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Warning: The Imported Food You Are about to Consume May (Or May Not) Be Harmful to Your Health

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COMMENTS

WARNING: THE IMPORTED FOOD YOU ARE ABOUT TO CONSUME MAY (OR MAY NOT) BE HARMFUL TO YOUR HEALTH

I. INTRODUCTION

The value of food imports into the United States totaled approximately thirty-seven billion dollars in 1996[1] and is projected to increase to forty billion dollars in 1997.[2] Of this amount, it is estimated that only one to two percent of imported fruits and vegetables will be subject to any inspection by the federal government through the United States Food & Drug Administration (FDA).[3] This fact is even more alarming when one considers that the number of food inspections carried out by the FDA has "dropped to less than half [of] what [it was] five years ago."[4]

In addition to the rise in the amount of imports, the number of annual illnesses directly or indirectly caused by foodborne diseases is also rising. Recent news reports estimate that foodborne pathogens cause up to nine thousand deaths and thirty-three million illnesses each year.[5] Annually, these illnesses and deaths cost the United States economy an estimated twenty-two billion dollars.[6]

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1. FOREIGN TRADE DIVISION, BUREAU OF THE CENSUS, EXPORTS AND IMPORTS OF GOODS BY PRINCIPAL END USE CATEGORY: JAN. 1996 TO AUG. 1997, FT 900, CB-97-172 (Aug. 1997).

2. This projection is based upon the Jan. 1997 through Aug. 1997 total of $26 billion. *See id.*

3. Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century - Who Is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13, 27 (1997).

4. *Increase in Food Imports to U.S. Linked to More Disease Outbreaks*, BALT. SUN, Sept. 29, 1997, at 8A.

5. *See* Bernard Gavzer, *We Can Make Our Food Safer*, WASH. POST, Oct. 19, 1997, Parade Mag. at 4 (quoting an estimate by the Council for Agricultural Science and Technology).

The rise in imports and foodborne illnesses has coincided with the United States entry into trade agreements with foreign countries. These international and regional trade agreements have made the United States market one of the most open in the world. In addition to international pressure to keep the United States market open, consumers continue to increase demand for the diverse cornucopia of fruit and vegetable products available to them.[7] These pressures will likely cause the amount of imported food to continue to rise.[8] The present regulatory system in the United States that monitors and controls food imports, however, is not set up to handle this increased supply of imports entering the United States market.[9]

Several recent incidents suggest that the problem is severe and requires the immediate attention of regulators. In early April 1996, approximately 180 Michigan residents were infected with the Hepatitis A virus[10] after consuming strawberries imported from Mexico.[11] The majority of those infected were school children who ate strawberries that were provided to them through their school lunch program.[12]

In July 1997, a bacteria outbreak caused by tainted basil infected ap-

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6. *See id.* (quoting an estimate by the General Accounting Office). At least one food expert has placed the occurrence of illnesses caused by foodborne diseases at 250 million episodes and has also posited that this is the number one cause of visits to the emergency room in the U.S. *See Testimony before the Senate Comm. on Agric., Nutrition and Forestry, Oct. 8, 1997, 105th Cong., available in* 1997 WL 14151979 (statement of Michael T. Osterholm, Ph.D., M.P.H.) [hereinafter *Testimony*].

7. *See* Chris Kraul, *A Full Plate of Issues on Food-Import Safety*, L.A. TIMES, Oct. 4, 1997, at D1.

8. *See* JAMES T. O'REILLY, THE FOOD AND DRUG ADMINISTRATION § 28.01 (2d ed. 1995).

9. *See* Jeff Gerth & Tim Weiner, *Imports Swamp U.S. Food-Safety Efforts*, N.Y. TIMES, Sept. 29, 1997, at A1. "We built a system back 100 years ago that served us very well for a world within our borders, . . . [w]e didn't build a system for the global marketplace." *Id.* (comments of David A. Kessler, Commissioner of the FDA, 1990-1997).

10. Hepatitis A is a mild strain of hepatitis that is rarely fatal and normally associated with symptoms of fever, nausea, abdominal pain, and jaundice. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 816-17 (16th ed. 1989).

