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Public Participation in International Pesticide Regulation: When the Codex Commission Decides, Who Will Listen?

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PUBLIC PARTICIPATION IN INTERNATIONAL PESTICIDE REGULATION: WHEN THE CODEX COMMISSION DECIDES, WHO WILL LISTEN?

Lewis Rosman *

The validity and moral authority of a conclusion largely depend on the mode by which it was reached.

—Joint-Anti Fascist Refugee Committee v. McRath,
341 U.S. 123, 171 (1951) (J.Frankfurter, concurring).

I know of no safe depository of the ultimate powers of society but the people themselves; and if we think them not enlightened enough to exercise their control with wholesome discretion, the remedy is not to take it from them but to inform their discretion.

—Thomas Jefferson

I. INTRODUCTION

Since the New Deal, public participation in governmental decision making has been central to the legitimacy of the growing administrative state in the United States. As the global economy grows and regulatory decision making moves to international bodies, the role of public participation in government affairs has become an important international issue. This Note examines how public participation fits into current initiatives emerging from the General Agreement on Tariffs and Trade (GATT) to “harmonize” national pesticide residue standards.

World trade policy negotiators are currently seeking to reduce the trade-inhibiting potential of national health and environmental regulations. Present GATT draft proposals offer new ways to resolve conflicts over whether domestic regulations are legitimate barriers to trade.¹ Environmental and consumer advocates fear that the interna-

* Editorial Board, *Virginia Environmental Law Journal*; Articles Review Board, *Virginia Law Review*. The author dedicates this Note to the memory of his brother, Daniel.

¹ The General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, 61 Stat. pts. 5, 6, T.I.A.S. No. 1700, 55 U.N.T.S. 187 [hereinafter GATT], is “the principal multilateral framework for the regulation of international trade.” Ronald A. Brand, *The Status of the General Agreement on Tariffs and Trade in United States Domestic Law*, 26 Stan. J. Int’l L. 479, 480 n.1 (1990). Established in 1947, it is both a trade agreement and a framework for the continuing rounds of trade and tariff negotiations which led to the adoption in the Tokyo Round of six “codes” of multilateral trade negotiations and which created the institution to administer these agreements. *Id.* Current GATT negotiations — the Uruguay Round — began in 1986 and cover such areas of trade as Rules of Origin, Import Licensing, Government Procurement, Technical Barriers to Trade and Food Safety Measures. See Trade Negotiations

tional effort to reduce trade barriers will weaken national environmental standards.²

Of particular concern is the effect of negotiations on food safety standards. By imposing strict pesticide residue limits,³ a nation can prevent entry of competing food product imports into the domestic market.⁴ Previous international efforts⁵ to prohibit "unnecessary" regulation have failed to resolve trade disputes like the one sparked by the European Community's rejection of American beef raised with the aid of a hormone additive.⁶

International efforts have recently focused on preempting such dis-

Committee, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (December 20, 1991) [hereinafter Draft Final Act] (Agreement on Technical Barriers, § G; Decision by Contracting Parties on the Application of Sanitary and Phytosanitary Measures, § L, pt. C).

For current versions of the GATT, see 4 General Agreement on Tariffs and Trade, Basic Instruments and Selected Documents (1969), reprinted in Edmond McGovern, International Trade Regulation: GATT, the United States and the European Community, Appendix III at 543 (1986). For a brief history of the GATT and its legal foundations, see *id.* at 3-49.

² See, e.g., Nancy Dunne, *Fears Over 'Gattzilla the Trade Monster'*, Fin. Times, Jan. 30, 1992, at 3, available in LEXIS, Nexis Library, FINTME File.

³ In trade parlance, food safety measures are known as sanitary and phytosanitary measures but will generally be referred to here as food safety measures or food safety standards. For a good introduction to consumer/environmentalist concerns regarding the GATT's potential effect on food safety regulations, see Eric Christensen, *Food Fight: How GATT Undermines Food Safety Regulations*, Multinat'l Monitor, Nov. 1990, at 12.

⁴ Most developed nations have some limits, although regulatory practices vary from country to country. See David A. Kay, *The International Regulation of Pesticide Residues in Food* 6-8 (1976).

Of course, barring entry depends upon the importing country's testing the product and enforcing its limits. This might not always happen. See Barry Meier, *As Food Imports Rise, Consumers Face Peril From Use of Pesticides*, Wall St. J., Mar. 26, 1987, at 1 (reporting that a small percentage of imported products are tested for pesticide residues and that a high level of pesticide residues above legal tolerance levels are found on imported products when they are checked). *But cf.* Food and Drug Admin., Pesticide Program, Residues in Foods 13 (1987) [hereinafter Residues in Food] (reporting that less than one percent of the 14,492 samples of domestically produced and imported foods inspected in 1987 had residues exceeding regulatory limits).

For the purposes of this Note, it will be assumed that illegal products are detected to the extent that an exporter might have a reasonable expectation that a product, by not meeting the domestic standard of the importer, may be rejected by customs officials.

⁵ International concern about the use of chemical substances in food production dates back to the 1950s. As varying regulatory practices emerged throughout the world's most developed countries, international concerns about the threat posed to international trade in agriculture also grew. In 1962, this led to the creation of the most important international standard-setting body for food safety, the Codex Alimentarius, discussed *infra* part III.A. Kay, *supra* note 4, at 16, 18. Kay argues that international concerns developed primarily with respect to trade and safety. *Id.* at 16.

⁶ See Adrian R. Halpern, Note, *The U.S.-EC Hormone Beef Controversy and the Standards Code: Implications for the Application of Health Regulations to Agricultural Trade*, 14 N.C.J. Int'l L. & Com. Reg. 135, 135 (1989).

putes by "harmonizing" national standards and thus promoting international standards to which countries would agree.⁷ Proposals developed during the recent Uruguay Round of the GATT have sought to establish international standards set by the Codex Alimentarius Commission as a baseline for trade disputes over food safety issues.⁸

The proposed international standard-setting process is in some respects similar to American standard setting. Important differences between the two systems, however, may create substantive discrepancies in standards for pesticide residues on food. Although no one has charged U.S. officials with establishing pesticide regulations to prevent trade,⁹ the proposed GATT regime would allow an importer to challenge those U.S. regulations that exceeded international standards as unfair barriers to trade.¹⁰ The United States is a major food importer¹¹ and has one of the most extensive systems of pesticide regulation in the world;¹² U.S. standards could be challenged as prohibitively high. Also, as the world's largest food exporter, the United States has a strong interest in preventing food safety standards from becoming trade barriers.¹³

Aside from the threat of reduced standards, however, the process by which the Codex formulates regulations fails to assimilate the democratic principles reflected in the U.S. pesticide regulatory regime. Specifically, the Codex process does not recognize that the public should check industry influence on decision making and that only by

⁷ See *infra* notes 36-46 and accompanying text.

⁸ See *infra* part II.C.

⁹ Indeed, "the vast majority of regulations and standards are not developed with any consideration of their trade effects, but as a result of totally unrelated national policies." R.W. Middleton, *The GATT Standards Code*, 14 J. World Trade L. 201, 202. See also Kay, *supra* note 4, at 6 (noting that the adverse impact of pesticides on health and the environment led the United States to develop new legislation regulating the use of pesticides).

¹⁰ The international food safety standard-setting body, the Codex Alimentarius Commission, has created standards both more and less strict than U.S. standards. See *infra* part III.C. (discussing differences between the U.S. system of pesticide regulation and the Codex).

¹¹ "U.S. agricultural imports have steadily grown from \$17 billion in 1980 to about \$23 billion in 1988." U.S. Gen. Accounting Office, *International Food Safety: Comparison of U.S. and Codex Pesticide Standards 8* (1991) [hereinafter GAO Report]. This figure is up from \$6 billion in 1971. Kay, *supra* note 4, at 13. See also Residues in Foods, *supra* note 4, at 4 ("Imported foods represent an increasing proportion of the U.S. food supply.").

¹² Recognizing the real dangers associated with treating food crops with toxic chemicals, the United States has created an extensive pesticide regulatory system, involving the participation of pesticide and food producers, consumer and environmental activists, the scientific community and government regulators. See *infra* notes 109, 119-40 and accompanying text.

¹³ "The United States is the world's largest exporter of agricultural goods, which amounted to about \$40 billion in 1990." GAO Report, *supra* note 11, at 8. This figure is up from \$8 billion in 1971. Kay, *supra* note 4, at 13.

accommodating public participation can an institution legitimately impose regulations in a democratic society.¹⁴

Part II of this Note explains the role pesticide regulations can play as trade barriers and describes past attempts to cure trade-inhibiting regulations. It also describes the developing role of the Codex Alimentarius Commission—the organization charged by the draft GATT agreement with maintaining international baseline standards for food safety—in the movement toward harmonization.¹⁵

Part III discusses the standard-setting process of the Codex Alimentarius Commission and its Pesticide Residue Committee. It explores the political nature of international standard setting and, in particular, how the Codex Commission's proceedings are more readily accessible to industry groups than to consumer groups.¹⁶ Part III also addresses the potential effects — direct or indirect— that internationally set pesticide standards could have on U.S. regulatory decisions.

Part IV reviews the U.S. regulatory scheme for pesticides and examines some of the ways in which the participation of consumer and environmental groups can and does affect the U.S. standard-setting process.¹⁷ It concludes with a look at how the American public would regard internationally set standards negotiated beyond the public eye.¹⁸

By acceding to a GATT agreement which created incentives for domestic regulations to conform to international standards and which assigned standard-setting responsibility to an international body that did not provide for public participation in its decision making, American officials could compromise U.S. pesticide regulation in subtle and costly ways. Most importantly, cutting public participation out of the standard-setting process could lead to the loss of a check on the unbalanced influence of industry groups and to the loss of the resulting standard's legitimacy among the citizenry.¹⁹

In their evaluation of the international movement to harmonize food safety standards, U.S. policymakers must be conscious of these implications. The absence of public participation in the international system for pesticide regulation suggests that U.S. policy makers

¹⁴ See discussion *infra* part IV.C.

¹⁵ See discussion *infra* part II.C.

¹⁶ See discussion *infra* part III.B.

¹⁷ See discussion *infra* part IV.A.2. and IV.B.

¹⁸ See discussion *infra* part IV.C.

¹⁹ See discussion *infra* part IV.B.

should be unwilling to accept the internationalization of pesticide standards as it is currently envisioned in the GATT.

II. PESTICIDE REGULATION AND INTERNATIONAL EFFORTS TO REDUCE NON-TARIFF TRADE BARRIERS

A. *The Trade-Inhibiting Potential of Domestic Pesticide Regulation in International Trade*

Pesticides are widely known for their dramatic benefit to crop production. By destroying otherwise debilitating insects, weeds and fungi, pesticides and other powerful chemicals vastly improve crop yield.²⁰ Along with appreciation of pesticides, however, has come fear of the real and potential health hazards associated with the exposure of human beings and their environment to these highly toxic chemicals.

Establishing the proper balance between these costs and benefits is the goal of pesticide regulation.²¹ To decide how much and what kind of pesticide to allow for use on or in food products, regulators must weigh safety against production or, in the international arena, against trade. This choice is essentially a political one: It reflects a choice between competing political interests, essentially those representing health and safety and those representing production.²²

²⁰ Kay, *supra* note 4, at 4-5; Nat'l Res. Council, *Regulating Pesticides in Food: The Delaney Paradox* 17-18 (1987) [hereinafter *Delaney Paradox*].

²¹ Such a balance is frequently termed "risk management" in this and other contexts. Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 *Yale J. on Reg.* 89, 89 (1988). Risk management is essentially a judgment about how much of the assessed risk of using a product like a pesticide is acceptable, given other factors such as the potential production benefits of the product. It is often argued that such judgments are best made by scientists; they are in the best position to conduct research about such risks and evaluate the results. See Paul B. Thompson, *Risk Objectivism and Risk Subjectivism: When are Risks Real?*, 1 *Risk* 3, 5 (1990). Of course, the methods and evaluations of risk assessment may vary considerably, and the accuracy and results of test data can often be — and often are — disputed. Witness the wide divergence in assessment techniques and outcomes between the United States and the international standard-setting systems discussed *infra* notes 87-97 and accompanying text. Such evaluations may often have political implications in themselves, since certain techniques of study and evaluation may be seen to bias studies in one way or another.

For a critique of the "neutrality" of risk assessment and a brief overview of the distinctions between risk management and risk assessment, see Latin, *supra*, at 89-90. See also Thompson, *supra*; Lee Clarke, *Acceptable Risk?: Making Decisions in a Toxic Environment* (1989).

