

1998

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Schaefer, Matthew, "FOOD SAFETY REGULATIONS - CROSS-BORDER IMPLICATIONS - A U.S. PERSPECTIVE" (1998).
College of Law, Faculty Publications. 51.
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FOOD SAFETY REGULATIONS – CROSS-BORDER IMPLICATIONS – A U.S. PERSPECTIVE

*Matthew Schaefer**

The United States and Canada are largely in agreement on food safety regulation issues. So, let me set up the debate between several parties not in the room. The debate at the time the Sanitary & Phytosanitary (SPS) Agreement was concluded was between the Office of the United States Trade Representative (USTR) and some consumer advocates, like Ralph Nader, and ex-presidential candidates, like Pat Buchanan. The claim by the USTR was that the SPS Agreement would allow an increase in trade by eliminating protectionist barriers under the guise of food safety standards while still allowing the United States to maintain its own high food safety standards, and, in fact, even increase those food safety standards, if they chose a higher level of protection than was being achieved by existing standards. The Buchanan/Nader claim was that, regardless of what would happen with trade under the SPS Agreement, U.S. food safety standards would be threatened or diminished and that we would have to follow the standards of international bodies such as the Codex Alimentarius.¹

I want to turn to the *Hormones* case² to settle this debate, or at least give some initial guidance on it, as the agreement has operated in practice. But I thought first I would put the *Hormones* case and SPS Agreement in the broader context of U.S. trade interests in agricultural and food products and U.S. food regulation more generally.

SPS measures are increasing in importance and visibility. If you pick up a newspaper, you may read about the United States and the European Union negotiating an agreement for mutual recognition in trade in animal products. You may have also read about a recent proposal to ban imports of animal

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¹ Codex Alimentarius is a joint undertaking of two U.N. bodies. It is explicitly referred to in the text of the SPS Agreement as the primary international standard-setting body for food safety. See <<http://www.tasinc.com/tas-code.html>> (visited on July 7, 1998).

² See *E.C. - Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R (Jan. 16, 1998).

products into the E.U. that contained specified risk materials (SRMs) which may contain Bovine Spongiform Encephalopathy (BSE), also known as "Mad Cow Disease." SRMs include animal parts such as skulls, brains, eyes, tonsils, pituitary glands, and spinal columns. Of course, even in my home state of Nebraska, SPS issues receive attention quite frequently after an E. coli 0157:H7 scare at a Nebraska meat plant.³ South Korea kept a ship with Nebraska meat off-shore. They would not even agree to inspect the meat for E. coli. In addition, Nebraska wheat shipments going through the Pacific Northwest had problems entering China because China feared that our wheat that was transported through that part of our country had TCK Smut. TCK Smut has no effect on human health, and China's measure would not survive scrutiny under the SPS Agreement. But, of course, China is not yet a WTO Member.

Let me turn to the importance of the production, processing, marketing, and trade of food and agricultural products to the U.S. standard of living and the economic health of the United States. There are ten million employees in the agricultural sector. We have five hundred billion dollars in GDP added to the U.S. economy by the sector. We have exports worth sixty billion dollars, and, of course, those are growing. There are more mouths to feed overseas than there are in the United States. And, of course, we cannot feed those mouths if there are hidden barriers under the guise of food safety regulation.

Next, let's take a look at the broader context of food safety regulation in the United States. Vice President Al Gore's national performance review called for a consolidation of food safety issues into a single agency. That is not going to happen for political reasons. As a result, primary jurisdiction over food safety issues remains split between the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). The USDA handles poultry and meat, and the FDA handles most of the rest. The FDA has responsibility for over 53,000 establishments. They have 250 full-time inspectors and inspect about 5,000 establishments annually. So, FDA inspections are somewhat infrequent. The USDA has responsibility for over 6,200 plants, has 7,300 full-time inspectors, and their inspections are being conducted on a daily basis.

