World Trade Institute Working Paper

The Perfect Storm: Risk Based Trade Dispute Emergence: the case of *EU-Hormones*

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The present working paper is part of a larger project that is underway to characterize the politics of risk based transatlantic trade conflict. In particular, attention is given to the role of science in the process for trade dispute emergence. This working paper suggests that the role of epistemic communities and scientific evidence played an important role in this context of trade conflict and seeks to chart when, where and how science was influential. As such, the contribution lies in systematically in discussing the interplay between political and economic interests and scientific ideas as a means to attempt to understand how all of these variables matter in risk based trade disputes emergence.

The formal trade dispute over Hormone-fed beef offers an instance where the US and Canada formally challenged European risk regulations. The succeeding section charts the evolution of this case up to the point of launching a formal WTO dispute, with particular emphasis on the interests present and the role of science used to justify the regulations, the forums used and the influence of epistemic communities to try and bring about a resolution. Whilst, these formal disputes have been the centre of much scholarship, there has been little consideration given to the role of science.

Disputing Restrictions on Hormone Fed Beef

In 1996 the US and Canada requested separate WTO dispute settlement panels over the EU ban of beef treated with growth hormones. At its root, this dispute was a challenge to the type of science used to justify policy in the EU. European officials consider growth hormones to be carcinogenic and therefore dangerous to human health. Indeed, the scientific evidence suggests that oestrogen, progesterone, testosterone, zeranol, trenbolone and melengestrol acetate (MGA)

are carcinogenic when present in human and animal tissue at high levels (IARC, 1987).[1] Both Canadian and American officials argue that the EU is ignoring the scientific evidence that demonstrates the safety of the six hormones when present at low levels in hormone treated beef.

The beginning of the trade tensions over growth hormones pre-dates the WTO and the existence of the SPS Agreement. Indeed, the hormones issue is considered the primary reason for the inclusion of the SPS Agreement and its science-based provisions in the Uruguay Round of trade negotiations (Wirth, 1994).[2] As a result, the hormones dispute does not follow the pre-dispute process as articulated in chapter two *per se*. As a Canadian official put it:

> "By 1996 it was quite evident that issue wasn't going to be resolved unless we went to a panel. This explains why we didn't go through the SPS Committee for a representation. In the early days of the SPS committee, STC's weren't really being used (Personal Interview, 2008).[3]"

However, a similar causal story exists in that bilateral consultations featured heavily in the backdrop of requests by Canadian and American private interests to investigate the matter. In the US, Section 301 was used to threaten and initiate retaliation against EU measures. Multilateral negotiations at international standard setting organisations, through the in-house dispute settlement mechanism located within the TBT Agreement and epistemic communities were employed to seek resolution. Only upon the failure of all these efforts and the SPS Agreement coming into force did a formal dispute emerge.

The hormone dispute represents the 'perfect storm' as significant political and economic imperatives were present as well as differing perceptions of what was legitimate scientific evidence. Fundamentally, American and Canadian officials did not believe the EU was using

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[1] International Agency for Research on Cancer. "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. ." In *Overall evaluations of carinogenicity: an updating of IARC Monographs 1-42. Suppl. 7*, edited by World Health Organisation. Lyon, France: WHO:IARC, 1987.
[2] Wirth, David A. "The Role of Science in the Uruguay Round and NAFTA Trade Discipline." *Cornell International Law Journal* 27 (1994): 817-60.
[3] Personal Interview with Canadian Department of Foreign Affairs and International Trade official. Ottawa, November 10, 2008.

science to guide its ban on hormone fed beef. However, this is not the case as the EU did cite a number of scientific studies expounding the risks of these hormones. The present case study examines just what type of scientific ideas were present through looking to what type of evidence was used and who was espousing these in the process leading up to a dispute.

The Political Economy of Beef

Concern in the EU over the use of hormones in meat production arose as a result of a series of health scares connected to the illegal use of growth hormones. At the time, the EU lacked a harmonized regulatory approach for hormones in meat. In 1977, a group of northern Italian school children exhibited signs of premature development. Despite no confirmation or definitive evidence of possible illegal hormone use, the media focused on meat in school lunches as the source (Kramer, 1989).[4] In 1980, numerous samples of veal in baby food tested positive for illegal growth hormone diethylstibersol (DES), a synthetic hormone used in animal feed (Roberts, 1998:386).[5] Such events caused serious public concern and motivated EU institutions, particularly the European Parliament, to take action (Josling *et al.,* 2009).[6] Given that EU member states all maintained differing policies and failed attempts at community harmonization, the only way to achieve a community-wide policy was to ban the use of hormones outright.

However, banning hormones also maintained an economic incentive. In 1994 a Court of Auditors report in the EU noted:

> "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

[4] Kramer, Carol S. "Food Safety and International Trade: The US-EC Meat and Hormone Controversies." In *The Political Economy of US Agriculture*, edited by Carol S. Kramer. Washington: National Center for Food and Agricultural Policy, Resources for the Future, 1989.
[5] Roberts D. "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations." *Journal of International Economic Law.* 1998. p. 386
[6] Josling, Tim, Donna Roberts, and Ayesha Hassan. 2009. *The Beef-Hormone Dispute and its Implications for Trade Policy: Working Paper*. Standford University 1999 Retrieved on July 24 2009 from http://iis-db.stanford.edu/pubs/11379/HORMrev.pdf.

> disposed of every year on the world markets has, over the past ten years, represented on average about 6% of Community production, which is tending to grow at slightly less than 0.5% a year (Court of Auditors, 1994:11).[7]"

As well, hormones were connected to the competitive advantage of North American beef (Lister, 1996:303,306).[8] As the EU was phasing out the use of subsidies officials sought to lessen competition of cheaper beef coming from North America (Ibid).[9]

In the US, the use of growth hormones is an accepted practice, dating back to 1956 when the FDA first approved them for use. When the EU ban came into place in 1989, it was estimated cost the industry approximately $250 million/year in lost exports (Vogel, 1997).[10] This was unacceptable to a politically powerful beef industry. The American Cattleman's Association was active in promoting action and mobilized a group of US politicians from states with significant beef interests to encourage President Reagan to take trade action under Section 301 (Devereaux *et al.,* 2006).[11]

In Canada, the use of hormones in beef production was also considered accepted practice. Health Canada deemed the use of the three natural hormones and two of the synthetic varieties to pose no threat to human or animal health (Health Canada, 2009).[12] Exports of beef to the EU were estimated to be worth CDN $75 million/year (Breuss, 2004:283).[13] The ban affected the Canadian beef industry significantly with officials arguing that by January 1989, exports of beef