For a more general bibliography of works addressing the problems of regulatory safety assessment in view of the complexity of modern technology, see Robert A. Bohrer, *Fear and Trembling in the Twentieth Century: Technological Risk, Uncertainty and Emotional Distress*, 1984 *Wis. L. Rev.* 83, 83 n.1.

²² See Kay, *supra* note 4, at 8-10. See generally Richard J. Pierce, Jr. et al., *Administrative Law and Process* 11-17 (1992) (discussing the importance of governmental regulation on the natural market forces of supply and demand, and the political forces that shape the drafting of

The most basic type of pesticide regulations, residue limits or tolerances, control the amount of pesticide residue allowable on or in a food product. A nation's residue limits apply to domestic products as well as to those imported from abroad. When residues on imported foods exceed legally permissible levels, the importing nation may prohibit the product's sale or distribution.²³

In the international arena, pesticide regulations can look like trade barriers. Few exporters would accuse importing nations of creating pesticide regulations with the invidious purpose of hindering trade or discriminatorily applying pesticide regulations. An exporter might nevertheless challenge a regulation devised by an importer purely for purposes of safety²⁴ if that regulation effectively limited trade to the exporter's dissatisfaction.²⁵

The case of procymidone, a fungicide used on wine grapes, provides an example of how health and safety regulations might inhibit trade. In 1990, procymidone residues were detected in French and Italian wines imported into the United States.²⁶ Because the EPA had not

the regulations). Of course, increased production could be considered a health *benefit* to the extent that cheaper, more nutritious food is produced using pesticides. Presumably such factors are also considered in risk management evaluations. Most of the more developed nations now have some regulatory scheme for controlling pesticide use that necessarily balances these interests. Kay, *supra* note 4, at 7-8.

²³ See Tina E. Levine, *Assessment and Communication of Risks from Pesticide Residues in Food*, 47 Food Drug Cosm. L.J. 207, 210 (1992). " 'Illegal residues' can be: chemicals found at a level that is higher than approved; residue of a chemical that has not been evaluated for that particular imported crop, but has been approved for another; or a chemical residue that has never been evaluated for any food use." *Id.*

²⁴ Most regulations are devised for genuine safety reasons, and not as barriers to trade. See *supra* note 9.

²⁵ As R.W. Middleton explains:

Divergences between national specifications give rise . . . to distortions of competitive conditions [rather] than to direct trade barriers. A manufacturer serving only his national market can adjust his production to a single technical specification, thereby gaining economies of scale. Such economies are denied to the exporter who has, as long as there is divergence, to adjust his production to the specifications of each individual market he serves The distorting effect on competitive conditions is obvious.

Middleton, *supra* note 9, at 203. See also McGovern, *supra* note 1, at 229 (asserting that the very diversity of international standards that requires export manufacturers to produce different versions of a product to comply with varying and sometimes conflicting international standards can pose the largest obstacle to international trade). Applying Middleton's analysis to pesticide residue regulation, a food producer exporting to a country with a tolerance more stringent than the exporter's domestic tolerance would presumably either have to reduce or eliminate pesticide use on the exported crop — seemingly putting the producer at a competitive disadvantage domestically — or sell only domestically. Although this obviously oversimplifies the extremely complicated economics of food production, it is a basic, problematic feature of divergent pesticide regulations.

²⁶ See Levine, *supra* note 23, at 211.

established a level for acceptable amounts of procymidone in wine, the wines were detained by the U.S. Food and Drug Administration (FDA).²⁷ Procymidone's manufacturer, the Sutinomo Chemical Company, then petitioned the EPA to establish such a tolerance. Sutinomo suggested that the EPA base its tolerance standards on a level earlier proposed by an international standard-setting body, the Codex Alimentarius.²⁸ During the ensuing administrative procedure to establish the procymidone tolerance, the U.S. effort to protect domestic consumers became an issue of international trade.²⁹ Because international efforts to promote free trade, like the GATT, seek to remove all types of non-tariff trade barriers,³⁰ domestic pesticide regulation has become a subject of international negotiation.

B. Shortcomings in Applying the GATT and the Standards Code to Resolve Non-Tariff Disputes

The first five rounds of GATT negotiations focused primarily on tariff reduction. Where the GATT Agreement did address non-tariff barriers, it dealt only with those that were facially discriminatory to importers.³¹ Specifically, although the GATT recognized the validity of national domestic safety standards,³² it prohibited regulations that

²⁷ *Id.*

²⁸ See *infra* note 54 and text accompanying notes 59-75.

²⁹ Another example of the way in which regulations ostensibly aimed at protecting public health and safety can inhibit trade is the case of the European Community's ban on beef raised with the use of hormones. After the development of consumer fears about the use of the hormones, the European Community imposed a ban on the use of all hormones in beef. See Halpern, *supra* note 6, at 136. Several types of hormones are commonly used by U.S. producers of cattle; these include DES, which facilitates rapid growth in beef cattle, and bovine somatotropic (BST), a naturally occurring hormone that increases milk production in dairy cattle. See Steven J. Rothberg, Note, *From Beer to BST: Circumventing the GATT Standards Code's Prohibition on Unnecessary Obstacles to Trade*, 75 Minn. L. Rev. 505, 508-11 (1990); Michael B. Froman, Note, *The United States-European Community Hormone Treated Beef Controversy*, 30 Harv. Int'l L.J. 549 (1989). Because the ban restrained cattle and beef export to the European Community by \$100 million annually and because U.S. producers and regulators deemed the hormones safe, the United States challenged the ban under the Standards Code, charging that the ban was merely a protection for European farmers whose production methods failed to take advantage of safe hormone use. See Halpern, *supra* note 6, at 138.

³⁰ See Dunne, *supra* note 2, at 3.

³¹ See Bradley Larson, Note, *Introduction to Non-Tariff Barriers to International Trade*, 7 U. Bridgeport L. Rev. 155, 162-63 (1986); Middleton, *supra* note 9, at 201.

³² Article XX of the GATT, which allows a broad range of general exceptions to its application, provides that as long as such measures are not applied in a discriminatory manner or as disguised restrictions on trade, "nothing in this agreement shall be construed to prevent the adoption or enforcement by any contracting party of measure . . . (b) necessary to protect human, animal or plant life or health." GATT, *supra* note 1, art. XX. However, a method for determining which standards were necessary was not defined. Although few clear disputes developed around this issue, the debilitating effects on trade of non-tariff barriers in general

held exporters to standards higher than those imposed on domestic producers in the importing nation.³³ Indeed, the text of the Agreement itself permitted countries to enact regulations "necessary to protect human, animal or plant life or health."³⁴ This "necessary" standard, however, was ambiguous. It offered little guidance to parties faced with deciding whether regulations were permissible tools for protecting health and safety or impermissible barriers to trade.³⁵

To address this shortcoming, GATT negotiators during the Tokyo Round enacted the Agreement on Technical Barriers to Trade, the "Standards Code."³⁶ The Standards Code set forth more detailed guidance in several articulated principles. Parties to the Agreement: (1) will not use technical regulations or standards for the purpose of blocking trade; (2) will not discriminate against other parties by using technical regulations and standards; and (3) will not adopt technical regulations and standards which have the practical effect of unnecessarily inhibiting trade.³⁷ In addition, the Standards Code required that nations "where possible and appropriate" base their regulations on established international standards.³⁸

Adopting international standards—"harmonizing" the domestic regulations of participating nations—should facilitate resolution of disputes over disparate national standards: It narrows the international debate from a general dispute over the abstract necessity of a safety regulation to an objective determination of how and why a national standard diverges from the determined international standard.³⁹ The Standards Code, too, however, has its own shortcomings as an instrument both for removing the non-facially discriminatory

were great enough to pressure for continued negotiation of these issues in later agreements. See Larson, *supra* note 31, at 162-63.

³³ See McGovern, *supra* note 1, at 229.

³⁴ GATT, *supra* note 1, art. XX.

³⁵ The exact extent of trade disruption caused by such non-tariff barriers is unclear, because no "persuasive economic analysis" of the costs arising from divergent food safety regulations has been made. Eliza Patterson, *International Efforts to Minimize the Adverse Trade Effects of National Sanitary and Phytosanitary Regulations*, 24 J. World Trade, Apr. 1990, at 91, 95.

³⁶ General Agreement on Tariffs and Trade: Technical Barriers to Trade, *opened for signature* Apr. 12, 1979, 31 U.S.T. 405, T.I.A.S. No. 9616, 1186 U.N.T.S. 276 (1979) [hereinafter Standards Code]. The Standards Code was one of six codes adopted during the Tokyo Round, trade negotiations distinguished for their emphasis on non-tariff barriers. Larson, *supra* note 31, at 169 ("The goal of the Tokyo negotiations was to eliminate or reduce barriers to international trade that took the form of non-tariff measures.").

³⁷ Standards Code, *supra* note 36, art. 2.1. The Standards Code applies to both industrial and agricultural products. *Id.* at art. 1. The technical regulations it covers would include food safety regulations like pesticide residue limits. See *id.* at annex I.

³⁸ Standards Code, *supra* note 36, art. 2.2. See Middleton, *supra* note 9, at 202.

³⁹ Middleton, *supra* note 9, at 206-07.

barriers that unnecessarily inhibit trade and for facilitating dispute resolution. First, it gives little substantive guidance to individual nations. The Standards Code fails to establish meaningful rules for determining what makes a regulation unnecessary or discriminatory. This lack of substantive guidance impedes efforts to resolve disputes when parties challenge regulations.⁴⁰ Because there are no substan-

⁴⁰ Dispute resolution procedures under the Standards Code mimic those available under the GATT. The dispute resolution procedures under the GATT center around the mediation of disputes between contracting parties, although the Standards Code provides for the more ready use of technical experts to aid in deciding disputes. Disputes under the GATT are covered by GATT Articles XXII and XXIII. Article XXII requires consultation by a contracting party at the request of another contracting party about any matter affecting the operation of the GATT. GATT, *supra* note 1, art. XXII. Article XXIII provides a more formalized opportunity for a party to protest if it feels another party's failure to carry out its obligations impairs its benefits from the Agreement, or if it feels another party is applying measures which conflict with the Agreement. *Id.* at art. XXIII. See also Judith H. Bello & Alan F. Holmer, *Settling Disputes in the GATT: Past, Present, and Future*, 24 Int'l Law. 519, 520-23 (1990) (providing overview of GATT dispute settlement procedures). For a more comprehensive view of the dispute settlement procedures of the GATT, see generally Guy L. de Lacharriere, *The Settlement of Disputes Between Contracting Parties to the General Agreement, in Trade Policies for A Better Future* 119 (Martinus Nijhoff ed., 1987).

After making a written representation to the offending party, the aggrieved party can refer the dispute to other contracting parties. The contracting parties must investigate the complaint and make "appropriate recommendations" or "give a ruling." GATT, *supra* note 1, art. XXIII(2). As the custom has developed, the GATT Council (the body through which the contracting parties function) makes its findings and rulings through GATT panels made up of selected representative of neutral parties. This practice is codified in the Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance, GATT Doc. L/4907 (Nov. 28, 1979). See Bello & Holmer, *supra*, at 521. For a discussion of how such panels are formed and how they are charged with carrying out their function, see *id.* at 521-522. If the recommendations of the panel are not implemented, the aggrieved party may request that the Council find an appropriate solution. The Council then decides whether to adopt the panel's decision. *Id.* at 523.

The contracting parties can then authorize the aggrieved party to "suspend the application to any other contracting party or parties of such concessions or other obligations under this Agreement as they determine to be appropriate in the circumstances." GATT, *supra* note 1, art. XXIII(2). "In other words, failure to implement the recommendations of the GATT Council . . . or to take actions in conformity with a GATT Council ruling may lead to GATT authorization for proportional countermeasures . . ." Bello & Holmer, *supra*, at 521. Essentially, a favorable GATT decision for the aggrieved party leads to legitimized retaliation. *Id.*

However, the progress of such proceedings can be stymied at various stages, for instance, by blocking panel rulings from adoption by the Council. Bello & Holmer, *supra*, at 523. New rules adopted during the Uruguay Round seek to limit such procedural abuses. See *infra* notes 49-52 and accompanying text.

