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THE FOOD QUALITY PROTECTION ACT OF 1996: BY REMOVING CHEMICAL IRRITANTS FROM OUR ENVIRONMENT WILL IT GENERATE TRADE IRRITANTS TO REPLACE THEM?

EDWARD M. McDONALD, JR. *

I. INTRODUCTION

After a number of aborted attempts to enact tougher laws on pesticide regulation, the U.S. Congress passed the Food Quality Protection Act (FQPA), which was signed by President Clinton in 1996.¹ The FQPA is a response to advances in science that revealed new dangers to humans posed by many of the pesticides used in the United States. While the FQPA seeks to update U.S. policy to address new scientific discoveries, the Act may also create trade irritants with many of our trading partners by setting tolerances for pesticide residues in food products which are much more stringent than the tolerances used by other countries.²

This note will consider some of the trade problems that could result from the ongoing implementation of the FQPA. Section II considers the regulatory regime that existed prior to the enactment of the FQPA. Section III describes the events leading up to the enactment of the FQPA and how the political climate during the 104th Congress shaped the legislation. Section IV describes the main features of the FQPA and the changes it has wrought in the way the United States regulates pesticides. Section V describes the manner in which the FQPA has been implemented thus far, including the science policies utilized by the Environmental Protection Agency (EPA) in its risk assessment procedures and some of the problems encountered in FQPA implementation. Section VI describes the features and procedures of the primary international organization dealing with pesticide regulation, the Codex Alimentarius. Section VII

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¹ Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996) (codified at 7 U.S.C. §§ 136i(2), 136r(1), 136w(5)-(7)).

² See Alanna Mitchell, *Pesticide Residues on Canadian Produce Doubles: Report*, GLOBE & MAIL, May 24, 1999, at A4.

describes the enactment and main features of the North American Free Trade Agreement (NAFTA) and how its provisions relate to pesticide regulation. Section VIII details some of the ways that the United States, Canada, and Mexico are attempting to work through problems posed by differences in their domestic environmental laws. Section IX details the General Agreement on Tariffs and Trade (GATT) and its administering body, the World Trade Organization (WTO), while Section X covers WTO cases concerning Sanitary/Phytosanitary provisions. Section XI considers some of the trade problems that the FQPA could create between the United States and other members of the WTO, with Section XII concluding the note.

II. THE PRE-FQPA REGULATORY REGIME

The two primary pieces of federal legislation that regulate pesticides on food products are the Federal Insecticide, Fungicide and Rodenticide Act³ (FIFRA) and the Federal Food, Drug and Cosmetics Act⁴ (FFDCA).⁵ Before a pesticide can be used on a food crop, the manufacturer or distributor must satisfy the requirements of both FIFRA and FFDCA.⁶

A. *Federal Insecticide, Fungicide, and Rodenticide Act*

The FIFRA was enacted in 1947 and administered under the auspices of the Department of Agriculture.⁷ The law followed the line of the earlier Federal Insecticide Act of 1910⁸ and focused entirely on labeling issues.⁹ In 1972, the administration of FIFRA was transferred to the newly created EPA, additional health and environmental standards were added, and the registration of older pesticides was required.¹⁰ Under the terms of FIFRA, the EPA sets the requirements under which pesticides

³ Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1994).

⁴ Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301-95 (1994).

⁵ Scott Douglas Bauer, Note, *The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation*, 75 N.C. L. REV. 1369, 1370 (1997) ("Food products" include raw and processed foods).

⁶ See Dominic P. Madigan, Note, *Setting an Anti-Cancer Policy: Risk, Politics, and the Food Quality Protection Act of 1996*, 17 VA. ENVTL. L.J. 187, 191 (1998).

⁷ James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273, 277-78 (1998).

⁸ The Insecticide Act of 1910, ch. 191, 36 Stat. 331 (repealed 1947).

⁹ See Smart, *supra* note 7, at 278.

¹⁰ See *id.*

can be used in the field.¹¹ Persons seeking to register a pesticide under FIFRA must provide certain information to the EPA, including the proposed use of the pesticide, data supporting that use, the pesticide's formula, and a request for classification.¹² Once the application is complete the EPA will make a determination on whether the pesticide will cause "unreasonable adverse effects on the environment."¹³ In making this determination the EPA was authorized to balance the risks and benefits of the pesticide use.¹⁴

B. *Federal Food, Drug and Cosmetic Act*

The FFDCA¹⁵ regulates pesticide residues on food products.¹⁶ Although the FFDCA was enacted in 1938,¹⁷ two of its most important sections, 408 and 409, were added much later.¹⁸

The Miller Amendment of 1954¹⁹ added Section 408 to the FFDCA.²⁰ Under Section 408, raw agricultural commodities are considered adulterated if they contain pesticide residues.²¹ Unless the adulterating pesticide has been granted a "tolerance," use of the commodity is prohibited.²² A "tolerance" is the level of a specific pesticide allowed on a specific agricultural commodity.²³

Like FIFRA, the EPA under FFDCA is allowed to take into consideration the benefits provided by a pesticide along with its risks when setting residue tolerances.²⁴ The EPA is to balance the "necessity [of the pesticide] for the production of an adequate, wholesome, and economical food supply" with the risks to human health posed by the pesticide.²⁵

¹¹ See Madigan, *supra* note 6, at 191.

¹² Bauer, *supra* note 5, at 1372.

¹³ 21 U.S.C. § 136a(c)(5)(C) (1994).

¹⁴ See Bauer, *supra* note 5, at 1373; Madigan, *supra* note 6, at 191-92.

¹⁵ 21 U.S.C. §§ 301-395 (1994).

¹⁶ Bauer, *supra* note 5, at 1373; Madigan, *supra* note 6, at 191; Smart, *supra* note 7, at 277.

¹⁷ Smart, *supra* note 7, at 278.

¹⁸ These sections were added in 1954 and 1958 respectively. *Id.*

¹⁹ 21 U.S.C. § 346(a) (1994), amended by FQPA, Pub. L. No. 104-170 (1996).

²⁰ Smart, *supra* note 7, at 278.

²¹ Madigan, *supra* note 6, at 192.

²² *Id.*

²³ Smart, *supra* note 7, at 278.

²⁴ See Bauer, *supra* note 5, at 1374.

²⁵ *Id.*

In 1958, the Food Additive Amendment²⁶ was enacted and became Section 409 of the FFDCA.²⁷ Section 409 requires "food additives" to be found safe before they can be placed on the market.²⁸ Pesticide residues fall under the definition of food additives when they are either concentrated in food products during processing or the reduction in the pesticide level in the food does not meet good manufacturing practice during food processing²⁹ (the "flow through provision").³⁰ Congress specifically exempted raw foods from the purview of the section.³¹ Thus Section 409 requires the setting of tolerances for processed food.³²

Under the EPA's interpretation of the Section 402 "flow-through" provision,³³ a Section 409 tolerance was required for a pesticide if the pesticide concentrated at all during food processing, even if the resulting residue still met the tolerance set under Section 408.³⁴ Although Section 409 did not explicitly require a risk-benefit analysis to be used in setting a tolerance, the EPA considered a pesticide's benefits when setting a Section 409 tolerance.³⁵

Section 409 contained a clause inserted by Congressman James J. Delaney (D-NY) that addressed the American public's growing concern over cancer-causing chemicals.³⁶ Section 409 was enacted during a period when scientists were unable to determine if a safe tolerance could be set for carcinogenic chemicals.³⁷ The clause states that: "[N]o additive shall be deemed safe [under Section 409] if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce

²⁶ FFDCA, 21 U.S.C. § 348 (1994), *amended by* FQPA, Pub. L. No. 104-170 (1996).

²⁷ *See* Smart, *supra* note 7, at 279.

²⁸ *See id.*

²⁹ *See id.*

³⁰ FFDCA, 21 U.S.C. § 342(a)(2)(C) (1994).

³¹ *See* Bauer, *supra* note 5, at 1374.

³² *See id.*

³³ When a tolerance or an exemption has been established for use of a pesticide on a raw agricultural commodity, then the FFDCA allows for the "flow-through" of such pesticide residue to processed foods, even when the pesticide may be a carcinogen. This flow-through is allowed, however, only to the extent that the concentration of the pesticide in the processed food does not exceed the concentration allowed in the raw food. *Les v. Reilly*, 968 F.2d 985, 987 (9th Cir. 1992).

³⁴ *See* Bauer, *supra* note 5, at 1375.

³⁵ *See id.* at 1374.

³⁶ *See* Andrew J. Miller, Note, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, DUKE ENVTL. L. & POL'Y F. 393, 395 (1997).

³⁷ *See id.* at 396.

cancer in man or animal . . .”³⁸ Thus the Delaney Clause banned cancer-causing food additives by automatically denying them tolerance provisions for carcinogenic pesticide residues.³⁹ The standard for cancer-causing additives was “zero-risk;” no matter how negligible the risk to human or animal health the chemical posed, its use was banned under the Delaney Clause.⁴⁰ The EPA interpreted the phrase “cancer-causing” in the Delaney Clause to mean oncogenic, meaning an agent that causes the formation of tumors, both benign and cancerous, in humans or animals.⁴¹

In an attempt to pursue a unified, logical approach to pesticide regulation, the EPA implemented a non-statutory “coordination policy” to tolerance setting.⁴² If a pesticide was intended for use on a food product, an applicant for a FIFRA registration would have to qualify for an FFDCA tolerance (or tolerances depending on whether the FFDCA required the pesticide to receive both Section 408 and 409 tolerances) as well.⁴³ The coordination policy also allowed the EPA to deny a Section 408 tolerance for a pesticide that might be used on food if it failed to receive a Section 409 tolerance because it violated the Delaney Clause.⁴⁴

C. *Pre-FQPA Pesticide Regulation*

Thus a pesticide had to navigate through a number of regulations to be legally used in the United States. A pesticide had to receive a FIFRA registration to be sold or distributed.⁴⁵ A pesticide used (i) for exclusive use on raw agricultural products that would never be processed or (ii) on raw products that might be processed but which would not concentrate during processing only required an FFDCA Section 408

³⁸ Bauer, *supra* note 5, at 1376 (citing FFDCA § 409, Delaney Clause).

