Thomas L. Freedman
12/09/99 10:42:20 AM

Record Type: Record

To: Clifford J. Gabriel/OSTP/EOP@EOP, Mary L. Smith/OPD/EOP@EOP

cc:
Subject: Options---Please comment ASAP

you should stay in touch with him to see what they finalize.
---------- Forwarded by Thomas L. Freedman/OPD/EOP on 12/09/99 10:42 AM ----------

Eric Olsen <Eric.Olsen@usda.gov>
12/08/99 06:33:00 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc: Thomas L. Freedman/OPD/EOP, ANDY.SOLOMON@usda.gov (Receipt Notification Requested)
Subject: Options---Please comment ASAP

Here are three options for possible statement for POTUS radio address. Need to be cleared by USDA OGC and policy. Please comment ASAP. Thanks.

Three years ago, I announced a new, science based meat and poultry inspection system that directly targets pathogens that cause foodborne illness like e coli and salmonella, and I'm pleased to report that this new system is dramatically reducing contamination of meat and poultry products.

Options--(1) if judge doesn't rule, (2) rules against us, (3) rules for us..

(1) While this new system is facing a court challenge, the American people can rest assured that my Administration will vigorously defend this new system and keep moving forward to further improve the safety of meat and poultry products.

(2) While I am disappointed that this new system suffered a setback today in a court challenge, the American people ....(same as above)

(3) While this new system recently faced a court challenge, I am pleased that the judge ruled in our favor and that we can keep moving forward to further improve the safety of meat and poultry products.

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32ND STORY of Level 1 printed in FULL format.

Beef

The New York Times

December 4, 1999, Saturday, Late Edition - Final

SECTION: Section A; Page 1; Column 1; National Desk

LENGTH: 1054 words

HEADLINE: New U.S. Standards for Meat Are Snared in a Court Fight

BYLINE: By MARIAN BURROS

BODY:

A federal judge in Dallas has halted the first effort by the United States Department of Agriculture to close a meat plant that consistently failed inspections, setting up a test of the government's tougher new standards for meat and poultry.

On Tuesday the department withdrew its inspectors from the Supreme Beef Processors plant in Dallas, which supplies up to 45 percent of the ground beef used in the national school lunch program, because the company had failed three tests for salmonella contamination over eight months. The company also supplies beef to Wal-Mart. Without the inspectors, the plant could not sell food legally in interstate commerce.

Responding the same day to a lawsuit by the company, Judge A. Joe Fish of Federal District Court for the Northern District of Texas said withdrawing the inspectors could result in irreparable harm to the company and issued a temporary restraining order instructing the department to return its inspectors pending a Dec. 10 hearing.

Food safety experts say the outcome of the case could determine whether the new science-based system for inspecting meat and poultry will remain in effect, or whether the Agriculture Department will be forced to return to methods no better than the poke-and-sniff system that had been in effect since the beginning of the century, under which meat was not inspected for bacteria.

In its lawsuit against the Agriculture Department, the company says the government has no authority to regulate salmonella, arguing that "because salmonella is not an adulterant and because salmonella is destroyed during normal cooking, the presence of salmonella is not a public safety issue."

It calls the agency's actions "arbitrary and capricious."

The case is seen as a test of the tougher standards for food safety that went into effect in 1995.

"The department had moved to a public-health-based system," said Carol Tucker

Foreman, director of the Food Policy Institute of the Consumer Federation of America and an assistant secretary of agriculture in the Carter administration. "If the company wins this case, we'll go back to a system where inspectors look for bumps and bruises that have no relationship to the bacteria that make people sick."

Under the new regulations, plants are required to adopt the Pathogen Reduction and Hazard Analysis Critical Control Points method of inspection, known as Haccp (pronounced HASS-ip). They must identify critical points in the production process where contamination is likely to occur and implement plans to prevent contamination. They are required to perform microbial tests for the presence of salmonella, disease-causing bacteria that cause mild to severe gastrointestinal distress and, in immune-compromised populations, even death.