The Standards Code also provides for the establishment of a Committee on Technical Barriers to Trade, which can be called upon to consult on the dispute before the establishment of a panel. Standards Code, *supra* note 36, art. 13. Also, the Committee can establish a technical expert group to examine the matter if "the issues in dispute relate to commercial policy considerations and/or to questions of a technical nature requiring detailed consideration by experts." *Id.* at art. 14.5. Such a technical expert group can make findings to assist the Committee in making recommendations, including, "findings concerning the detailed scientific judgements involved, whether the measure was necessary for the protection of human, animal or plant life

tive rules to guide dispute settlement panels, few parties have seen the benefit of filing a formal complaint under the Standards Code.⁴¹

In addition, dispute resolution panels shy away from unilaterally encroaching on a nation's discretion in the traditionally national role of setting health and safety regulations.⁴² National regulations developed for health and safety reasons reflect domestic policies; efforts by an outside authority to dictate domestic safety regulations are threatening to national sovereignty.⁴³ Although any trade negotiation involves some trade-off between national sovereignty and the free-trade benefits, control over health and safety issues is more jealously guarded by regulating nations.⁴⁴

Finally, the Standards Code has proved an incomplete arrangement for harmonizing national regulations. It does not firmly establish which international standards should form the baseline for judging domestic regulations.⁴⁵ Additionally, it provides a fairly broad escape clause; parties need not follow harmonized standards wherever "such international standards or relevant parts are inappropriate for the [p]arties concerned, for *inter alia* such reasons as . . . protection for human health or safety, animal plant life or health or the environment."⁴⁶

C. Current GATT Proposals to Harmonize

Subsequent negotiation has sought to further refine substantive standards for domestic regulation and to emphasize harmonization as a means of preempting international regulatory disputes. Amend-

or health, and whether a legitimate scientific judgment involved." *Id.* at art. 14.9. See also Middleton, *supra* note 9, at 217. According to Middleton:

This is an important innovative concept in the GATT dispute settlement procedures; it recognizes the high technicity of some of the problems likely to arise under the Code and offers a procedure for bringing forward objective technical judgment rather than leaving the matter, as frequently [occurred] in previous disputes under GATT, to settlement on broad trade-policy grounds.

Id. The enforcement provisions for the Code are the same as those under Article XXIII of the GATT. *Id.*

⁴¹ Patterson, *supra* note 35, at 94.

⁴² See *id.*

⁴³ Patterson, *supra* note 35, at 95. See Larson, *supra* note 31, at 185 ("It is the balancing of restrictive trade effects against legitimate domestic purposes that makes this area so technically difficult."); Middleton, *supra* note 9, at 202. In the pesticide area, David Kay has noted that while "[t]he importing nation is properly concerned that its citizens not be exposed to dangerous amounts of pesticides on the food it imports . . . the exporting nation is concerned that food standard laws not be used as non-tariff barriers to trade." Kay, *supra* note 4, at 13.

⁴⁴ Kay, *supra* note 4, at 13.

⁴⁵ Middleton, *supra* note 9, at 206.

⁴⁶ Standards Code, *supra* note 36, art. 2.2.

ments to the GATT during the Uruguay Round in progress since 1986⁴⁷ have produced the "Decision by Contracting Parties on the Application of Sanitary and Phytosanitary Measures,"⁴⁸ a draft agreement which focuses on food safety regulation. The Decision directly confronts shortcomings of prior negotiations by requiring that domestic food safety measures be based on "sound and verifiable scientific evidence" and encouraging "the harmonization of national measures through the adoption of international standards established by appropriate international standardizing bodies."⁴⁹

The Uruguay Round has sought to eliminate the arbitrariness of vague, qualitative criteria for substantive standards. Like Article XX and the Standards Code, the Decision allows nations to promulgate "[food safety] measures *necessary* for the protection of human, animal or plant life or health."⁵⁰ The Decision departs from previous meas-

⁴⁷ Matthew C. Vita, *Economic Summitry Strains Group of Seven*, Atlanta Const., July 9, 1992, at A8. Although the Uruguay Round of GATT negotiations was set to conclude in December 1990, a final agreement was withheld due to disputes over European agricultural subsidies. Stuart Auerbach, *EC Rejects U.S. Arbitration Demand in Soybean Dispute*, Wash. Post, Oct. 2, 1992, at A26.

The Uruguay Round of GATT negotiations has developed draft agreements in a wide range of trade areas including agreements regarding Rules of Origin (§ D), Import Licensing (§ H), Government Procurement (§ K), Technical Barriers to Trade (§ G) and Food Safety Measures (§ L). The negotiators have also substantially strengthened measures designed to resolve disputes. See Draft Final Act, *supra* note 1.

⁴⁸ Draft Final Act, *supra* note 1, at § L, pt. C. This agreement specifically includes the regulation of pesticide residues in that it "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade." *Id.* at § L, pt. C, at L.36. The definition of Sanitary and Phytosanitary measures includes:

Any measure applied . . . to protect human or animal life or health within the territory of the contracting party from risks arising from additives, contaminants, toxins or disease-causing organisms, in foods, beverages or feedstuffs Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria

Id. § L, pt. C, annex A, at L.45.

A separate draft was created for technical standards outside of the food safety area, the Agreement (1991) on Technical Barriers to Trade. *Id.* § G.

⁴⁹ *Uruguay Round: Further Papers on Selected Issues*, United Nations Conference on Trade and Development, U.N. Development Programme, at 35, U.N. Doc. CTAD/ITP/42 (1990) [hereinafter United Nations Conference]. See also *Codex Alimentarius Commission, Report on the GATT/Uruguay Round of Multilateral Trade Negotiations in Relation to Sanitary and Phytosanitary Measures and Barriers*, Joint FAO/WHO Food Standards Programme, 19th Sess., Agenda Item 9, at 3, 4, U.N. Doc. ALINORM 91/9 (1991) [hereinafter *Report on the GATT/Uruguay Round*] (citing these as the primary goals of a special working group on Sanitary and Phytosanitary measures in the GATT negotiating group on Agriculture).

⁵⁰ Draft Final Act, *supra* note 1, § L, pt. C, at L.36. This Note's analysis of the draft language of the GATT is taken in part from Lori Wallach, *Memorandum to Environmental, Health and Consumer Advocates: The Dec. 20, 1991 Uruguay "Final Act" is Worse Than Expected on Environmental, Health and Consumer Issues*, Public Citizen Update (Public Citizen, Washington, D.C.), Dec. 26, 1991.

ures, however, by requiring that "necessary" measures be based on "scientific principles" and not contradict "available scientific evidence."⁵¹ A country can thus enforce a regulation stricter than the international standard only if that regulation has a documented scientific basis.⁵²

The Decision advances harmonization of domestic regulations to an international standard in several ways.⁵³ First, it specifically names those international bodies whose standards will be considered the international standard. For pesticide residue limits and other food safety regulations, the Decision names the Codex Alimentarius Commission as the international standard-setting body.⁵⁴ Second, the agreement calls for parties to base national standards on international

⁵¹ Under the Decision, parties are obliged to "ensure that [food safety] measures are applied only to the extent necessary to protect human, animal or plant life or health, are based on scientific principles and are not maintained against available scientific evidence." Draft Final Act, *supra* note 1, § L, pt. C, at L.36.

⁵² Contracting parties may introduce or maintain [food safety] measures which result in a higher level of [food safety] protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a contracting party determines to be appropriate in accordance with the relevant provisions of paragraphs 16 through 23.

Id. § L, pt. C, at L.37.

Paragraphs 16-23 place affirmative burdens on the contracting parties to "ensure" that their food safety measures be based on valid assessment procedures and proper risk analysis methods, take into account "the objective of minimizing negative trade effects" and be the "least restrictive to trade, taking into account technical and economic feasibility." *Id.* § L, pt. C, at L.38-39.

Arguably the provisions of paragraphs 16-20 place the burden on the challenged regulator to legitimize its standard under these provisions. *Id.* § L, pt. C, at L.38. The United States has proposed that "a contracting party which did not use an international standard would have the burden of proving that its measures were based on sound scientific evidence." U. N. Conference, *supra* note 49, at 36. One commentator's reading of the draft finds that the agreement does place such an obligation on the regulating party. See Wallach, *supra* note 50, at 19. At the least these provisions require a party to provide an explanation of the reasons for a challenged measure to a challenging party. Draft Final Act, *supra* note 1, § L, pt. C, at L.39.

⁵³ The preamble to the Decision states that the contracting parties desire "to further the use of harmonized sanitary and phytosanitary measures between contracting parties, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations . . ." in an effort to establish "a multilateral framework of rules and disciplines to guide the adoption, development and the enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade." Draft Final Act, *supra* note 1, § L, pt. C, at L.35. Harmonization is defined in the Decision as "[t]he establishment, recognition and application of common sanitary and phytosanitary measures by different contracting parties." *Id.* § L, pt. C, annex A, at L.45.

⁵⁴ *Id.* § L, pt. C, annex A(3), at L.46. Acknowledging the desirability for all food safety measures to be based on internationally recognized standards and principles, the draft text specifically identifies the applicable standards, guidelines and recommendations underpinning enforcement of the decision of the Codex Alimentarius for food safety, the International Plant

ones except "as otherwise provided for in this decision."⁵⁵ International standards thus would provide a baseline for measuring a party's compliance with the agreement, creating an objective basis for dispute resolution.⁵⁶

III. CODEX DECISION MAKING AND ITS U.S. IMPLICATIONS

As pressure for harmonization grows, the influence of internationally set health and safety standards on domestic pesticide regulation will increase. Today, standards set by the Codex Alimentarius Commission have binding authority only insofar as individual nations have adopted them as domestic standards.⁵⁷ Even though non-binding, however, Codex standards have begun to influence domestic regulation in the United States; pesticide tolerances advocated by the Commission have already been proposed for adoption in the United States.⁵⁸

Protection Convention for plant health and the International Office of Epizootic for animal health. *Id.*

Notably, the Codex Commission itself sees the Uruguay Round as a "unique opportunity to strengthen immeasurably the importance of Codex in international trade . . ." *Report on GATT/Uruguay Round, supra* note 49, at 3.

⁵⁵ The parties decide that in order "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, [they] shall base their [food safety] measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this decision." Draft Final Act, *supra* note 1, § L, pt. C, at L.37.

⁵⁶ Food safety measures "which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this decision and of the General Agreement." *Id.*

Additionally, the Decision establishes a Committee on Sanitary and Phytosanitary Measures, which would provide a "regular forum for consultations . . . [which] shall carry out the functions necessary to implement the provisions of this decision and the furtherance of its objectives, in particular with respect to harmonization." *Id.* § L, pt. C, at L.42. The provisions of paragraphs 39-44 provide the ways in which the Committee is to carry out its mandate. *See, e.g., id.* § L, pt. C, at L.42 (The Committee shall "encourage the use of international standards, guidelines or recommendations by all contracting parties and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for . . . establishing tolerances for contaminants in food . . .").

⁵⁷ Kay, *supra* note 4, at 21 ("The Codex-proposed standards are simply recommendations which derive their binding effect solely from their acceptance by governments."). The Codex provides for a complicated scheme whereby nations are to communicate the extent of their adoption of Codex standards. *Id.* at 31-32; *see also* Joint FAO/WHO Food Standards Programme, Codex Alimentarius Procedural Manual 65 (7th ed. 1989) [hereinafter Procedural Manual] (stating that governments should attempt to accept the standards formally and include conditions to, deviations from and explanations for them in their responses to the Codex).

⁵⁸ *See infra* notes 96-97 and accompanying text.

A. *The Codex Alimentarius Commission and Its Trade Bias*

The Codex Alimentarius⁵⁹ Commission was established under the auspices of the United Nations in 1962 by the Food and Agricultural Organization and the World Health Organization (FAO/WHO) to serve two purposes: to encourage international trade in food products and to protect the health and economic interests of consumers.⁶⁰ To meet these objectives, the Commission has established a committee structure under which expert representatives from participating member states meet to discuss and adopt standards for food production.⁶¹

Three types of committees perform most of the tasks required by the Codex: Regional coordinating committees address questions of special importance for specific geographic regions; commodity committees consider issues relating to specific foodstuffs, like cocoa products or fish products; and general subject committees handle issues like food additives and pesticide residues.⁶² The Codex Alimentarius Commission has created the Codex Alimentarius, an elaborate code regarding all manner of food production including: the composition of products; the use of food additives; the setting of maximum limits for pesticide residues; requirements for food labelling; recommendations on food processing techniques; and suggested procedures for inspecting food production and products.⁶³

The Codex Committee on Pesticide Residues (CCPR), a general subject committee, creates standards for pesticide residues.⁶⁴ In line with the Commission's overarching mission, the CCPR operates both

⁵⁹ The term means "Food Code" in Latin.