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[7] Court of Auditors. "Special Report No 3/94 on the Implementation of the Intervention Measures Provided for by the Organisation of the Market in Beef and Veal." *Official Journal of the European Communities* C356, no. 1 (1994): 11.
[8] Lister, Charles. "A Sad Story Told Sadly: The Prospects for U.S.-EU Food Trade Wars." *Food and Drug Law Journal* 51 (1996): 303,306.
[9] Ibid.
[10] Vogel, David. *Barriers or Benefits*: Brookings Institution Press, 1997.
[11] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006.
[12] Health Canada. "Hormonal Growth Promoters." edited by Health Canada Drugs and Health Products. Ottawa: Government of Canada, 2009. Retrieved on September 11, 2009 from www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/hormon/index-eng/php
[13] Breuss, Fritz. "WTO Dispute Settlement: An Economic Analysis of Four EU-US Mini Trade Wars - a Survey." *Journal of Industry, Competition and Trade* (2004): 283

to the EU had suffered a 72% decline (WTO, 1997: para 77).[14] Prior to the implementation of the EU ban the Canadian Cattleman's Association and the Canadian Beef Export Federation, which represent many beef farmers from rural and farming constituencies, were vocal in calling for Canadian trade officials to investigate and attempt to resolve differences with the EU (Personal Interview, 2008).[15]

Another factor that contributed to American and Canadian interest in the case was the threshold that accepting the ban would set in the multilateral trading system for erecting regulatory barriers to trade (Shunder, 1989).[16] At the time, the WTO and the SPS Agreement were fledgling institutions stemming from the Uruguay Round of trade negotiations. These new institutions were largely untested and there was concern that by allowing the EU measures to go unchallenged, the international trading system and the science-based provisions of the SPS would be undercut. US Agriculture Secretary Yeutter noted, "[i]f we permit [the hormones ban] to occur, in the [EU] or elsewhere, then we've opened up a gigantic loophole in the GATT which will result in major impediments to agricultural trade throughout the world for years to come" (Dunne, 1989:D6).[17] As a result, it appears that science or the perception that the ban lacked any scientific basis was a factor in the decision-making process to launch a trade dispute for officials in North America.

The Risks of Hormones

The scientific debate over the risks of hormones such as estradiol, progesterone, testosterone, zeranol, trenbolone and MGA is portrayed by the EU as a contentious issue amongst scientists. However, the science when addressing the probable risks associated with consuming hormone fed beef is by and large consistent. Since the hormone issue emerged back in the early eighties numerous studies have been conducted trying to establish if there is a link between hormone fed beef and carcinoma. All, except two studies published in 1999 (after the Appellate Body ruled

[14] *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R (1997) para. 77.
[15] Personal Interview with Canadian Department of Foreign Affairs and International Trade official. Ottawa, November 10, 2008.
[16] Shunder, Janet. "Beef Hormone Dispute." Harvard Business School Case no.9-590-035, Rev. 12/89, 1989.
[17] Dunne, Nancy. "Phony Peace Breaks out in US-EC Clash over Farm Trade." *Financial Times*, April 27 1989, D6.

against the EU) have argued that there is no evidence supporting the notion that growth hormones are a risk at the levels present in cattle or beef (Joint FAO/WHO Expert Committee on Food Additives, 1999).[18] The two dissenting studies concurred with the supporting studies in terms of the scientific evidence and the probability of risk being low but considered that given there is a *potential* carcinogenic effect from their presence, it was best to limit exposure (Adnersson and Skakkeback, 1999; Scientific Committee on Veterinary Measures Relating to Public Health, 1999).[19] This determination is not a scientific one, or not one that was based on the scientific evidence, but rather a public policy position. Indeed, the two dissenting studies were conducted and published in the EU, one by a EU scientific committee.

The principal argument forwarded by the EU in the hormones dispute is that estradiol and testosterone cause cancer in hamsters and rats therefore there is the possibility of the hormones might be carcinogenic in humans (Liehr, 1995).[20] But this argument is the same as saying that sugar in high concentrations is carcinogenic and therefore we should not consume sugar. This type of study has been extrapolated to suggest a risk to consuming hormone fed beef when really it has only demonstrated that the hormones are carcinogenic. No consideration was given to the threshold at which point the hormones become carcinogenic or if it was possible for the hormones to be passed through the hormone fed meat. This is an important consideration as estradiol, progesterone and testosterone are hormones naturally present in the body. Their presence varies depending on the age, sex, diet, exercise and stage in the reproductive cycle. Their mere presence does not result in cancer.

The six hormones do present a carcinogenic risk to human health but only at levels 750 times greater then normal levels, which could not possibly be achieved through consuming hormone

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[18] Joint FAO/WHO Expert Committee on Food Additives. 1999. Summary and Conclusions of the Fifty-Second Meeting. Rome. 2-11 February 1999.

[19] Andersson, A.M., and N.E. Skakkebaek. "Exposure to Exogenous Estrogens in Food: Possible Impact on Human Development and Health." *European Journal of Endocrinology* 140, no. 6 (1999): 477-85. Scientific Committee on Veterinary Measures Relating to Public Health. "Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health: Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products. XXIV/B3/SC4." edited by Consumer Policy and Consumer Health Protection: European Commission, 1999.

[20] Liehr, J.G. "Induction of DNA Adduct Detectable by 32p-Post Labeling in the Dorso Lateral Prostate of Nbl/Cr Rats Treated with Oestradiol-17ß and Testosterone." *Carcinogeneis* 16 (1995): 951-54.

fed beef over a lifetime (IARC, 1997: para 8.150).[21] For example, it has been observed that estradiol stimulates cell division in hormonally sensitive tissue thereby increasing the chance for mutation to occur and for tumours to develop (Henderson and Feigelson, 2000).[22] High levels of testosterone have been linked to prostatic cancer in men but there is no empirical, theoretical, or correlative evidence suggesting that eating meat from hormone fed animals creates high enough levels of circulating hormones (IRARC, 1987; Henderson and Feigelson, 2000; Doyle, 2001).[23] There is a hypothetical possibility suggesting that it is possible for hormone residues in cattle to persist, be transferred and accumulate in meat eating consumers as suggested through the Italian school children issue. But the fact is that no scientific study to date has been able to demonstrate that residues occur at a significant enough level or that bioaccumulation happens from eating this sort of meat. It has been established, that when introducing natural growth hormones orally, there is a low amount of residue with the rest mostly being washed out of the body (Doyle, 2001:6).[24] Evidence also exists for synthetic hormones suggesting they are excreted within seventy-two hours after consumption and maintain no detectable signs in the body (Pottier *et al.,* 1981; Spranger and Metzler, 1991; Doyle, 2001).[25]

Science in Disputing the Fattened Calf

In the aftermath of the health scares connected to the illegal use of growth hormones in beef, public opinion was against the use of growth hormones in meat. As a result, the European Council was under pressure to prohibit their use. After much debate, Directive 81/602/EEC was

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[21] International Agency for Research on Cancer. "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. ." In *Overall evaluations of carinogenicity: an updating of IARC Monographs 1-42. Suppl. 7*, edited by World Health Organisation. Lyon, France: WHO:IARC, 1987. *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para. 8.150.

[22] Henderson, B.E., and H.S. Feigelson. "Hormonal Carcinogenesis." *Carcinogeneis* 21, no. 3 (2000): 427-33.

[23] Ibid. International Agency for Research on Cancer. "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. ." In *Overall evaluations of carinogenicity: an updating of IARC Monographs 1-42. Suppl. 7*, edited by World Health Organisation. Lyon, France: WHO:IARC, 1987. Doyle, Ellin. "Human Safety of Hormone Implants Used to Promote Growth in Cattle: A Review of the Scientific Literature." In *FRI Briefings*, edited by Food Research Institute. Madison, WI: University of Wisconsin, 2001.