The Centers for Disease Control and Prevention recently estimated that there were more than one million cases of food-borne salmonella poisoning a year and 556 deaths.

The tests for salmonella contamination are the government's only check to ensure that the Haccp plan is actually controlling food hazards in the plants.

The phasing in of the plan began in 1998. Since then, 90 percent of the more than 3,000 plants covered by the regulations have met the performance standards set by the Agriculture Department.

Those standards permit no more than 7.5 percent of a plant's ground beef to contain salmonella. In the latest analysis of the testing, covering the first half of 1999, 2.6 percent of the ground beef in the largest plants and 3.3 percent of the ground beef in the small plants, of which Supreme Beef Processors is one, was found to be contaminated.

The government does not say that any of the company's meat caused illness.

According to Supreme Beef's own documents, filed in its lawsuit against the Agriculture Department, as many as 20 percent of the samples in the three sets of tests contained salmonella.

"This is an indicator that this plant is not keeping its food safety hazards under control," said Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest, a consumer advocacy group based in Washington. "It means their Haccp system is not working."

Ms. Foreman said the Agriculture Department picked its test case carefully. "It's clear the government didn't go to a company where it was going to be a tight squeeze," she said. "They got a company that failed big."

While the meat industry has not objected to the new methods, it has been complaining that the salmonella testing standards are not fair.

Rosemary Mucklow, executive director of the National Meat Association, a trade association representing meat packers and processors, said the industry had had "some very serious concerns about salmonella performance standards in ground beef for about three or four months." Supreme Beef, she said, is "experiencing the consequences of a requirement that we think has some serious

problems. It would have been better if U.S.D.A. had tried to work it out."

Asked why Supreme Beef was unable to meet the Agriculture Department's standards when 90 percent of the plants covered by the regulations had been able to, Ms. Mucklow replied, "I think it's true that Supreme Beef has been unlucky."

Ground beef from the Supreme Beef plant is included in the school lunch program, which is operated by the Food and Nutrition Service of the Agriculture Department. The Agricultural Marketing Service canceled its contract with Supreme Beef on Nov. 30 because it said the company's beef did not meet the agency's minimum standards.

A spokeswoman for Wal-Mart said the company had only become aware of the Supreme Beef lawsuit on Friday. The spokeswoman, Jessica Moser, would not say how much meat Wal-mart bought from Supreme Beef.

"Whether we buy one packet of meat from them, whether we buy thousands of packets of meat from them, this is a concern of ours because customer safety is a top priority and we're going to continue to watch it very closely," Ms. Moser said.

Steven F. Spiritas, the company's president and chief executive, said he was disappointed with the government's action. The company was in discussions with Agriculture Department officials, Mr. Spiritas said, but he said he was "confident that together we can bring this matter to a positive resolution."

http://www.nytimes.com

LANGUAGE: ENGLISH

LOAD-DATE: December 4, 1999

Beef

USDA REACTION TO SUPREME BEEF RULING

December 10, 1999

- ***We intend to pursue this matter fully.***

  [IF ASKED, we will be consulting with our Justice Department lawyers to determine the best course of legal action to do that.]

- ***Our science-based food safety inspection system has been proven effective.***

  [Can refer to CDC data showing decline in Salmonellosis due, in part, to new system. Also, can refer to dramatic decline in incidence of *Salmonella* on raw product (at least 25% declines for each category of raw product).]

- This is ***the only meat or poultry plant in the country*** (except for the company's own slaughter operation) ***that has failed three times*** to meet our *Salmonella* performance standard.

- We believe that these *Salmonella* standards are ***key to our ability to continue ensuring the safety of meat and poultry and further reducing foodborne illness among Americans***.