⁶⁰ Procedural Manual, *supra* note 57, at 5. For an introductory look at the Codex, see Joint FAO/WHO Food Standards Programme, *Introducing Codex Alimentarius (1990)* [hereinafter *Introducing Codex*]. See also Procedural Manual, *supra* note 57, at 65; Sharin Sachs, *U.N. of the Food World: Decoding Codex*, FDA Consumer, Feb. 1990 at 28, 28; Kay, *supra* note 4, at 18.

⁶¹ Codex membership is open to all member nations of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO). Some 130 countries were Codex members by 1988. *Introducing Codex*, *supra* note 60, at 5.

⁶² An outline of Codex committees can be found in *Introducing Codex*, *supra* note 60, at 22-23.

⁶³ The Codex has established some 200 "commodity standards" for the composition or identity of end products, approximately 500 "maximum levels" for food additives, 2700 "maximum residue limits" for pesticide residues in foods and food crops and more than 40 "codes and guidelines" for food production and processing techniques. Sachs, *supra* note 60, at 29. There are currently seventeen volumes of Food Standards and eight volumes of recommended international Codes of Practice and Guidelines. *Introducing Codex*, *supra* note 60, at 10. Along with establishing safety, labelling and processing standards, the Codex issued the Code of Ethics for International Trade in Food in 1980, which covers ethical aspects of food dumping and the need to follow international standards when exporting food to countries with inadequate means to monitor and control food safety. *Id.* at 5.

⁶⁴ Procedural Manual, *supra* note 57, at 46.

to protect consumers and to facilitate trade.⁶⁵ When deciding pesticide tolerances, the CCPR seeks the advice of an expert committee of scientists⁶⁶ on the health effects of pesticide standards.⁶⁷

The procedures for adopting standards are complex. "In principle, the chairmen of the committee and the Codex [Commission] synthesize a majority of opinion among members and if no major opposition is voiced a standard is approved and adopted."⁶⁸ More specifically, general subject committees formulate draft standards for the Commission, which in turn seeks comments on them. In seeking a consensus on the standard, the Commission works closely with the relevant committee.⁶⁹ Once a consensus is reached, the Commission approves and adopts a standard.⁷⁰

The central concern of the committee is, in practice, to eliminate trade concerns, not to research the health and safety effects of pesti-

⁶⁵ *Id.* at 5, 23.

⁶⁶ The opinion of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), an independent body of experts, plays a significant role in the creation of Codex pesticide standards. Their recommendations are in no way binding on the Committee, however. *See infra* notes 69-70 and accompanying text. *See also* Kay, *supra* note 4, at 51 ("Tolerance proposals for pesticide residues from the very beginning involved more of a scientific assessment than other areas of Codex efforts.").

⁶⁷ Introducing Codex, *supra* note 60, at 23.

⁶⁸ GAO Report, *supra* note 11, at 38.

⁶⁹ In the case of pesticide residues, the selection of a pesticide is made by a priorities working group of the Codex Committee on Pesticide Residues (CCPR). GAO Report, *supra* note 11, at 38. The Committee then requests the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), made up of the FAO working party of experts and the WHO Expert Committee on Pesticide Residues, appointed in their individual capacities by the General Directors of WHO and FAO, to formulate a proposed draft standard. The draft is sent to member nations and interested international organizations for comment "on all aspects, including possible implications . . . for their economic interests." Procedural Manual, *supra* note 57, at 46. *See also* GAO Report, *supra* note 11, at 38 n.1 (stating that draft MRLs are available to international organizations for comment).

Based on these comments, the Committee either sends the proposed draft standard on to the Commission to be considered for adoption (taking into account the need for urgency and the likelihood of new evidence becoming available in the immediate future) or sends them back to the JMPR for another round of evaluation and comment by member states. Procedural Manual, *supra* note 57, at 46. When the standard has been forwarded to the Commission, it is again sent to members for comment and now called a draft standard. Based on comments received, the Commission can send the standard back to the Committee to reconsider or change the standard or, if it believes consensus has been reached, can approve its adoption as a standard. *Id.* at 38-41, 46; GAO Report, *supra* note 11, at 38. This lengthy process may take several years to complete. *Id.*

For further discussion of Codex standard-setting process, see Donna L. Malloy, *The Codex Alimentarius Provides International Standards for Food Production and Safety*, 12 J. of Agric. Tax'n & L. 334, 336-37 (Winter 1991). For more specific discussion of the procedures of the Codex Committee on Pesticide Residues, see Kay, *supra* note 4, at 22-32.

⁷⁰ GAO Report, *supra* note 11, at 38.

cides.⁷¹ Though the CCPR incorporates scientific experts into its process from the start, the CCPR is a negotiating body with an overarching goal of establishing internationally agreed-upon tolerances for pesticide residues, standards which in effect remove the greatest non-economic obstacle to international trade in food.⁷² Promoting free trade, David Kay has suggested, has traditionally overshadowed the CCPR's goal of setting standards for safe pesticide use.⁷³ Indeed, the CCPR was developed "primarily to facilitate international trade within a context that assumed the health of the consumer would be protected."⁷⁴ By contrast, according to Kay, the domestic regulatory systems of individual nations like the United States "tend to be far more interested in the health hazards and environmental impact of pesticide residues in food . . . than with fear that food laws would be used as an artificial trade barrier."⁷⁵

⁷¹ "Not surprisingly, discussions in CCPR tend to be more political than scientific, i.e. the discussions of proposed tolerance levels tend to revolve around what the particular national tolerance levels are and the impact of proposed tolerances on a particular nation's agricultural trade." Kay, *supra* note 4, at 29.

⁷² *Id.* at 38. Hence, pesticide regulation schemes, labelling standards, human health and environmental concerns arising out of pesticide regulation have been outside of the CCPR purview. *Id.*

⁷³ *Id.* at 38, 46.

The ten-step Codex standard setting process applicable to all areas of the Commission's work is a highly articulated harmonization process designed to allow nations to bargain out a common set of standards. It was not conceived as a scientifically based international standard setting process.

Id. at 50.

Some Codex statements seem at times to belittle variance in national regulation and to aggrandize the Codex's role in ensuring the world's food supply:

Food regulations do not have a place for those differences in political approach which characterize so many international discussions: as regards their needs for food and the elimination of adverse effects from food, human beings are remarkably consistent over the whole world. They differ considerably in customs, habits, beliefs, political systems and have shown the great lengths to which they are prepared to go to defend "their way." In relation to food this only applies as regards choice and variety. The basic needs for nutrients and the necessity for wholesomeness are universal.

. . . .

Somehow these differing views have to be brought from the emotional or instinctive level and considered in a scientific and logical atmosphere. Somewhere the balance between benefits and risks must be brought out and resolved if there is to be any international harmonization and the world food supply is to be maintained.

Introducing Codex, *supra* note 60, at 3,7.

This does not mean, however, that standards will necessarily be bargained to a lowest common denominator. In fact, Codex standards historically have neither been consistently higher nor lower than U.S. standards. See *infra* notes 87-93 and accompanying text.

⁷⁴ See Kay, *supra* note 4, at 46.

⁷⁵ *Id.*

B. Public Access to Codex Standard-Setting Proceedings

Historically, participation in the standard-setting proceedings of the Codex Alimentarius Commission and the CCPR has reflected a bias toward trade at the expense of consumer interests. Simply put, industry has generally had access to the standard-setting procedure, but consumer groups have not.⁷⁶ Industry's role in the Commission's work has been salient,⁷⁷ and industry continues to play an important role in the development of Codex standards. According to the Commission's own publication:

Industry and trade . . . have an important role in Codex. They can and do make valuable contributions in terms of scientific and economic information. Acting both as advisers to the government representatives in national delegations and through international industry associations, they bring a great wealth of information and advice to the Codex discussions.⁷⁸

The U.S. delegation, too, relies heavily on industry's ongoing input for developing the U.S. position in the Codex:

The Department of Agriculture and the Food and Drug Administration have evolved a two-step method for soliciting outside advice regarding the Codex process. First, the agencies solicit advice from industry advisors by providing them [with] a copy of the agenda for upcoming Codex meetings, as well as the draft U.S. position and background documents, and then following up with a meeting. Second, the agencies invite a group of industry advisors to accompany the U.S. delegation to the Codex conferences. During the conference, they advise the delegation on whatever issues may arise.⁷⁹

⁷⁶ *Id.* at 51 ("Existing CCPR standard setting procedure provides regular access to only three groups: governments, agricultural producers, and pesticide producers."). As noted above, international organizations have the opportunity to comment or draft standards. See *supra* note 69. Of the international groups that have attended CCPR meetings, only the International Organization of Consumer's Union can be said to represent consumer interests. See GAO Report, *supra* note 11, at 38 n.1. Other participating organizations include the International Group of National Associations of Manufacturers of Agrochemical Products and the International Union of Pure and Applied Chemistry. *Id.*

⁷⁷ Indeed, because the U.S. State Department refused to contribute to Codex funding at its inception, the United States initially participated in the Codex through the private contributions of the U.S. food industry. Kay, *supra* note 4, at 18.

⁷⁸ Introducing Codex, *supra* note 60, at 5.

⁷⁹ Tom Hilliard, Public Citizen's Congress Watch, Trade Advisory Committees: Privileged Access for Polluters 27-28 (Dec. 1991) (unpublished report, on file with the author) (citing letters from the U.S. Department of Agriculture to industry representatives, 1985-1991). Hilliard's analysis of the Codex Advisory Committee is part of a larger analysis of the unbalanced access of industry reflected in all trade advisory committees. Hilliard also suggests that this unequal access violates the provisions of the Federal Advisory Committee Act that require

Sheer numbers indicate industry's unbalanced access to the Codex process, a phenomenon evident in recent proceedings of the CCPR where only two of seventy-three non-governmental participants identified themselves as representing consumer interests.⁸⁰ Industry and commodity organization representatives typically accompany the U.S. delegation to CCPR meetings. For instance, two representatives of the National Agricultural Chemicals Association, representatives of California and Florida citrus growers associations and a representative of Hershey Foods accompanied the most recent U.S. government delegation to the CCPR as observers.⁸¹

Consumer groups, on the other hand, do not generally participate in the Codex standard-setting process; their advocates have in the past been absent even from the U.S. delegation. Although several consumer representatives recently have been allowed to join U.S. Codex advisory bodies,⁸² "[t]his process, dating back at least to 1985, contains no institutionalized role for consumer advocates or experts on consumer health."⁸³

Industry's lopsided participation in the Commission's proceedings

advisory committees to be "fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee." *Id.* at 9 (quoting the Federal Advisory Committee Act, 5 U.S.C. app. 2 § 5(b)(2) (1988)).

⁸⁰ One hundred ninety-seven participants attended the April 1991 CCPR Committee meeting, including: 124 government representatives; fifty agrichemical company representatives; fourteen food company representatives; seven participants with no named affiliation; and two consumer representatives. Tim Lang, *Food Fit for the World?: How the GATT Food Trade Talks Challenge Public Health, the Environment and the Citizen 21* (Mar. 1992) (unpublished paper, on file with the author) (citing participants lists, Codex Alimentarius Commission Pesticide Residues Committee, April 15-19, Rome).

⁸¹ Telephone Interview with USDA official Dr. Stanford N. Fertig, U.S. delegate to the CCPR (Mar. 25, 1992). According to Dr. Fertig, industry members of the U.S. delegation do not act as *per se* advisors. Yet although the U.S. position on a proposed Codex tolerance generally is determined with reference to an established U.S. tolerance, decisions on whether to accept or reject a tolerance in conflict with U.S. standards are made by a delegation with "important input" from industry observers. *Id.*

⁸² In 1991, four consumer representatives were permitted to join the corps of U.S. Codex advisors. An April 1991 list of all U.S. Codex Advisors provided by a U.S. Codex representative included: fifteen industry representatives; fifteen trade group representatives; six independent consultants; and four consumer representatives. List of U.S. Codex Advisors provided by Patty Woodall, Staff Assistant for Codex Alimentarius, U.S. Department of Agriculture (Apr. 1991) (unpublished list, on file with the author). For a list of attendees at a July 1991 meeting of the Codex (thirteen from industry, seven from trade associations and two from consumer groups), see Hilliard, *supra* note 79, at 35-36. The consumer representatives are the first ever U.S. consumer representatives in the Codex Advisory Committee. *Id.* at 28 (citing Lester M. Crawford, former Chief of the U.S. delegation to the Codex and now a lobbyist for the National Food Processors Association). For a review of Mr. Crawford's background and the problems facing the USDA's Food Safety and Inspection Service, see Daniel P. Puzo, *Crawford leaves USDA Inspection Service Post*, Los Angeles Times, Aug. 22, 1991, at 31.