The USDA inspectors actually view the carcasses as they go through the plants. Visual inspection can determine whether a carcass is diseased, but it certainly cannot spot microbial pathogens like E. coli 0157:H7. There are other federal agencies involved, most importantly, the Environmental Protection Agency, which sets pesticide residue levels. State and local governments have primary jurisdiction over inspecting restaurants. Of course, we as

³ See Michael Janofsky, *25 Million Pounds of Beef is Recalled*, N.Y. TIMES, Aug. 22, 1997, at A6.

consumers all have roles to play in protecting our health with respect to our food, not as regulators, but in the new mode of thinking, farm to table, we need to properly store our food in refrigerators, wash our hands and utensils, and properly cook our food.

Reforms are underway. For instance, the Hazard Analysis and Critical Control Point System (HACCP) is being implemented. Basically, it requires plants and slaughter houses to have certain procedures and record-keeping processes in place that will allow the limited enforcement resources to be better utilized. For instance, when the FDA comes in on one of its inspections, they will not just get a snapshot of a plant. Instead, the record keeping with respect to the procedures followed by the plant will give them a much broader view of what is going on in the plant. The system will also assist plants in reducing some of the pathogens that cannot be seen during a visual inspection.

With regard to imports, the FDA inspects only one to two percent of import shipments and conducts relatively few overseas inspections of food processing plants. The USDA inspects five to ten percent of import shipments and has a much more elaborate system of equivalence inspections overseas. The United States is moving toward requiring the HACCP System to be established overseas in order to gain access to the U.S. markets. This is good because you simply cannot inspect every shipment that comes into the United States, no matter how great the resources become.

What I hope this overview has led you to believe, even before I have moved to the *Hormones* case and the SPS Agreement, is that the lack of inspections and resources, and the pace at which reforms are implemented, are a much greater threat to U.S. food safety than the SPS Agreement. In fact, I would argue the SPS Agreement is no threat at all to U.S. food safety.

So let us turn to the WTO Appellate Body report in the *Hormones* case.⁴ I will not give a long history of the case. Europe, in response to some consumer fears, banned the import of beef treated with hormones. They also prohibited their own domestic producers from using hormones for growth promotion purposes in their cattle. The import ban created a long-standing trade dispute between the European Union and the United States. The United States imposed retaliatory sanctions under Section 301 in the late 1980s. Then, when the WTO Agreement entered into force, to show our confidence in the system, we removed the unilateral sanctions and brought what has ultimately been a successful case against the Europeans.

I think the Appellate Body report shows that the USTR's claims about the effects of the SPS Agreement are much more on target than the claims of

⁴ See *supra* note 2.

Buchanan, Nader, and the like. In fact, if you look at the Appellate Body report and their interpretation of various provisions of the Agreement, it tracks very closely the explanations the USTR gave in what is called the Statement of Administrative Action, which is a document that accompanies the implementing bill and explains various provisions of the Uruguay Round Agreements.

Article 3, Paragraph 1, of the SPS Agreement which intended to harmonize sanitary and phytosanitary measures on as wide a basis as possible, says, "Members shall base sanitary and phytosanitary measures on international standards where they exist, except as otherwise provided for in this Agreement."⁵ Well, the third paragraph of Article 3 gives a case where it is otherwise provided. You do not have to use international standards where there is a scientific justification for not relying on them, i.e., science has shown that international standards will not achieve your level of protection, or you have simply chosen a higher level of protection. The language is somewhat redundant in this regard, but a footnote was added to make clear that you did not need to follow international standards where you had chosen a higher level of protection, and where science showed that the international standards would not meet your level of protection.

The Nader/Buchanan claim is that the United States is going to have to follow standards of the Codex Alimentarius, to which 151 nations are a party. It was created in 1962 as a joint undertaking of two U.N. bodies, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). However, it is clear from the *Hormones* Appellate Body report that you do not need to follow international standards such as those promulgated by the Codex Alimentarius where you have chosen a higher level of protection.