[24] Ibid. p.6.

[25] Pottier, J., C. Cousty, R.J. Heitzman, and I.P. Reynolds. "Differences in the Biotransformation of a 17 Beta-Hydroxylated Steroid Trenbolone Acetate, in Rat and Cow." *Xenobiotica* 11, no. 7 (1981): 489-500. Spranger, B., and Metzler M. "Disposition of 17 Beta-Trenbolone in Humans." *Journal of Chromatography* 564, no. 2 (1991): 485-92. Doyle, Ellin. "Human Safety of Hormone Implants Used to Promote Growth in Cattle: A Review of the Scientific Literature." In *FRI Briefings*, edited by Food Research Institute. Madison, WI: University of Wisconsin, 2001

adopted in 1981 banning the use of growth hormones in beef production. The issue was contentious amongst the fifteen member states with Belgium, Ireland and the UK disagreeing with an outright ban. As a compromise, member states agreed to delay a ban and set up a working group to conduct a scientific review of the effects of these hormones on human health (European Council, 1981:31-32).[26] The European Economic Community Scientific Working Group on Anabolic Agents (Lamming Group) begun work assessing the risk to human health and reported back in 1982.

> "The Scientific Working Group is of the opinion that the use of oestradiol-17B, 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." "Evaluation of data on trenbolone and zeranol reveal that some data on the hormonal non-effect level and the toxicology of these compounds and their metabolites are still missing. The scientific working group considers it necessary that additional information be provided before a final conclusion can be given on trenbolone and zeranol. Proper programmes to control and monitor the use of anabolic agents are essential. It is necessary to continue scientific investigations on the relevance of the present use of the no-hormone effect level related to the harmful effects of anabolic agents" (Lamming, 1982).[27]

It appears that members of the Lamming Group did not believe the hormones posed much of a risk under strict monitoring and controlled conditions but that more research should be conducted to fill the informational gaps. The results of the Lamming Report were widely supported within the EU by three Scientific Committees (Veterinary, Animal Nutrition, and Food) and internationally by the OIE. In fact, in 1983 the OIE held a scientific symposium on

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[26] European Council. "Council Directive 81/602/EEC of 31 July 1981 Concerning the Prohibition of Certain Substances Having a Hormonal Action and of Any Substances Having Thyrostatic Action." *Official Journal of the European Communities* L 222, no. 7.8.1981 (1981): 32-33.

[27] Lamming, G.E. "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." 1982.

anabolics in animal production and concluded:

> "Hormones *generally* pose no cancer risk where exposure is to levels below those required for detectable hormonal activity…Mutagenicity and carcinogenicity test data for trenbolone and zeranol suggest that these agents and their metabolites are neither mutagenic nor clastogenic and that they would only influence cancer risk – either increase it or decrease it – if there was exposure at hormonally effective levels…Therefore, in judging whether it is safe to use trenbolone or zeranol as anabolic agents in meat production the emphasis needs to be on making sure that any residue of these agents in meat are below the levels that could have any hormonal effect on the meat-eater…" (Roe, 1983:339).[28]

The European Commission took the overarching opinions of the reports to be definitive evidence of safety and developed a proposal to amend Directive 81/602/EEC and allow the use of the growth hormones. In the final draft of COM(84) 295 three conditions were set out for the use of hormones that followed the recommendations of the Lamming Group and the OIE: 1) implantation would only occur in a part of the animal discarded at slaughter; 2) treated animals would be identified; and 3) implants had to be administered by a veterinarian. However, both the European Parliament and Council of Ministers rejected the proposal as they considered the results of the report to be far from definitive and questioned the validity of their outcomes. For example, concerns about the safety of the other five hormones remained, especially when mixed together, as the traits of only trenbolone and zeranol had been considered. In addition, the level at which the hormones became "effective" or carcinogenic had not been determined (European Parliament, 1985:158).[29]

So, EU member states and representatives in the Parliament believed that using the empirical evidence available for two of the synthetic hormones to infer safety across the other four hormones, which were similar in properties and effect, was not an appropriate basis for policy development. Indeed, questions surrounding these two issues remained and were considered by

[28] Roe, F.J.C. Anabolics in Animal Production. In *Symposium held at the OIE*. Paris. 15-17 February 1983. P.339.
[29] European Parliament. Doc. A2-100/85. *Official Journal of the European Communities* C288 (1985):158.

scientists at the OIE and Lamming Group. But these matters were not believed to be significant, as the hormones were never used in conjunction with each other and all maintained similar properties. As a result, it was believed that uniformity across the hormones could be theoretically implied from the information that existed.

In light of the concerns about the validity of the scientific claims, Kerr and Hobbs (2002:289) highlighted how the European Parliaments' Social and Economic Committee also advocated for a "fourth pillar" to be taken into account in regulation and that was social and economic factors.[30] Professor Lamming purported this was the real source of the European Parliaments rejection of the use of growth hormones:

> "The British Minister has claimed, and rightly so, that [EU Agriculture Commissioner] Andriessen freely admits that the scientific background or scientific considerations 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 that 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 increase production of European beef and that probably motivated them more than the scientific background" (Lamming, 1986:11).[31]

In light of the opposition from the European Parliament and member states, the European Council approved Directive 85/649/EEC in 1985 prohibiting the use in livestock farming of certain substances having hormonal action. The Directive indicated that by January 1st 1988 that three natural hormones: oestradiol 17ß progesterone and testosterone, and three synthetic hormones: zeranol, trenbolone and MGA would be banned from use.

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[30] Kerr, William A., and Jill E. Hobbs. *The North American-European Union Dispute over Beef Produced Using Growth Hormones: A Major Test for the New International Trade Regime*: Blackwell Publishers Ltd., 2002. P.289.
[31] Lamming, G.E. "Anabolic Growth Promotants and the EEC." Paper presented at the Technical Services Centre, Kingston, ACT, 29 April 1986 p.11.

After receiving concerns from the American and Canadian Cattlemen's Associations, officials from the US and Canada engaged in informal bilateral consultations with their European counterparts on this issue. American officials set up a four person negotiating team that included scientists and trade diplomats to try and resolve the matter (Devereaux *et al.,* 2006).[32] In Canada, a team of negotiators was assembled including members from External Affairs and Health Canada (Personal Interview, 2008).[33] Consultations with both parties focused on the nature and presence of oestradiol, progesterone and testosterone in everyday goods like soybeans, cherries, green beans, alfalfa, palms and licorice. It was also noted that they were present in hens eggs at 1000 times higher concentration than in an implanted steer (Riboleau, 1983).[34] Whilst it was agreed that more research should be done, it was believed that enough information existed about the characteristics of the hormones under question to make judgments on their safety.