⁸³ Hilliard, *supra* note 79, at 28.

raises questions about whether the Commission can adopt health and safety regulations without an undue bias in favor of production and trade interests.⁸⁴ Pesticide residue standards substantially affect the businesses they regulate. If these businesses in turn exert considerable unchallenged influence on the Codex standard-setting bodies responsible for those regulations, the regulations will inevitably favor the interests of trade to a greater extent than would regulations promulgated under the influence of countervailing interests.⁸⁵

Although the divergence of domestic pesticide standards worldwide will likely impede a wholesale move toward harmonization in the near future, the implications of the Decision and its designation of the Codex Alimentarius Commission as the international standard-setting body for food safety regulation are important for U.S. law. Whether or not the international community adopts specific current proposals, it will surely advance the broad trend toward harmonization as the primary means to reduce trade friction.

C. Implications for U.S. Pesticide Regulation

Analysis of the impact international standards might have on U.S. decision making necessarily depends on a broad, somewhat abstract assumption that U.S. and Codex standards can be evaluated “apples-to-apples,” that is, that one standard when compared with the other demonstrates objectively higher, lower or comparable health risks. In fact, such a comparison is difficult: Not only do the goals and methods of regulation under each system differ, but so do the very pesticides and commodities regulated. The U.S. system has produced roughly 8500 pesticide-by-commodity tolerances, next to the Codex Commission’s 3300; only 1267 of these combinations are common to both systems and ratable as higher, lower or comparable to one another.⁸⁶

⁸⁴ See generally *Introducing Codex*, *supra* note 60, at 3 (discussing the need to set international standards for protecting consumers and also to promote free and fair trade).

⁸⁵ See *supra* notes 76-83 and accompanying text; *Introducing Codex*, *supra* note 60 and accompanying text.

⁸⁶ The Codex system includes about 170 pesticides and, when commodity groupings are converted to individual commodities, over 3,300 pesticide-by-commodity MRLs as compared to over 400 pesticides and 8,500 pesticide by commodity tolerances (MRLs) in the U.S. system. GAO compared, where possible, U.S. pesticide MRLs and ADIs against the smaller set of Codex standards.

...
In 62 percent of the Codex cases (2,069), MRLs cannot be directly compared because the United States either has no standard or standards are defined differently.

GAO Report, *supra* note 11, at 4.

The fact that even some tolerances can be compared suffices for understanding the potential impact of harmonization on U.S. law. Very simply, where Codex standards are more tolerant of pesticide use, the American consumer risks being exposed to increased pesticide residues. For example, to resolve a one-time trade controversy, the U.S. government might accept a foreign product that met the Codex standard but not some stricter U.S. standard. For the longer term, the EPA could seek to ameliorate an existing conflict in the GATT or even anticipate a potential conflict by harmonizing U.S. standards with international ones, that is, by raising tolerance for pesticide residue on an imported product to some higher level set internationally by the Codex Commission.

Available comparison data indeed suggest a wide divergence between actual, comparable U.S. and Codex tolerance levels.⁸⁷ In some cases, the U.S. tolerance is lower than the Codex standard, especially when the EPA has rated the pesticide as a possible carcinogen.⁸⁸ Maintaining U.S. standards below the international level, according to the General Accounting Office, means that "the potential for international trade problems will remain. Yet, reducing potential trade problems by harmonizing general standards could affect food safety."⁸⁹ For some pesticides used abroad, the U.S. tolerance is not only lower but nonexistent: The United States has no tolerance levels for a full thirty percent of the pesticides for which the Codex has set tolerance levels. In some cases, the pesticide has never been used in the United States and no tolerance has been sought; for others, the tolerance has been revoked for health or environmental concerns.⁹⁰ Health risks could arise under these if the United States were to rely

⁸⁷ In a recent study of these divergences, the General Accounting Office found that "[m]any differences exist between U.S. and Codex pesticide standards. These differences are a reflection of both technical factors pertaining to pesticide uses and agricultural practices and factors related to the procedures used to evaluate and establish standards." *Id.* at 36.

⁸⁸ In the 1267 pesticide-by-commodity combinations that are comparable:
the United States has lower MRLs for 19 percent of the cases; the Codex for 34 percent

. . . .
Among the pesticides studied that EPA has rated as probable carcinogens, the United States has lower MRLs in 55 percent of the cases; the Codex, in only 27 percent. A study of the magnitude of the differences between U.S. and Codex MRLs for major U.S. agricultural exports and imports revealed that the United States has lower MRLs for about 20 percent of the pesticide-by-commodity combinations; the Codex, for 37 percent.

Id. at 4. See *id.* at Appendix II for a more comprehensive evaluation of the differences in standards.

⁸⁹ *Id.* at 36.

⁹⁰ *Id.* at 32.

on an unsafe Codex tolerance level because of incomplete data in the U.S. system⁹¹ or because a previous U.S. ban on the ordinary use of a pesticide like DDT leaves a vacuum for the persistent Codex tolerance levels to fill.⁹² The GAO has recognized the risk: "Foods that are treated with pesticides for which the United States has not established tolerances run the risk of creating possible health concerns."⁹³

Direct challenges to U.S. laws are possible under the Decision's draft language. If American standards are more strict than international standards, dispute settlement proceedings under the Decision would scrutinize the American standards for their basis in "sound science." If unable to provide such a basis, the United States might be subject to retaliatory measures under the GATT. To settle such a dispute, U.S. officials might be inclined to lower the U.S. standard to international levels, although the legality of such action would be open to question.⁹⁴

American administrations might be reluctant to maintain — or

⁹¹ In the case of U.S. detention of imported wine containing procymidone residues, no U.S. standard had been established; a draft Codex MRL was considered by the EPA in establishing an interim tolerance. See *supra* notes 26-29 and accompanying text (discussing procymidone); see generally GAO Report, *supra* note 11, at 33 (noting trade implications in cases where the Codex has an MRL but the United States does not).

⁹² For a history of the ban on DDT in the U.S., see *infra* note 119. The United States maintains some tolerances for DDT to account for residues left in soil deposits. Codex maintains many more tolerances for DDT, generally at much higher levels, allowing some general application of the pesticide. GAO Report, *supra* note 11, at 42.

⁹³ GAO Report, *supra* note 11, at 35.

⁹⁴ See *National Coalition Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875 (D.C. Cir. 1987). The petitioners sought review of EPA official actions regarding tolerance levels for ethylene dibromide (EDB) in imported mangoes. *Id.* at 876. In 1985, the EPA had lowered tolerances to zero p.p.b., with an interim allowance of 30 p.p.b. on imports for one year, in order to "remove EDB from the diet long term while avoiding significant economic disruptions by allowing a year to develop alternative treatment methods." *Id.* at 876-77 (quoting 50 Fed. Reg. 2547, 2550-51 (1985)). The EPA initially rebuffed efforts to extend the interim tolerance, but pressure from the State Department, which was concerned about economic effects on friendly countries in South and Central America, forced "an about face." *Id.* The court held that, in relying exclusively on concerns for foreign well-being without considering the health factors specified in domestic food safety law, the EPA had acted arbitrarily and capriciously; its administrative decision was thus subject to court review. *Id.* at 883-84.

The court, however, withheld further decision on the EDB tolerances and instead directed the EPA to reconsider whether an extension of the interim tolerance was justified. *Id.* at 884. On remand to the EPA, the Agency reaffirmed its extension, this time explicitly finding that the interim tolerance "is justified, is adequate to protect the public health, and will best serve the interest of assuring an adequate and wholesome food supply." *National Coalition Against the Misuse of Pesticides v. Thomas*, 815 F.2d 1579, 1581 (D.C. Cir. 1987) (citation omitted). The court refused petitioner's request for further review on the grounds that the EPA had again failed to perform its duty. The court found that the "EPA has now approached the issue at hand with proper attention to factors relevant under [food safety law]" and "resolved the matter in a reasoned fashion." *Id.* at 1582.

promulgate — regulations in conflict with Codex standards, even absent specific challenges to U.S. regulations by exporters. A major food exporter itself, the U.S. has a strong interest in preventing other importing nations from using food safety standards as trade barriers and thus arguably has a strong obligation to promote the GATT's ongoing harmonization program. The United States has advocated a stronger role for the Codex Alimentarius in harmonizing international standards.⁹⁵ Indeed, some U.S. regulations have already been based on particular Codex standards,⁹⁶ and there seems to be some interest in a policy shift to more firmly embrace Codex standards.⁹⁷

IV. PUBLIC PARTICIPATION'S ESSENTIAL CONTRIBUTION TO U.S. PESTICIDE REGULATION

The importance of the Codex Alimentarius Commission and other international standard-setting bodies would be magnified by acceptance of the draft Decision. Yet the process by which the Commission sets standards poses problems for U.S. consumers accustomed to protection from dangerous pesticide residues in domestic products by an administrative system that fully incorporates public participation.

Like the tolerances themselves, the systems that produce the Codex and the U.S. standards are, despite some similarities, in many respects not comparable. To state definitively which system's standards are superior is a difficult task beyond the scope of this Note. Rather, the Note seeks to address an important reason why the task is so difficult: In the broadest terms, without public access to the Codex decision-

⁹⁵ Patterson, *supra* note 35, at 94. U.S. representatives to the Codex continue to advocate a strong position for the Codex in an international regulatory system. *See, e.g.*, Dr. Lester Crawford, former coordinator of U.S. Codex activities and former Administrator of the Food Safety and Inspection Service, USDA, Remarks at Presentation to the 19th Sess. of the Codex Alimentarius Commission (July 1991) (transcript on file with the author).

⁹⁶ A survey of the Federal Register shows several instances where Codex standards have been proposed as U.S. standards. *See, e.g.*, Procymidone Residues in Wine: Request for Comments on Potential EPA Actions under Food, Drug and Cosmetic Act, 55 Fed. Reg. 39,171 (Sept. 25, 1990) (requesting comments on manufacturer's petition to establish Codex tolerances as U.S. law); Methidathion: Proposed Pesticide Tolerances, 53 Fed. Reg. 15,855 (Apr. 4, 1988) (proposing that Codex tolerances for residue in citrus fruit be adopted as U.S. law); Pesticide Tolerances for Ebufos, 57 Fed. Reg. 30,180 (July 8, 1992) (requesting comments on proposal to set tolerance for imported bananas in agreement with Codex limits); Levine, *supra* note 23, at 211 (discussing Codex standards proposed for difluanid, a pesticide which appeared on frozen Polish strawberries and for which no U.S. standard existed).

⁹⁷ "[S]everal federal agencies are proposing that Codex pesticide standards be used for imported foods for which the Environmental Protection Agency ("EPA") does not have a tolerance." Letter from Public Citizen to USDA Secretary Madigan and FDA Commissioner David Kessler (Dec. 16, 1991) (on file with the author) (citing U.S. Gen. Accounting Office, Food Safety and Quality: Five Countries' Efforts to Meet U.S. Requirements on Imported Produce 79 (1990)).

making process, we cannot even begin to know which system's standards are better. Unlike American administrative rulemaking, the Codex Commission offers few opportunities to the regulated public to check the Commission's work, to know if the balance struck between costs and benefits is the right one.

Furthermore, however sound the decisions behind closed doors are, without public participation the resulting regulations may not be effective. The American system surpasses the Codex in one very important respect wholly separate from scientific or economic considerations: Public participation in the regulatory process legitimates administrative decision making, in effect democratizing regulatory decisions.

A. Comparing Systems: Pesticide Regulation in the United States and in the Codex Commission

1. Setting Maximum Residue Limits: Cost-Benefit Balancing, Scientific Input, but Divergent Methods and Definitions

The process by which U.S. officials regulate pesticide residues on food products in some respects bears strong resemblance to the analogous process followed in the Codex Commission. Stated broadly, both processes result in tolerances based on cost-benefit analysis and independent scientific evaluation.

In the United States, pesticides proposed for use on food products must clear two separate but interdependent regulatory hurdles, each of which employs cost-benefit balancing:⁹⁸ registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)⁹⁹ and tolerance setting under the Food, Drug and Cosmetics Act (FDCA).¹⁰⁰ FIFRA mandates the registration of any pesticide proposed for sale or use in the United States. Registration requires the EPA¹⁰¹ to balance the "economic, social, and environmental costs and benefits of

⁹⁸ Frederick R. Anderson et al., *Environmental Protection Law and Policy* 519-20 (1984).

⁹⁹ 7 U.S.C. §§ 136-136y (1988).

¹⁰⁰ 21 U.S.C. §§ 301-94 (1988).

