I. INTRODUCTION

The establishment in 1995 of the World Trade Organization (WTO) and the adoption of international trade agreements pertaining to food regulation currently have a significant impact on domestic regulatory policies established by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA) and other agencies responsible for protecting consumers and ensuring the safety of the food supply.

This article discusses the impact of WTO's Agreement on Sanitary and Phytosanitary Measures (SPS),1 with regard to its effect on food regulation at both the federal and state levels.2 It begins with a brief review of the provisions of the SPS Agreement, discusses how it is being implemented to date, and identifies some of the impacts the SPS Agreement is having on food safety regulation. The article then suggests various reforms that may take place in this area. The article concludes that the growth of the international food trade is creating new food safety problems that should be addressed on an international level, but that the SPS Agreement does little to address these challenges—it merely represents a method by which nations can create exemptions to each other's food safety laws to advance trade. The globalization of the food industry, in brief, necessitates an international food safety agreement, not just an international trade agreement on food safety.

II. THE SPS AGREEMENT IN PRACTICE

Under the SPS Agreement, WTO may force a nation to choose between weakening its health standards for humans, animals, or plants,3 or paying an international penalty. The penalty

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2 The WTO Agreement on Technical Barriers to Trade (TBT) also affects consumer protection requirements pertaining to food that do not explicitly involve health or safety issues.

3 In a number of cases involving U.S. environmental regulations and the General Agreement on Tariffs and Trade (GATT), the United States weakened domestic regulations when they were found to have violated trade rules. In one case, the United States changed its gasoline cleanliness regulations after they were challenged by Venezuela and Brazil. See WTO, United States—Standards for Reformulated and Conventional Gasoline (WT/DS2/R), Report of the Panel (Jan. 29, 1996); Regulation on Fuels and Fuel Additives, Baseline Requirements for Gasoline Produced by Foreign Refiners; 62 Fed. Reg. 24,776 (1997). In another case, a GATT panel ruled against a U.S. law that excluded from the U.S. market tuna caught by domestic or foreign fishers that used nets that were dangerous to dolphins. The United States responded by weakening its standard for "dolphin-safe" tuna. See GATT, United States—Restrictions on Import of Tuna (DS21/R), Report of the Panel (Sept. 3, 1991); Taking of Marine Mammals Incidental to Commercial Fishing Operations; Tuna Purse
can take the form of either compensating the foreign government whose exports to the nation are limited by the stricter standard or permitting that country to impose additional trade restrictions on exports from the nation with the more protective health standard.

A national health standard is illegal under the SPS Agreement if WTO decides that it is not based on scientific principles and is...maintained without sufficient scientific evidence. In making this judgment, WTO examines the extent to which the country has done a scientific assessment of the risk to human, animal, or plant life or health.

Article 5 of the SPS Agreement further provides that members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility. By contrast, most federal and state food safety laws do not contain such requirements.

The first and only WTO decision applying the SPS Agreement to food regulation has led to numerous problems. In January 1998, the appellate body of WTO affirmed a Panel decision sustaining complaints by the United States and Canada that the European Union's (EU's) ban on imported beef produced from cattle treated with growth hormones violated the SPS Agreement because the EU had not conducted the type of risk assessment required by Article 5. Growth hormones were used in the EU until the mid 1980s. Opposition to their use arose after newspapers reported that farmers in Italy were misusing the drugs and that consumption of hormone-treated meat could interfere with the normal development of children. European consumer groups waged a


4The SPS Agreement says Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. Article 2.2 of SPS Agreement, supra note 1, reprinted in COMPILATION, supra note 1, at 273. Article 5.7 says, in cases where scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. See COMPILATION, supra note 1, at 275.

5COMPILATION, supra note 1, at 275. Article 5 deals at some length with the assessment of risk and determination of the appropriate level of sanitary or phytosanitary protection. Article 5.1 says Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. at 274.

6The SPS Agreement explains that this latter provision means that a measure is illegal if there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

7For a discussion of the impact of the SPS Agreement on state food safety requirements, see Robert Stumberg, WTO Impact on State Law: California, Center for Policy Alternatives, 2 (1994).