³⁹ See Madigan, *supra* note 6, at 195.

⁴⁰ See *id.*

⁴¹ See Smart, *supra* note 7, at 308. This was in contradistinction to the FDA’s (that regulated all non-pesticide food additives under the FFDCA) interpretation that “cancer causing” meant carcinogenic or something causing the formation of cancerous tumors only. Thus the EPA’s interpretation was more stringent. The pesticide industry tried to challenge this interpretation of “cancer causing” as meaning oncogenic and not carcinogenic. However, they challenged the interpretation after the *Les v. Reilly* decision in 1992 relied on the EPA definition. Thus the EPA utilized “res judicata” to retain the interpretation. See *id.*

⁴² See Madigan, *supra* note 6, at 196-97.

⁴³ See *id.*

⁴⁴ See *id.*

⁴⁵ See *id.* at 191.

tolerance.⁴⁶ Pesticides used on raw products that might be processed and that concentrated during processing required both FFDCA Section 408 and 409 tolerances.⁴⁷ The Delaney Clause, in conjunction with the EPA's coordination clause, denied Section 408 and 409 tolerances and FIFRA registrations to pesticides in this group that were found to be cancer-causing.⁴⁸ Pesticides that were used during or after food processing required a Section 409 tolerance and were denied tolerances and FIFRA registrations if they were found to be cancer-causing.⁴⁹ Thus the Delaney Clause created a split in the standards applied to pesticides depending on whether they were used on raw or processed food.⁵⁰ Pesticides on raw foods and non-cancer causing pesticides on processed foods were assessed tolerances according to a "reasonable certainty of no harm" standard that included a risk-benefit analysis.⁵¹ Cancer-causing pesticides on processed foods were denied FIFRA registration and FFDCA tolerances under the "zero-risk" standard of the Delaney Clause.⁵²

III. THE ENACTMENT OF THE FQPA

A. *Growing Dissatisfaction with the Delaney Clause*

During the years leading up to the passage of the FQPA, various groups criticized the Delaney Clause and the manner in which the EPA implemented it.⁵³ The EPA utilized a number of ways of avoiding strict application of Delaney including the "constituents" policy and the "sensitivity of method" approach, both of which were first developed and used by the Food and Drug Administration.⁵⁴ The constituents policy allowed the EPA to establish Section 409 tolerances for pesticides if the pesticide was not cancer-causing as a whole but contained cancer-causing contaminants.⁵⁵ The sensitivity of method approach allowed the EPA to establish Section 409 tolerances for cancer-causing residues as long as they were undetectable at the level prescribed by EPA testing

⁴⁶ Bauer, *supra* note 5, at 1376-77.

⁴⁷ *See id.* at 1377.

⁴⁸ *See id.*

⁴⁹ *Id.* at 1376-77.

⁵⁰ This was termed the "Delaney Paradox." Bauer, *supra* note 5, at 1377-78.

⁵¹ *Id.* at 1378.

⁵² *Id.*

⁵³ *Les v. Reilly*, 968 F.2d 985, 987-88 (9th Cir. 1992).

⁵⁴ Smart, *supra* note 7, at 284.

⁵⁵ *Id.*

procedures.⁵⁶ These approaches came under more and more criticism from consumer protection and environmental groups as scientific advances produced increasingly sophisticated testing methods that could detect pesticide residues at levels lower than were possible when the pesticide regulations were formulated.⁵⁷

Scientific advances also indicated that cancer was not the only risk posed by pesticides. Studies revealed that pesticide residues could also cause birth defects and problems associated with infant and child development.⁵⁸ Thus the system developed during the 1950s was focused too narrowly on the risk of cancer. Under FIFRA, pesticides that were registered prior to 1984 required re-registration.⁵⁹ As knowledge of problems other than cancer caused by pesticides increased, the regulatory system appeared to generate some perverse outcomes such as allowing the registration or re-registration of some pesticides that were much more injurious to health than many of the oncogenic pesticides banned under the Delaney Clause.⁶⁰ In addition, the approach utilized by the EPA conceivably increased the risk of developing cancer due to pesticide exposure because the Delaney Clause did not ban cancer-causing residues on raw commodities⁶¹ that were more carcinogenic than some of the cancer-causing pesticide residues on processed food that were banned outright by Delaney.⁶²

In 1987, a National Research Council (NRC) study recommended that a single standard be used to set tolerances for pesticide residues on raw and processed foods.⁶³ The study suggested using a "negligible risk" standard, a pesticide residue tolerance set so that people would not experience greater than a one in a million chance of developing cancer from exposure over the course of a human life span of seventy years.⁶⁴

In 1988, the EPA adopted a new approach to setting pesticide residue tolerances, termed the "de minimis" standard, which incorporated

⁵⁶ *Id.*

⁵⁷ Frank B. Cross, *The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act*, 75 WASH. U. L.Q. 1155, 1159 (1997).

⁵⁸ Smart, *supra* note 7, at 275.

⁵⁹ *Id.* at 399.

⁶⁰ Cross, *supra* note 57, at 1161.

⁶¹ The raw commodities in such a case would have to be found to generate benefits that outweighed their risk of cancer.

⁶² Cross, *supra* note 57, at 1161.

⁶³ Allison D. Carpenter, Note, *Impact of the Food Quality Protection Act of 1996*, 3 ENVTL. L. 479, 482 (1997).

⁶⁴ Miller, *supra* note 36, at 401.

the findings of the NRC study.⁶⁵ The EPA relied on the de minimis standard to set tolerances for all pesticide residues on all types of food products from 1989 to 1992.⁶⁶

B. *Judicial Challenges to the De Minimis Standard*

In October 1988, at the same time it introduced the new de minimis standard, the EPA published a list of carcinogenic pesticides⁶⁷ and announced that under the new standard it would not revoke the Section 409 tolerances for four of the pesticides that satisfied the de minimis standard.⁶⁸

A number of environmental and consumer groups⁶⁹ filed an administrative petition in 1989 asking that the EPA revoke the tolerances for the pesticides.⁷⁰ After the EPA published a final order denying the petition, the groups filed a petition for review of the EPA decision in federal court.⁷¹

The Court of Appeals for the Ninth Circuit in *Les v. Reilly*⁷² set aside the EPA order holding that "the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved."⁷³ The court said that the Delaney Clause language was "clear and mandatory" and did not allow any pesticide to be deemed safe (and thus receive a tolerance) if it was found to induce cancer.⁷⁴ The court found that the Delaney Clause did not provide the EPA the flexibility needed to legally implement the de minimis standard.⁷⁵

⁶⁵ Carpenter, *supra* note 63, at 482.

⁶⁶ *Id.*

⁶⁷ *Les v. Reilly*, 968 F.2d 985, 988 (9th Cir. 1992). Some of the pesticides included carcinogenic chemicals such as paraquat, parathion, arsenic acid and alachlor 6. Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, App. B. (1988).

⁶⁸ *Id.* The pesticides were benomyl, mancozeb, trifluralin, and phosmet.

⁶⁹ The petitioners were the AFL-CIO, the Natural Resources Defense Council and Public Citizen. Order Responding to Objections to EPA's Response, 56 Fed. Reg. 7750 (1991).

⁷⁰ *Les*, 968 F.2d at 988.

⁷¹ *Id.*

⁷² *Id.* at 985.

⁷³ *Id.*

⁷⁴ *Id.* at 988.

⁷⁵ *Id.* at 990.

The Statute unambiguously provides that pesticides, which concentrate in processed foods, are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409 [of the FFDCA]. If pesticides which concentrate in processed foods induce cancer in humans or animals, they render the food adulterated and must be prohibited.⁷⁶

The court noted that the same issue was litigated in a D.C. Circuit case involving FDA regulation of color additives.⁷⁷ In that case the D.C. Circuit court arrived at the same conclusion as the court in *Les*: that Congress intended the Delaney Clause to be strictly applied.⁷⁸

In answer to the EPA's argument that the de minimis standard was a more logical application of the regulatory scheme, the court said,

the EPA in effect asks us to approve what it deems to be a more enlightened system than that which Congress established . . . Revising the existing statutory scheme, however, is neither our function nor the function of the EPA If there is to be a change, it is for the Congress to direct.⁷⁹

Thus, the *Les* decision sounded the death knell of the de minimis approach and forced the EPA to begin applying the Delaney Clause to all pesticides that were determined to be cancer-causing.⁸⁰ After *Les*, the EPA began proposing the revocation of a large number of pesticide tolerances.⁸¹ The media predicted that the loss of so many pesticides would result in crop losses and a rise in the price of food, thus Congress came under pressure from both industry and consumers to reform the old regime.⁸²

In 1993, the NRC released another report that caused further impetus to reform pesticide regulation laws.⁸³ The report stated that the

⁷⁶ *Les v. Reilly*, 968 F.2d 985, 990 (9th Cir. 1992).

⁷⁷ *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987).

⁷⁸ *Les*, 968 F.2d at 988.

⁷⁹ *Id.* at 990.