THE U.S. - EU HORMONE DISPUTE

February 24, 1999

Overview

For the past 15 years, the United States and the European Union (EU) have been disputing the safety of growth promotants used in cattle. The disagreement over the use of hormones in cattle peaked in 1989 when the EU banned the import of beef from cattle treated with growth promotants, effectively cutting off U.S. exports of beef. The United States has always maintained that U.S. beef from cattle treated with certain approved growth hormones poses no public health risk, and therefore, the EU's hormone ban is unjustified. Numerous scientific studies and evaluations, including those conducted by the EU and CODEX, the international food safety standard setting body, have supported the U.S. position.

This dispute took a turn in 1996 when the United States presented its case against the EU's hormone ban to the World Trade Organization (WTO). After a thorough review of the scientific evidence, the WTO Panel upheld the U.S. position and ruled that there was no scientific basis for the EU's hormone ban. The EU's hormone ban is inconsistent with WTO principles. After an appellate decision upheld this ruling, the EU was given until May 13, 1999 to bring its measure into compliance.

The debate now is over the EU's compliance with the WTO rulings and honoring its obligations under international agreements. During the Uruguay Round negotiations, the EU committed to uphold the principles of the WTO. In maintaining its unscientific ban, the EU does nothing to further the objective of protecting public health, but instead undermines the WTO Sanitary and Phytosanitary Agreement (SPS) and invites other countries to renege on their international obligations.

History of the U.S. - EU Hormone Dispute Settlement Process

The WTO Dispute Settlement Understanding (DSU) was developed to provide security and predictability to the multilateral trading system and to preserve the rights and obligations of WTO Members. The EU's recalcitrance in implementing the adopted WTO rulings in this case will seriously threaten the viability of the DSU.

The DSU outlines a progression of steps for resolving disputes between countries beginning with consultations between the disputing parties. If, through consultations, a solution is not reached, the complaining member may request a "panel" to review the dispute. The panel is composed of well-qualified individuals who are selected with a view to ensuring independence and diversity of background and experience. The disputing members must agree on the panel members. Once the panel is chosen, the disputing members present their case. The parties can appeal the panel's findings to the WTO Appellate Body for a final decision.

WTO rules call for the member whose measure has been found to be inconsistent to bring the measure

into compliance "within a reasonable period of time". If the disputing members can not agree on the reasonable period of time, they can proceed to arbitration. The arbitrator will then make a binding determination of the "reasonable period of time".

The objective of dispute settlement is the withdrawal of measures found to be inconsistent with the provisions of the WTO. The DSU is clear on the issue of compensation. Compensation must be mutually agreed upon by both parties and is only temporary pending the withdrawal of the offending measure. Finally, the DSU outlines the procedures by which an injured member may suspend concessions if an acceptable solution is not found.

The United States and the European Union are now approaching the end of this lengthy dispute settlement process. The panel, the appellate body, and the arbitrator have all stated in their findings that the EU's hormone ban is inconsistent with WTO principles **I** it is not based on science -- and must be withdrawn by May 13, 1999.

WTO Dispute Settlement Panel

Following unproductive WTO consultations in March 1996 (in which the United States was joined by Canada, Australia, and New Zealand), the United States requested a WTO dispute, settlement panel. Each side presented its case, incorporating both verbal and written testimonies from expert scientists. The panel thoroughly reviewed the case, including information from independent scientific experts convened by the Panel. On August 18, 1997, the panel found 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 Sanitary and Phytosanitary (SPS) Agreement. In particular, the panel's report affirms that the EU's ban is not supported by scientific evidence. The panel found that the ban was not based on a risk assessment or on the relevant international standards. This was the first dispute involving the new SPS Agreement, and the panel's ruling is a clear endorsement of the principles espoused in the new Agreement - the use of sound science as the basis for non-tariff import restrictions.

Results of the Appellate Body

In September 1997, the EU appealed the Panel's findings. In its report, the Appellate Body (AB) firmly upheld the Panel's finding that the EU's ban is inconsistent with the SPS Agreement and must be brought into conformity with the WTO principles. The AB clearly affirmed the Panel's findings that the EU ban was imposed and maintained without credible evidence of any health risks posed by eating beef from cattle treated with hormones, and despite scientific evidence showing such meat to be safe.