But who bears the burden of proof in a challenge under the SPS Agreement? The original dispute settlement panel (hereinafter "Panel") claimed that Paragraph 3 was an exception to the general rule in Paragraph 1 that you should follow international standards. The Appellate Body said, no, Paragraph 3 is not an exception. It found that following Paragraph 1 or 3 were equal alternatives. Under the Panel's reasoning, the challenger would only have to show that there was an international standard and that the challenged measure was not based on the standard in order to establish a prima facie case. The Appellate Body said, you, as challenger, do have to make a prima facie case, but it is not enough just to show that there is an international standard, and show that the measure at issue is not based on the standard. Instead,

⁵ Agreement on the Application of Sanitary and Phytosanitary Measures, art. 3.1 <<http://www.wto.org.goods.spsagr.htm>> (visited on June 28, 1998).

the challenger must show that the measure does not have the scientific basis, and it was not based on a risk assessment.

So the Appellate Body's analysis of the relationship between Articles 3.1, 3.3, and 3.2, which grants a presumption of legality to measures that conform with an international standard, does not interfere with a nation's ability to choose its own level of protection. In particular, there is no requirement to use an international standard, and you are not damaged in terms of the burden of proof by failing to rely on an international standard.

Let us turn to Article 5.1.⁶ It obligates governments to base their SPS measures on a risk assessment as appropriate to the circumstances. If you choose a level of protection, such as one death per million persons, or a zero-risk standard, all risk assessment tells you is how much of a certain product you can tolerate without exceeding that level of risk. Choosing a level of protection is a public policy choice; risk assessment gives you the scientific justification for constraining a particular chemical or additive in a certain level. The Appellate Body made clear that there was no minimum magnitude of risk that needed to be shown in a risk assessment. Theoretical uncertainty is not enough, but, of course, a precautionary principle is built into the Agreement in Article 5.7, where, if there is insufficient scientific evidence, you can preliminarily establish a standard and then go out and try to get the science that would affirmatively support your measure.⁷

The language of the SPS Agreement stating that Members shall base their SPS measures on a risk assessment only requires a rational relationship between the measure and the risk assessment. The Appellate Body took into account that there will be scientific uncertainty. Indeed, I think it is clear from the Appellate Body's report that a measure need not be supported by science adopted by a majority within the field. But I think it is clear that science advocacy in its worst form is not sufficient. Having a single scientist that conducts a risk assessment which does not focus on the specifics, i.e., the risk of hormones used for growth promotion purposes and the residues left in the beef as a result, is not sufficient.

Nevertheless, I do think the *Hormones* case shows that the Appellate Body is willing to give a great deal of deference to national governments on this. In terms of the factors that can be taken into account in a risk assessment, the Appellate Body made clear that it is not just the physical sciences. A government does not have to look just at science in the laboratory. It can look at risks in the real world as well. For instance, all the science has shown that hormones for growth promotion purposes in beef is safe, provided it is

⁶ *Id.* at art. 5.1.

⁷ *Id.* at art. 5.7.

done under good veterinary practice. The E.U. argued that they do not know whether hormones are administered under good veterinary practice within the United States. The Appellate Body said the E.U. was allowed to take that into account. Are the U.S. and Canadian producers using good veterinary practice when they administer these growth promotion hormones? One needs to look to the actual problems and experiences in the United States and Canada. In fact, the E.U., in response to the report, wants to go back and conduct just such a risk assessment. I think that just goes to show you how much deference the Appellate Body is giving to national food safety officials.

The last provision I want to look at is Article 5.5, which has the objective of achieving consistency in the application of the concept of appropriate levels of SPS protection. It states that, "each Member shall avoid arbitrary and unjustifiable distinction in levels it considers to be appropriate in different situations, if such distinctions result in discrimination or disguise restriction on international trade."⁸ Let me break that provision into three parts as did the Appellate Body.

First, with regard to the objective of achieving consistency in levels of protection, a committee is going to undertake further work on this, but the Appellate Body noted that this is not a legal obligation. A government should seek consistency, but, of course, different measures are enacted at different times, and levels of protection may differ. There is no absolute obligation to have levels of protection uniform with respect to all chemicals and all products. What you must avoid are arbitrary and unjustifiable distinctions, if such distinctions result in discrimination or disguise restriction on international trade.