⁸⁰ *Id.*

⁸¹ See Smart, *supra* note 5, at 308; Bauer, *supra* note 3, at 1382.

⁸² See Cross, *supra* note 57, at 1160; Smart, *supra* note 7, at 307.

⁸³ Carpenter, *supra* note 63, at 483 (citing the report as NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN (1993)).

current risk assessment methods for determining acceptable pesticide residue tolerances might under-protect infants and children from the adverse effects of pesticide exposure.⁸⁴ The study indicated that children and infants might be more sensitive to pesticides⁸⁵ and that more should be learned about the adverse effects of pesticide residues on children.⁸⁶ The report also called for dietary studies to determine which residues children were ingesting.⁸⁷

During the years surrounding the *Les* decision, Congress made several attempts to pass legislation revamping the legal framework through which pesticide residue tolerances were established.⁸⁸ The 104th Congress finally provided the right circumstances under which legislation could be passed. In 1995, the EPA settled on a timetable for reassessment of a large number of cancer causing pesticides, thus giving the pesticide industry a good indication of when their products would become illegal.⁸⁹ The 104th Congress thus came under industry pressure to act.⁹⁰ The Congress was already under pressure from environmental and consumer groups because its "Contract With America" was perceived as a major setback in environmental protection.⁹¹

This resulted in a compromise between Republicans, Democrats, the chemical industry lobby and environmental groups, which generated the Food Quality Protection Act of 1996.⁹² The law was a victory for the chemical industry in a number of ways: the FQPA removed pesticides from the reach of the Delaney clause and the FQPA allowed benefits to be considered when setting all tolerances.⁹³ Environmentalists succeeded in inserting requirements (i) to consider the special susceptibility of children

⁸⁴ Cross, *supra* note 57, at 1162.

⁸⁵ *Id.*

⁸⁶ Carpenter, *supra* note 63, at 483.

⁸⁷ *Id.*

⁸⁸ A number of bills were introduced in the House and Senate during the Congresses preceding the 104th Congress but failed due to opposition from either the environmental or chemical industry lobbies. See Smart, *supra* note 7, at 309-19.

⁸⁹ *Id.* at 319.

⁹⁰ *Id.* at 320.

⁹¹ *Id.* at 318.

⁹² *Id.* at 332-33.

⁹³ "The term 'pesticide chemical residue' means a residue in or on raw agricultural commodity or processed food of—(A) a pesticide chemical; or (B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical. FFDCA, 21 U.S.C. § 321(q)(2) (Supp. V 1999). "The term 'food additive' . . . does not include—(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical." *Id.* § 321(s).

and infants;⁹⁴ (ii) to develop tolerances that addressed pesticides with a “common mechanism of toxicity” as a single group for determining maximum acceptable exposure levels;⁹⁵ (iii) to screen pesticides for potential estrogenic and endocrinic effects;⁹⁶ (iv) to provide consumers with information about pesticides and their effects;⁹⁷ and, (v) to set tolerances with data from all sources of exposure.⁹⁸ Thus, the FQPA reflected a success for industry on traditional points of contention, while providing a victory to environmentalists on issues raised by more recent advances in science.⁹⁹

IV. THE FOOD QUALITY PROTECTION ACT OF 1996

The FQPA revises FFDCA in a number of ways. The most famous revision is the change in Section 405 of the FFDCA.¹⁰⁰ The FQPA explicitly exempts pesticides from the Delaney Clause’s definition of “food additives,” thus effectively removing the dichotomy in approaches to pesticides on raw and processed foods.¹⁰¹ All pesticide residues on food products are thus regulated under Section 408 of the FFDCA.¹⁰² This new single regulatory approach to pesticide residue regulation removes the “zero-risk” standard of the Delaney Clause, but on the whole, actually represents a tightening of standards for setting pesticide residue tolerances.¹⁰³ This is because tolerances must be set to address a host of new risk considerations while the incorporation of pesticide benefits into the tolerance levels are limited to certain circumstances.¹⁰⁴

The FQPA modifies FFDCA Section 408 by requiring the EPA to ensure that a pesticide is “safe” before issuing or reissuing it a tolerance.¹⁰⁵ “Safe” is defined as a “reasonable certainty that no harm will

⁹⁴ *Id.* § 346a(b)(2)(C).

⁹⁵ *Id.* § 346a(b)(2)(D)(v).

⁹⁶ *Id.* § 346a(b)(2)(D)(viii).

⁹⁷ FFDCA, 21 U.S.C. § 346a(o) (Supp. V 1999).

⁹⁸ *Id.* § 346a(b)(2)(D)(vi).

⁹⁹ Smart, *supra* note 7, at 345.

¹⁰⁰ FFDCA, 21 U.S.C. § 346a(b)(2)(D)(vi) (Supp. V 1999).

¹⁰¹ James Handley, *The Food Quality Protection Act + EPA's Pesticide Adverse Effects Reporting Rule = New Data and Better Pesticide Risk Decisions*, 28 ENVTL. L. REP. 10,241, 10,242 (1998).

¹⁰² Carpenter, *supra* note 63, at 485.

¹⁰³ Kenneth Weinstein et al., *The Food Quality Protection Act: A New Way of Looking at Pesticides*, 28 ENVTL. L. REP. 10,555, 10,556 (1998).

¹⁰⁴ *Id.*

¹⁰⁵ Handley, *supra*, note 101, at 10,242.

result from aggregate exposure to the pesticide residue, including all anticipated . . . exposures for which there is reliable information."¹⁰⁶ This "reasonable certainty of no harm" standard essentially equates to the standard the EPA had attempted to use under the "de minimis" approach,¹⁰⁷ namely that a pesticide residue tolerance pose no more than a one in a million chance of harm to a person during the average human lifespan.¹⁰⁸

The FQPA allows the EPA to renew or continue tolerances for pesticide residues not satisfying the "reasonable certainty of no harm" standard under certain circumstances.¹⁰⁹ To qualify for this provision, the EPA must be able to quantify both the threshold and non-threshold risks posed by the pesticide and determine that a proposed tolerance adequately addresses the threshold risks.¹¹⁰ After making these determinations, the EPA can issue a tolerance for the pesticide if not issuing the tolerance would result in greater harm than issuing it or if not issuing the tolerance would result in a significant disruption of an adequate, wholesome and economical food supply.¹¹¹

The FQPA also requires the EPA to consider the cumulative effects of pesticides with a "common mechanism of toxicity."¹¹² This means that pesticides such as organophosphates, which kill insects (and people if used at high enough levels) by disrupting certain neurological processes, would be grouped together as pesticides with a common

¹⁰⁶ Carpenter, *supra* note 63, at 485 (quoting the FFDCA, 21 U.S.C. § 346a (b)(2)(A)(ii) (Supp. V 1999)).

¹⁰⁷ For an explanation of the "reasonable certainty of no harm" standard under the FQPA see Valerie Watnick, *Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children*, 31 ARIZ. ST. L.J. 1315, 1337 (1999). For an explanation of the EPA's "de minimus" approach see Smart, *supra* note 7, at 293.

¹⁰⁸ See Erin E. Moran, *The Food Quality Protection Act of 1996: Does the Delaney Clause Effectively Protect Against Cancer or Is It Outdated Legislation?*, 30 J. MARSHALL L. REV. 1127, 1140 (1997); see also Cross, *supra* note 57, at 1164 (stating that the House Report on the FQPA set "reasonable certainty that no harm will result standard" by adding a hundred-fold safety factor to the level at which a pesticide generated no observable effect (especially when extrapolating from animal studies)).

¹⁰⁹ FFDCA, 21 U.S.C. § 346a(c)(3)(A), (B) (Supp. V 1999).

¹¹⁰ Carpenter, *supra* note 63, at 485. Threshold risks are ones that can be eliminated by setting a tolerance at a low enough level. Non-threshold risks are ones for which a safe level cannot be determined (usually non-threshold risks are associated with carcinogens). *Id.* at 497 n.61-62.

¹¹¹ Moran, *supra* note 108, at 1140.

¹¹² Handley, *supra* note 101, at 10,243.

mechanism of toxicity.¹¹³ When setting a tolerance for a pesticide, the EPA would determine the aggregate tolerance allowable for all pesticides with the same method of toxicity.¹¹⁴ Once the aggregate tolerance is determined, the EPA determines if the individual tolerances for all the pesticides with the same mechanism of toxicity exceed the aggregate tolerance.¹¹⁵ If they do, then tolerances must be reset or some tolerances must be cancelled.¹¹⁶ If an aggregate tolerance has been met, new pesticides seeking to register and receive a tolerance cannot do so unless the EPA determines that for some reason (such as in the case of a new pesticide that was deemed to constitute a lower risk than older pesticides) the newer pesticide should displace a registered pesticide.¹¹⁷

As noted above, the EPA must consider all forms of exposure for which there is sufficient data.¹¹⁸ The EPA has determined that in addition to the traditional dietary data used to establish exposure levels, it will also use data on pesticide levels in drinking water and in residential environments.¹¹⁹

In response to the discoveries regarding infant and child sensitivity to the toxic effects of pesticides, the FQPA explicitly addresses the need to provide higher safety margins to protect this population sub-group.¹²⁰ The FQPA requires regulators to set pesticide residue tolerances with regard to the specific dietary habits of infants and children as well as any special sensitivities exhibited by the sub-group to the cumulative effects of pesticides with a common mechanism of toxicity.¹²¹ When the data on effects specific to infants and children is incomplete, the EPA can apply an additional safety factor of up to ten to the tolerance.¹²²

The FQPA sets a rigorous timetable for the reassessment of all¹²³ of the tolerances in existence under the regulatory system.¹²⁴ One-third of

¹¹³ *Id.*

¹¹⁴ Cross, *supra* note 57, at 1169. This is termed the "Risk Cup" approach.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 1169-70. Once the risk cup is full, regulators must assess new applications for tolerances to determine if they pose less of a risk than pesticides within the group that already have a tolerance. If they do, the more dangerous tolerances can be cancelled, or the tolerances can be lowered to allow in another tolerance. *Id.* at 1170.

