



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

**Date:** 11/13/2003

**GAIN Report Number:** E23217

## European Union

### Trade Policy Monitoring

### EU Presentation on Hormone Ban Directive (2003/74/EC)

### 2003

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**Report Highlights:**

On November 3, 2003, DG-SANCO, DG-Trade and DG-Agri presented their position on the hormone issue as expressed in Directive 2003/74/EC to USTR, FDA and USDA. USEU/FAS has recently developed several GAIN reports on this Directive and the hormone ban. There does not appear to be anything "new" in the presentation.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Brussels USEU [BE2]  
[E2]

## EU Presentation on Hormone Ban (Directive 2003/74/EC)

On November 3, 2003, DG-SANCO, DG-Trade and DG-Agri presented their position on the hormone issue as expressed in Directive 2003/74/EC to USTR, FDA and USDA. USEU/FAS has recently developed several GAIN reports on this Directive and the hormone ban. There does not appear to be anything "new" in the presentation.

However, in response to questions, the EU indicated that the "17 studies" funded by the Commission<sup>1</sup> beginning in 1998 were not intended as a to serve as a risk assessment, but instead were to fill in the gaps. Although at first glance this may appear to be a contradiction from language in the EU's press release<sup>2</sup>, which spoke of the need for a scientific risk assessment of the risk associated with meat consumption to bring them into compliance with the WTO, and how "The EU has delivered a thorough risk assessment based on current scientific knowledge, fully respecting its international obligations." (Quote from David Byrne), it must be understood that the EU believes that the April 1999 "Opinion" of the Scientific Committee on Veterinary Matters relating to Public Health (SCVPH) is to be considered their risk assessment on estradiol. This conclusion appears to be based solely on their assessment of the genotoxicity of estradiol.

It is important to recognize that a UK Veterinary Products Committee (UKVPC) review (October 1999) refuted the conclusions in the SCVPH's April 1999 "Opinion", with specific attention to the mischaracterization of the genotoxicity of estradiol. The UKVPC also questioned the scientific competence of the SCVPH, based on the selectivity of the papers chosen by the SCVPH for review and the SCVPH analysis and conclusions. The SCVPH subsequently reviewed ("Opinion" of April 2002) the additional 17 "independent studies" on the six hormones.<sup>3</sup> *Not surprisingly, the SCVPH, with virtually unchanged membership, held to its original position.* While the SCVPH mentioned the UKVPC review in their subsequent "Review" (May 2000), they dismissed the UKVPC's conclusions without providing any data or analysis in support of their position.<sup>4</sup>

The Commission revised its legislation, and brought out a new proposal in 2000, which after having been reviewed by the Council and the European Parliament, went into effect in October 2003 as Directive 2003/74/EC.

Rather strangely, under Directive 2003/74/EC, estradiol remains available for use within the EU, until October 2006 for estrus induction in cattle, horses, sheep and goats. No later than October 14, 2005, the Commission will revisit the continued use of products containing estradiol for specified therapeutic purposes versus use of alternative veterinary medical products for those same purposes. Within the following year (2006), the Commission will publish any necessary proposals to replace use of estradiol "in due time." Estradiol is not permitted for these purposes in the US because other medications are widely available as alternatives in the US and worldwide, but not, apparently, throughout all Member States.

In response to a question regarding the existence of any empirical evidence to demonstrate the risk of hormones implants to those who consume hormone-treated beef, the EU responded that each Member State is subject to yearly "monitoring plans." These monitoring

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<sup>1</sup> [http://europa.eu.int/comm/food/fs/sc/scv/out50\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scv/out50_en.pdf)

<sup>2</sup> [http://europa.eu.int/rapid/start/cgi/guesten.ksh?p\\_action.gettxt=gt&doc=IP/03/1393|0|RAPID&lg=EN&](http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/03/1393|0|RAPID&lg=EN&)

<sup>3</sup> Although the relevance and independence of many of the 17 studies may be questioned, one study clearly indicated that a single small hen's egg (50 g) has ~ 30% more estradiol than 250 gm of beef from hormone-treated cattle.