¹⁰¹ Delaney Paradox, *supra* note 20, at 18. See also GAO Report, *supra* note 11, at 14 (noting the EPA's large role in regulating pesticides under the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug and Cosmetics Act). The U.S. pesticide regulation scheme is a complicated one. Whereas the EPA is charged with the initial registration of pesticides for use and the setting of tolerances for residues, the FDA and USDA play important roles in the enforcement of pesticide regulations, not generally discussed herein. The FDA has the power to seize foods containing levels of pesticide that exceed tolerance levels under 21 U.S.C. § 334. Jeffrey H. Nicholas, *Problems in the Control of Pesticide Residues or Imported Foods*, 36 *Food Drug Cosm.* L.J. 573, 575 (1981). For two opposing views of the success of the EPA's detection of foods in the market with residues exceeding tolerance levels, see *supra* note 4.

the use of any pesticide"¹⁰² as a prerequisite to determining whether the pesticide causes "unreasonable adverse effects" on humans or the environment.¹⁰³ For pesticides used on food products, registration further requires the EPA to set a "tolerance," a maximum allowable residue level.¹⁰⁴ Residue limits for pesticide residues in or on raw products are set "to the extent necessary to protect the public health."¹⁰⁵ Regulations must consider "the necessity for the production of an adequate, wholesome, and economical food supply."¹⁰⁶ For processed foods, residue limits are regulated as "food additives" under the FDCA.¹⁰⁷ If no specific tolerance has been set for a particular product, "a processed food bearing residues at levels in excess of that authorized in the raw product is considered 'adulterated' and prohibited in interstate commerce."¹⁰⁸

¹⁰² 7 U.S.C. § 136(bb). Under FIFRA, the EPA is charged with determining which pesticides can be registered in the United States. 7 U.S.C. § 136a(a).

¹⁰³ 7 U.S.C. §§ 136(bb). See *Nader v. United States EPA*, 859 F.2d 747, 748 (9th Cir. 1988) (summarizing the statutory framework of FDCA and FIFRA).

¹⁰⁴ Delaney Paradox, *supra* note 20, at 23.

¹⁰⁵ 21 U.S.C. § 346a(b). The EPA is responsible for setting residue tolerance levels for pesticides under the FDCA. 21 U.S.C. §§ 301-393 (1988). Tolerances are to be set for chemicals "which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health." 21 U.S.C. § 346a(b). More simply, a tolerance need not be set for any pesticide "generally recognized, among [qualified] experts . . . as safe . . ." 21 U.S.C. § 346a(b). Additionally, the EPA Administrator may exempt a pesticide from the tolerance level requirement. 21 U.S.C. § 346a(a)(2). There are over 8500 tolerances for all pesticides currently in the Code of Federal Regulations, most of which are for raw commodities. Delaney Paradox, *supra* note 20, at 19. The Administrator may establish a "zero level," banning foods containing any residue of a pesticide, if the scientific data before the Administrator do not justify the establishment of a greater tolerance. 21 U.S.C. § 346a(b).

¹⁰⁶ 21 U.S.C. § 346a(b). See also *Nader*, 859 F.2d at 748 (listing the factors that the EPA Administrator must consider when establishing pesticide tolerances).

¹⁰⁷ 21 U.S.C. § 348. This section specifically excludes pesticide residues on raw products, 21 U.S.C. § 321(s)(1), which are regulated solely by § 346a, but by implication includes pesticides on processed foods. Delaney Paradox, *supra* note 20, at 25. The reorganization plan that established the EPA in 1970 transferred the authority to set pesticide tolerances under § 348, from the FDA to the EPA. See *Nader*, 859 F.2d at 748 n.1 (citing Reorg. Plan No.3 of 1970, § 2(a)(4), (a)(8)(i), 40 C.F.R. pt. 1 (1970)).

¹⁰⁸ *Nader*, 859 F.2d at 748 (citing 21 U.S.C. § 342(a)(2)(C) (1988)). Additionally, the standard for food additives is a risk-only standard, which requires that no food additive tolerances be issued unless "a fair evaluation of the data . . . establish that the proposed use of the food additive . . . will be safe." 21 U.S.C. § 348(c)(3)(A). See also Delaney Paradox, *supra* note 20, at 19 (discussing the EPA's balancing of benefits against the potential human health effects). This does not allow § 346a's same risk-benefit analysis and places a greater affirmative burden on the manufacturer to prove with "reasonable certainty that no harm to consumers will result when the additive is put to its intended use." Delaney Paradox, *supra* note 20, at 26 (citing 21 C.F.R. § 170.3(i)). This "strictly risk-based" analysis "seems to preclude consideration of any economic or other benefits." *Id.*

An additional provision of § 348, known as the Delaney clause, dictates that no additive that concentrates in processed foods is safe "if it is found to induce cancer when ingested by man or

Both the U.S. regulatory regime and the Codex Commission's procedures employ some form of cost-benefit balancing, although the sought-after benefits of each are necessarily different — for the Codex, the fewest possible international trade barriers, and for the United States, economic food production. Moreover, both seek input from independent scientific bodies — the FAO/WHO Committee for Codex Commission decisions, and various advisory committees for U.S. administrative agency proceedings.¹⁰⁹

Despite broad similarities, important differences in the substantive definitions and analytical methods employed in the two systems — let alone the disparity of pesticides and commodities regulated by each — render comparison of the tolerances produced by each very complicated and difficult. Different priorities, for example, govern which pesticides require tolerances.¹¹⁰ Different definitions identify pesticide residues¹¹¹ and commodities.¹¹² Formal requirements govern data submission under the U.S. system; similar submissions to the Codex Commission are important but not guaranteed.¹¹³ Carcinogenic substances in processed foods warrant special treatment in the U.S. system; the Codex system subjects such substances to the same risk calculation as all others.¹¹⁴ Each regime has its own method for data interpretation.¹¹⁵ Each treats the relationship of tolerance levels and

animal" 21 U.S.C. § 348(c)(3)(A). This creates the Delaney "paradox": Raw products that contain pesticides which evidence shows cause cancer in man or animal may be considered safe, if residues remain under a tolerance level, but any residue of that pesticide which concentrates in the processed product will automatically make it unsafe and not allowable in commerce. Delaney Paradox, *supra* note 20, at 20.

¹⁰⁹ The U.S. system by statute requires participation by expert advisory bodies in the tolerance-setting process. See 21 U.S.C. § 346a(g). See also *supra* note 66 (discussing input of FAO/WHO Committee).

¹¹⁰ GAO Report, *supra* note 11, at 19 n.2.

¹¹¹ The Codex process stresses evaluation of an indicator compound; the U.S. system includes evaluation of the total residues of the parent or indicator plus additional metabolites. *Id.* at 21.

¹¹² The definition of a particular commodity can affect its maximum residue limits (MRLs). *Id.* at 22. "An MRL may be set on only a portion of a commodity such as the edible part (shelled peanuts) or on the entire commodity (peanuts including the shell)." *Id.*

¹¹³ The U.S. system has formal requirements for data submission under the FDCA and FIFRA. The Codex does not have the authority to demand submission of specific data for review, although national data is often available to the Codex when a review is being made. *Id.* See *supra* note 66. For a brief comparison of the selection of data used to set standards in the two systems, see Levine, *supra* note 23, at 209-10.

¹¹⁴ Under the Delaney clause, the U.S. system treats carcinogenic substances concentrated in processed foods specially. See *supra* note 108 (discussing U.S. statutory treatment of carcinogens). See also GAO Report, *supra* note 11, at 24 (summarizing the EPA's treatment of carcinogenic pesticides).

¹¹⁵ GAO Report, *supra* note 11, at 23.

the assessment of dietary intake rates differently.¹¹⁶

2. Public Participation in U.S. Pesticide Rulemaking

Despite divergent methods and definitions, the U.S. and Codex pesticide regulation regimes could both conceivably produce for some single pesticide-commodity combination comparably safe, scientifically sound and economically beneficial tolerances. Reaching that result under the Codex system, however, takes place beyond the public eye and without public input.¹¹⁷ The Codex system "provides regular access to only three groups: governments; agricultural producers; and pesticide producers."¹¹⁸ In striking contrast, the U.S. system accommodates not only governmental officials, producers and other industry representatives, but also all manner of citizens and citizen organizations.¹¹⁹

¹¹⁶ *Id.* at 24-25.

¹¹⁷ As referred to herein, the "public" is meant to include groups that have a specific non-pecuniary interest in the outcome of regulatory decisions, such as consumer and "public interest" groups as well as interested individuals. For a preliminary discussion of who is "the public," see Thomas O. McGarity, *Public Participation in Risk Regulation*, 1 Risk: Issues in Health and Safety 103, 106-11 (Spring 1990). See also Pierce, *supra* note 22, at 16-17 ("Public interest groups seek regulation that has a widely dispersed economic or social effect By comparison, private interest groups support results that have a narrowly dispersed economic effect.").

¹¹⁸ Kay, *supra* note 4, at 51.

¹¹⁹ The U.S. system has evolved to incorporate consumer interests, particularly as a result of growing public fears about the dangers of pesticides. After World War II, when the insecticidal properties of the chemical DDT were discovered and its uses in fighting malaria and typhus established, concern about the potentially harmful effects of pesticides were disseminated by Rachel Carson in *Silent Spring*. Rachel Carson, *Silent Spring* (1962). Widely regarded as the first modern "environmentalist" work, *Silent Spring* first brought national attention to public fears about pesticides. The fight against the use of DDT became the first major effort of the now thriving environmental movement. Public interest in DDT led to an array of government studies about DDT's effects on humans. See Mary Jane Lurge, Comment, *The Federal Environmental Control Act of 1972: A Compromise Approach*, 3 Ecology L.Q. 277, 277 n.2 (1973). Citizen involvement in litigation surrounding the use of DDT focused on registration requirements, which opened up citizen access to the pesticide regulation process and led to a broadened statutory framework for public participation. See *id.* at 290-309 for a discussion of the increased statutory rigor in regulating the registration of pesticides under the Federal Environmental Pesticide Control Act of 1972.

For highlights of the litigation over DDT registration, see *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093 (D.C. Cir. 1970) (providing standing for an environmental public interest group to challenge Secretary of Agriculture inaction in response to request for registration suspension of DDT under FIFRA, before amended by 1972 Act); *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1970) (providing that where substantial question concerning safety of pesticide exists, statute requires formal proceeding to determine whether registration should be canceled, shifting burden to the manufacturer to prove the pesticide safe); *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 489 F.2d 1247 (D.C. Cir. 1973) (upholding June 14, 1972, cancellation of registration for most uses of DDT as supported by substantial evidence). The original petition to cancel

The U.S. pesticide registration process, for example, invites public participation in rulemaking while protecting the proprietary interests of the manufacturer applicant. Specific product registrations, ostensibly a matter between the proponent of registration and the EPA, are not subject to public notice and comment; general registration standards based on the year's various registration applications are subject to public rulemaking.¹²⁰ Data concerning the safety hazards of the pesticide, plus all other information regarding the rulemaking for general registration standards, become part of the record for the public notice and comment rulemaking.¹²¹

FIFRA allows "any person who will be adversely affected,"¹²² a phrase that the D.C. Circuit has defined broadly,¹²³ to seek judicial review of final registration decisions. Moreover, even after a pesticide has been registered, the public may still challenge its use. Proceedings to revoke a registration may be initiated "at the suggestion of any interested person," with "interested person" broadly defined.¹²⁴

DDT registration was brought by the Environmental Defense Fund, the National Audubon Society, the Sierra Club and the West Michigan Environmental Action Council. See *Hardin*, 428 F.2d at 1095 n.5. For additional historical background on consumer and environmentalist movements concerning pesticides, see Joan Goldstein, *Demanding Clean Food and Water: The Fight for a Basic Human Right* 21-47 (1990).

¹²⁰ A manufacturer's petition to register a pesticide is regulated by the provisions of 40 C.F.R. §§ 152-186, which requires the manufacturer to submit data about the safety hazards of the pesticide. EPA Pesticide Programs, 40 C.F.R. §§ 152-186 (1992). The underlying statutory provisions of FIFRA, 7 U.S.C. § 136h specifically provide for the maintenance of secrecy for the trade information involved in pesticide registration, which is codified in the procedures in 40 C.F.R. §§ 152.80-99. This section also provides for the compensation of contributors of registration information used by other proponents of registration. 40 C.F.R. § 152.93(b)(2).