¹¹⁷ *Id.* at 1169-70.

¹¹⁸ FFDCA, 21 U.S.C. § 346a(b)(2)(A)(ii) (Supp. V 1999).

¹¹⁹ Weinstein et al., *supra* note 103, at 10,558 n.37.

¹²⁰ FFDCA, 21 U.S.C. § 346a(b)(2)(C) (Supp. V 1999).

¹²¹ See Cross, *supra* note 57, at 1167; Handley, *supra* note 101, at 10,243.

¹²² FFDCA, 21 U.S.C. § 346a(C) (Supp. V 1999).

¹²³ There are over 9,000 tolerances in existence. Weinstein et al., *supra* note 103, at 10,561.

the tolerances had to be reassessed using the new criteria set under the FQPA by 1999; two-thirds by 2002 and all must be reassessed by 2006.¹²⁵ The first group of pesticides to be reassessed includes organophosphate pesticides.¹²⁶ After the initial reassessment process, the EPA must conduct new reassessments of pesticide residue tolerances on a fifteen-year cycle.¹²⁷

The FQPA requires that the EPA have a screening program implemented by August 8, 1999 to determine which pesticides are endocrine disruptors.¹²⁸ The FQPA unifies tolerances within the United States to a certain extent because it explicitly states that tolerances set under federal law preempt stricter tolerances set according to state procedures.¹²⁹ Consumers are provided with more information regarding the risks and benefits associated with specific pesticides, as well as ways that consumers can avoid possible exposure to certain pesticides.¹³⁰ The EPA must provide grocers with information brochures, which they can display in their establishments.¹³¹ The Act increases the amount that can be appropriated for monitoring of pesticide levels in food and provides criminal and civil remedies for violations of the Act.¹³²

Finally, the Act recognizes that the United States is part of an increasingly interconnected global economy and thus encourages tolerance harmonization with the "maximum residue levels" (MRLs) set by the international body responsible for setting pesticide residue tolerances, the Codex Alimentarius Commission.¹³³

¹²⁴ Len Richardson, *Beyond Zero Risk*, CAL. FARMER, Sept. 1996, available at <http://www.ecologic-ipm.com/rich2.html> (last visited Mar. 27, 2001).

¹²⁵ *Id.*

¹²⁶ Handley, *supra* note 101, at 10,243.

¹²⁷ *Id.* at 10,243 n.28.

¹²⁸ Moran, *supra* note 108, at 1145; Carpenter, *supra* note 63, at 488. Xenoestrogens, which are present in some pesticides, have been found to cause breast cancer in women. Moran, *supra* note 108, at 1145.

¹²⁹ Carpenter, *supra* note 63, at 489. A state can set a stricter tolerance only if the state convinces the EPA to grant an exemption based on the special population needs or increased needs due to local conditions. *Id.* at 497 n.100.

¹³⁰ See *id.* at 488; Stephen L. Johnson, *Implementation of the Food Quality Protection Act*, 52 FOOD & DRUG L.J. 525, 528 (1997).

¹³¹ See Carpenter, *supra* note 63, at 488; Johnson, *supra* note 130, at 528. Starting in 1998, the EPA was required to distribute the brochures to large retail grocers each year. See Carpenter, *supra* note 63, at 488.

¹³² See *id.* at 490.

¹³³ *Id.* at 490-91.

V. FQPA IMPLEMENTATION

The enactment of the FQPA evinces an increase in congressional confidence in the ability of science to adequately identify and assess risk and of regulators to utilize risk assessments in risk management.¹³⁴ This confidence grew from scientific advances in analytical chemistry that allow detection of trace residues in food that are many orders of magnitude greater than was possible in the 1950s.¹³⁵ Increasingly sophisticated and sensitive methods of pesticide residue detection were coupled with advances in other areas such as a better understanding of the conditions leading to cancerous growths and dangers other than cancer that exposure to pesticide residues posed.¹³⁶ The Delaney Clause was a bright-line rule developed by a Congress that believed that many of the risks presented by pesticides were real but unquantifiable.¹³⁷ The unified standard presented by the FQPA reflects Congressional confidence in scientists' ability to quantify more of the risks posed by pesticides and thus set specific tolerances for them.¹³⁸ However, the risk assessment and management policies that the EPA has developed in response to the increased reliance on science generated by the FQPA indicate that increasingly sophisticated approaches to scientific analysis do not always result in procedures that produce pesticide residue tolerances that better correspond to the health risks posed by a pesticide.¹³⁹

The risk assessment procedures that the EPA continues to use are often based on extremely conservative default assumptions.¹⁴⁰ The 1987 NRC study¹⁴¹ utilized the EPA's tolerances and risk assessment methodology.¹⁴² The study estimated a lifetime risk of cancer of 1 in 6000 when adding the total risk of the twenty-eight carcinogenic pesticides used in the study.¹⁴³ When independent studies recalculated the risk based on

¹³⁴ Madigan, *supra* note 6, at 230.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* at 236.

¹³⁸ *Id.*

¹³⁹ See Cross, *supra* note 57, at 1167; see generally Bauer, *supra* note 5, at 1480-81; Miller, *supra* note 36, at 417.

¹⁴⁰ Implementation Working Group, *EPA's Implementation of FQPA to Date*, at <http://www.fqpa.com/index> (last visited Mar. 27, 2001) [hereinafter Implementation Working Group, *Implementation of FQPA*].

¹⁴¹ Carpenter, *supra* note 65, at 497.

¹⁴² Cross, *supra* note 57, at 1173.

¹⁴³ See *id.*

actual dietary exposures, the risks were determined to be between 4600 and 100,000 times lower than the NRC estimates.¹⁴⁴

EPA methodology also assumes that pesticides are used to the maximum amount allowable under their tolerances.¹⁴⁵ In circumstances where pesticide pollution is not regulated, pesticide users have a built-in economic incentive to use as little pesticide as possible in order to maximize profits.¹⁴⁶ When the default assumption of maximum usage was compared to the average amount of combined pesticides actually used on crops, studies in California indicated that EPA risk assessment methodology overestimated exposure rate by up to twenty-five times the actual exposure rate.¹⁴⁷

In order to meet the difficult reassessment schedule provided under the FQPA, the EPA has decided to rely on assumptions regarding pesticide toxicity; factors related to pesticide exposure including nature, level, duration and effect; and exposure to multiple pesticides with common mechanisms of toxicity.¹⁴⁸ The EPA has also applied the ten-fold uncertainty factor in assessing risk to children in almost every risk assessment case, a policy that contradicts its initial policy on use of the uncertainty factor.¹⁴⁹

The first major groups of pesticides that the EPA is reassessing under the FQPA are the organophosphates (OPs), carbamates and carcinogenic pesticides.¹⁵⁰ As per its approach to risk assessment in general, the EPA's assessment of tolerances for OPs and carbamates are very conservative.¹⁵¹

Organophosphates and carbamates both share cholinesterase (ChE) inhibition as their common mechanism of toxicity.¹⁵² Muscles and nerve

¹⁴⁴ See *id.* at 1174.

¹⁴⁵ See *id.* at 1173.

¹⁴⁶ See *id.*

¹⁴⁷ See *id.* at n.74

¹⁴⁸ Implementation Working Group, *Implementation of FQPA*, *supra* note 140.

¹⁴⁹ See *id.*

¹⁵⁰ See *id.*

¹⁵¹ See Implementation Working Group, *Choice and Use of Endpoints in Risk Assessments of Cholinesterase Inhibitors*, at <http://www.fqpa.com/index> (last visited Mar. 27, 2001) [hereinafter Implementation Working Group, *Use of Endpoints*]. For example, the EPA relies on default assumptions that each user of pesticide will use it to the maximum amount. The EPA factors in several 10X factors to account for differences across population, differences between animals and people (in animal studies) and for special sub-populations like children. In the case of cholinesterase inhibitors, the EPA looks at plasma cholinesterase inhibition which is not considered a "harm." *Id.*

¹⁵² Extension Toxicology Network, *Cholinesterase Inhibition*, at <http://ace.orst.edu/>

fibers are both stimulated by the activation of synapses, which are electrical on/off switches in the body.¹⁵³ The enzyme acetylcholine activates the synapse, while acetylcholinesterase (AChE) deactivates the synapse.¹⁵⁴ ChE inhibitors block the ability of AChE to break down acetylcholine, thus causing continual synaptic stimulation leading to a neurological overload. This overload can be fatal if the ChE inhibitor is present in sufficient quantities.¹⁵⁵

In setting "reference doses" (RfD), the EPA considers "no observable adverse effect levels" (NOAEL).¹⁵⁶ RfDs are used to establish tolerances for pesticide residues.¹⁵⁷ However in setting reference doses, and thus pesticide residue tolerances for organophosphates, the EPA has based its determinations on evidence of a drop in levels of plasma cholinesterase (primarily BuChE).¹⁵⁸

Blood contains two types of ChE, AChE and butyrylcholinesterase (BuChE).¹⁵⁹ Neither Red Blood Cell AChE (RBC AChE) nor BuChE is involved in neurotransmission, thus basing tests on organophosphate inhibition of RBC AChE or BuChE does not directly indicate that an animal or human is experiencing harm.¹⁶⁰ Only by combining evidence of RBC AChE inhibition with the observable effects of the physical manifestations of toxicity can scientists generate an acceptable indication of an adverse effect caused by OP poisoning.¹⁶¹ Researchers can also measure drops in AChE in brain tissue to determine if harm has occurred due to OP poisoning.¹⁶² Drops in blood ChE are only indications of exposure to ChE inhibitors, not observable adverse effects.¹⁶³

info/extoxnet/tibs/cholines.htm (last visited Mar. 22, 2000).