Canadian and American officials recognizing the political problems in the EU over the regulation of risk issues, decided to coordinate strategies for trying to bring about change (Personal Interview, 2008).[35] Key to this was shifting the debate into the *Codex*. American and Canadian officials were worried that there was too much opportunity for non-scientific factors to influence the EU policy-making process. Thus, it was determined if the *Codex* Committee on Residues of Veterinary Drugs in Food (CCRVDF) could be formed it would be the best way to develop an international standard based on science and achieve a resolution. Committee chair, Lester Crawford from the USDA believed that it was crucial from the American perspective that the CCRVDF recommend the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to consider the safety of the hormones as it would focus on the science. In commenting on the process for electing the chair for the CCRVDF, Crawford noted that there was a strong belief that "…had the vote gone the other way [that is, electing a European chair], there could have

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[32] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. 2006. *Case studies in US trade negotiation*. 2 vols. Washington, DC: Institute for International Economics.
[33] Personal Interview with Canadian Department of Foreign Affairs and International Trade official. Ottawa, November 10, 2008.
[34] Riboleau, J. 1983. Teneuren substances oestrogènes de l'oeuf faconde des pietaux. *Comptes Rendus des séances de la Societe de Biologie*:129-914.
[35] Personal Interview with Canadian Department of Foreign Affairs and International Trade official. Ottawa, November 10, 2008.

been a lot of trouble for the US" (Devereaux *et al.,* 2006:45).[36]"

During the work of JECFA a series of studies were released which raised competing information about the effect of the hormones on human health and animal welfare. In 1985, a study reviewing the toxic effect of zeranol and oestradiol 17ß acknowledged that whilst it was "virtually impossible to visualize any hazard to humans ingesting meat from animals…unlawful and improper use of oestrodial might result in residue levels some 300 fold in excess of established tolerance limits" (Truhaut *et al.,* 1985).[37] Another indicated that zeranol was an unlikely threat to human health even in limited contexts of abuse due to safety margins applied to its use.[38] Conversely, in 1986, Liehr et al, released their study on hamsters.[39] Liehr (1986) would subsequently come to play an important role as a scientific expert in the WTO dispute. His claims of carcinogenicity were criticized by other scientists advising the panel as being way more than the comparable average daily production rate in men (WTO, 1997: para 8.150).[40] In respect to animal welfare, one study provided correlative evidence showing that offspring of heifers treated with MGA had increased deformities (Herenda, 1987:33-36).[41]

The most influential of the emerging scientific reports on the EU was the study released by the International Agency for Research on Cancer (IARC). In 1987 the IARC classified steroidal oestrogens (including oestrodial) as carcinogenic to humans; andogenic steroids such as testosterone as *probably* carcinogenic to humans; and progestins as *possibly* carcinogenic to humans. The report primarily relied upon epidemiological evidence to infer the cancer risks of these anabolic steroids. For example, testosterone was involved in prostatic cancer growth based on "a number of epidemiological observations… testosterone levels may increase the risk for

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[36] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. 2006. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics. p.45

[37] Truhaut, R., P. Shubik, and Tuchmann-Duplessis H. "Zeranol and 17 Beta-Estradiol: A Critical Review of the Toxicological Properties When Used as Anabolic Agents." *Regulatory Toxicology and Pharmacology* 5, no. 3 (1985): 276-83.

[38] Sundlof, S.F., and C. Strickland. "Zearalenon and Zeranol: Potential Residue Problems in Livestock." *Veterinary and Human Toxicology* 28, no. 3 (1986): 242-50.

[39] Liehr, J.G., T.A. Avitts, E. Randerath, and K. Randerath. 1986. Estrogen-induced endogenous DNA adduction: Possible mechanisms of hormonal cancer. *Proceedings of the National Academy of Sciences of the United States of America* 83:5301-5305.

[40] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para. 8.150.

[41] Herenda, D. "An Abattoir Survey of Reproductive Organ Abnormalities in Beef Heifers." *Canadian Veterinary Journal* 28 (1987): 33-36.

prostatic cancer…" (IARC, 1987:96-97).[42] Oestrogen "…[showed] a consistent, strongly positive [correlative] association between exposure to a number of oestrogenic substances and risk of endometrial cancer, with evidence of positive dose-response relationships both for strength of medication and duration of use" (Ibid:280).[43]

JECFA reviewed work of IARC in 1988 and determined that the results did not suggest a threat from hormone fed beef as IARC did not consider risk at the low levels of residue (Joint FAO/WHO Expert Committee on Food Additives, 1988:20-21).[44] In addition, the IARC study was in no way designed to assess human cancer risks resulting from oral ingestion of low doses of oestradiol 17ß as real life like conditions were not followed. It appears that the principle objective of the study was to produce tumours experimentally and draw a correlation with the presence of a hormone as opposed to determine the safety of the quantity of the hormones used for growth purposes. Indeed, IARC used extremely high dosages that were considered inadequate because the conditions were not realistic for determining carcinogenicity" (Ibid).[45]

American officials considered that "the operating principle [of the IARC study] was to determine the ability of the chemical to produce cancer or other genetic and related effects without the strictures of mode of human use or the magnitude of the doses" (IARC, 1987:272).[46] It was argued that it was not possible to extrapolate risk using a high-to-low does or linear extrapolation as it was not a general principle of toxicology or pharmacology but was instead one model used to explain experimental observations. American officials thought that more was needed to establish when or at what point these hormones became carcinogenic, like a threshold model (WTO, 1997: para 8.135).[47]

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[42] International Agency for Research on Cancer. 1987. IARC monographs on the evaluation of carcinogenic risks to humans. . In *Overall evaluations of carinogenicity: an updating of IARC Monographs 1-42. Suppl. 7*, edited by World Health Organisation. Lyon, France: WHO:IARC. pp. 96-97

[43] Ibid.p.280

[44] Joint FAO/WHO Expert Committee on Food Additives. 1988. Residues of some veterinary drugs in animals and foods. Estradiol. *FAO Food and Nutrition Paper* 41:17. Joint FAO/WHO Expert Committee on Food Additives. 1988. Residues of some veterinary drugs in animals and foods. Progesterone. *FAO Food and Nutrition Paper* 41:20-21

[45] Ibid. pp.1-47.

[46] International Agency for Research on Cancer. 1987. IARC monographs on the evaluation of carcinogenic risks to humans. . In *Overall evaluations of carinogenicity: an updating of IARC Monographs 1-42. Suppl. 7*, edited by World Health Organisation. Lyon, France: WHO:IARC. P.272.

[47] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para. 8.135

So, it appears that the question of whether or not the hormones were carcinogenic was not at issue, it was rather at what point they become carcinogenic and if hormone fed beef was a threat. Both Canadian and American officials argued that internationally accepted thresholds existed, confirming the safety of hormone fed beef but that an international standard was necessary. Officials from North America advocated that EU officials wait for the results of the JECFA review before implementing the ban. However, EU policy-makers considered the correlative evidence as definitive proof that these hormones represented a threat to human health and in bilateral consultations advocated that both the US and Canada implement a ban (Daily Bulletin, 1987:10)[48] The EU request was rejected outright and the American beef industry filed a Section 301 petition with the USTR (U.S.C, 1974).[49]

For American officials, Section 301 was a means by private interests to force action on the pending EU measure. Whilst, the EU ban had not come into force, the beef industry was concerned that the deadline was fast approaching and no resolution was in sight. In reaction, the USTR did not immediately proceed with taking unilateral action, instead requested multilateral consultations and investigation under Article 14.1 of the TBT Agreement (also called the Standards Code) in October of 1987 (USTR, 1987).[50] This was a clear signal by American officials that unless an informal resolution was achieved, a GATT panel would be sought (Meng, 1989).[51] A panel of experts was requested to consider the matter but was rejected by the EU, who argued that more bilateral consultations should come first (Daily Bulletin, 1987:8).[52] Frustrated with the process, American officials threatened to retaliate under Section 301 unless a panel of experts was formed or that a delay in the ban was implemented (International Trade Reporter, 1987).[53]