The burden rests upon the manufacturer seeking to register the pesticide to provide the data needed for registration and to establish that the pesticide meets registration requirements. *Delaney Paradox*, *supra* note 20, at 24. See also *Dow Chemical Co. v. Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973) (placing the burden on the registrant). The EPA regulations that spell out the requirements of registration are in 40 C.F.R. §§ 158, 162.

While EPA regulations require publication of information related to specific pesticide registrations, 40 C.F.R. § 152.102, such regulations are not subject to public notice and comment, probably because they are considered individual adjudications and not rulemaking. Such issues are determined in large part by interpretations of the Administrative Procedures Act, 5 U.S.C. §§ 551-559 (1988). For a brief look at the different types of procedures used to develop rulemaking, see James T. Harrington & Barbara A. Frick, *Opportunities for Public Participation in Administrative Rulemaking*, 15 Nat. Resources Law. 537, 539-46 (1983).

¹²¹ 40 C.F.R. § 155.25 (1992).

¹²² 7 U.S.C. § 136n (1988).

¹²³ *Hardin*, 428 F.2d at 1096-97 (holding that petitioner need not be a registrant or applicant for registration in order to request review, so long as the petitioner alleges sufficient injury).

¹²⁴ 40 C.F.R. § 154 contains the provisions for revocations of registrations. Section 154.3(f), which defines persons who can initiate such procedures, includes environmental groups, labor unions or any "other individual or group of individuals interested in pesticide

The FDCA has also established avenues for public participation in the tolerance-setting process.¹²⁵ Establishing the tolerances necessary for registering pesticides that leave residues in or on food products involves rules of general application, subject to the notice and comment provisions of the Administrative Procedure Act.¹²⁶ Though a manufacturer generally may conceal "confidential proprietary information" about the pesticide, the disclosure of such information may be compelled where that pesticide raises significant safety concerns.¹²⁷

Public participants may specifically petition that a tolerance standard be lowered or revoked,¹²⁸ object to rejections of such petitions and demand a formal hearing on the establishment of a tolerance.¹²⁹ Although the legislative history of the FDCA does not contemplate the objection of parties other than registrants, growers and manufacturers,¹³⁰ the FDCA provides that "any interested party" may appeal to the courts in objection to an established tolerance,¹³¹ and several appellate courts would allow consumer and environmental groups to object to a tolerance and request a hearing.¹³²

regulation," as well as manufacturers, registrants, applicants and pesticide users. 40 C.F.R. § 154.3(f) (1992). In such revocation procedures the proponent of registration maintains the burden of proving the acceptability of the pesticide. 40 C.F.R. § 154.5 (1992).

¹²⁵ *Nader v. EPA*, 859 F.2d 747, 754 (9th Cir. 1988).

¹²⁶ Notice and comment provisions for establishing tolerance levels for pesticides on raw and processed products are codified in 40 C.F.R. §§ 180.29(e), 177.130(b) (1992). The ability to comment on proposed tolerances is severely limited, because the underlying data used in establishing tolerances is usually not subject to public examination; it is considered to be the registrant's "confidential proprietary information." *Delaney Paradox*, *supra* note 20, at 27 n.11. For the statutory basis of restrictions on access to pesticide testing information, see 7 U.S.C. § 136h (1988). Public access to the information may be allowed "when the agency regards the tolerance decision as difficult or potentially controversial, such as when significant safety questions are posed." *Delaney Paradox*, *supra* note 20, at 27 n.11.

¹²⁷ *Delaney Paradox*, *supra* note 20, at 27 n.11.

¹²⁸ 21 U.S.C. § 346a(d)(5), (e) (1988). *Nader*, 859 F.2d at 748.

¹²⁹ 21 U.S.C. §§ 346a(d)(5), 348(f)(1) (1988). These provisions are codified in 40 C.F.R. § 180.32(a) and 40 C.F.R. § 177.81. *See also Delaney Paradox*, *supra* note 20, at 29 (stating that these formal proceedings are rarely used).

¹³⁰ Act of July 22, 1954, Pub. L. No. 83-518, 1954 U.S.C.C.A.N. (83 Stat.) 577, 578-85 (codified at 21 U.S.C. §§ 341-46 (1988)). At the time of the Act, before the existence of environmental organizations as we now know them, objection by such groups was undoubtedly not contemplated.

¹³¹ 21 U.S.C. § 346a(i). *See also National Coalition Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 879 (D.C. Cir 1987) [hereinafter *National Coalition*] (holding that administrative remedies such as a request for a hearing under § 346a(d)(5) need not be exhausted in order to appeal a tolerance to the courts under § 346a(i)). *But cf. Nader*, 859 F.2d at 753 (finding that petitioner for revocation of a pesticide tolerance could not get direct court review of that revocation in part because an available objection and request of an agency hearing for the recently proposed tolerance was not made).

¹³² *See Nader*, 859 F.2d 747; *National Coalition*, 809 F.2d at 880 n.4 (dicta).

B. *The Effects and Importance of Public Participation in the U.S. System*

The American public takes an active part in shaping and implementing U.S. pesticide regulation. In the U.S. system, consumer and environmental groups play a role largely reserved for industry's advisors in the Codex Commission's proceedings: They influence decision making and ensure that resulting regulations take full account of their interests. By providing a check on industry's participation, consumer and environmental groups in the United States can ensure, for example, that deliberations account for the detrimental human health effects of pesticide use.¹³³

In practice, tolerance setting has rarely provoked public interest groups to follow formal channels for public participation.¹³⁴ Where formal procedures are invoked and public interest groups involve themselves in pesticide regulation, however, the influence the groups have on regulation is aggressive and effective. Several important battles have been selectively fought, for example, over chemicals like DDT,¹³⁵ Alar,¹³⁶ and EDBs.¹³⁷ Most recently, consumer groups were

¹³³ Kay, *supra* note 4, at 51.

¹³⁴ See Delaney Paradox, *supra* note 20, at 28-29 ("Both statutes [for tolerances for raw products and processed products] permit opponents of a tolerance to object, request a hearing, and ultimately challenge the EPA's final decision in court, but these formal procedures are almost never invoked. Indeed, relatively few tolerance petitions evoke written comment from members of the public other than those affiliated with the pesticide industry.").

Several factors may explain why the public infrequently invokes formal procedures for objecting to pesticide standards. First, the unavailability of information about the safety research done on pesticides for registration and tolerance-setting purposes, often kept from public evaluators by statute, severely limits the opportunity for public evaluation and objection. See 40 C.F.R. § 155.25 (1992) (regulating public announcement of final decision whether to initiate a special review). Second, the cost of pursuing such issues on a regular basis is sufficiently high that public interest groups choose to challenge only a few pesticides most feared for their effects on health. As a result, public interest groups typically can mobilize public sentiment only in particularly sensitive or critical cases and where private sources or the government make information concerning the pesticide available to the public. See Pierce, *supra* note 22, at 15-16 (describing a market for regulation through which public interest groups must expend resources to obtain desired regulation). For a discussion of the cost of public participation in the regulatory process, see generally Roger C. Cramton, *The Why, Where, When and How of Broadened Public Participation in the Administrative Process*, 60 *Geo. L.J.* 525 (1972).

¹³⁵ See *supra* note 119.

¹³⁶ For a discussion of consumer and environmentalist opposition to the use of Alar on apples, see Marina M. Lolley, Comment, *Carcinogenic Roulette: The Game Played Under FIFRA*, 49 *Md. L. Rev.* 975 (1990). See also *Nader v. United States EPA*, 859 F.2d 747, 749-51 (9th Cir. 1988) (noting consumer advocates' "zero tolerance" objections to the EPA's final rule not to ban the use of the carcinogenic pesticide but to reduce the tolerance for Alar residues in apples from 30 p.p.m. to 20 p.p.m.).

¹³⁷ See *National Coalition Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 880 (D.C. Cir. 1987) [hereinafter *National Coalition*]. Cases like *Nader* and *National Coalition*

active in a five-year fight over the continued registration of fungicides known as EBDCs.¹³⁸

Public participation can shape U.S. regulation even without resort to formal administrative procedures. Persistent consumer groups might challenge a product even after its initial acceptance by the EPA; fearing bad publicity from citizen activism against the product, a pesticide manufacturer or food grower will likely temper its approach in regulatory proceedings.¹³⁹ Furthermore, public attention to pesticides has not been lost on members of Congress, who recognize the potential economic impact of consumer fears about products from their districts.¹⁴⁰

Public participation has thus had a demonstrated effect on how U.S. regulators have undertaken pesticide regulation. Although regulators could plausibly make comparably sound decisions in a system that afforded no public access, democratic intuitions suggest that these decisions would suffer if made beyond the public eye. Administrative history and political theory indicate that the benefits of public participation in the American regulatory system are two-fold: Not only does it provide oversight to promote sound decision making, but it also increases the likelihood that the decisions made will be well received by a democratic citizenry.

1. *Historical and Political Underpinnings*

Public access to the regulatory process is part of a larger scheme of law created to provide checks on the ever-burgeoning administrative state that has arisen during the second half of the twentieth cen-

attest to the ongoing willingness of public interest groups to pursue vigorously their right to participate in the pesticide regulating process. An exhaustive look at the extent of public participation in commenting on proposed rules or opposing adopted rules is beyond the scope of this Note.

¹³⁸ See Rudy Abramson, *EPA Shifts, Will Allow Fungicides to be Used on 45 Fruits, Vegetables*, Philadelphia Inquirer, Feb. 14, 1992, at A13 (announcing the EPA's reversal of a preliminary decision banning the use of EBDCs).

¹³⁹ An example of this can be seen in comments — both positive and negative — by various officials like Surgeon General C. Everett Koop and by consumer and industry representatives like Janet S. Hathaway of the Natural Resources Defense Council regarding the impact of consumer action and public reaction on the regulatory disputes over Alar, which was subsequently withdrawn from the market by Uniroyal, Alar's sole manufacturer. *Safety of Pesticides in Food, Hearing before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce*, 102d Cong., 1st Sess. 58, 147 (1991) [hereinafter *Safety of Pesticides in Food*].

¹⁴⁰ See, e.g., *Safety on Pesticides in Food*, supra note 139, at 271 (comments of Congressman Sid Morrison of the State of Washington) (presenting extensive discussion of proposed amendments to the FDCA through statements of various officials and representatives of consumer and industry organizations).

tury.¹⁴¹ During the 1960s and 1970s, public concern about regulatory decisions grew in part out of fear that regulators were not adequately protecting the public interest.¹⁴² From its inception, the “New Deal model” of regulatory decision making envisioned the enactment of rules in the “public interest” by neutral experts.¹⁴³ That view, however, came under criticism in the 1960s by dissatisfied groups, including those concerned about issues like the health effects of pesticides.¹⁴⁴ This criticism in turn developed into the “interest group model” of public administration, a political theory that treats regulatory decision making as a function of competition among contending political interests.¹⁴⁵

The interest group model identifies two basic purposes for public participation in the U.S. regulating process. First, public participation “checks” a decision-making process otherwise vulnerable to undue influence from the regulated industry. Second, it “legitimizes” risk-management decisions made by officials removed from the political process and thus not directly accountable to the voting public.¹⁴⁶

2. *Checking the Work of the Administrative State*

The interest group model works from the proposition that the interaction of regulatory bodies and the industries they regulate generally leads to heightened influence by industry on regulation.¹⁴⁷ Such influence in the extreme, exemplified by “revolving door” employment between government officials and industry, can leave the agency “cap-

¹⁴¹ For a history of the development of procedural controls on the administrative state and the passage of the Administrative Procedure Act, 5 U.S.C. §§ 551-559, see Kenneth C. Davis, 1 *Administrative Law Treatise* § 1:7 at 17 (2d ed. 1978). For a discussion of the various avenues of public participation in regulatory decision making generally, see Harrington & Frick, *supra* note 120.

¹⁴² See generally Cramton, *supra* note 134, at 525 (discussing the development of broadened public participation in the administrative process).

¹⁴³ For the best known expression of this view, see James M. Landis, *The Administrative Process* (1938). For a quick overview of some of the economic justifications for the regulatory system's development, see Pierce, *supra* note 22, at 10-17.

¹⁴⁴ See McGarity, *supra* note 117, at 109. Consider the following 1960s-era critique of the Landis New Deal model:

The Administrative Process is an eloquent declaration of faith in discretionary government carried on by an assumed enlightened and apolitical elite. The only serious shortcoming of the book is its author's neglect of the possibility that a governing elite might be neither enlightened, nor apolitical, nor wisely selected. Time was to disconcert many men, including Landis, by demonstrating this possibility.

Arthur E. Sutherland, *The Law at Harvard* 305-06 (1967).