¹⁵³ See *id.*

¹⁵⁴ See *id.*

¹⁵⁵ See *id.*

¹⁵⁶ See Implementation Working Group, *Use of Endpoints*, *supra* note 151. A reference dose is a level of exposure to a chemical that someone can endure over a lifetime without suffering harm. It is usually calculated by dividing a "no observable adverse effect level" (NOAEL) developed in animal experiments by a factor of 100 for use in determining reference doses for humans. *Id.*

¹⁵⁷ See *id.*

¹⁵⁸ See *id.*

¹⁵⁹ See *id.*

¹⁶⁰ See *id.* The World Health Organization/Joint Meeting on Pesticide Residues has stated that inhibition of plasma and brain BuChE levels are toxicologically non-significant although they can be used as indicators of exposure to ChE inhibitors. See Implementation Working Group, *Use of Endpoints*, *supra* note 151.

¹⁶¹ See *id.*

¹⁶² See *id.*

¹⁶³ See *id.*

The current EPA approach to setting tolerances for ChE inhibiting pesticides, such as OPs and carbamates, involves measuring drops in plasma ChE, with or without physical manifestations of toxic reaction, and then applying an uncertainty factor of 100 to generate a tolerance.¹⁶⁴ This approach was rejected as overly conservative by the EPA's Science Advisory Board in 1990, when the EPA first suggested it.¹⁶⁵

While the United States is using plasma ChE as a toxicological endpoint, the EU and Canada are using Red Blood Cell ChE and the brain as toxicological endpoints.¹⁶⁶ The Codex Alimentarius Commission, the international pesticide residue setting body, has twice rejected EPA lobbying efforts for the Codex to adopt plasma ChE as the endpoint in Maximum Residue Levels (MRLs, which is another term for pesticide tolerances) set by the Codex.¹⁶⁷

The use of different toxicological endpoints will generate different tolerances for the pesticides involved.¹⁶⁸ The United States imports more than 5.4 billion dollars worth of food products from EU nations¹⁶⁹ and more than 6.1 billion dollars worth of food products from its NAFTA partners.¹⁷⁰ In markets involving billions of dollars, even slight differences in tolerance levels could result in the loss of considerable amounts of money to the party with the less stringent pesticide residue tolerance.¹⁷¹

In addition to the differences surrounding endpoints for ChE inhibitor risk studies, the United States and the EU are using different points along the statistical distribution curve of acute dietary exposures to

¹⁶⁴ See *id.*

¹⁶⁵ See *id.* In the Standard Operating Procedure for measuring ChE, the EPA indicates it measures plasma AChE and plasma BuChE drops in laboratory rats and dogs to assess effects of ChE inhibitors. Environmental Protection Agency, *Standard Operating Procedure (SOP): Clinical Methodology for Measuring Cholinesterase Activity in Laboratory Rats/Dogs*, at <http://www.epa.gov/fedrgstr/EPA-PEST/1996/April/Day26/pr666DIR/Support/SOP.pdf> (last visited Mar. 27, 2001).

¹⁶⁶ See *FQPA Implementation Could Have Serious Trade Impacts, Analysts Warn*, FOOD CHEMICAL NEWS, May 10, 1999.

¹⁶⁷ See *id.*

¹⁶⁸ Implementation Working Group, *Use of Endpoints*, *supra* note 151.

¹⁶⁹ This approximation was generated by adding together the value of 1998 exports from France, the United Kingdom, Italy, the Netherlands, Germany, Spain, Denmark, Belgium, and Ireland to the U.S. International Trade Administration, *Top 25 Import Sources for: Processed Food and Beverages*, at <http://www.ita.doc.gov/> (last visited Mar. 27, 2001).

¹⁷⁰ Generated by adding together the value of 1998 exports from Canada and Mexico to the United States. *Id.*

¹⁷¹ *Id.*

set tolerances.¹⁷² While the EPA indicated in a science policy paper issued on April 7, 1999 that it will set tolerances that will theoretically prevent 99.9% of the possible harm posed by certain pesticides, the Europeans plan to regulate at the 95th or 97.5th percentile.¹⁷³ The difference in regulation points would affect the tolerance levels set and result in possible trade irritants between the United States and the EU.¹⁷⁴ The use of a 99th percentile tolerance as opposed to a 97.5th or 95th percentile tolerance has been characterized by some analysts as a “purely social choice.”¹⁷⁵ While the EPA has not made a final decision on where to regulate on the distributional curve, it has adopted the 99.9th percentile as an interim policy.¹⁷⁶ Given the tight schedule for pesticide reassessment, many of the pesticides due for the initial rounds of reassessment could be affected by the interim policy.¹⁷⁷

Tougher risk assessments resulted in the voluntary cancellation of seven of the fourteen pesticides reassessed during fiscal year (FY) 1999.¹⁷⁸ The science policies the EPA is using to implement the provisions of the Food Quality Protection Act could conceivably create or reinforce disparities in tolerances between the United States and its trading partners resulting in trade irritants and possible international litigation through an international trade forum such as the Dispute Settlement Procedure of NAFTA or the World Trade Organization’s (WTO) Dispute Settlement Understanding.¹⁷⁹

¹⁷² See *FQPA Implementation Could Have Serious Trade Impacts*, *supra* note 166.

¹⁷³ See *id.*

¹⁷⁴ See *id.*

¹⁷⁵ See *id.* Risk assessment is a scientific endeavor, however, risk management is a policy endeavor. But in many cases there is a very fine line between the two calculations. See, e.g., David A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT’L L.J. 817, 833 (1994).

¹⁷⁶ *Pesticides: EPA Releasing Nearly All Papers on Science Policies Under Food Safety Law*, CHEM. REG. DAILY NEWS (BNA), Oct. 22, 1999, at d8.

¹⁷⁷ See *id.* (explaining that in FY 1999, the EPA completed only fourteen reassessment evaluation decisions, less than half of the thirty-four scheduled for FY 1999. *Id.*

¹⁷⁸ See *id.* With the more stringent chemical residue standards established by the FQPA, many registrants voluntarily withdrew their products during the registration process, knowing that their product would fail to meet the new standards. *Pesticides: EPA FY 1999 Reregistration Results in Seven Cancellations*, CHEM. REG. DAILY NEWS (BNA), Oct. 27, 1999, at d7.

¹⁷⁹ See generally Alanna Mitchell, *Pesticide Residues on Canadian Produce Doubles: Report*, GLOBE & MAIL, May 24, 1999, at A4 (discussing the enormous growth rate in pesticide residue on fresh fruits and vegetables); *Pesticides: Insecticide Review Could Affect Trade with Canada, Mexico, Work Group Says*, CHEM. REG. DAILY NEWS (BNA), Aug. 28, 1998, at d7 (suggesting possible trade irritants caused by organophosphate

VI. INTERNATIONAL STANDARDS-SETTING ORGANIZATIONS

Both the NAFTA and the WTO encourage member compliance with relevant international standard setting organizations.¹⁸⁰ The international organization responsible for setting pesticide tolerances, or MRLs is the Codex Alimentarius Commission (Codex).¹⁸¹ The Codex is run under the auspices of both the World Health Organization (WHO) and the U.N. Food and Agriculture Organization (FAO).¹⁸² The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was established in 1963 and is independent of the Codex structure.¹⁸³ It is comprised of eminent scientists who are recognized as experts in the field of pesticides, environmental chemicals and their residues.¹⁸⁴ The JMPR works closely with the Codex Committee on Pesticide Residues (CCPR) providing input to CCPR preliminary MRLs before they are forwarded to the Codex Commission for approval or rejection.¹⁸⁵ The JMPR also recommends

reassessment); *Pesticides: Pest Control Disparities, Trade Irritants Seen as Factors in Harmonizing Efforts*, CHEM. REG. DAILY NEWS (BNA), May 10, 1999, at d5 (offering that disparities in pest control tools need to be addressed); *FQPA Implementation Could Have Serious Trade Impacts, Analysts Warn*, FOOD CHEM. NEWS, May 10, 1999.

¹⁸⁰ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1 LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND, art. 3, available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (last visited Mar. 27, 2001); Agreement to Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1 LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND, art. 2.6, available at http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf (last visited Mar. 27, 2001); North American Free Trade Agreement, Dec. 17, 1992, U.S.-Canada-Mexico, art. 764(3), 32 I.L.M. 289 (1993) [hereinafter NAFTA U-C-M].

¹⁸¹ In pursuance of harmonization, with regard to food safety the [Sanitary/Phytosanitary Agreement of the General Agreement on Tariffs and Trade] has identified and chosen the standards, guidelines and recommendations established by the Codex Alimentarius Commission for . . . pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. This means that Codex standards are considered scientifically justified and are accepted as the benchmarks against which national measures and regulations are evaluated.

Codex and the International Food Trade, at <http://www.fao.org/docrep/w9114e/W9114e06.htm> (last visited Mar. 27, 2001).