A vigorous campaign to prohibit the use of hormones. While such groups acknowledged that most problems could be avoided if hormones were used appropriately, they argued that regulatory officials could not be relied upon to effectively regulate the use of such drugs on the farm. Hence, the only way to protect the public was to ban their use completely. Such a large controversy never arose in the United States where hormone use generally is regarded as safe. While this matter is thus of more concern to European consumers rather than their U.S. counterparts, it illustrates how food regulations designed to protect consumers can come under attack.

While the United States won this case, its legal victory at WTO has not led to any exports of hormone-fed beef to the EU because the EU refused to comply with WTO's decision. In July 1999, the United States announced that it would impose 100% tariffs on $117 million of food imports from Europe because the EU refused to repeal its ban. These higher tariffs have, in turn, led to higher prices for U.S. consumers and social unrest in France and other parts of the EU where farmers and others have retaliated by attacking McDonald’s restaurants. Recently, the EU reiterated its opposition to WTO's decision. Thus, the current operation of the SPS Agreement has led to higher prices and social unrest, two of the very problems that free trade is supposed to help prevent. Clearly, not even the most ardent free trade supporters -can say that the current system is off to a smooth start.

Even more problems are occurring behind the scenes. For example, governments may threaten action under the SPS Agreement as a way of pressuring another country to lower its food safety standards by accepting imports that do not meet that country's sanitary requirements. This type of informal activity, often invisible to public scrutiny, may represent a more insidious threat to a nation's food safety standards than an actual WTO challenge, which is at least subject to some established rules. The U.S. Office of the Trade Representative (USTR), for instance, seeking to promote U.S. sales of antibiotics used in livestock, told the European Commission in the summer of 1999 that the EU's ban on the use of human-use antibiotics as growth promoters in livestock feed might be illegal under the SPS Agreement because the EU had failed to notify the United States of its actions and had not done a proper risk assessment. The USTR made this statement even though the risk of feeding human-use antibiotics to animals, while not precisely quantified, is well recognized. For example, the U.S. Centers for Disease Control had concluded that the EU ban is scientifically justifiable and protects the public health, the World Health Organization (WHO) had recommended in 1997 that antibiotics used to treat humans should not also be used to promote animal growth, and the U.S. National Academy of Sciences had concluded in 1999 that

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11 See Letter from Peter L. Sher, Special Trade Ambassador, to Guy Legras, Director General, European Commission (Aug. 17, 1999).

12 See National Center for Infectious Diseases, Centers for Disease Control and Prevention, NCID/CDC Position on the Use of Antimicrobial Drugs as Growth Promotants (Feb. 22, 1999).

13 See Medical Impact of the Use of Antimicrobials in Food Animals, Report from a WHO Meeting, Berlin, Germany (Oct. 13-17, 1997). WHO now recommends that the practice of utilizing antibiotics that are used in human medicine as growth promoters in animals be terminated or rapidly phased out in the absence of
Here is a link between the use of antibiotics in food animals, the development of bacterial resistance to these drugs, and human disease.

Trade agreements also can be used behind the scenes by governments to attack food labeling requirements that enjoy widespread support among consumers.\footnote{\textit{NATIONAL RESEARCH COUNCIL, THE USE OF DRUGS IN FOOD ANIMALS: BENEFITS AND RISKS} 8 (Nat'l Acad. Press 1999).} For example, the USTR claimed that the EU's 1998 requirement for labeling foods containing genetically modified corn or soybeans is a barrier to international trade because the United States believes that such labeling is unnecessary, in the absence of an identified and documented risk to safety or health. Public opinion polls, however, show that most Americans (as well as Europeans) favor labeling of genetically engineered food.

In an analogous case, EU officials asserted that the mandatory nutrition labeling required by the United States is a trade barrier.\footnote{\textit{Fifteenth Annual Report on United States Barriers to Trade and Investment}, European Commission (Aug. 31, 1999). The report states that U.S. nutrition labeling requirements differ from international labeling standards set by Codex and present serious negative consequences on EU-U.S. trade in foodstuffs.} The U.S. requirement was instituted to help Americans improve their diets and reduce their risk of heart disease and cancer. Nonetheless, the European Commission has claimed that the U.S. labeling law favors American producers and is a barrier to trade. Consumer surveys, however, show that more than two-thirds of Americans rely on nutrition labeling and European consumer groups are actively seeking similar requirements. Clearly in these instances, the United States and the EU are attempting to use trade agreements to challenge food labeling regulations that enjoy the popular support of consumers on both sides of the Atlantic.