Arbitration Report on Implementation of WTO Rulings

On March 13, 1998, the EU announced only that it would implement the Appellate Body finding in "as short a time as possible." This was unacceptable to the United States. Because the parties were not able to agree on a "reasonable period of time" for implementation, the EU requested binding arbitration. The arbitrator decided that the EU only needed 15 months. The arbitrator's ruling was clear in 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.

Compensation and Suspension of Concessions

According to Article 22.2 of the DSU, if the EU fails to comply within the reasonable period of time

and no mutually acceptable temporary compensation has been agreed to, the United States has the right to request authorization to suspend trade concessions.

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Last modified: Monday, March 01, 1999

Statement by Secretary of Agriculture Dan Glickman On the Beef Hormone Issue April 19, 1999

Release No. 0169.99
FAS PR 0136-99

"The United States remains committed to working with the European Union (EU) to bring about the timely and complete lifting of the EU's ban on beef produced with the aid of growth promoting hormones. In three separate decisions on the matter, the World Trade Organization (WTO) has ruled that the EU ban violates the EU's obligation to base such actions on sound science and that the EU must act promptly to comply with the WTO directive to end the ban.

"The EU has acknowledged, and the United States recognizes, that the EU will not be in compliance by the WTO-imposed deadline of May 13, 1999. For that reason, and until the ban is removed, the United States has proposed to label U.S. beef, and the EU has made a general offer of compensation. The U.S. is open to either labeling or compensation as an interim solution, but only if the EU first commits to end its ban by a date certain. Nearly twenty years of scientific studies attest to the safety of beef hormones, and additional uncertainty and delay threaten the WTO's rules-based system of compliance and enforcement.

"The simple objective of the United States is to obtain compliance with the WTO decision and an end to the EU's illegal ban. To secure that objective, the United States is prepared to impose sanctions on EU products imported by the United States. Indeed, in order to fully preserve its rights under the WTO system, the United States has already begun, and will continue to pursue this option until the EU comes into compliance."

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Chronology of the European Union's Hormone Ban

Revised February 1999

The issue between the United States and the European Union (EU) over the use of hormones as growth promotants in cattle goes back to the 1980s. The United States, through its scientific and regulatory review process, has approved five hormones for use in finishing cattle. Three natural hormones (estradiol, progesterone, and testosterone) are found in all food animals, humans, and in many other food products. Two other hormones (zeranol and trenbolone acetate) have a similar growth promotion effect, but do not occur naturally in cattle. The three natural hormones are approved for use in the EU for therapeutic purposes, but none can be used for the purpose of growth promotion.

On January 1, 1989, the EU implemented a ban on imports of red meat from animals treated with growth-promoting hormones, cutting off U.S. beef exports to the EU valued at about $100 million annually (85 percent of these exports was offal for human consumption).

This fact sheet traces the origins of the problem between the United States and the EU.

1981		EC Council adopts Directive 81/602 to prohibit the use of hormones, except for therapeutic purposes, but later postpones action on five hormones pending EC study.
1982		Interim report by EC 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*	EC Commission proposes amending Directive 81/602 to allow the use of natural hormones.
1985	*October*	European Parliament 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.
	December	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	*September*	U.S. raises 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. EC refuses to address U.S. concerns during two sessions of bilateral consultations. The EC 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 Aare unlikely to pose a hazard to human health."
	November	Nov. EC delays application of the hormone ban to imports for one year, until January 1, 1989.
	December	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.
	December	President Reagan announces, and suspends, retaliatory tariffs (100 percent ad valorem) on about $100 million worth of EC imports. Despite lack of scientific justification, EC unwilling to resolve dispute.
1988	*November*	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 and U.S. retaliation measures take effect.
	Mid January	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	*January*	The GATT Uruguay Round Agreement, including the Sanitary and Phytosanitary Agreeement (SPS) enters into force.
	June	EU 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

need, and to what extent there are possibilities for adjusting the EC hormone ban."