¹⁸² See *id.*

¹⁸³ See *id.*

¹⁸⁴ See *id.*

¹⁸⁵ See *id.*

methods of sampling and analysis.¹⁸⁶ Codex MRLs are eventually ratified by the WHO and the FAO and are then forwarded to individual governments for acceptance or rejection.¹⁸⁷

The Codex appears to be closer to the EU's approach to setting tolerances at a risk avoidance level between the 95th and 97.5th percentile instead of the 99.9th percentile approach being utilized by the EPA.¹⁸⁸ However, in an April 1999 meeting at the Hague, the CCPR stated that the Codex would leave individual governments to work out MRLs based on pesticide interaction and acute dietary risk assessments.¹⁸⁹ Although the CCPR has reiterated that countries should be willing to harmonize their standards with those set by the Codex, the CCPR would not oppose the implementation of the FQPA.¹⁹⁰

VII. NORTH AMERICAN FREE TRADE AGREEMENT

One of the two major international trade agreements that the United States is a party to is NAFTA.¹⁹¹ In December 1987, Canadian Prime Minister Brian Mulroney and President Ronald Reagan set the groundwork for NAFTA when they signed the Canada-U.S. Free Trade Agreement.¹⁹² Shortly after the agreement between Canada and the United States was finalized, Mexico expressed an interest in negotiating a similar agreement with the United States.¹⁹³ Canada eventually entered the bilateral negotiations and all three entered into NAFTA in November 1993.¹⁹⁴ Public concerns over Mexico's lower environmental standards prompted U.S. officials to insert a number of mechanisms into the agreement to ensure that NAFTA would not undercut U.S. domestic

¹⁸⁶ See *id.*

¹⁸⁷ *Pesticides: Risk Methods, Extraneous Limits Focus of Codex Residue Committee*, CHEM. REG. DAILY NEWS (BNA), Apr. 27, 1999, at d3.

¹⁸⁸ *FQPA Implementation Could Have Serious Trade Impacts, Analysts Warn*, FOOD CHEM. NEWS, May 10, 1999. The JMPR has proposed using the 97.5th percentile. See *id.*

¹⁸⁹ *Pesticides: Risk Methods, Extraneous Limits Focus of Codex Residue Committee*, *supra* note 187.

¹⁹⁰ *Pesticides: Codex Commission Not Expected to Oppose U.S. Implementation of FQPA*, CHEM. REG. DAILY NEWS (BNA), Oct. 23, 1998, at d7.

¹⁹¹ NAFTA U-C-M, *supra* note 180, at art. 724.

¹⁹² See Ignacia S. Moreno et al., *Free Trade and the Environment: The NAFTA, the NAAEC, and Implications for the Future*, 12 TUL. ENVTL. L.J. 405, 410 (1999) (citing Canada-U.S.: Free-Trade Agreement, Dec. 22, 1987 - Jan. 2, 1988, 27 I.L.M. 281 (1988)).

¹⁹³ See *id.*

¹⁹⁴ *Id.* at 415.

environmental standards. Like GATT, NAFTA contains a Sanitary/Phytosanitary¹⁹⁵ provision that allows a party to NAFTA to "protect animal or plant life or health in its territory . . . from the introduction, establishment or spread of a pest or disease, . . . the presence of an additive, contaminant, toxin or disease-causing organism in a food, beverage or feedstuff," and "to prevent or limit other damage arising in its territory from the introduction, establishment or spread of a pest."¹⁹⁶ The NAFTA SPS provision allows a member to adopt SPS measures that are more stringent than an international standard, guideline or recommendation if necessary and adopted in accordance with the SPS agreement.¹⁹⁷ A party adopting an SPS measure must ensure that the SPS measure is: "(a) based on scientific procedures, taking into account relevant factors including, where appropriate, different geographic conditions; (b) not maintained where there is no longer a scientific basis for it; and (c) based on a risk assessment, as appropriate to the circumstances."¹⁹⁸ Members are prohibited from using SPS measures that arbitrarily or unjustifiably discriminate against other NAFTA members.¹⁹⁹ SPS measures can only be applied to the extent necessary to achieve the appropriate levels of protection desired by the member nation.²⁰⁰

The United States, Canada, and Mexico also negotiated an environmental side agreement to NAFTA entitled the North American Agreement on Environmental Cooperation (NAAEC).²⁰¹ The objective of the NAAEC was, *inter alia*, to work cooperatively to protect the environment of all three countries by enhancing enforcement and compliance with environmental laws and regulations, promote transparency, and avoid creating distortions and barriers to trade based on differing environmental standards.²⁰² In order to accomplish the aims of the NAAEC, the agreement created the North American Commission for

¹⁹⁵ "Sanitary" refers to measures to protect animal and human health. "Phytosanitary" refers to measures designed to protect plant health. See NAFTA U-C-M, *supra* note 180, at art. 724.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at art. 713, para. 3.

¹⁹⁸ *Id.* at art. 712, para. 12. The NAFTA SPS agreement defines "scientific basis" as a "reason based on data or information derived using scientific methods." *Id.* at art. 724.

¹⁹⁹ North American Free Trade Agreement, Dec. 17, 1992, U.S.-Canada-Mexico, 32 I.L.M. 289 (1993).

²⁰⁰ *Id.* at art. 754(5). The "appropriate level of protection" is defined as what the invoking party feels is appropriate. *Id.* at art. 712, para 5. In addition NAFTA members are not allowed to use SPS measures as a proxy for trade restrictions. *Id.* at art. 754(6).

²⁰¹ Moreno et al., *supra* note 192, at 422.

²⁰² *Id.* at 422-23.

Environmental Cooperation, which consists of cabinet-level officials who serve as a guiding council for an implementing body entitled the Secretariat.²⁰³ The Secretariat receives public input through a Joint Public Advisory Committee.²⁰⁴

The Commission for Environmental Cooperation has instituted a number of provisions to coordinate NAFTA members' approach to environmental issues. One of the initiatives seeks to phase out two pesticides, DDT and Chlordane, over the next decade.²⁰⁵

VIII. HOW NAFTA IS DEALING WITH PROBLEMS CAUSED BY THE FQPA

The passage of the FQPA in 1996 set the stage for trade problems between the United States and its NAFTA trading partners by creating a regulatory regime in the United States that would be much stricter than either the Canadian or Mexican regulations in place.²⁰⁶ Trade disputes arose along the Canada-U.S. border in the fall of 1998 due to the disparity in pesticides available for use on canola, wheat, and barley crops.²⁰⁷ The concern over trade irritants developing between the two countries was further highlighted by a report in 1999 by the Canadian Food Inspection Agency finding that detectable pesticide residue on Canadian fruit had more than doubled since 1994.²⁰⁸

The United States and Canada quickly moved to address the problems.²⁰⁹ Fortunately structures already exist to address the need to coordinate pesticide regulations. The NAFTA Technical Working Group on Pesticides [TWG] was established to work toward harmonization of pesticide regulations among the three parties to NAFTA.²¹⁰ The TWG continues to negotiate harmonization agreements among the parties, such as draft guidance on pesticide labeling which harmonizes labeling across

²⁰³ See *id.* at 424-25.

²⁰⁴ See *id.* at 425.

²⁰⁵ See *id.* at 428.

²⁰⁶ See generally *Pesticides: Insecticide Review Could Affect Trade with Canada, Mexico, Work Group Says*, CHEM. REG. DAILY NEWS, Aug. 28, 1998, at d7 (suggesting possible trade irritants caused by organophosphate reassessment) [hereinafter *Insecticide Review*]; *Pesticides: Pest Control Disparities, Trade Irritants Seen as Factors in Harmonizing Efforts*, CHEM. REG. DAILY NEWS, May 10, 1999, at d5 (offering that disparities in pest control tools need to be addressed) [hereinafter *Pest Control Disparities*]; *FQPA Implementation Could Have Serious Trade Impacts*, *supra* note 166.

²⁰⁷ See *Pest Control Disparities*, *supra* note 206.

²⁰⁸ Mitchell, *supra* note 179.

²⁰⁹ *Pest Control Disparities*, *supra* note 206.

²¹⁰ See *id.*

countries and individual companies and guards against over-spraying which can increase insect resistance to pesticides and result in a need to apply higher levels of pesticide or utilize a more toxic pesticide to control pests.²¹¹ The TWG has also begun to address the effect the FQPA is having on the use of organophosphate-based pesticides.²¹² The TWG has issued a report indicating that it intends to "share pesticide regulation efforts, harmonize scientific and policy considerations for such regulation, and reduce trade barriers."²¹³ The report indicates that Canada and Mexico have begun to "identify critical uses and potential alternatives to the organophosphate and carbamate pesticides in order to minimize the potential barriers to trade."²¹⁴ In addition, the TWG emphasizes the need to build on the NAFTA structures already in place to ensure that the FQPA causes as little conflict as possible.²¹⁵ The FQPA can, and already has, caused some trade problems between the United States and its NAFTA partners. Fortunately, the three countries have extensive structures in place working to smooth over trade disputes and harmonize standards, tolerances and risk assessment approaches so that trade disputes do not need to be settled through NAFTA's official dispute settlement procedure, which could conceivably sour trade relations between the NAFTA members.²¹⁶

This situation is not necessarily mirrored in the United States' relations with its WTO partners, particularly the EU.

IX. THE GATT AND THE WTO

The international legal framework through which the United States conducts trade with most of the nations of the world is the GATT, which was incorporated into the WTO at its creation on January 1, 1995.²¹⁷ The GATT is a legal framework designed to lower trade barriers among member nations.²¹⁸ It began in 1947 by requiring members to lower tariffs

²¹¹ *Pesticides: Label Guidance on Insect Resistance Expected from EPA; Developed Under NAFTA*, CHEM. REG. DAILY NEWS (BNA), July 1, 1999, at d5.