If the global trading system raised food standards to a consistent level of excellence, consumers worldwide would be well served. If the current system, however, tends to reduce standards to some acceptable international norm, then consumer health and safety may be the basis of potentially 

\footnote{\textit{It is not clear whether the SPS or TBT Agreements would govern such disputes. The TBT Agreement deals with food labels and other national requirements established for reasons other than to protect the life or health of people, animals, or plants. Article 2 of the TBT Agreement provides that such a labeling requirement—even if does not treat imports differently than domestic products--is illegal if it restricts international trade more than is necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment [of that objective] would create.}}

jeopardized regardless of the economic benefits brought about by free trade. Both the Bush and Clinton administrations have paid lip service to this point. As early as 1998, President Clinton, in a speech to the WTO, called for a leveling up, in his words, of consumer protection regulations and not a leveling down. Bush administration officials have made similar pronouncements. But what is happening in fact? The current operation of the SPS Agreement reveals numerous instances of leveling down, not up. This is occurring for several reasons.

III. WHY THE SPS DOES NOT SERVE THE NEEDS OF CONSUMERS

First, the SPS is not a public health agreement. It is a business-oriented trade agreement intended to reduce regulation and facilitate international trade. Thus, under the SPS Agreement, a nation may challenge another nation’s food safety standards only for being too high—there is nothing in the agreement that permits a nation to challenge another nation’s standards as being too low. In brief, pressure for downward harmonization is built directly into the SPS Agreement because it is designed to facilitate trade, not to raise health and safety standards.

Second, in applying the SPS Agreement, WTO relies extensively on decisions by the Codex Alimentarius Commission (Codex), a United Nations (UN) subsidiary body primarily supported by the UN Food and Agriculture Organization. Article 3 of the SPS Agreement provides that a national health standard for food is presumptively legal if it conforms to a standard, guideline, or recommendation established by Codex. A national standard that provides a greater level of protection than Codex is a trade barrier unless WTO decides that the stricter national standard is based on a proper risk assessment that demonstrates that the Codex standard, guideline, or recommendation does not provide sufficient protection or that the country maintaining the stricter standard has other scientific justification.

In light of the new role of Codex under the SPS Agreement, proceedings of the Commission have often become trade battlegrounds and forums for deregulation. As a result, recent Codex decisions reflect political compromises designed to promote international trade. For example, at its June 1999 meeting, Codex approved, with the acquiescence of the United States, a maximum residue level for methyl parathion (and other pesticides) even though two months later the Environmental Protection Agency (as mandated under U.S. law) banned, methyl parathion for fruits and vegetables, because of its potential adverse effects on children.

19 Remarks by President Clinton at the Commemoration of the 50th Anniversary of the World Trade Organization (May 8, 1998). Similarly, Robert Zoellick, the U.S. trade representative appointed by the Bush administration stated “. . . we need to align the global trading system with our values . . . [we] can encourage respect for core labor standards, environmental protection, and good health without slipping into fear-based campaigns and protectionism.” Remarks by Robert Zoellick to “The Kangaroo Group,” Strasbourg, France, (May 15, 2001).

20 See Article 2.2 of SPS Agreement, supra note 1, reprinted in COMPILATION, supra note 1, at 273.

21 Id.

22 Article 2.4 of the TBT Agreement provides that countries shall use Codex or other international standards except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of a legitimate objective.

23 See U.S. Environmental Protection Agency, Office of Pesticide Programs, Methyl Parathion Risk
Similarly, Codex approved by consensus a maximum level for aflatoxin—a naturally occurring carcinogen produced by a mold that grows on peanuts—of 15mg/kg. That level was higher than the level sought by the EU and represented a compromise with the United States, which permits greater amounts of aflatoxin in peanuts for further processing. Thus, the trade concerns of nations were satisfied, but at the expense of lowering international health standards.