The American and Canadian positions were assisted on October 24, 1987 when Professor

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[48] No.4587. 1987. *Daily Bulletin*, July 10, 10.
[49] 19 U.S.C. § 2411 (1974)
[50] Office of the United States Trade Representative. "Unfair Trade Practices; European Community Hormone Directive." *The Federal Register* 52 [FR 45304] (1987).
[51] Meng, Werner P. 1989. The Hormone Conflict Between the EEC and the United States Within the Context of GATT. *Michigan Journal of International Law* 11:819-839.
[52] No.4636. 1987. *Daily Bulletin*, October 10, 8.
[53] 4 Int'l Trade Rep. (BNA) 1184 (Sept 30, 1987)

Lamming published an account of further work undertaken on zeranol and trenbolone indicating they would probably be safe when used in accordance with "accepted husbandry practice" (Lamming, 1987:389).[54] Canadian officials supported the findings of this report stating that it was unequivocal in that "the levels of trenbolone and zeranol and their major metabolites found in edible tissue, following accepted husbandry practices are substantially below the hormonally effective doses in animal tests and therefore do not present a harmful effect to health" (Ibid).[55] Canadian officials also noted that Lamming had examined all the studies available and none of the sources used by the EU had determined with any degree of quantitative likelihood that at the levels used for growth promotion in cattle posed a risk to human health. In particular none had empirically or theoretically verified that they would cause cancer in humans consuming meat containing the residue of such hormones (WTO, 1997: paras 50-52).[56] Indeed, little evidence existed establishing that hormones left residues in meat, at all.

EU officials disagreed with the Canadian position and argued that the term "accepted husbandry practice" had not been defined (Scientific Working Group on Anabolic Agents, 1987).[57] Furthermore, the report called for monitoring and control systems but did not articulate what these should look like. It was apparent that EU officials were avoiding dealing with the emerging scientific consensus in light of the lack of consensus amongst member states. Spain, Belgium, Greece and Ireland all opposed the use of hormones, whilst France, Denmark and the UK advocated for a delay in the implementation of the ban. On November 18, 1987 the EU Council agreed to delay implementing the proposed ban for one year until January 1, 1989 (European Council, 1987; International Trade Reporter, 1987).[58]

Whilst, the move temporarily appeased Canadian and American concerns, it was only meant to buy more time for more negotiations and scientific research to occur. In an attempt to increase

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[54] Lamming, G.E. 1987. Special Report: Scientific Report on Anabolic Agents in Animal Production. *Veterinary Record* October 24:389.
[55] Ibid.
[56] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS48/R/CAN (1997) paras 50-52.
[57] Scientific Working Group on Anabolic Agents. 1987. Scientific Report on Anabolic Agents in Animal Production. *Veterinary Record* 121 (17):389-392.
[58] European Council. "Council Decision 87/561/EEC on Transitional Measures Concerning the Prohibition of Certain Substances." *Official Journal of the European Communities* 30, no. L339 (1987). 4 Int'l Trade Rep. (BNA) 1453 (Nov 25, 1987)

the stakes and to demonstrate to the American beef industry that the government was taking this issue seriously, the USTR published a list worth $100 million of European products that would be retaliated against for implementing the proposed ban (International Trade Reporter, 1988).[59] Whilst, the list angered the European negotiators they did not immediately react as there were internal events in the EU that served as a distraction.

In 1988, the ECJ voided the Directive on hormones after a compliant from the UK and Denmark highlighted the use of an incorrect voting procedure in establishing the ban (Covey *et al.,* 1988).[60] This action provided a perfect opportunity for the EU to back down over the hormone measures without loosing any face domestically or on the international stage. However, a matter of weeks later, the European Council revisited the issue and reinstated the ban (European Commission, 1988:16-18).[61] Such a move was confounding to North American officials who realized that at this stage informal bilateral negotiations were not moving the issue closer to resolution. The discovery of 15,000 illegally injected calves and an underground network of veterinarians giving hormone injections in Belgium and the Netherlands in August 1988 did not help matters or improve EU negotiating flexibility (Devereaux *et al.,* 2006:48).[62] In this context, there was extreme political pressure on EU and member state officials to remain firm on its ban.

The European Parliament established a "Committee of Enquiry into the Problem of Quality in the Meat Sector" (also referred to as the Pimenta Report). The Pimenta Report was released in 1989 and endorsed the ban as it would: restore consumer confidence, as ten out of twelve national veterinary experts argued that a ban would best facilitate control of hormone usage, and the strict conditions for use of the hormones advocated by the science were not realistic. The report went on to note:

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[59] 5 Int'l Trade Rep. (BNA) 16 (Jan 6, 1988)
[60] Covey, T.R., D. Silvestre, M.K. Hoffman, and J.D. Henion. "A Gas Chromatographic/Mass Spectrometric Screening, Confirmation, and Quantification Method for Estrogenic Compounds." *Biomedical and Environmental Mass Spectrometry* 15, no. 1 (1988): 45-56.
[61] European Commission. "Council Directive 88/146/EEC of 7 March 1988 Prohibiting the use in Livestock Farming of Certain Substances having a Hormonal Action." *Official Journal of the European Communities* L 70, no. 16.3 (1988): 16-18.
[62] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006.p.48.

> "…the scientific evidence does not address the question of *potential* interaction of these substances with other substances or the multiplier effect of these substances with other hormones to an animal with an already high level of endogenous hormones and the ingestion of the meat (or milk) of that animal by a female taking the oestrogen-based contraceptive pill" (Pimenta Report, 1989:6).[63] [*emphasis added*]

To American and Canadian officials, the Pimenta Report was nothing but a political exercise that did not assess the probability or likelihood of risk associated with hormone usage but talked about unsubstantiated hypothetical possibilities. However, this highlights a different set of ideas around what sort of scientific evidence is considered legitimate in the EU. As a result, in November the USTR formally threatened to retaliate under Section 301 (International Trade Report, 1988).[64] In response the EU offered to exclude pet food from the ban and increase the quota for high quality beef (so called, Hilton quota). The US indicated that it would only reduce the retaliation by the amount of pet food and high quality beef exported but would not eliminate retaliation all together (International Trade Daily, 1988).[65]

Canadian officials during this period continued with bilateral negotiations and did not threaten unilateral retaliation. Given the amount of trade and the relative economic size of Canada, acting unilaterally was not a viable option. Indeed, the emphasis for Canada focused more on the Uruguay Round trade negotiations and the inclusion of science based provisions in the SPS Agreement.