²¹² *Insecticide Review*, *supra* note 206.

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ *See id.*

²¹⁶ *See id.*

²¹⁷ TRADING INTO THE FUTURE: WTO, THE WORLD TRADE ORGANIZATION 4 (2d ed. 1999), available at http://www.wto.org/english/res_e/download_e/tif.pdf (last visited Mar. 27, 2001).

²¹⁸ *See id.* at 9.

between themselves and treat all GATT members the same.²¹⁹ The GATT also covers non-tariff barriers including domestic regulations which create undue barriers to market entry.²²⁰

However, Article XX of GATT²²¹ allows members to impose trade restrictions in order to protect, among other things, "human, animal or plant life or health."²²² Article XX barriers must be applied according to certain requirements including a Sanitary/Phytosanitary (SPS) measure similar to the one in NAFTA.²²³ The GATT SPS provisions can only be used when they are "(a) 'necessary to protect human, animal or plant life'; (b) 'based on scientific principles' and (c) not be 'maintained without sufficient scientific evidence.'"²²⁴ The measures are presumed "necessary" if they are based on standards set by an international standard setting organization such as the Codex.²²⁵ Where information is insufficient, a member may establish interim standards but must adopt a permanent standard as quickly as possible.²²⁶ The United States interprets the measure as allowing a member to set an acceptable level of risk through a political or policy process and then supplying a sufficient scientific rationale for the measure after the policy is in place.²²⁷

One of the main contributions of the WTO has been to establish a forum for settling trade disputes between members.²²⁸ The Dispute Settlement Body (DSB) of the WTO establishes a "panel" which is a tribunal set up to hear these members' trade disputes.²²⁹ The decision of a

²¹⁹ *See id.*

²²⁰ *Id.* at 33.

²²¹ General Agreement on Tariffs and Trade (GATT), opened for signature Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 188, reprinted in GATT, Basic Instruments and Selected Documents, 4th Supp., 37-38 (1969) [hereinafter GATT 1947].

²²² John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 100 (1996) (quoting Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Article XX.)

²²³ Agreement on the Application of Sanitary and Phytosanitary Measures, Dec. 15, 1993 reprinted in Law & Practice of the World Trade Organization Booklet 1, 59 (Joseph F. Dennin ed., 1995) [hereinafter GATT SPS Agreement]; see also North American Free Trade Agreement, art. 754, Dec. 17, 1992, U.S.-Canada-Mexico, available at <http://www.tech.mit.edu/Bulletins/Nafta/07.agro> (last visited Mar. 27, 2001).

²²⁴ Barton, *supra* note 222, at 101 (quoting GATT SPS Agreement).

²²⁵ *See id.*

²²⁶ *See id.*

²²⁷ *See id.* at 101-02.

²²⁸ *See* TRADING INTO THE FUTURE: WTO, THE WORLD TRADE ORGANIZATION, *supra* note 217, at 38.

²²⁹ *See id.* at 39.

WTO panel can be appealed.²³⁰ If the DSB adopts the decision of a panel, or the Appellate Body if a panel's decision is appealed, the offending member must rectify its violation of the GATT.²³¹ If the offending member nation chooses, it can continue to keep the violative trade restriction in place and compensate the complainant.²³² The complainant can also request the WTO's General Council to allow the complainant to apply retaliatory tariffs to the offending nation in particular areas of interest to the complainant.²³³ Under the WTO, a panel can request scientific or technical advice before issuing a decision.²³⁴ This ability, when viewed in conjunction with the GATT SPS requirement that an SPS measure be supported by "sufficient scientific evidence,"²³⁵ has led at least one court to the conclusion that the framework exists in the WTO/GATT to enable an international tribunal to review domestic science policy decisions,²³⁶ such as risk assessment methodology and tolerance setting, if the tribunal determines that domestic regulations create an unjustified barrier to trade.²³⁷

X. WTO CASES ADDRESSING SANITARY/PHYTOSANITARY PROVISIONS

Several cases surrounding the GATT SPS agreement have been adjudicated.²³⁸ The most famous of the SPS cases is a beef hormone dispute between the EU and the United States.²³⁹ In 1989, the EU invoked

²³⁰ See *id.* at 40.

²³¹ See *id.*

²³² See *id.*

²³³ See *id.*

²³⁴ See Barton, *supra* note 222, at 103.

²³⁵ The term "sufficient" is absent from the NAFTA SPS agreement. See *id.* at 102.

²³⁶ See David A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT'L L.J. 817, 845 (1994) (asserting that in a 1989 GATT Panel Report, the Panel substituted its own judgment in place of that of scientific experts' numerical determinations under the U.S.-Canada bilateral free trade agreement).

²³⁷ *Id.*

²³⁸ The WTO DSB has decided three cases under the GATT SPS agreement: (i) the European Union (EU) beef hormone dispute, (ii) the Australian salmon dispute, and (iii) the Japanese agricultural products dispute. See Terence P. Stewart & David S. Johnson, *The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics*, 26 SYRACUSE J. INT'L L. & COM. 27, 29 (1998).

²³⁹ The complaints came from both the United States and Canada and generated two WTO Panel Reports, *EC Measures Concerning Meat and Meat Products (Hormones)*, *Complaint by the United States*, WT/DS26/R/USA and *EC Measures Concerning Meat*

GATT's SPS provisions to ban the importation of live animals and meat from animals treated with any of six hormones.²⁴⁰ The United States and Canada challenged the ban, claiming that the ban constituted an SPS measure that constrained trade²⁴¹ and was unsupported by scientific evidence.²⁴² The United States uses hormones in its beef products and the EU ban cost the United States hundreds of millions of dollars in lost sales.²⁴³

The parties took the dispute before a WTO panel in the fall of 1996.²⁴⁴ The United States contended that the ban was illegal under the SPS because: (a) the risk assessment performed prior to the ban did not support a ban; (b) the ban "lacked a scientific foundation;" (c) the ban did "not apply only to the extent necessary to protect human life or health;" and (d) the measure was "more trade-restrictive than required to achieve the appropriate level of sanitary protection."²⁴⁵

The EU claimed that the SPS agreement allowed the invoking country to determine what level of protection was appropriate for its citizens.²⁴⁶ The EU contended that it set a more stringent standard on hormones than the United States did because it weighed consumer health over economic interests in contrast to the purported United States assessment.²⁴⁷ The WTO panel held that the EU had violated the SPS agreement.²⁴⁸ The EU appealed and the appellate body affirmed in part and reversed in part.²⁴⁹

In regard to the issue of the standard of review that should be applied to the validity of scientific determinations made by domestic administrative bodies, the Appellate Body refused to establish a standard of review (including the deferential standard proffered by the United

and Meat Products (Hormones), Complaint by Canada, WT/DS48/R/CAN, available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm (last visited Mar. 27, 2001) [hereinafter WTO Panel Reports].

²⁴⁰ See Lisa K. Seilheimer, Note, *The SPS Agreement Applied: The WTO Hormone Beef Case*, 4 ENVTL. LAW. 537, 537 (1998) (listing the hormones as oestradiol-17(beta), progesterone, testosterone, trenbolone, zeranol, and melengestrol acetate (MGA)).

²⁴¹ See *id.* at 544.

²⁴² See *id.* at 537.

²⁴³ See *id.* at 543.

²⁴⁴ See WTO Panel Reports, *supra* note 239.

²⁴⁵ Seilheimer, *supra* note 240, at 544.

²⁴⁶ See *id.* at 545.

²⁴⁷ See *id.*

²⁴⁸ See David A. Wirth, *International Decisions*, 92 AM. J. INT'L L. 755, 755 (1998).

²⁴⁹ See *id.*

States).²⁵⁰ Instead, the Appellate Body declined to reverse the panel determinations unless they constituted a "deliberate disregard of evidence or gross negligence amounting to bad faith."²⁵¹ The Panel had refused to apply a "deferential reasonableness standard" urged by the EU²⁵² and had ruled that a general "precautionary principle" does not guide the use of SPS measures allowing member nations to err on the side of caution when the precautionary principle undercuts Article 5 of the SPS Agreement, which requires that protective measures be based on a risk assessment.²⁵³ The Panel determination amounted to a finding that the EU standard was over-protective and had utilized too many assumptions, which biased the risk assessment up to a scientifically unsupportable level.²⁵⁴ The evidence of the "risk assessment" proffered by the EU indicated that the ban on hormone treated beef was instituted after a number of conferences on the subject of food quality control had discussed the possibility that abusive use of hormones could cause health risks and would be difficult to detect.²⁵⁵ But the conferences had not resulted in any empirical studies that backed up the alleged risks.²⁵⁶ Both the Panel and Appellate Body found that "[a]t best, this study may represent the beginning of an assessment of such risks."²⁵⁷ Both decisions also held that the EU's policy

²⁵⁰ See *id.* at 758. For the U.S. approach see Barton, *supra* note 222, at 102 (quoting *EC Measures Concerning Meat and Meat Products (Hormones): Report of the Appellate Body*, WT/DOC WT/DS26/AB/R and WT/DS48/AB/R, paras. 100-19 and 253(b), at http://www.wto.org/wto/english/tratop_e/distab_e.htm (last visited Mar. 27, 2001) [hereinafter *Appellate Report*]).

²⁵¹ Wirth, *supra* note 248, at 758.

²⁵² *Appellate Report*, *supra* note 250, at para. 113.

