USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network
Template Version 2.09

Voluntary Report - public distribution

Date: 11/7/2003

GAIN Report Number: E23206

European Union

Trade Policy Monitoring

Historic Overview and Chronology of EU's Hormone Ban

2003

Approved by:
Justina Torry
U.S. Mission to the European Union, Brussels

Prepared by:
Michael K. Hoffman

Report Highlights:
This report and chronology trace the use of hormone implants used in raising beef cattle as well as the history of the EU's ban on the US-approved hormone implants. Web linkages are provided to scientific reviews and EU legislation and reports when they are available.

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

Historic Overview and Chronology of the European Union's Hormone Ban

Introduction

The following information was assembled to provide background information on the issues surrounding the use of hormones in raising beef. A chronology highlighting specific events in the long-standing disagreement between the United States (US) and the European Union (EU) on the safety of using hormones follows a short overview of the history of the hormone debate. Within the chronology, web linkages have been provided to the original documents when that is possible.

The U.S.-EU dispute now focuses on the use of six hormones that have been used without negative effects on public health in raising cattle for decades. Within the US and other countries, the hormones (three natural – *estradiol, progesterone, testosterone – and three synthetic ones - melengestrol acetate, trenbolone acetate, and zeranol)* have been used as implants in cattle, dating back to the years after the Second World War. The use of growth-promoting substances in raising cattle had also been legal within the countries that now comprise the EU for more than a generation, beginning in the years after World War II until their being banned in the late 1980's. There is no evidence of adverse human health effects from the use of hormone implants in raising beef that have been recognized within the EU's population that can be attributed to their use[1].

The U.S. Food and Drug Administration (FDA) has thoroughly researched the effects of growth hormones since the 1950s. FDA and other scientific experts have found that there is essentially no difference in hormone levels between beef from animals raised using hormones and those raised without their use. No measurable or adverse health effects have been associated with use of the six hormones in raising cattle.

There is a clear world-wide scientific consensus supporting the safety of these approved and licensed hormones when used according to good veterinary practice. This consensus is reflected in the 1984 and 1987 Lamming Committee reports-- the scientific expert group commissioned by the European Community; the 1987 Joint Expert Committee on Food Additives (JECFA)[2] of the World Health Organization and the Food and Agriculture Organization of the United Nations; the Codex Committee on Residues of Veterinary Drugs in Food (CC/RVDF), the Codex Alimentarius Commission; the safety assessments of FDA and comparable institutions in many countries throughout the world. As recently as 1995, the European Commission assembled a scientific conference of the world's foremost experts. They came to the same conclusion: that hormone usage was safe.

---

1 With the exception of the now banned DES (diethylstilbestrol), which under a different useage regimen produced vaginal cancers in "DES daughters." http://www.cdc.gov/DES/consumers/daughters/ Efforts to ban DES began in the US in 1972, based on the Delaney Amendment. It was finally banned in 1979, whereas the drug was not banned in the EU until 1987, after several scandals involving DES in veal-based baby foods in Italy (~1965 – 1981).

2 Information regarding JECFA, FAO, and Codex can be found at the following sites, although the older reports mentioned above do not appear to be available. http://jecfa.ilsi.org/; http://www.codexalimentarius.net/ An interesting report can be found at: http://reports.eea.eu.int/environmental_issue_report_2001_22/en/issue-22-part-14.pdf

Since 1995, JECFA and other groups have examined the issue. The only scientific reports suggesting a potential for adverse human health effects are those authored by the EU's Scientific Committee for Veterinary Matters Relating to Public Health (SCVPH). The scientific competence of the SCVPH and its April 30, 1999 "opinion" were brought into question as part of a devastating point-by-point review by a UK Committee on Veterinary Products[3] issued in October 1999.

In 1989, the US instituted a 100% *ad valorem* duty on a variety of imports from the EU at a value of about $93 million per year because of the inability to reach a mutually agreed upon solution over the EU hormone ban. This measure was removed in May 1996 following the EU's seeking a WTO panel against the US action. The US sought a WTO panel, which received reports in August 1997. The EU was found to be out of conformity with the SPS provisions and appealed the decision in September 1997. The Appellate Body upheld the decision that the EC prohibition of imports of meat from hormone-treated animals was not based on an assessment risk to human health. In May 1998, a WTO Arbitrator provided a 15-month period (beginning February 13 1998 and ending on May 13 1999) for the EU to bring itself into compliance with the WTO Dispute Settlement Body's recommendation.