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

	July	The four principles developed by the Codex Committee are adopted 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.
	November	The EU=s Scientific Conference on Growth Promotion in Meat Production concludes that there is no evidence of health risk from the five hormones approved for use in the United States. The WTO Panel, Appellate Body, and Arbitrator would all later find that the studies from this Conference did Anot rationally support the EC import prohibition@.
1996	*Jan. 18*	The European Parliament votes 366 to 0 (out of 626 total Parliamentarians) 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.
	March 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 panel be formed. The EU blocks the request
	May 20	U.S. makes a second request for a WTO panel.
	July 2	A 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.
	October	Canada requests a panel, which meets Jan. 7 and Feb. 18, 1997.
1997	*Feb. 17*	Meeting of technical experts (selected by the Panel), 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	Panel issues its interim reports for both the U.S. and the Canadian panels.
	June 30	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

science, i.e., on a risk assessment or on the relevant international standards. AIn 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 Amost, 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 Dispute Settlement Body.

March 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 in that the Areasonable period of time@ is provided to bring the measure into compliance and not A..to conduct studies to demonstrate the consistency of a measure already judged to be inconsistent ...@ with WTO principles. The Areasonable period of time@ for the EU to come into compliance with the WTO rulings ends on May 13, 1999.

1999 *May 13* Deadline for EU compliance with the WTO rulings.

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Last modified: Tuesday, March 02, 1999

A PRIMER ON BEEF HORMONES

February 24, 1999

The Issue

The U.S.-EU dispute at the World Trade Organization (WTO) over hormones used for cattle growth promotion around the use of six scientifically approved hormones: *estradiol, melengestrol acetate, progesterone, testosterone, trenbolone acetate, and zeranol.* All six have been used without negative effects on public health in the United States and many other countries for decades. The clear international scientific consensus is that these approved and licensed products are safe when used in accordance with good veterinary practice. ***Even the EU's own scientists agree with these findings.***

What Are Hormones?

Hormones are produced throughout the lifetime of every man, woman and child, and are required for normal physiological functioning and maturation. Three of the hormones in question-- estradiol, progesterone and testosterone -- are naturally occurring hormones produced by all humans and food animals. The other three substances -- trenbolone acetate, zeranol and melengestrol acetate (MGA) -- are synthetic hormones: trenbolone acetate mimics testosterone, zeranol mimics estradiol, and MGA mimics progesterone. Hormones are produced by all animal and plant species to regulate growth.

Why Use Hormones?

The six hormones are approved and can be used safely for growth promotion. The use of hormones provides several benefits in beef production. A hormone-treated animal gains weight more rapidly, producing a more flavorful and tender product. By reaching market weight sooner, there is a reduction in the cost of beef production. Thus, consumers are provided with a higher quality of meat at lower prices.

A Record of Safety and Effectiveness

The U.S. Food and Drug Administration (FDA) has been thoroughly researching the effects of growth hormones since the 1950s. FDA and other scientific experts have found that there is essentially no difference between beef from animals raised using hormones and those raised without their use. On all occasions of testing, the six hormones have always been found to pose no measurable or adverse health effects.

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) 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; and most recently by the assembly of the world's foremost experts on the subject at the 1995 Scientific Conference convened by the European Commission. **The world's scientific community has agreed that estradiol, melengestrol acetate, progesterone, testosterone, trenbolone acetate, and zeranol are safe when used according to label directions in food-producing animals.**

The United States has an extensive regulatory control system to ensure the proper use of these hormones. The U.S. system includes comprehensive food safety standards that are based on sound, internationally-recognized scientific criteria. The FDA and the U.S. Department of Agriculture (USDA) work together to provide consumers with a safe food product by ensuring the proper use of hormones in cattle.