²⁵³ See *id.* at para. 125. Article 5 of the SPS Agreement of the WTO requires that members: (1) base SPS measures on a risk assessment; (2) take into account available scientific evidence, as well as relevant sampling and testing methods; (3) seek to minimize negative trade effects; and (4) avoid arbitrary or unjustifiable distinctions in the levels of protection the member nation applies in different circumstances. See Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 31 LEGAL INSTRUMENTS—RESULTS URUGUAY ROUND 5.1-5.5, at http://www.wto.org/english/docs_e/legal_e/final_e.htm (last visited Mar. 27, 2001) [hereinafter SPS Agreement].

²⁵⁴ Seilheimer, *supra* note 240, at 557-59.

²⁵⁵ See *EC Measures Concerning Meat and Meat Products (Hormones), Complaint By the United States*, WT/DS26/R/USA (Aug. 18, 1997) available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm (last visited Mar. 27, 2001) [hereinafter *U.S. Complaint*]; see also *Appellate Report*, *supra* note 250, at para. 207.

²⁵⁶ See *Appellate Report*, *supra* note 250, at para. 207.

²⁵⁷ *Id.*

went against numerous studies that indicated that hormone treated beef was safe if administered in accordance with good practice.²⁵⁸

The Appellate Body reversed the Panel's finding that the defending party initially bear the burden of proof, stating that a challenger to an SPS measure must first present a *prima facie* case for each alleged violation of the SPS agreement before the burden could be shifted onto the member invoking the SPS measure.²⁵⁹ The appellate opinion reversed the Panel's holding that the EU's ban was required to "tightly conform to" standards set by an international standard-setting organization such as the Codex.²⁶⁰ The Appellate Body upheld the panel ruling that found the EU ban to lack a scientific reason for applying the ban.²⁶¹ Additionally, the Appellate Body held that SPS agreement does not "require a risk assessment to establish a minimum quantifiable magnitude of risk, nor do[es the Agreement] exclude *a priori*, from the scope of a risk assessment, factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences."²⁶² The United States has recently received permission to apply retaliatory trade measures to the EU.²⁶³ Thus the Appellate Body decision in the beef hormone case seemingly gave a great deal of discretion to the Panel in reviewing whether SPS measures were maintained with sufficient scientific evidence.

In a recent decision on Japan's use of SPS measures to block U.S. food products potentially infested with the codling moth,²⁶⁴ the Appellate Body explicated its holdings in the SPS cases to date. The Appellate Body explained that Article 2.2 of the SPS Agreement, which requires that members "ensure that any sanitary and phytosanitary measure . . . is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5,"²⁶⁵ was to be read in close conjunction with the risk assessment requirement of Article 5.1²⁶⁶ as well as with the

²⁵⁸ See *U.S. Complaint*, *supra* note 255; *Appellate Report*, *supra* note 250, at para. 250.

²⁵⁹ See *Appellate Report*, *supra* note 250, at para. 109.

²⁶⁰ See *Wirth*, *supra* note 248, at 756 (quoting *U.S. Complaint*, *supra* note 255, at § 8(D)(1)).

²⁶¹ See *id.* at 757.

²⁶² *Id.* (quoting *Appellate Report*, *supra* note 250, at para. 253(j)).

²⁶³ *EU/US: US Pushes Ahead with Beef Hormone Sanctions*, EUR. REP., July 21, 1999, available at 1999 WL 8306681.

²⁶⁴ GATT Secretariat, *Japan—Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22, 1999), available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm (last visited Mar. 27, 2001) [hereinafter *Japan*].

²⁶⁵ SPS Agreement, *supra* note 253, at art. 2.2.

²⁶⁶ See *id.* at art. 5.5.

requirement under Article 3.3 that standards more stringent than international standards be scientifically sufficient.²⁶⁷ The Appellate Body concluded that risk assessment must reasonably support the SPS measure at issue.²⁶⁸ The Appellate Body found "there is a 'scientific justification' for an SPS measure, within the meaning of Article 3.3 [which is triggered when a measure is more stringent than the international standard], if there is a rational relationship between the SPS measure at issue and the available scientific information."²⁶⁹

The Appellate Body in the *Japan Agricultural Products* case also elucidated Article 5.7²⁷⁰ of the SPS Agreement, which allows members to impose provisional measures:

Article 5.7 of the *SPS Agreement* sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:

- (1) imposed in respect of a situation where "relevant scientific information is insufficient"; and
- (2) adopted "on the basis of available pertinent information."

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

- (3) "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
- (4) "review[s] the . . . measure accordingly within a reasonable period of time."²⁷¹

Thus the most recent SPS case adjudicated under the WTO Appellate Body has recognized a rational basis review standard for

²⁶⁷ See *id.* at art. 3.3. The Appellate Body states "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1." *Japan, supra* note 264, at para. 75 (quoting *Appellate Report, supra* note 250, at para. 180).

²⁶⁸ See *Japan, supra* note 264, at para. 76.

²⁶⁹ *Id.* at para. 79.

²⁷⁰ SPS Agreement, *supra* note 253, at art. 5.7.

²⁷¹ *Japan, supra* note 264, at para. 89 (quoting SPS Agreement, *supra* note 253, at art. 5.7).

determining the scientific sufficiency of risk assessments that form the basis of health standards related to food products. Even when there is insufficient evidence, a member can invoke a temporary SPS measure under certain circumstances.

XI. POTENTIAL PROBLEMS POSED BY THE IMPLEMENTATION OF THE FQPA

The Beef Hormone decision appears to allow a WTO panel to review the scientific validity of the risk assessment methodology utilized by domestic regulators.²⁷² The FQPA represents an increased demand on science to provide the justification for the very stringent standards detailed in the Act.²⁷³ The FQPA is sure to cause trade friction as countries with less stringent pesticide standards unsuccessfully try to import food products into the United States and are turned away when the products reveal pesticide residue levels exceeding the new tolerances set by the FQPA reassessment process. In the case of Canada and Mexico, the United States is working to harmonize standards to the requirements of U.S. legislation. However the United States could find itself in a position similar to that of the EU in the beef hormone case, if a WTO member challenges the scientific credibility of the stringent requirements set out under the FQPA and the DSB determines that the extremely conservative risk assessment methodology utilized by the EPA fails to satisfy the scientific requirements under the GATT's SPS agreement.

The rational basis review standard established in the *EC-Hormone* and *Japan-Agriculture* cases makes a finding against the United States very unlikely for the moment.²⁷⁴ The Appellate Body in the *Japan-Agriculture* case required risk management methodologies to be connected to a risk assessment.²⁷⁵ The Appellate Body did not require that the risk assessment utilize the "best" procedure, members invoking an SPS measure need only show that a risk assessment follow a scientific method and be based on more than a hunch that harm might occur.²⁷⁶ Even the extremely conservative methodology utilized when reassessing the

²⁷² See *Appellate Report*, *supra* note 250, at para. 253(b), (e) (Jan. 16, 1998) (holding that the Panel had used the proper standard of review to make an objective assessment of the facts).

²⁷³ See Bauer, *supra* note 5, at 1372; Madigan, *supra* note 6, at 191-92.

²⁷⁴ See *Japan*, *supra* note 264.

²⁷⁵ See *id.*

²⁷⁶ See *id.*

organophosphate/carbamate pesticide group clearly follows a scientific method.²⁷⁷

However, the FQPA has a number of provisions that are taking the EPA into new areas of inquiry where there is paucity of the data needed to conduct empirical tests.²⁷⁸ The EPA must still assess and reassess a large number of tolerances while continuing to develop its policies on the special needs of children and infants, the endocrine screening requirements of the FQPA, and other areas mandated by the new law.

The EU has already suggested that there is no need for the United States to establish separate acceptable daily intake levels for infants and children.²⁷⁹ The EU has also stated that the ten-fold uncertainty factor that the EPA uses is unjustified since the risk assessment methodology used is already extremely conservative.²⁸⁰ The United States may be moving closer to the area described in the *EU-Hormone* case as "the beginning of an assessment of . . . risks"²⁸¹ but insufficient to sustain a showing of scientific sufficiency.

With the passage of the FQPA of 1996, the U.S. government signaled that it is placing more and more confidence in the ability of science to detect and deal with toxins in the environment. However, the EPA should consider revamping its risk assessment methodology and use of safety factors so that they are more realistic and less likely to violate one of the many international regimes to which the United States is now a party.

XII. CONCLUSION

A recent editorial in *Science* magazine observed that the "need for a more credible, scientific basis for environmental regulation continues. Current models of exposure to environmental pollutants and their associated health effects are based on conservative and often outdated assumptions."²⁸² U.S. regulators should use this advice because a failure

²⁷⁷ See Section V of this Note.

²⁷⁸ See Cross, *supra* note 57, at 1179-1204.

²⁷⁹ *Pesticides: U.S. Position on Children's Safety Factor Opposed by International Groups*, CHEM. REG. DAILY NEWS (BNA), Feb. 4, 1998, at d6.

²⁸⁰ See *id.* The debate continues in the United States over the same issues. See *Pesticides: Industry, Environmental Groups Split over Use of FQPA Children's Safety Factor*, CHEM. REG. DAILY NEWS (BNA), Nov. 3, 1999, at d3.

²⁸¹ *Appellate Report*, *supra* note 250, at para. 207.

²⁸² William J. Madia, *A Call for More Science in EPA Regulations*, SCIENCE, Oct. 2, 1998, at 45.

to bring scientific policies in line to support legislation such as the FQPA could eventually result in a legal wrangle that may undermine the perceived credibility of the legislation and at the same time subject the United States to sanctions under the international legal regimes which are becoming increasingly important as the world continues to integrate its legal, economic, and political institutions.