Because of the EU's continued failure to permit US hormone-treated beef into the European market, in 1999, the WTO permitted the US to apply tariffs amounting to $116M per year against products imported into the US from the EU.

In October 2003, the EU passed legislation permanently banning the use of estradiol for growth-promoting purposes. This action was based on the April 10 2002 opinion of the SCVPH that examined the results of 17 studies, commissioned by them to fill in the data gaps and answer questions regarding the six hormones. In a press release, the EU stated that the SCVPH's opinions constitute "thorough" risk assessments and fulfill the EU's requirement to the WTO.

Review of the SCVPH opinions strongly suggests that they cannot be construed as being more than the very beginnings of the very first step of a lengthy multi-step risk analysis process[4]. In fact, it appears as if the EU has jumped from raising the question of whether a substance (estradiol) is hazardous (Step A1 in the footnote below) as if it were all of the risk assessment process to invocation of the Precautionary Principle as a risk management tool (Step B) and then issuing a press release as their risk communication (Step C).

It is important to recognize that beef produced within the EU is not "hormone-free" - estradiol, testosterone and progesterone are naturally present in all food-producing animals

---

3 This report no longer appears to be available on line.

4 A complete Risk Analysis is a multi-stage process, consisting of assessment, management, and communication. The steps can be briefly summarized as:

A. Risk Assessment (identifying and defining a specific problem, determining what scientific information is available and what must be obtained; determining all routes of exposure of a substance, and estimating what the risk is to defined groups based on age, habits, etc.)

1. Hazard Identification
2. Hazard Characterization
3. Exposure Assessment
4. Risk Characterization

B. Risk Management (determining acceptable societal risks and benefits from use/non-use of a substance, based on data analysis rather than arbitrary use of a zero risk concept as embodied in the precautionary principle.)

C. Risk Communication

as well as in people. Hormones are required for life to exist.

There is substantial evidence that the absence of safe, approved hormone implants has led to the use of illegal growth-promotants. Almost yearly, there are discoveries of new and illegal hormones being used in raising European beef[5]. The human health effects of these unapproved and illegal substances are unknown, and could subject consumers of EU-produced beef to real and true adverse health effects. It has recently been stated, "that a defensible overall estimate for the use of these compounds (illegal hormones) in the European Union based on results from annual regulatory residue testing programmes could be in the range of 5-15 percent."[6].

In conclusion, the US and other countries believe not only that hormone implants in cattle are safe but also that their use facilitates production of higher quality meat (more rapid weight gain producing a more flavorful and tender product that reaches market weight sooner) at lower prices. Since the early 1980's, the EU has adopted the view that the use of hormones in raising food-producing animals is dangerous. Early discussions of the hormone issue (circa 1988) within the European Parliament indicate that one of their original concerns was not health-related, but the costs to the EU of over-production of meat and meat products ("whereas there is overproduction of meat and meat products in the European Community which adds considerably to the cost of the CAP."[7]). Although that issue is little spoken of today, and while EU has financed numerous studies regarding the six hormones, there continues to be little international support for their scientific position. The EU continues to ban the import of meat from hormone-treated cattle just as its scientific efforts fail to meet the bar of the risk assessment called for by the WTO. Perhaps the unspoken issue requires more attention.

5 See, for example, speech by Commissioner David Byrnes on MPA contamination. September 5, 2002 http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech147_en.pdf

6 R.W. Stefany, "Hormones in meat: different approaches in the EU and in the USA" in Hormones and Endocrine Disrupters in Food and Water, APMIS 109 (Suppl. 103): S357-64, 2001.

7 See OJ C 288 11/11/1985, p 158.

CHRONOLOGY

1981

European Council (EC) adopts Directive 81/602 (no longer in force; See OJ L 125 23.5.96, p 3-9) to prohibit the use of hormones, except for therapeutic purposes, but later postpones action on five hormones ("oestradiol-17-ß", Progesterone, Testosterone, Trenbolone and Zeranol) pending study by the Commission of the European Community (CEC) study.

1982

Interim report by CEC Working Group concludes that the three natural 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" and that further research is necessary on the two synthetic hormones.

1984

June CEC proposes amending Directive 81/602 to allow the use of natural hormones.