An important factor ensuring that hormones are used safely is the way in which they are applied. FDA regulations allow the use of hormones only in the form of implants, which have very specific instructions on proper usage. Each implant contains a specific, legally authorized dosage of the hormone. The implant itself is inserted into the ear, which is discarded at slaughter and does not enter the human food chain. With an implant, the hormone is released into the bloodstream very slowly, so that the concentration of the hormone remains relatively constant and very low. USDA provides educational programs for producers and veterinarians that provide instruction in the proper use of hormones.

Furthermore, the prescribed dosage is the level which produces the maximum economic response in the animal -- the law of diminishing returns -- so that there is no economic incentive for a farmer to use additional implants. A U.S. control system ensures that animals taken to slaughter have normal hormone levels. Thus, farmers have no incentive, economic or otherwise, to misuse the implants.

Beef Hormones in Perspective

The hormone levels in beef produced using growth promotants are well within the range of natural levels of these hormones. Beef from a bull (which is not castrated and to which hormones have not been administered) contains testosterone levels over ten times higher than the amount in beef from a steer (which is castrated) that has received hormones for growth promotion. Since the European beef market is predominantly bull-sourced, while American meat is steer-sourced, American hormone-treated beef generally contains lower levels of hormones than most European beef.

To put this issue into perspective, it is important to remember that many foods contain significant levels of hormones. ***The fact is consumers are exposed every day to foods with far higher hormone levels than those found in any beef from animals treated with hormones.*** For example:

- Hormone levels (estradiol equivalent) in beef are far less than those found in eggs. A person would need to eat over 6 kilograms of beef from animals treated with these hormones in order to equal the amount of those hormones in one egg. For example, a hen's egg (about 50 grams) contains about 45 times as many estradiol equivalents as 250 grams of steer meat raised with this natural hormone.

- A one pint glass of milk from an untreated cow contains about 9 times as much estradiol as a

250 gram portion of meat from a steer raised using hormones.

- Wheat germ and soybean oil contain phytoestrogens at several thousand times higher hormone equivalent concentrations than a serving of beef from a steer raised with growth promotants.

- The amounts of estradiol, progesterone and testosterone in animals raised using hormones as growth promotants are extremely low compared with their production in humans. Even a young boy would need to eat more than 7000 grams (about 16 pounds) of beef raised using estradiol daily in order to produce a one percent increase in his production of this hormone. A 500-gram portion of beef raised using estradiol contains approximately 15,000 times less of this hormone than the amount produced daily by the average man, and about nine million times less than the amount produced by a pregnant woman.

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Last modified: Monday, March 01, 1999

INFORMATION MEMORANDUM FOR THE SECRETARY

FROM: Catherine E. Woteki, Ph.D., R.D.
Under Secretary for Food Safety

SUBJECT: EU Studies on Human Health Effects of Growth Promotion Hormones in Cattle

DG XXIV is sending Tom Billy, Administrator of the Food Safety and Inspection Service, two reports from their ongoing reviews of growth promotion hormones in cattle. In a letter dated (Saturday), May 1, 1999, Horst Reichenbach conveys two documents: a summary of a report on the human health effects from consuming beef from cattle treated with growth promotion hormones, and a draft report evaluating the risks resulting from misuse of growth promoters in cattle. Both studies were evidently undertaken to respond to the deadline of May 13, 1999 set by the WTO Arbitrator for the EC.

We have worked today on a preliminary review of these documents and have provided copies of them to various responsible authorities in the U.S. government including the Center for Veterinary Medicine, Food and Drug Administration, to FSIS and to USDA's ORACBA.

Human Health Effects

Because we were only sent a short summary, it is difficult to evaluate to what extent new information informs the report's findings and conclusions. The copy of the letter to Mr. Billy indicates the summary report is based on an extensive report which "is now subject of editorial amendments and will be available within a few days."

The summary purports to review the potential adverse effects on human health from residues in beef and beef products that include endocrine, developmental and neurobiological, immunological, carcinogenic, genotoxic and immunotoxic effects. The summary concludes that "a risk to the consumer has been identified with different levels of conclusive evidence for the 6 hormones in question," particularly in prepubertal children. Most of the analysis hangs on the case of 17-beta estradiol which is considered by IARC to be a carcinogen.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the data on the same questions earlier in 1999, and concluded that in the case of 17-beta estradiol "the presence of drug residues ... does not present a health concern."