In a sign of the EU Commissions efforts to resolve the matter a compromise was proposed. A memorandum was drafted for signature indicating that the hormone fed beef in North America was done for therapeutic reasons only. This would have been a way for both Canada and the US to circumvent the ban as therapeutic use of hormones in cattle was permitted within the EU legislation. However, this was not viable as the American Meat Institute President, Len Condon

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[63] European Parliament. "Report Drawn up on Behalf of the Committee of Inquiry into the Problem of Quality in the Meat Sector." edited by Mr. Carlos Pimenta, 1989. P.6.
[64] 5 Int'l Trade Rep. (BNA) 1447 (Nov 2, 1988)
[65] Int'l Trade Daily (BNA) 9-10 (Nov 23, 1988)

noted:

> "[w]hen hormones are used therapeutically, they are primarily used for reproduction purposes, synchronization of estrus for example. We said…50% of the animals we give hormones too and slaughtered are steers, so how could we claim we're using hormones therapeutically for these animals?" (Devereaux *et al.,* 2006:48)[66]

Before the ban came into effect on January 1, 1989 JECFA released its review of the current ADI and MRLs for the hormones in question. JECFA based its position on the empirical evidence available. For example, it was noted that oestradiol 17ß studies showed that oral and parenteral administration of oestradiol 17ß can increase incidence of tumours and that tumours did occur in tissues with high levels of specific hormone receptors. However, the Committee concluded that the carcinogenic response was related to the hormonal activity of oestradiol 17ß at levels considerably higher than those required for a physiological response (Joint FAO/WHO Expert Committee on Food Additives, 1988).[67] The same conclusions were also made for progesterone, testosterone, trenbolone acetate and zeranol (Ibid: 18-28).[68]

Thus, JECFA argued that no ADI or MRLs for oestrodial needed to be established. Residue levels after treatment with oestradial were shown to be at or within normal physiological limits. The JECFA compared the lowest human daily production rate of oestradiol as observed in prepubertal boys (6 μg/d) against the amount of oestradiol that humans theoretically will be exposed to through ingestion and considered the risk as biologically insignificant and virtually incapable of exerting a hormonal effect in human beings. The EU considered this to be unacceptable as oestradiol was a proven carcinogen therefore thresholds needed to be set. The US disagreed with the EU position arguing that there was no scientific evidence to support the

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[66] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006p.48.
[67] Joint FAO/WHO Expert Committee on Food Additives. "Residues of Some Veterinary Drugs in Animals and Foods. Estradiol." *FAO Food and Nutrition Paper* 41 (1988): 7-17..
[68] Joint FAO/WHO Expert Committee on Food Additives. "Residues of Some Veterinary Drugs in Animals and Foods. Progesterone." *FAO Food and Nutrition Paper* 41 (1988): 18-23. Joint FAO/WHO Expert Committee on Food Additives. "Residues of Some Veterinary Drugs in Animals and Foods. Testosterone." *FAO Food and Nutrition Paper* 41 (1988): 24-28..

claims (WTO, 1997: 8.161).[69]

The report from JECFA, despite considering all the available scientific information, had little effect on the European position. On January 1, 1989 EU Directive 88/146/EEC came into effect banning the importation of hormone fed beef. EU officials maintained that the assessment of the effect of these hormones on human health was varied justifying prohibition. Immediately, the US unilaterally retaliated focusing on EU pork products, canned tomatoes, fruit juices, fermented drinks, packaged pet foods and instant coffee. These products mainly came from Denmark, Italy and Spain (Devereaux *et al.,* 2006:50-51).[70] The EU protested against the unilateral approach and sought to bring a GATT case against the US (Daily Bulletin, 1989:7).[71] This effort was blocked from moving forward as it was not so much about standards as opposed to health and safety, which is outside of the provisions of the TBT Agreement. At this stage, the SPS Agreement negotiations were still underway and not completed. At an impasse, American and EU officials agreed to a seventy-five day cooling off period where no more tariffs or threats would be made (Meng, 1989).[72] An US-EU Task Force was set up to deal with the problem but made little progress as the parties were just too far apart in their positions (Devereaux, *et al.,* 2006:53-54).[73]

In the period of 1990 to 1994 American and Canadian officials focused on completing the Uruguay Round of trade negotiations which included the SPS Agreement. Despite the controversy over the hormones issue, the SPS negotiations went smoothly and the inclusion of the science-based provisions in the final agreement were accepted without controversy. It appears that EU officials did not consider the SPS Agreement to be a political priority rather focusing on the *Codex* process for developing international standards for the natural and synthetic hormones. Deveraux et al., contend that this was due to the fact that the European Parliament was not involved in the trade negotiation as it had no authority to intervene whilst it

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[69] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para. 8.161
[70] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006 pp. 50-51
[71] No.5104. 1989. *Daily Bulletin*, October 5:7.
[72] Meng, Werner P. "The Hormone Conflict between the EEC and the United States within the Context of GATT." *Michigan Journal of International Law* 11 (1989): 819-39.
[73] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006 pp.53-54.

did for public health issues (Ibid:58).[74]

In 1991, despite an extensive review of the relevant science the *Codex* process was put on hold (ALINORM, 1985).[75] This was after an open vote of the *Codex* membership. It has been argued that the hold occurred because a secret ballot was not called for in the vote on accepting the new international standards (Devereaux *et al.,* 2006:60).[76] The logic flows that by having an open vote, the EU was able to exert enough political pressure on smaller states dependent upon access to EU markets, preventing the supporters of hormone fed beef succeeding (Ibid).[77]

Regardless of whether or not the political influence of the EU mattered, it is apparent that officials were able to convince a majority of the members of the necessity to take more time to consider the use of growth hormones. This was in light of support for the international standard by such interest groups as the World Federation of the Animal Health Industry and the international federation representing manufacturers of veterinary medicines, vaccines and other products (Codex Alimentarius Commission, 1991: paras 155-59).[78]

Indeed, a number of scientific studies were released in the immediate aftermath of the *Codex* vote that challenged the safety of growth hormones. For example in 1992, Roy and Liehr observed that oestradiol promoted kidney tumour growth in hamsters.[79] Another paper inferred that carcinogenic effect of oestrogens is a result of hormonal characteristics and their conversion to catechol metabolites (Zhu *et al.,* 1993).[80] Legoshin et al., (1994) observed that there was a correlation between using zeranol and the behaviour of bulls… "spent more time idling, eating

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[74] Ibid P.58
[75] ALINORM 91/31 Appendix IV, as adopted by the 21st session of the Codex Alimentarius Commission. Rome, 2-8 July 1985.
[76] Devereaux, Charan, Robert Z. Lawrence, and Michael Watkins. *Case Studies in US Trade Negotiation*. 2 vols. Washington, DC: Institute for International Economics, 2006 p.60.
[77] Ibid p.60.
[78] Codex Alimentarius Commission. Report of the Nineteenth Session of the Joint FAO/WHO Codex Alimentarius Commission. Rome, 1-10 July 1991 paras 155-59.
[79] Roy, D., and J.G. Liehr. "Target Organ-Specific Inactivation of Drug Metabolizing Enzymes in Kidney of Hamsters Treated with Oestradiol." *Molecular and Cellular Biochemistry* 110 (1992): 31-39.
[80] Zhu, B.T., D. Roy, and J.G. Liehr. "The Carcinogenic Effect of Ethinyloestrogens is determined by both their Hormonal Characteristics and their Conversion to Catechol Metabolites." *Endocrinology* 132 (1993): 577-83.

and ruminating than controls."[81] Lopez-Bote et al., (1994) demonstrated that trenbolone changed the genital tract in male pigs.[82] Liehr (1995) inferred that hormones cause damage to prostatic tissue and mutagenic DNA.[83] However, all of these studies differed from the issue at hand as they were injected/fed directly to the animals as opposed to passing first through another animal. As well, the levels of hormones administered to animals in these studies were above normal physiological levels. The US protested against the EU position and cited a series of risk assessments released by the US FDA that indicated growth hormones at the levels likely to be present posed no risk to human or animal health (Center for Veterinary Medicine, 1991; 1994; 1995; 1996).[84]

Given the contrary scientific information that existed over the safety of growth hormones, EU Agriculture Commissioner Fischler announced plans to hold a scientific conference in November 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" (US FAS, n/d).[85] This was welcome news to Canadian and American industry and officials.