1985

Oct. European Parliament (EP) adopts a resolution that endorses a ban on two synthetic hormones and rejects the proposed authorization of the three natural hormones except for therapeutic purposes.

Dec. The EC bans the use of natural hormones (except for therapeutic purposes), bans the use of synthetic hormones, and prohibits imports of animals and of meat from animals to which hormones have been administered, effective no later than January 1, 1988.

1986

Sept. U.S. raises the EC hormone ban in the Committee on Technical Barriers to Trade ("Standards Code") of the General Agreement on Tariffs and Trade (GATT).

1987

U.S. invokes dispute settlement under the Tokyo Round Agreement on Technical Barriers to Trade. The European Union (EU) refuses to address U.S. concerns during two sessions of bilateral consultations. The EU blocks formation of the technical expert group.

June Joint Expert Committee on Food Additives (JECFA) of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) establishes acceptable daily intake levels and acceptable residue limits for synthetic hormones and decides that levels do not need to be set for the naturally occurring hormones because they "are unlikely to pose a hazard to human health."

Nov. EC delays application of the hormone ban to imports for one year, until January 1, 1989.

Dec. Committee on Veterinary Drugs of the Codex Alimentarius Commission agrees on safe limits for two synthetic hormones and agrees that limits are unnecessary for the three natural hormones.

Dec. President Reagan announces, and suspends, retaliatory tariffs (100 percent ad valorem) on about $100 million worth of EU imports. Despite lack of scientific justification, EU unwilling to resolve dispute.

1988

Nov. EC bans all U.S. meat. Despite the fact that the U.S. has no hormonal substances approved for use in pork or horsemeat, the Commission indicates that the U.S. needs a residue-testing program for these meats to be in compliance with Directive 81/602.

1989

Jan. 1 EC hormone ban takes effect. The U.S. apply measures in the form of 100% *ad valorem* duty on a variety of EC exports at a value of about $93 million per year since 1989.

Mid Jan. U.S. and EC agree to a 1-month grace period for products in the "pipeline."

May U.S. and EC agree to interim measures that enable U.S. producers to ship to the EC meat from cattle not treated with hormones.

1993

The issue of the role of science in the Codex decision-making process is delegated to the Committee on General Principles. With participation by both the U.S. and the EU, the Committee develops four principles that re-enforce the pre-eminent role of science.

1995

Jan. The GATT Uruguay Round Agreement, including the Sanitary and Phytosanitary Agreement (SPS) enters into force.

June CEC Commissioner Fischler announces plans for an EU hormone conference at the end of 1995, saying that "on the basis of the findings of this conference, I shall make up my mind as to whether there is a need, and to what extent there are possibilities for adjusting the EU hormone ban."

U.S. Secretary of Agriculture Glickman targets the end of 1995 for resolving the dispute.

July Codex adopts four principles affirming that health standards will be based on sound science despite EU opposition. In addition, the Codex Commission decides that maximum residue limits (MRLs) are not necessary for the three natural hormones and adopts MRLs for the two synthetics.
http://www.fao.org/docrep/meeting/005/V7950E/V7950E03.htm#App2
http://www.fao.org/docrep/meeting/005/V7950E/V7950E01.htm#ch8.3.1

Nov. The CEC's Scientific Conference on Growth Promotion in Meat Production (SCGPMP) concludes that there is no evidence of health risk from the five hormones approved for use in the United States. [The proceedings of the "Scientific Conference On Growth Promotion In Meat Production. Proceedings. Brussels, 29 Nov. To Dec. 1, 1995" were published as a book by the European Communities Publications EEC.] [The WTO Panel, Appellate Body, and Arbitrator would all later find that the studies from this Conference did "not rationally support the EC import prohibition". See WTO below, Jan 26, 1996.]

1996

Jan. 18 The EP votes 366 (of 626 Parliamentarians) to 0 for a resolution to maintain the ban.

Jan. 22 The Agriculture Council discusses the final report of the Hormone Conference and also re-affirms its commitment to maintaining the ban.

Jan. 26 The U.S. requests consultations under Article XXII of the World Trade Organization (WTO) regarding the EU's hormone ban. [All WTO activities and actions related the hormone issue may be found at: http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk63

Mar. 27 Consultations are held in Geneva with Australia, Canada, and New Zealand joining the U.S. in its complaint.

May 8 U.S. requests, at WTO Dispute Settlement Body (DSB) meeting, that a WTO Arbitration Panel be formed. The EU blocks the request.

