT Agreement*

318. The *TBT Agreement* sets out two basic obligations with respect to technical regulations, in Articles 2.1 and 2.2. Neither of these obligations has been met by the EC measures at issue.

a. Article 2.2 of the TBT Agreement

319. Article 2.2 of the *TBT Agreement* provides:

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products. (emphasis added)

320. Canada has argued that the EC measures have created obstacles to Canadian trade with the EC by stopping the importation by the EC of Canadian beef produced with growth promoting hormones. What remains to be determined by the Panel is whether these obstacles

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[300] Annex 1 of the *TBT Agreement* defines a technical regulation as a "Document which lays down product characteristics or their related processes and production methods.... with which compliance is necessary...."

are more trade-restrictive than necessary to fulfil a legitimate objective.

321. As discussed above, the EC measures were motivated by four sets of concerns: first, anxiety regarding the danger to human health; second, the pressure of public opinion; third, the economic consequences of a "sensationalist campaign", and fourth, the distortions in the conditions of competition among the Member States owing to dissimilar provisions and regulations governing the manufacture, distribution and use of substances.[301] While protection of human health is among the policy objectives listed in Article 2.2, this in itself does not justify a complete import prohibition. As has been demonstrated above[302], the EC import prohibition lacks scientific justification. The EC has failed to prove that an import prohibition is necessary to provide protection to the health of its consumers. Furthermore, it has also been demonstrated[303] that the EC maintains regulatory control over antimicrobial growth promoters that is significantly less restrictive to trade than the complete ban on the use for growth promotion of the six growth promoting hormones and the import prohibition of beef produced outside the EC with the same hormones. Thus the EC measures are more trade restrictive than necessary, in contravention of Article 2.2 of the *TBT Agreement*.

b. Article 2.1 of the *TBT Agreement*

322. Article 2.1 provides:

> Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country. (emphasis added)

323. A panel examining a measure under Article 2.1 must determine if the measure in question is a measure to which the provision applies (*i.e.* whether it is a technical regulation), if the products in question are like products, and if the measure results in less favourable treatment for the imported Canadian product than for the like domestic and imported products. While Article 2.1 incorporates the non-discrimination principles set out in *GATT* Articles I and III, the non-discrimination principle of Article 2.1 is significantly broader since there is no language in Article 2.1 that qualifies or limits the scope of the non-discrimination obligation.

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[301] See Part I, Section D

[302] Part II, Section E. 5

[303] Part I, Section C. 1 and Part III, Section C. 4. c

324. It has been demonstrated above, in paragraph 317, that the EC measures constitute "technical regulations" as defined in the *TBT Agreement*. The next question to address is that of "like product". Article 2.1 incorporates the non-discrimination principles set out in GATT Articles III and I but is broader. There is no language in Article 2.1 of the TBT Agreement that qualifies or limits the scope of the non-discrimination obligations in the TBT Agreement. While Article 2.1 is broader than *GATT* Articles I and III, there is an obvious link between these provisions. Although a panel assessing the consistency of a measure with Article 2.1 may be guided generally by the type of analysis that might be conducted under GATT Articles III and I, it is not required to adhere rigidly to the precise form of such analysis.

325. In Canada's view, beef produced with growth promoting hormones is a "like product" in reference to beef produced in the EC from animals to which the same growth promoting hormones have been administered for therapeutic reasons or in reference to beef that contains residues of antimicrobial growth promoters, and other veterinary drugs. Canada's argument on the issue of "like product" was elaborated above, in relation to Article III of the *GATT 1994*.[304] It is Canada's submission that by excluding Canadian beef from the EC market, the EC has treated Canadian products less favourably than like products of EC origin, in contravention of Article 2.2 of the *TBT Agreement*.

F. THE EC MEASURES OTHERWISE NULLIFY AND IMPAIR BENEFITS ACCRUING TO CANADA UNDER THE *WTO AGREEMENT*

326. The inconsistency of the EC measures with the *SPS Agreement* and the *GATT 1994*, or in the alternative with the *TBT Agreement*, establishes a *prima facie* case of nullification or impairment pursuant to *GATT* Article XXIII:1(a) and Article 3.8 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU").[305]

327. However, even if the Panel were to decide that the EC measures are consistent with the *WTO Agreement*, the application of the EC measures nullifies or impairs benefits accruing to Canada under that Agreement, within the meaning of Article XXIII:1(b) of the *GATT 1994*. Article XXIII:1(b) has been interpreted in *GATT 1947* practice to mean even if a measure is not inconsistent with a provision of the *GATT*, it may be challenged as nullifying

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[304] Part III, Section D. 1

[305] Previous GATT 1947 Panels have determined that a *prima facie* case of nullification and impairment is established where there is an infringement of obligations under the GATT. The DSU codifies this in Article 3.8 which provides that where obligations under an agreement such as the GATT or the TBT Agreement are infringed, the action is considered *prima facie* to constitute a case of nullification or impairment.

or impairing benefits. Article 26(1) of the *DSU* makes it clear that complaints concerning non-violation nullification and impairment can be made within the new framework of the *WTO Agreement.*[306] Traditionally, three conditions were required by *GATT 1947* panels for determining whether a case of "non-violation" nullification or impairment exists. These conditions are:

a. the negotiation of a tariff concession;

b. the subsequent introduction of a government measure that upset the competitive relationship between the bound product with regard to like or directly

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[306] The text of Article 26(1) of the DSU is as follows:

> 1. *Non-Violation Complaints of the Type Described in Paragraph 1(b) of Article XXIII of GATT 1994*
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> Where the provisions of paragraph 1(b) of Article XXIII of GATT 1994 are applicable to a covered agreement, a panel or the Appellate Body may only make rulings and recommendations where a party to the dispute considers that any benefit accruing to it directly or indirectly under the relevant covered agreement is being nullified or impaired or the attainment of any objective of that Agreement is being impeded as a result of the application by a Member of any measure, whether or not it conflicts with the provisions of that Agreement. Where and to the extent that such party considers and a panel or the Appellate Body determines that a case concerns a measure that does not conflict with the provisions of a covered agreement to which the provisions of paragraph 1(b) of Article XXIII of GATT 1994 are applicable, the procedures in this Understanding shall apply, subject to the following:
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> (a) the complaining party shall present a detailed justification in support of any complaint relating to a measure which does not conflict with the relevant covered agreement;
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> (b) where a measure has been found to nullify or impair benefits under, or impede the attainment of objectives, of the relevant covered agreement without violation thereof, there is no obligation to withdraw the measure. However, in such cases, the panel or the Appellate Body shall recommend that the Member concerned make a mutually satisfactory adjustment;
>
> (c) notwithstanding the provisions of Article 21, the arbitration provided for in paragraph 3 of Article 21, upon request of either party, may include a determination of the level of benefits which have been nullified or impaired, and may also suggest ways and means of reaching a mutually satisfactory adjustment; such suggestions shall not be binding upon the parties to the dispute;
>
> (d) notwithstanding the provisions of paragraph 1 of Article 22, compensation may be part of a mutually satisfactory adjustment as final settlement of the dispute.

competitive imported products; and

c. that the measure at issue could not have been reasonably anticipated at the time of the negotiation of the tariff concession.[307]

328. In the present case, all of the relevant tariff items are subject to tariff concessions by the EC.[308] These concessions include Canadian access to a tariff rate quota of 11,500 tonnes, with an in quota rate of 20%, for high quality, fresh, chilled or frozen beef allocated to Canada and the USA (the "Hilton beef quota").[309]

329. The Hilton beef quota was originally granted by the EEC during the Tokyo Round Multilateral Trade Negotiations (contained in the EEC schedule of concessions annexed to the Geneva (1979) Protocol), prior to the events which ultimately led to the EC hormone ban. The Hilton beef quota originally was a 10,000 ton levy free tariff quota. [310]

330. When the Hilton beef quota was established, the EC adopted regulations which excluded Canadian high quality beef from its scope. Canada made representations on several occasions in 1979 and 1980 to the EEC and consultations were held between the EEC and Canada several times on the issue of access for Canadian beef under the quota. On 18 June 1980, the GATT Council agreed to Canada's request to establish a Panel. Panel proceedings followed, which resulted in a report that ruled in Canada's favour. This report was adopted

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[307] See *European Community: Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins*, Report of the Panel adopted on 25 January 1990, BISD 37S/86, paras. 142-154.

[308] *Uruguay Round Schedule LXXX - European Communities*, Part I Most Favoured-Nation Tariff, Section I - Agricultural Products, Section I A Tariffs and Section I B Tariff Quotas, as subsequently modified. Tariff items covered by the EC beef and veal regime are:

02011050; 02012015; 02012035; 02012055; 02012090; 02013000; 02021000; 02022010; 02022030; 02022050; 02022090; 02023010; 02023050; 02023090; 02061010; 02061091; 02061095; 02061099; 02062100; 02062210; 02062290; 02062910; 02062991; 02062999; 02102010; 02102090; 02109041; 02109049; 16025010; 16025090; 16029061; and 16029069.

[309] *Schedule CXL - European Communities*, Part I Most-Favoured-Nation Tariff, Section I - Agricultural Products, Section I B Tariff Quotas

[310] *European Economic Community - Imports of Beef from Canada*, BISD 28S/92

by the Council on 10 March 1981.[311] The European Community subsequently amended its regulations to allow Canadian high quality beef access under the Hilton beef quota.

331. As a result of the Uruguay Round Trade Negotiations, the EC converted the Hilton beef quota to a tariff rate quota of 10,000 tonnes with an in quota rate of 20%, allocated to Canada and the USA. Subsequently, in the Article XXIV negotiations of 1995, due to the accession of Finland, Sweden and Austria to the EC, the EC increased the Hilton beef quota to 11,500 tonnes.[312]

332. Thus, the first requirement of the traditional analysis of *GATT 1947* Panels has been met.

333. Second, the introduction of the EC measures has upset the competitive relationship between Canadian and EC beef.

334. Third, at the time when Canada won access to the Hilton beef quota, it could not have reasonably foreseen the introduction of the EC measures.

335. Therefore, benefits accruing to Canada under the *WTO Agreement* have been nullified or impaired.

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311 *Ibid.*

312 Therefore, the increase in the Hilton beef quota did not amount to a rebalancing of concessions between Canada and the EC. See *European Community: Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins*, Report of the Panel adopted on 25 January 1990, BISD 37S/86, para. 145.

PART IV CONCLUSION

336. In view of the facts and arguments presented above, Canada respectfully requests the Panel to find that:

i) the EC measures are contrary to the *SPS Agreement*, and in particular Articles 2, 3 and 5 thereof;

ii) the EC measures are contrary to the *GATT 1994*, and in particular Article III or XI thereof;

iii) in the alternative, if the EC measures are not sanitary measures within the terms of the *SPS Agreement*, they are technical regulations and are contrary to the *TBT Agreement*, and in particular Article 2 thereof; and

v) the application of the EC measures otherwise nullifies or impairs the benefits accruing to Canada pursuant to the *WTO Agreement*.