Misuse of Hormones

This report starts with the language and definitions of the SPS Agreement about risk assessment, emphasizing that risk assessment should be "appropriate to the circumstances" but also take into account "available scientific evidence; relevant processes and production methods; and relevant inspection, sampling and testing methods." It then builds the argument that previous scientific assessments of risk to human health from the use of the six hormones assumed that they were

used "in accordance with good animal husbandry practice" which the report equates with "Good Veterinary Practice (GVP)." The report describes risks that could occur from the abusive use of hormones: misplaced implants, other off-label uses, simultaneous multiple implants, and use of black market drugs. It supplies new data from a small EU study of hormone residues from cattle with hormone implants at sites other than the label-designated sites. These data are then used to create three scenarios for potential exposure to different levels of hormones. These levels are compared to the Acceptable Daily Intake (ADI) levels for infants, children, and adults.

The report criticizes both the U.S. and Canadian programs for lack of: control over sales of hormones, veterinary oversight of implantations, and residue monitoring.

The report concludes that there is "evidence that a significant increase in risk is created by the abusive use of the six hormones for growth promotion purposes." It finds that "regulatory controls over residues of hormones in meat introduced into commerce are deficient in the USA and are insufficient in Canada." Utilizing calculations derived from the earlier referenced study of animals receiving "unapproved" implants, the report alleges that food use of these animals could lead to exposures up to "two orders of magnitude greater than the ADIs established by Codex Alimentarius."

Next Steps

CVM and FSIS will review the two documents and prepare talking points to be available on Monday, May 3. Although the letter is addressed to Mr. Billy, it is really FDA's Center for Veterinary Medicine (CVM) which bears major responsibilities for the regulation of the hormones.

ORACBA will provide copies of the documents to a team of USDA and DHHS scientists to review. ORACBA has already identified the members and they have agreed to participate. The group will represent the full breadth of human health and animal health expertise required for these reviews.

FSIS will work with CVM to draft a response to the documents. The cover letter provides 25 days for the response.

Abusive use and difficulties of controls of growth hormones increase risks

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Commission press release 5/3/99

IP/99/290

Brussels, 3 May 1999

Abusive use and difficulties of controls of growth hormones increase risks

There is presently evidence that the abusive use of six growth hormones for growth promotion purposes creates a significant increase in risk. This is the main result of a report by the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) and a draft report on the assessment of risks of hormonal growth promoters in cattle arising from abusive use and difficulties of control. Both reports were made public on Monday and sent to the United States and Canada for comments. Human exposure and risk are in particular increased by the fact that regulatory controls over residues of hormones in meat placed on the market are deficient in the USA and are insufficient in Canada. There is a clear potential for adverse effects on human health arising especially from the presence of residues of these hormones in undetected implantation sites following the misplacement of implants.

Abusive uses can include misplacement of approved implants, off-label uses of hormonal growth promoters, use of multiple implants simultaneously or within very short time intervals and the use of unapproved substances obtained on the black market. In detail, the report points to the following deficiencies :

- In the USA and Canada, approved hormonal growth promoters are freely available over the counter. They can be obtained without veterinary prescription and used without supervision by a veterinarian.
- Although regulations require that implantation be restricted to the animal's ear, it cannot be excluded as examples prove that implantations or injections are also made elsewhere on the animal's body.
- When implantation sites enter the food chain, the exposure and risk to humans increases. For example, a single implantation site can contaminate a batch of 4000 glasses of baby food so much that consuming even one glass would result in a dose to a baby of up to 33 times of what would be acceptable consumption for one day.
- Although hormonal growth promoters are not approved for use in veal calves, recent Canadian surveys showed residues of the synthetic hormone trenbolone in 32-40 % of liver samples from veal calves.
- Although melengestrol acetate is approved for use in heifers only, it has been proven to be applied in US male animals, too.