May 20 U.S. makes a second request for the WTO Panel.

July 2 A WTO Panel to examine the EU's hormone ban is formed with members agreed upon by both sides. Two panel meetings held on October 10 and on November 11.

Oct. Canada requests a WTO Panel, which meets Jan. 7 and Feb. 18, 1997.

1997

Feb. 17 Meeting of technical experts selected by the WTO Panel, with the U.S., the EU, and the Codex Secretariat. Report delayed due to Canada's decision to pursue its own WTO case against the EU ban.

May 7 WTO Panel issues its interim reports for both the U.S. and the Canadian panels.

June 30 WTO Panel report finds that the EU's ban on the use of hormones to promote the growth of cattle is inconsistent with the EU's obligations under the SPS Agreement, in that the EU's ban is not based on science, i.e., on a risk assessment or on the relevant international standards. "In our view, the scientific conclusions reflected in the EC measures in dispute...does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities."

Sept. 24 EU notifies the WTO of its decision to appeal the Panel's finding.

1998

Jan. 16 The Appellate Body (AB) releases its report, firmly upholding Panel findings that the ban is inconsistent with the SPS Agreement and must be brought into conformity with WTO rules. The AB clearly affirms the Panel's findings that the EU ban was imposed and is maintained without credible evidence to indicate that there are health risks posed by eating U.S. beef from cattle treated with hormones, and despite the fact that "most, if not all, of the scientific studies referred to by the European Communities, in respect of the five hormones, involved here, concluded that their use for growth promotional purposes is 'safe'."

Feb. 13 The Panel and AB reports on the EU hormone ban are adopted by the WTO DSB.

Mar. 13 At the DSB meeting, the EU announces only that it will implement the AB finding in "as short a time as possible," but must wait for the outcome of additional risk assessments. The United States and Canada insist on a firm deadline for compliance. Because the parties are not able to agree on a "reasonable period of time" for implementation, the EU requests binding arbitration.

May 29 The arbitrator decides that the EU needs only 15 months to comply. The arbitrator's ruling is clear that the "reasonable period of time" is provided to bring the measure into compliance and not "…to conduct studies to demonstrate the consistency of a measure already judged to be inconsistent …" with WTO principles. The "reasonable period of time" for the EU to come into compliance with the WTO rulings ends on May 13, 1999.

1999

Feb. 10 The CEC adopts a Communication on the options regarding the WTO decision on the EU hormone ban [http://europa.eu.int/abc/doc/off/bull/en/9901/p103242.htm]. This paper was presented to the Member States and the EU Parliament and outlined three options - compensation, removal of the ban coupled with a suitable labeling system, and the conversion of the ban to a temporary measure - to resolve the U.S. - EU hormone dispute. Concurrently, US Secretary of Agriculture Glickman and USTR Ambassador Barshefsky sent a letter to Commissioner Franz Fischler (Agriculture) and Leon Brittan (Trade) outlining a possible labeling system.

Mar. 22 The United States published a preliminary list of products that may be subject to increased tariffs if the United States and the EU cannot resolve this dispute.

Apr. 30 The SCVPH releases a report stating that it had evidence to show that a growth hormone (estradiol) used in U.S. cattle production is carcinogenic. However, after a preliminary review of a summary of the EU study, U.S. scientists determine that the report repeats the same unsubstantiated arguments the EU made during the WTO panel process that were flatly rejected. In addition, the report ignores the most recent conclusions of JECFA and FAO reconfirming the safety of the three natural hormones when administered in accordance with good veterinary practices. The EU report also alleges possible misuse of the hormone implants in the United States, but it provides no evidence to support that claim. **http://europa.eu.int/comm/food/fs/sc/scv/out21_en.html**

May 13 Deadline for EU compliance with the WTO rulings.

May 18 The United States requested a special meeting of the Dispute Settlement Body for June 3rd so that the United States could formally request authorization to suspend concessions on approximately $202 million of EU products imported into the United States.

June 3 The United States (as well as Canada) formally requested authorization to suspend concessions. In response, the EU formally requested Arbitration on the amount of trade damage quoted by the United States.

June 11 The United States, Canada, and the EU submitted their First Submission for Arbitration.

June 18 The United States, Canada, and the EU submitted their rebuttal briefs to the Arbitration Panel.