What is arbitrary or unjustifiable discrimination? Do we compare between products with similar pesticides, between similar pesticides on a particular product, or between different pesticides on different products? This is not altogether clear. The Appellate Body notes that you only compare what is comparable. There must be some similarity to make such a comparison and then judge whether a distinction arising from that comparison is arbitrary or unjustifiable. But the Appellate Body went on to overturn the Panel on several comparisons in which the Panel found arbitrary or unjustifiable distinctions.

The first was hormones occurring naturally in beef versus hormones injected for growth promotion purposes. The E.U. makes a distinction between these two levels of protection. The Appellate Body says that is not arbitrary. To regulate naturally occurring hormones in beef would require massive governmental intervention. Second, the E.U. makes the distinction between

⁸ *Id.* at art. 5.5.

the levels of protection for therapeutic use of hormones and growth promotion purposes. The Appellate Body says that distinction is not arbitrary or unjustifiable. The therapeutic uses are on a small scale. They are rare, and they are under the care of a veterinarian.

As to the distinction between Carbadox, an anti-microbial agent given to swine so that they do not get intestinal disease, thus making them gain weight more quickly, and the growth hormones used on beef, the Appellate Body did find these comparable, and did find that there were arbitrary and unjustifiable distinctions in the levels of protection between the two. But, in fact, the E.U. had almost admitted as much because the E.U. directive regulating the use of Carbadox is under review by the E.U. Commission. The Appellate Body made clear with respect to this arbitrary and unjustifiable distinction between Carbadox given to swine and hormones given to beef, that it must result in discrimination or disguise restriction on trade, the third part of Article 5.5's test.

Despite the fact that the U.S. and Canadian beef producers were the primary users of growth promotion hormones prior to the E.U. directive and that there is a large difference in the residue levels allowed between Carbadox and hormones for growth promotion purposes, the Appellate Body found that this was not a disguised restriction on international trade. Again, it showed great deference to national authorities.

I think it is clear from this brief review of the *Hormones* case that the USTR's version of the Agreement's impact on food safety is correct. This is only the first WTO dispute settlement case concerning the SPS Agreement. There is another one coming out on salmon soon that will give us additional guidance, but I think the claims of Buchanan and Nader ring hollow.

What should we conclude with respect to the SPS Agreement's impact on U.S. sovereignty? Entering into the SPS Agreement was a wise exercise of U.S. sovereignty. It is in the national interest of the United States. It does not reduce our food safety program, and it enhances the significant interest in U.S. agriculture and food trade. The *Hormones* case gives us the first initial proof that the SPS Agreement is, in fact, not a threat at all to U.S. standards.

If there is a total breakdown in a future dispute settlement case involving a U.S. food safety measure, such as if a Panel did something totally outrageous, the United States maintains the right to appeal to the Appellate Body, and the right to maintain the measure should the Appellate Body fail to correct an egregious mistake of a panel. Panel and Appellate Body reports do not change U.S. law or regulations; only the democratically elected Congress can change U.S. law. There are built-in protections for sovereignty in our constitutional structure in the way Congress implemented the Uruguay Round Agreements. Furthermore, you have to look at the real politics of the

situation. The Appellate Body is going to be sensitive in this area. I think you see it coming through in the *Hormones* case. They are not likely to run astray.

Since everybody knows state and local governments are my favorite topic, I will conclude with a little footnote with respect to them. There is no doubt that state and local governments can continue to set their own levels of protection. The SPS Agreement does not require states to harmonize their standards or adopt federal levels of protection. Of course, other federal laws may pre-empt the states in this regard. I repeat, there is nothing in the SPS Agreement that pre-empts states from choosing different levels of protection. Lastly, it is clear that a state can continue to set levels of protection via referendum rather than through state regulation or state law. This was a major concern for states and localities as the SPS Agreement was being negotiated and yet another area in which the claims of Buchanan and Nader ring hollow.