Third, the SPS Agreement does not adequately provide for special consideration of the needs of developing countries. In recognition of the difficulty that developing countries have in complying with the SPS Agreement, Article 10 of the agreement requires that WTO members shall, when preparing and enforcing food safety measures, take into account the special needs of developing countries. Article 9 of the SPS Agreement requires that developing countries be provided with technical assistance to assist them in complying with health and safety standards. But developed countries have not lived up to their obligations in this area. Absent adequate technical assistance, governments representing developing countries are sometimes forced to argue at Codex for downward harmonization on the grounds that they cannot meet high, international standards. This situation is not acceptable for either developing or developed countries. Developed countries must provide developing nations with technical assistance that will allow them to meet world class standards to both benefit their own citizens and compete effectively in international markets. The United States has acknowledged the need to provide more technical assistance to developing countries, but significant increases in such assistance have not occurred.

Fourth, the SPS Agreement provides for so-called equivalency agreements whereby one country recognizes another country's food safety regulatory system as "equivalent" to its own, even though the two systems are different. This provision of the SPS Agreement also operates to lower food safety standards because it is designed to facilitate trade, not raise consumer protection standards. For example, in 1998, the United States began enforcing new rules for meat and poultry inspection. Almost two years after the final regulations became effective for large plants with 500 or more employees, USDA began to determine whether meat and poultry exporters who chose not to comply with the new rules were nonetheless following Aequivalent procedures that achieved the same level of public health protection. During this time, USDA allowed companies to continue to export meat and poultry to the United States based on a mere assertion by their government that they were adhering to Aequivalent standards. USDA ultimately found in December 1999 that only thirty-two of the thirty-six countries exporting meat and poultry to the United States actually had an equivalent system. By the time USDA made these determinations,


27Id. at 5.

28Id. at 13.
the remaining four countries already had exported more than one million pounds of meat and poultry to the United States that did not meet standards considered by USDA to be equivalent to U.S. requirements.

The USDA Inspector General issued a report critical of the Department's equivalency determinations. The Inspector General found that USDA not only missed the time frames established for requiring exporters to comply with the Department's new food safety regulations, but also granted equivalency status before it performed on-site equivalency verification reviews and failed to adequately document deficiencies that were found during those reviews.29

IV. IMPACT ON STATE GOVERNMENT

These problems with the SPS Agreement should be of special concern to state officials because Article 13 states that the federal government shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional…or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement.30 Thus, states and localities may be pressed by the federal government to comply with the terms of the SPS Agreement.

Among the most significant policy questions facing regulatory officials is determining what level of government should be charged with setting standards and making rules. Traditionally, the issue of preemption has been understood, at least in the United States, to focus upon whether certain rules should be left to states and localities instead of the federal government. Article 13 of the SPS Agreement, however, represents a new type of preemption involving the degree to which international bodies may displace or inhibit federal, as well as state and local, regulatory authority.31

State and local governments in the United States are valued as laboratories of democracy because they are able to experiment and adapt regulatory measures to changing needs much more quickly and efficiently than the federal government. In addition, Americans generally value the role that state and local governments play within the federal system. These values, however, are not shared by some U.S. trading partners. The EU, for example, has described state-level innovation as the multiplicity of standards, which creates impediments and even barriers to trade.32

At times, U.S. consumer groups have been forced to accept state and local preemption as


30See Article 2.2 of SPS Agreement, supra note 1, reprinted in COMPILATION, supra note 1, at 277.


32European Commission, Report on U.S. Barriers to Trade and Investment - 1994 (Brussels, Apr. 1994) at 9. Those values also are not shared by certain members of Congress. Legislation sponsored by Senator Pat Roberts (R-KS) would amend the Federal Food, Drug, and Cosmetic Act to preempt the states in many areas of food safety and dietary supplement legislation. An identical bill was introduced in the House of Representatives by Representative Richard Burr (R-NC).
the price to pay for obtaining progressive federal legislation. For example, when the Nutrition Labeling and Education Act of 1990 (NLEA)33 passed the House of Representatives, the chief sponsor of the bill, Representative Henry Waxman (D-CA), decided to add preemption language to the legislation in order to obtain political support for the bill from the food industry. Consumer groups had no choice but to go along with this plan. In retrospect, the deal benefited consumers—the NLEA became law and revolutionized federal food labeling requirements, while few significant state laws were nullified.