Growth Hormones in Meat Pose Risk to Consumers Different Levels of Evidence

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EU Commission press release 5/3/99

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Brussels, 3 mai 1999

Growth Hormones in Meat Pose Risk to Consumers Different Levels of Evidence

The use of six growth hormones 17β-oestradiol, progesterone, testosterone, zeranol, trenbolone and melengestrol acetate (MGA) for growth promotion in cattle pose a risk to the consumers, but with different levels of conclusive evidence. This is the main finding of the Scientific Committee for Veterinary Measures relating to Public Health which has unanimously adopted an opinion on potential risks to human health from hormone residues in meat and meat products. The adverse effects include developmental, neurobiological, genotoxic and carcinogenic effects. These effects can be attributed to either the parent compound or the metabolites.

There is substantial recent evidence that the natural hormone 17ß-oestradiol has to be considered as a complete carcinogen, concluded the independent scientists. It exerts both tumour initiating and tumour promoting effects. In plain language this means that even small additional doses of residues of this hormone in meat arising from its use as a growth promoter in cattle has an inherent risk of causing cancer. The data available does not allow a quantitative estimate of the risk. For the other five hormones, particularly for MGA, the currently available information was considered inadequate for a quantitative assessment.

For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged, but the available data do not enable a quantitative estimate of the risk. Even exposure to small levels of residues in meat and meat products carries risks and no threshold levels can be established for any of the six substances, stressed the experts. Of the various risk groups, prepubertal children are the group of greatest concern.

The Committee further emphasised that adequate residue control programs for each of the six hormones is essential to monitor legal and illegal use. It also stated that previous risk assessments relating to the use of these substances disregarded a number of important factors.

17ß-oestradiol, progesterone and testosterone are natural hormones, zeranol, trenbolone and melengestrol are synthetic products. These hormones are authorised for growth promotion purposes in some third countries.

The full scientific report will soon be available on the internet under the following address: http/europa.eu.int/dg24/health/sc/scv/index_en.html

The executive summary is already available.

DRAFT

Talking Points
Hormones in Cattle

Q. What did the EU say on May 1, 1999 about hormones in beef?

A.

Q. Who has responsibility for the regulation of hormones in beef in the United States?

A. As with many other responsibilities, the United States government has chosen to have one group of scientists do the research regarding the use of veterinary substances and drugs in animals, and if the substances are found to be safe that agency sets the standards for use of the drugs in animals. The Center for Veterinary Medicine (CVM) within the Food and Drug Administration (FDA) of the United States Department of Health and Human Services (HHS) is responsible for the research on hormones and for setting standards for their use. They have been setting these standards since 19__.

While animals are on the farm or in a feedlot, the farmer or rancher has responsibility to assure that hormones and veterinary drugs are used properly. The use of drugs or hormones is monitored by FDA.

Industry purchasers of animals have responsibility to require suppliers to provide healthy animals which have not been exposed to hormones or other veterinerary drugs for The propeor number of days and in the proper doses prior to slaughter.

When an animal is presented to a slaughter house for processing, the veterinarian from the Food Safety and Inspection Service (FSIS) within the United States Department of Agriculture (USDA) performs an ante-mortem inspection of the animals, and a post-mortem inspection of the carcasses. When these procedures are performed the veterinarian examines the animal for signs of disease. At post mortem, a statistical sample is taken to test for use of illegal drugs and hormones, and carcasses could reveal the pinpricks and ear piercing through which illegal or excessive doses of the substances may have been applied.

Q. I am confused who has responsibility?

A. HHS does the research and sets the standards and performs the enforcement. USDA examines the animals for evidence of abnormal use and utilizes a statistically based residue testing program That is formulated to provide a 95% assurance that substances will be found if they are used in only 1% of the animals.. The industry is responsible for contractual arrangements for healthy animals and for assuring what the animals contain is within standards.

Q. What are the 6 hormones about which the EU is talking?

A.