Before the scientific conference, the *Codex* held another vote on the creation of international standards for the hormones in question. This time, the vote was held by secret ballot and five international standards for growth hormones were approved. EU officials contested the results arguing that it was not possible to set standards as the epigenetic effect could not be proved. The

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[81] Legoshin, G.P., N.F. Dzyuba, O.N. Mogilenets, V. Yu. Kuleshov, and N.V. Kulagin. "The Effect of Zeranol on Meat Productivity, Meat Quality and Behaviour of Calves." *Sel'skokhozyajstvennaya biologiya*, no. 4 (1994): 64-67.
[82] Lopez-Bote, C., G. Sancho, M. Martinez, J. Ventanas, A. Gazquez, and V. Roncero. "Trenbolone Acetate Induced Changes in the Genital Tract of Male Pigs." *Journal of Veterinary Medicine* 41, no. 1 (1994): 42-48.
[83] Liehr, J.G. "Induction of DNA Adduct Detectable by 32p-Post Labeling in the Dorso Lateral Prostate of Nbl/Cr Rats Treated with Oestradiol-17ß and Testosterone." *Carcinogeneis* 16 (1995): 951-54.
[84] Center for Veterinary Medicine. "Summary of NADA 140-897: Revalor®-S (Trenbolone Acetate and Estradiol)." 1991. [cited August 6, 2009] Available from http://www.fda.gov/cvm/efoi/section2/140897.html. Center for Veterinary Medicine. 2009. *Summary of NADA 009-576: Synovex® (estradiol benzoate and progesterone)* 1994 [cited August 6 2009]. Available from http://www.fda.gov/cvm/efoi/section1/009576s81994.html Center for Veterinary Medicine. 2009. *Summary of NADA 140-992: Revalor®-H (trenbolone acetate and estradiol)* 1994 [cited August 6 2009]. Available from http://www.fda.gov/cvm/efoi/section2/140992.html. Center for Veterinary Medicine. 2009. *Summary of NADA 038-233: RALGRO® (zeranol)* 1995 [cited August 6 2009]. Available from http://www.fda.gov/cvm/efoi/section1/038233s040695.html. Center for Veterinary Medicine. 2009. *Summary of NADA 141-043: Synovex® Plus (trenbolone acetate and estradiol)* 1996 [cited August 6 2009]. Available from 1996. http://www.fda.gov/cvm/efoi/section2/141043022296.html.
[85] US Federal Agricultural Service. "Chronology of the European Union's Hormone Ban." [cited September 11, 2009] from www.fas.usda.gov/itp/policy/chronology/html.

EU argued that further metabolic studies were required to understand if these hormones (particularly synthetic ones) had any toxic effect. Key to understanding this was establishing the 'no observed effect levels' of the hormones (European Commission, 1996:393).[86]

Canadian officials disagreed with the EU position noting "uncertainty in the safety evaluation process is primarily addressed through the use of safety factors. Their respective values are arbitrary and have no measured biological significance, however, their appropriateness is somewhat borne out by experience" (Codex Alimentarius Commission, 1993:11).[87] Note here how Canadian officials placed emphasis on 'measured biological significance' arguably meaning that the significance must be quantitatively assigned. In addition, it was argued that the naturally occurring hormones were perfectly safe to administer because they were already present in cattle. "The fact that these substances were administered exogenously had no bearing on whether or not they were carcinogenic" (WTO, 2004: para 1.74).[88] Canadian officials purported that a similar risk also existed in untreated beef.

At this stage, the Uruguay Round trade negotiations had successfully completed and the WTO was formed with a stronger dispute settlement system and the SPS Agreement, which privileged scientific information and international standards from the *Codex*. Despite, it appears that American and Canadian officials decided to wait until after the upcoming EU scientific conference to take any action. Indeed, the US Agriculture Secretary Glickman set the end of 1995 as the deadline for resolving the hormone dispute (US FAS, n/d).[89]

In November, the European Agricultural Commission Scientific Conference on Growth Promotion in Meat Production got underway. The overall conclusions found that there was no empirical or theoretical evidence suggesting a possible health risk to consumers from the natural sex hormones. Three reasons were given; residue levels fell within the physiological range

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[86] European Commission. "Proceedings of the Scientific Conference into the Growth Promotion in Meat Production." Brussels, Belgium, November 1996. p.393.
[87] Codex Alimentarius Commission. "Risk Assessment Procedures Used by the Codex Alimentarius Commission and Its Subsidiary Advisory Bodies." Codex Alimentarius Commission, 1993. p.11.
[88] WTO. 2004. "Canadian First Written Submission: SPS Article 3.1" *EC-Measures Affecting the Approval and Marketing of Biotech Products*. (WT/DS291, DS/292 and DS/293). April 21 2004 para. 1.74.
[89] US Federal Agricultural Service. "Chronology of the European Union's Hormone Ban." www.fas.usda.gov/itp/policy/chronology/html.

observed in meat of comparable untreated animals; the daily production of sex hormones by humans is much higher than the amounts possibly consumed from meat, even in prepubertal children and menopausal women; and due to an extensive first-pass metabolism, the bioavailability of ingested hormones is low, thus providing a further safety margin (European Commission, 1996:20-21).[90] In regards to the synthetic hormones zeranol and trenbolone, the conference concluded that "…at the doses needed for growth promotion, residue levels of trenbolone and zeranol are well below the levels regarded as safe. There are at present no indications of a possible human health risk from low levels of covalently-bound residues of trenbolone" (Ibid).[91]

Despite the overarching conclusions, EU officials focused on a few dissenting opinions presented at the conference as a means to justify continuing the ban (WTO, 1997: para 8.122).[92] This effectively ignored the assessments conducted by *Codex* and other epistemic community scientific opinions. The EU cited concerns that the carcinogenic effect of these hormones could not be defined in normal physiological levels, as levels for animals were not appropriate for humans (Kuiper, 1996:370-1).[93] This view contradicted the position of the *Codex* and the OIE. The EU reliance on the dissenting reports prompted Canadian officials to question how they related to the threat posed by injecting hormones into cattle and the effect of residues (Personal Interview, 2008).[94] Given residues in the meat were not an issue, officials felt the concerns raised had no connection to the threat of hormones injected into cattle and therefore were not valid.