June 22 The Arbitration Hearings were held in Geneva.

July 12 The World Trade Organization announced that the U.S. loss due to the EU ban on U.S. beef treated with hormones totals $116.8 million. See WT/DS26/ARB at

http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk63

July 19 The United States announced the list of EU products that will be subject to 100% tariffs as of July 29, 1999. The list of products includes beef, pork, goose livers, cheese, truffles, onions, carrots, preserved tomatoes, sausage casings, soups, yarn, mustard, juice, chicory, rusks, glue, wool grease, chocolate, and jams. The list targeted France (24%), Germany (24%), Italy (21%), and Denmark (15%).

July 29 The U.S. list of products subject to increased duties becomes effective.

Aug. 13 EU sends letter to the United States stating that list exceeded the WTO sanctioned number of $116.8 million. (Note: There was no follow-up by EU on their allegation, issue dies)

Oct. UK study finds fault in Scientific Committee's conclusion of April 1999 concerning the risks of hormones. The study was unable to support the conclusion of the Scientific Committee's report and found flaws in their scientific reasoning.

Nov. Congress passes legislation on "carousal" retaliation. That is the retaliation list for hormones and bananas must be reviewed and new products put on every 6 months. Carousal legislation has yet to be implemented.

Dec. Report of Committee on Veterinary Products of the European Community (CVMP) notes that estradiol-17β "has a carcinogenic effect only after prolonged exposure and at levels considerably higher than those needed for a physiological response." http://www.emea.eu.int/pdfs/vet/mrls/oestradiol.pdf

2000

Feb. Joint FAO/WHO Expert Committee on Food Additives

May 3 Scientific Committee rejects UK's report of Oct. 1999. In a statement, the Scientific Committee states that the UK report as well as other recent scientific information did not provide convincing data and arguments demanding revision of the conclusion drawn in their study of April 30, 1999. http://europa.eu.int/comm/food/fs/sc/scv/out33_en.pdf and http://europa.eu.int/comm/food/fs/sc/scv/out21_en.html

2001

June 8 Commission provides documentation of studies and journals for publications.

Sept U.S. and EC begin compensation discussions.

2002

Apr. 23 Commission announces that following the review of the 17 studies, the SCVPH, by ignoring data from other studies (see Oct and Dec 1999), confirms results of previous studies (April 1999 and May 2000), and still claim that growth promoting hormones pose health risk to consumers. The SCVPH focuses on inappropriate models and ascribes "Any disparities between the various evaluation reports" to be "based on the different interpretation of individual research data." http://europa.eu.int/comm/food/fs/sc/scv/out50_en.pdf

2003

July 22 European Council approves second reading of a Directive implementing the ban on the use of estradiol-17β in food-producing animals except certain therapeutic and zoonotic purposes will be permitted until 2006. EP previously held a second reading on July 2, 2003. Text of Directive states that the provisionally prohibited hormones (testosterone, progesterone, trenbolone acetate, zeranol, and melengestrol acetate) shall remain in that category because "in spite of the individual toxicological and epidemiological data available…the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers." http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=157483#354074

Sept. 22 EP and Council sign Directive 2003/74/EC amending 96/22/EC, permanently banning estradiol and extending provisional prohibition of the remaining 5 hormones.
http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_262/l_26220031014en00170021.pdf

Oct. 14 EU issues press release claiming compliance with the earlier WTO ruling "condemning the EU for banning the use of certain growth promoting hormones without a state of the art scientific risk assessment of the risk associated with meat consumption." This action was based on implementation of 2003/74/EC and calls on USA and Canada to lift trade sanctions. The press release claims that the 22 April 1999 and 10 April 2002 "Opinions" of the SCVPH constitute "a thorough risk assessment based on current scientific knowledge, fully respecting its (the EU's) international obligations."

Oct. 15 US responds, focusing on the absence of new scientific data or an actual risk assessment to support the EU's press release.

Oct. 28 The US continues to believe that the EU has failed to meet its WTO obligations.

Visit our website: our website **www.useu.be/agri/usda.html** provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. E-mail: AgUSEUBrussels@usda.gov

Related reports from USEU Brussels:

Report Number	Title	Date Released
E23012	EU Veterinary Legislation Guide	1/28/03
E23079	Hormone Ban – Backing Lawsuits against EU	5/22/03
E23193	European Union Directive on Growth-Promoting Substances	10/15/03