¹⁴⁵ See Pierce, *supra* note 22, at 15-22; McGarity, *supra* note 117, at 103-105.

¹⁴⁶ See Cramton, *supra* note 134, at 525-30.

¹⁴⁷ Pierce, *supra* note 22, at 18.

tered" by industry.¹⁴⁸ Public servants labor under a mandate to pursue the public good; nevertheless, in a captured agency their decision making can be distorted by the influence of particularly familiar, well-connected interest groups.¹⁴⁹

Industry influence is not automatically ameliorated by the existence of quantifiable standards in pesticide regulation. Early views of regulation simplistically concluded that because regulatory decision making is highly technical and because "managerial rationality" held regulators to actions justified by guidelines, precedents and expertise,¹⁵⁰ regulators would be led to make neutral, expert decisions. In fact, the complexity of technical decision making and, in particular, the difficulty inherent in balancing opposing interests, make regulatory decisions difficult even for experts.

Moreover, the "managerial rationality" of neutral decision makers is particularly susceptible to interest group lobbying pressures when decision makers are afforded discretion to choose from a broad spectrum of "rational" choices. Such discretion exists, for instance, in the regulation of carcinogenic substances like pesticides, where data is indefinite: "[A]n administrator can choose any one of several answers concerning the level of exposure at which a chemical becomes danger-

¹⁴⁸ "An agency is captured when it favors the concerns of the industry it regulates, which is well-represented by its trade groups and lawyers, over the interests of the general public, which is often unrepresented." *Id.* (citation omitted).

¹⁴⁹ The interest group model of regulation offers a stark view of the regulatory process:

When interest groups clash over whether new regulations should be adopted, the outcome will depend on which group or groups can offer the greatest rewards to the legislators or administrators responsible for the decision In the case of unelected administrators, the favors concern activities that will affect the person's career objectives. The activities could improve the person's professional advancement (a better job outside of the agency), bureaucratic advancement (a bigger budget and more prestige for the agency), or political advancement (increased opportunity for elected office).

Id. at 17 (citations omitted). Cramton, however, offers a more forgiving view:

The view that government regulation tends to give inadequate weight to the general public interest, as distinct from the special interests which participate so effectively in regulatory processes, does not rest on simplistic notions that regulators are incompetent, narrow-minded, or corrupt. . . . [O]ur regulators . . . are generally persons of ability who are trying to do the best job they can under difficult circumstances. But their perspectives are limited by the information that is available to them, and their attitudes are shaped by the rewards and feedback that our system provides to them. When attention is given to the rewards and incentives that are applicable to regulators, the need for broad public participation becomes apparent.

Cramton, *supra* note 134, at 529-30 (citations omitted). For an interesting look at the subtle pressures of the attentions paid to regulators by special interests, presented as a "parable" on the "care and feeding" of regulators, see *id.* at 530 n.14.

¹⁵⁰ See Pierce, *supra* note 22, at 22.

ous. The administrator, therefore, is free to make a policy judgment which can be influenced by the dynamics of the interest group process."¹⁵¹

Where policy makers face a broad range of rational choices, public participation can act as an essential check on the influence of groups having a pecuniary interest in the outcome of regulation.¹⁵² The public's perception and opinions are important at every stage of the decision-making process: assessing the problem; discerning unresolved questions; determining what information is missing; deciding how to interpret existing information; and choosing how to implement interpreted information into a regulation.¹⁵³

3. *Legitimizing Regulation in a Democracy*

Public participation is also valuable for its own sake as an expression of democratic values. The knowledge that decisions are made not only on technical grounds but on democratic ones as well increases the public's faith in the regulatory process. Confidence that interest group representatives communicate the public's interest to decision makers who account for those interests in their decisions renders the regulatory process legitimate.¹⁵⁴

¹⁵¹ *Id.*

¹⁵² McGarity, *supra* note 117, at 104. "The demand for public participation in risk regulation . . . stems from a distrust of experts, a corresponding distrust of regulatory decision makers, and a conviction that most important risk regulations issues are not resolvable solely by reference to expertise." *Id.* at 106. See also Cramton, *supra* note 134, at 527-28 ("The demand for broadened public participation . . . is usually premised on the notion that the public staffs of agencies cannot be relied upon" to represent consumer groups.).

¹⁵³ Frances M. Lynn, *Public Participation in Risk Management Decisions: The Right to Define, the Right to Know and the Right to Act*, 1 Risk 95, 96 (1990). "For risk managers the challenge is to give public participation plans and activities the same priority and resources as technical studies." *Id.* (citation omitted).

Thomas McGarity also notes the costs of time consumption and resource expenditure associated with public participation in risk management. He concludes, however, that "a sufficiently large variety of vehicles for channeling public participation into the decision-making process exists to facilitate a fair and efficient balance of the advantages of participation against its disadvantages." McGarity, *supra* note 117, at 113.

¹⁵⁴ See Pierce, *supra* note 22, at 23-38. In the pluralistic concept of democracy, to be legitimate, agency government must:

have a structure that facilitates the bargaining process, so that the power of agencies is checked by the power of the groups with which they must bargain. Government must be structured therefore to require the participation of groups in the decision-making process. Further, government must be open, rather than secretive, so that groups find out what actions are contemplated and seek to support or oppose those actions as warranted.

Id. See also Lynn, *supra* note 153, at 101 ("What the American public has been doing in the last twenty years—and more increasingly in the last ten—is very normal, and very 'American.' They have formed volunteer organizations in order to work toward their definition of what is

Reconciliation of technical values with democratic ones in risk decision making is, according to EPA policy advisor Daniel Fiorino, essential to the legitimacy of regulations.¹⁵⁵ The intuitive risk assessments of the public — expressions of democratic values — differ from the technical concerns of risk evaluators in three principle ways: The public gives greater weight to low-probability/high-consequence events, places a higher value on public consent and control in the social management of risks, and more readily links the reasonableness of a risk to public confidence in the institution evaluating that risk.¹⁵⁶ When these concerns are not addressed, Fiorino asserts, the legitimacy of regulatory decision making is undermined.¹⁵⁷

The public's concern over pesticides clearly demonstrates its high regard for low-probability/high-consequence events. The probability that harm will develop from low-level exposure may be small; however, the anticipated harm — for example, cancer — is severe enough to sound an alarm among many members of the public.¹⁵⁸ The public also may mistrust determinations of low probability if it perceives that experts are making extrapolations from only limited knowledge about the prospects of future harm.¹⁵⁹

The public's desire for consent and control in risk management, the second distinctly public value Fiorino identifies, provokes the following questions: Who agrees to levels of risk and what social processes govern their decision? Fiorino notes that issues of consent and control are particularly important in American political culture:

Attitudes will be shaped strongly by perceptions of the sources of risks (whether one's exposure is to someone else's benefit) and of the acceptability of social processes for making decisions about risk. Augmenting the influence of American values on participation are a traditional skepticism of administrative authority, technical expertise, and concentrated power. Ours is a political culture in which citizens are reluctant to defer without question to governmental authority and are willing to challenge corporate power. These cultural differences explain many

good, right and just. They have, in the process, broadened the parameters of the debate about risk and have become, whether welcomed or not, major actors in the risk management process. I view this as healthy not only for the environment but also for our democracy.”).

¹⁵⁵ Daniel J. Fiorino, *Technical and Democratic Values in Risk Analysis*, 9 *Risk Analysis* 293 (1989).

¹⁵⁶ *Id.* at 295-96.

¹⁵⁷ *Id.* at 296.

¹⁵⁸ See, e.g., Statements of Jay Feldman, National Coordinator, & Melvin Reuber, M.D., Staff Toxicologist, of the National Coalition Against Misuse of Pesticides, in *Safety of Pesticides in Food*, *supra* note 139, at 253-80.

¹⁵⁹ Fiorino, *supra* note 155, at 295.

of the contrasts in regulatory policy styles between the U.S. and the other Western democracies.¹⁶⁰

Finally, Fiorino suggests that the public respects a risk-based regulation only to the extent that it has confidence in the institution that makes the regulation. To illustrate this third democratic instinct and how it contributes to the regulation's legitimacy, Fiorino argues that heightened public awareness of environmental health risks has contributed significantly to generally declining confidence in U.S. regulatory institutions.¹⁶¹ Public judgments about risks are directly linked to confidence in the institutions that evaluate risk; this confidence can be augmented only by ensuring that participatory democratic values are joined with technical values in the risk evaluation process.¹⁶²

C. Implications for U.S. Public Confidence in the Codex Commission

The Codex regime undermines the policies and purposes embodied in the U.S. system's provision for public participation in pesticide regulation. To be sure, the trade bias of the Codex Commission and its disproportionate exposure to industry input obstructs a public check on industry's influence over international regulators although, as noted above, whether this will expose U.S. citizens to greater health risks is currently difficult to determine. More importantly, though however close Codex standards would come to comparable U.S. standards, the Commission's work falls short: The Codex regime threatens the legitimacy essential to maintaining a system of regulatory decision making in a democratic society. The Codex Commission makes its decisions by means of a regulatory system with which the American public is unfamiliar and to which it has no substantial access. Understood in terms of Fiorino's framework for regulatory legitimacy, the Codex regime would undermine public confidence in pesticide regulations in three ways.

First, Codex's decision-making process would inevitably exacerbate the regulated public's fear that its regulators do not give adequate consideration to the potential low-probability/high-consequence health effects arising from pesticide use. Unlike the U.S. system, which provides the public with an opportunity to challenge the risk assessments and cost-benefit balancing undertaken by regulators, the

¹⁶⁰ *Id.* (citations omitted).

¹⁶¹ *Id.* at 295-96.

¹⁶² *Id.* at 297-98. See also Daniel Fiorino, *Environmental Risk and Democratic Process: A Critical Review*, 14 *Colum. J. Envtl. L.* 501 (1989) (outlining various perspectives on how to reconcile the demands of risk assessment with the goal of public participation).

process by which the Codex Commission adopts standards is a veritable black box. The Codex regime provides no mechanism for assuaging the public's fear that internationally set standards unduly discount public health and safety. As a result, the American public would not likely support the Commission's pesticide standards regardless of their relative stringency.

Second, the mere absence of formal mechanisms for public input into the Commission's risk-assessment and cost-benefit processes stands to render the Codex Commission untrustworthy as a protector of the public's health and safety. Avenues for public involvement assure the public that to some extent citizens influence essential decisions regarding their own health. By contrast, the process by which the Codex Commission promulgates standards for pesticides gives the impression that international bodies — relatively indifferent to the health concerns of average American citizens — set U.S. domestic pesticide regulations. The American public could conclude that this removal of health and safety decision making from public control is undemocratic and unacceptable.

Third, Americans would distrust Codex pesticide regulations because of the perceived institutional inadequacy of the Codex Commission as a regulator of public health and safety. Assigned a new role and granted new authority under the auspices of an organization designed to eliminate trade barriers, the Commission could be perceived as unsympathetic to valid health-based standards that block trade. The potential for industry bias in the Commission's proceedings would further undermine its reputation for protecting human health and safety. Americans would likely deem Codex standards — regardless of the standards' substantive content — to be products of an undemocratic body and illegitimate in a democratic society.

V. CONCLUSION

The international trade regulatory system is moving toward harmonization of domestic food safety standards as the main way of controlling regulatory trade barriers. International trade agreements currently under consideration would forcefully promote harmonization by establishing the Codex Alimentarius as the international standard-setting body for harmonized pesticide regulations. Even if current GATT proposals do not succeed, there is evidence that the concept of harmonization has begun to have greater meaning for and influence on U.S. food safety regulation and will continue to play an important role in future world trade policy making.

As international trade regulation evolves and harmonization of food safety standards becomes a more strongly advocated goal, U.S. regulators must evaluate the international system carefully. The lack of public participation in the international system has problematic consequences: The system offers little if any check on the influence of private groups on regulators and could produce standards of only questionable legitimacy for an American public dedicated to participatory, democratic values.

To settle these concerns to some extent, new methods of access for public advocates could be incorporated in the international process. U.S. officials could provide for greater public participation in the international process, for example, by allowing public interest groups direct access to those U.S. representatives participating in Codex meetings, or by creating notice-and-comment opportunities for the U.S. policy positions taken overseas to the Codex. Of course the international system might not lend itself to public-interest scrutiny and influence. By its very nature as an international negotiating process, harmonizing the domestic standards of many nations to a politically acceptable international standard might preclude input from non-governmental sources. Nevertheless, as long as industry has access to and influence over positions taken by U.S. policy makers in Codex Commission proceedings, it seems likely that ongoing appeals to balance input and legitimate the process by incorporating citizen participation are justified.