Canadian officials also criticized the exclusion of scientists directly employed by the commercial companies with an interest in the sale of growth promoters, despite the fact that these companies "hold much of the proprietary information that is required for review by national regulatory

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[90] European Commission. "Proceedings of the Scientific Conference into the Growth Promotion in Meat Production." Assessment of Health Risk, Working Group IT. Brussels, Belgium, November 1996. pp.20-21.
[91] Ibid.
[92] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para 8.122
[93] H.A. Kuiper, "Risk Assessment Strategies for Xenobiotics," Proceedings of the Scientific Conference into the Growth Promotion in Meat Production. Brussels, Belgium, November 1996.pp.370-371
[94] Personal Interview with Canadian Department of Foreign Affairs and International Trade official. Ottawa, Canada. November 10, 2008.

agencies and international bodies such as the JECFA" (MacNeil, 1996).[95] Indeed, in the aftermath of the conference, Sir John Maddox, the conference chair and editor of *Nature* commented on how scientists were outnumbered by lobby groups and non-scientist, reflecting how politicized the issue had become in the EU (Maddox, 1995:553).[96] This supported the American view argued that the conference did not really conduct risk assessments of the hormones, thus provided no new information (WTO, 1997: para 8.112).[97]

After the scientific conference had concluded, the European Parliament and Council of Agricultural Ministers considered the lack of consensus affirmed the need for a ban. It is apparent that both the Parliament and Council of Agricultural Ministers were reacting to the significant political/public pressure not to permit the commercial sale of hormone-fed beef. On January 18, 1996 the European Parliament unanimously voted in favour of maintaining the ban in Directive 88/146/EEC (Anonymous, 1996:3A).[98] This commenced formal action by the US and Canada at the WTO. On January 26, 1996 formal consultations under the WTO DSU were requested and shortly afterward panels were formed.[99] It is apparent that the type of scientific evidence used to justify the hormones restrictions mattered to Canadian and American officials suggesting that ideas of what constitutes legitimate scientific evidence differ between the regions. In contrast, EU policy-makers appeared to be guided by hypothetical scientific concerns raised by researcher that was not valid to the question at hand: do growth hormones at the levels present in beef threaten human health?

The Ideas-Interest Interplay

In understanding the hormone dispute, it is important to recognize the pressing political and economic imperatives that were present in decision-making to impose the ban, maintain it and dispute it. It is evident that in North America, private interests were active in pressuring government officials to take action against the EU. In the EU, pressure from public concern over

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[95] MacNeil, J.D. Canada's Comments on the EU Scientific Conference, Report and Conclusions. In Proceedings of the Scientific Conference into the Growth Promotion in Meat Production. Brussels, Belgium, November 1996.
[96] Maddox, John. "Contention over Growth Promoters." *Nature* 378 (1995): 553.
[97] *EC Measures Pertaining to Meat and Meat Products (Hormones)*, WT/DS26/R/USA (1997) para. 8.112.
[98] "EU Votes to Continue Hormone Ban on Beef." *Journal of Commerce* January 19 (1996): 3A.
[99] US requested a panel on May 8, 1996 whilst Canada waited until October.

the health effect of growth hormones in beef and industry competitiveness was significant. These groups exerted significant pressure on state actors to maintain the trade restricting measures, as well as pursuing a dispute. In the US, Section 301 was enacted to compel USTR officials to take retaliatory action. To justify the various position it is possible to see differing perceptions of legitimate science being used.

In both the US and Canada, preference was given to scientific evidence where cause-effect is established quantitatively. This sort of information had traction with the private interests and policy-makers and appears to have played a role in decision-making over whether to pursue a dispute. In contrast, the EU relied upon scientific evidence where cause-effect was inferred qualitatively through hypothetical consideration as the basis for policy. Whilst the science discussing how the hormones were carcinogenic was rooted in empirical and theoretical evidence, the extrapolations to meaning there was a threat to human health from consuming hormone fed beef was hypothetical in nature. This position held traction with EU public and private interests.

In considering the role that science had in the decision-making process to formally dispute the hormone case, it is possible to see a correlation between the presence of a certain set of ideas about what constituted legitimate scientific information, their traction with the private and public interests in each jurisdiction, and the emergence of a formal trade dispute.

It is interesting to note that the role of epistemic communities in this context held little traction in the final policy outcomes despite consensus across jurisdictions and multilateral organisations. Instance after instance, the epistemic communities and multilateral forums established to consider this issue were not able to find any evidence to support the EU and interest groups concerns. Tests were even performed on the hypothetical possibilities raised by the EU, such as the potential for residues. Here it was shown that the hormones were “washed out” of the tissue through animal and human metabolic processes, inferring that the cancer risk was negligible. Instead, EU officials and interest groups rallied around ideas of individual scientific experts that suggested these hormones caused cancer. Studies that were based on unrealistic and down right impossible levels of hormones present. Officials considered such an expert view to legitimize

their concerns over risk and imply that little understanding about how science works, exists. Returning to the typology of scientific evidence in the introduction, it is possible to see that the science being relied upon was a legitimate form of evidence. But it was not valid given the availability of differing information about cause-effect of these hormones.

What this suggests is not a transatlantic divide in how scientists in the EU and North America conceptualize legitimate science, rather how policy-makers engage and understand science. The science that EU policy-makers and interest groups rallied around was legitimate. It is and was scientifically sound, but it was not relevant, realistic or the most up-to-date information. This suggests a misunderstanding of how legitimacy is applied in science by EU officials. Whilst it is clear that the attempt here was to rely on evidence that suited a sticky political situation in Europe, officials and interest groups tried to suggest uncertainty in the evidence where it simply did not exist. What this case suggests is that when ideas of what constitutes legitimate science held by EU policy-makers and interest groups differs from those held by epistemic communities, the effect and influence of epistemic communities on the type of science used in the regulation of risk is limited. This does not imply a lack of the use of scientific information but rather a real misunderstanding of how science works.

It also suggests, that the type of information that interest groups rally around matters too. In this context, interest groups rallied around scientific information that suggested the hormones were a risk without considering the continued relevance of that information. This suggest that the perception of risk became entrenched and that there was little ability amongst these groups to revaluate the identified risk in light of new information. This confounded EU policy-makers attempts to resolve this risk based trade conflict.

Such a case, challenges the idea that epistemic communities play a role in resolving differences between jurisdictions but supports the idea that differences in the perception of legitimacy of particular types of scientific evidence appears to be emerging.

It is evident that in this risk based trade conflict case, differing ideas of what was legitimate science influenced and impeded a resolution emerging. Despite the effort to use side-payments or

transfers to offset North American concerns, it appears the opportunity for settlement relied more on resolving ideas of what constituted a legitimate threat to human health. Clarifying what constitutes a legitimate scientific basis for imposing a trade restricting regulation became a matter of principle and Canadian and American officials were not willing to accept the European justification regardless of the side-payment. This suggests that North American officials were also interested in addressing the lack of clarity about what is considered sufficient scientific evidence in the fledgling SPS Agreement.

Of course, economic interests in Canada and the US remained influential in this process. Despite offers of side-payments, the industry was sufficiently unified as to avoid partial buy-offs for accepting the hormones ban. Indeed, it is evident that they were rooted in the scientific evidence that hormone-fed beef posed a negligible risk of cancer or other health effect. The result in a dispute is understandable in this context; strong interests, entrenched in specific scientific ideas that aligned with multilateral epistemic communities.