<sup>4</sup> The EU's position, including all legislation, press releases, SCVPH "Opinions" and "Review", etc., may be found at: [http://europa.eu.int/comm/food/fs/him/him\\_index\\_en.html](http://europa.eu.int/comm/food/fs/him/him_index_en.html)

plan reports are focused on if, how and why hormones have been used<sup>5</sup> and the monitoring plans are considered by the EU to be in the nature of a “compliance mechanism.” In spite of having this “compliance mechanism” in place, there are regular occurrences of hormone misuse found in food-producing animal. However, the misuse is usually found by the special Community Reference Laboratories rather than by the “regular” Member State monitoring programs.<sup>6</sup>

DG SANCO believes there may be increasing sympathy within the WTO membership for the Commission point-of-view, but emphasized that the EU continues to be open to new scientific evidence, suggesting that it may be industry’s role to come forth with evidence to show that these substances are safe.

The new Directive states that the Commission specifically had asked (February 1999) “the U.S., Canada, other third countries, ... or interested party to provide any relevant ... scientific information that can be taken into account in the complementary risk assessment.”<sup>7</sup> However, such information had been provided in the past, through letters from FDA and USDA to the Commission, in WTO testimony and by independent scientific organizations, both prior and subsequent to the SCVPH “Opinion.” All information has been rejected by both the SCVPH and the Commission, perhaps because of their focus on zero potential risk defined in terms of the precautionary principle.

Lastly, the EU formally presented its Communication to the WTO Dispute Settlement Body (DSB) on November 7 2003<sup>8</sup>, making the case that it is now in compliance with WTO requirements, and asking the U.S. and Canada to lift sanctions. The Commission apparently intends to present its case to the WTO DSB based on only scientific evidence used in the discredited SCVPH “Opinion” of 1999 and the SCVPH’s subsequent “Review” and “Opinion” of 2000 and 2002, respectively.

#### Conclusions:

- The US does not believe that the new EU Directive (2003/74/EC) brings the EU into compliance with the WTO Dispute Settlement Body Ruling that rule against its ban on the importation of meat from animals treated with growth hormones.
- The WTO found the EU was in breach of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures because there was no risk assessment based on scientific information to support the ban.
- There has been no new risk assessment based on scientific information and reasoning presented by the EU.
- Although the new Directive imposes new restrictions on usage of estradiol, they may not come into force for a number of years. There do not appear to be sufficient controls in place to prevent animals treated with estradiol for zootechnical or therapeutic purposes from being sold for slaughter and subsequent human consumption.

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<sup>5</sup> Illegal hormones for which the human toxicological effects are not known are regularly found in beef raised within the EU. It has been estimated that use of these compounds (illegal, unknown hormones) could be in the range of 5 – 15% of EU-raised beef.

<sup>6</sup> For example, see BBC News report on the finding of MPA in pigs in 2002.

<http://news.bbc.co.uk/1/hi/world/europe/2131353.stm>

<sup>7</sup> [http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/c\\_056/c\\_05619990226en00170018.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/c_056/c_05619990226en00170018.pdf) Note that the request for additional information was issued 2 months before the April 1999 SCVPH “Opinion” was released. This “Opinion” is now considered to be the EU’s risk assessment.

<sup>8</sup> For WTO actions on the hormone issue, see:

[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_subjects\\_index\\_e.htm#bkmk63](http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk63)

- Scientific committees and panels truly independent from the Commission (Codes Alimentarius, FAO, the UKVPC) have all found the approved hormones to be safe.

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**Related reports from USEU Brussels:**

<b>Report Number</b>	<b>Title</b>	<b>Date Released</b>
E23012	EU Veterinary Legislation Guide	2/5/03
E23079	Hormone Ban – Backing Lawsuits against EU	5/27/03
E23193	European Union Directive on Growth-Promoting Substances	10/21/03
E23206	Historic Overview and Chronology of the European Unions Hormone Ban	11/12/2003