But what benefits to consumers are provided by the SPS Agreement? An analysis of the SPS Agreement reveals that it may actually lower, rather than raise, federal food safety requirements. In that situation, the preemptive effect of the SPS Agreement on state and local authorities is unjustified.

V. RECOMMENDATIONS

Consumer groups around the world are calling for reform of the SPS Agreement. In October 1999, the Transatlantic Consumer Dialogue (TACD), a coalition of more than sixty consumer organizations in the United States and Europe,34 stated that the SPS Agreement undercuts governments' ability to establish and maintain legitimate, nondiscriminatory food safety and food-related, consumer information labeling policies.

The TACD's specific recommendations for reforming the SPS Agreement included the deletion of the word "provisional" in Article 5.7 of the SPS Agreement (which would clarify that countries can, in the absence of scientific data, make regulatory decisions on the basis of the "better safe than sorry" approach). The TACD also urged reconsideration of the current rules relating to the burden of proof to demonstrate that a regulatory measure is justified. Currently, the burden is on the country maintaining the regulatory measure. The TACD believes the burden of proof should be on the country challenging the regulatory measure as an unjustified barrier to trade. The TACD also called for changes to Article 3 of the SPS Agreement that would limit the legal significance of certain decisions by Codex. Presently, all Codex actions, including recommendations and guidelines that were intended by the Commission to be non-binding, are actionable in WTO. The changes to the SPS Agreement supported by the TACD would mandate that only full-fledged Codex standards could form the basis of a WTO complaint. The TACD also is urging changes to Article 4 of the SPS Agreement that would remedy problems dealing with how equivalency agreements between countries currently are negotiated.36


33CSPI is the U.S. co-chair of the Food Working Group of TACD. TACD was organized by the United States and the EU to provide balance to the Transatlantic Business Dialogue, which lobbies governments on regulatory matters that are of interest to companies both in the United States and Europe.


35Id. The TACD's specific recommendations for changing the TBT Agreement included making it easier for a country to have a national standard that provides more protection than an existing or imminent international standard.
These changes likely would require amending or reinterpreting the SPS Agreement. Fortunately, at least some of these issues are on the table at WTO negotiations on agriculture that currently are taking place in Geneva. Unfortunately, these changes are not being supported by the United States. Apparently, multinational food and agribusiness companies seem to have the ear of USDA and FDA, which support the Administration’s trade agenda. As a result, the United States is championing the concerns of business—not those of the consumer community. Hopefully, the position of the federal government in the ongoing WTO negotiations on agriculture will change.

In the long run, however, simple reforms to the SPS Agreement may not be sufficient to protect consumers because the growth of international food trade is creating new threats that call out for a completely new international food safety agreement, not just reforms of the current international trade agreement on food safety. For example, the growth of the international food trade means that pathogens that were once confined to a particular region can now travel around the world on airplanes in a matter of hours. In short, the globalization of the food industry calls for a new international food safety agreement, not just an international trade agreement on food safety.

The WHO has recognized the relationship between trade concerns and health issues. In May 2000, the World Health Assembly (WHA) adopted a resolution, which inter alia, instructs the Director General to support the inclusion of health considerations in international trade in food. In addition, the WHO is considering revising its International Health Regulations (IHR) to cover the spread of food-borne illnesses. As part of the revision process, WHO officials met with members of the WTO/SPS committee in June 2000. At the meeting, possible conflicts between the SPS Agreement and the proposed revisions of the IHRs were discussed along with strategies to resolve such conflicts. In May, 2001, the WHA reaffirmed plans to proceed with the revision and expansion of the IHR’s to cover food safety problems involving international trade.

The participation of WHO in matters affecting international food trade should be welcomed by supporters of trade liberalization. Consumers will not support free trade unless they can be confident that imports meet world-class regulatory standards that are the same or better than U.S. domestic regulatory requirements. By playing an increasingly active role in food safety regulation, international health agencies can help build public confidence by ensuring that food safety problems not adequately addressed by the SPS Agreement are addressed by a new international food safety agreement.

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39 See WHO, Summary of the Main Points Raised at the Informal Meeting of the SPS Committee of the WHO International Health Regulations (June 22, 2000).