11. *See* Kenneth Cole et al., *State Fears More Hepatitis Cases*, DETROIT NEWS, Apr. 3, 1997, at 1C.

12. *See id.*

proximately 126 consumers in the Washington, D.C. metropolitan area.[13] The basil, infected with the cyclospora parasite,[14] had been used in various food dishes of an upscale grocery chain.[15] Although the exact origin[s] of the basil remain unconfirmed, the cyclospora parasite is often found in developing countries where produce is regularly irrigated or washed with contaminated water.[16] Incidents such as these caused an outcry among the public and lawmakers for a trading regime that will protect Americans from increased susceptibility to illness.[17] While similar contamination situations can, and do, occur as a result of domestic mishandling of foods,[18] there exists a popular belief that the risk from foreign producers and handlers creates a greater threat to the health and security of the United States than domestically produced foods.[19] Therefore, it is argued that imported foods should be subject to greater government regulation.[20] Due to the increase in imports, illnesses, and the accompanying public attention, the issue of regulation of food imports is ripe for debate.

This Comment will concentrate on safety issues surrounding the importation of produce because this is one of the most underregulated segments of the food industry[21] and the current target of much public

13. *See* Brooke A. Masters, *Food Poisoning is Linked to Basil Products*, WASH. POST, July 19, 1997, at B1.

14. Cyclospora is a bacterium found in food that has been washed with contaminated water. The bacteria may cause diarrhea, bloating, fever, and fatigue. It carries up to a two-week incubation period and is treatable with antibiotics. *See id.*

15. *See id.*

16. *See id.*

17. For example, numerous editorials appearing in U.S. newspapers are reporting the public attitude. *See* Editorial, *America, The World's Food Policeman*, ROANOKE TIMES & WORLD NEWS, Oct. 13, 1997, at A8; Editorial, *Forbidden Fruit - Food Safety Need Not Be Sacrificed in Push for Free Trade*, PITTSBURGH POST-GAZETTE, Oct. 14, 1997, at A22 [hereinafter *Forbidden Fruit*]; Robert Kuttner, Editorial, *When 'Protectionism' is a Good Word*, SAN DIEGO UNION TRIB., Oct. 12, 1997, at G3; Editorial, *Tougher Food Import Checks*, BOSTON GLOBE, Oct. 14, 1997, at A16.

18. Hudson Foods, a meat processor was shut down in August 1997 for using tainted meat in its production process. *See Hudson Foods*, WALL ST.J., Aug. 22, 1997, at A1.

19. *See supra* note 17.

20. *See id.*

21. *See* Taylor, *supra* note 3, at 27.

attention. The existing infrastructure designed to regulate food imports, including the international agreements to which the United States is a party and international organizations that help shape the world trading regime, will be identified and their effectiveness analyzed. This Comment will then explore the current political atmosphere surrounding food imports and safety. Finally, a number of proposals will be set forth that suggest ways to address existing and potential problems.

II. THE EXISTING FOOD SAFETY FRAMEWORK

A. Role of Domestic Institutions

The federal system set up to oversee food importation and inspection consists of numerous federal agencies.[22] The United States Congress derives jurisdiction to regulate food imports from its explicit power "[t]o regulate commerce with foreign Nations."[23] Congress chose to delegate its powers to regulate food importation to a number of administrative agencies.[24] The delegation is primarily to the Food and Drug Administration of the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA).[25]

1. The Primary Regulators: HHS and FDA

HHS oversees the FDA,[26] which is the primary regulator of non-meat and poultry food imports. The FDA, to a large extent, finds its origins in the Pure Food and Drug Act of 1906.[27] Furthermore, the Food, Drug & Cosmetic Act of 1938 (FDC Act) substantially overhauled the FDA.[28] The FDA's mandate is "to protect, promote and enhance the health of

22. *See id.* at 18.

23. U.S. CONST. art. I, § 8, cl. 3.

24. Congressional delegation of responsibilities was upheld by the Supreme Court, though limitations have been placed on that power. *See, e.g.*, America Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952); Yakus v. U.S., 321 U.S. 414 (1944); Amalgamated Meat Cutters & Butchers of North America v. Connally, 337 F. Supp. 737 (D.D.C. 1971).

25. *See* O'REILLY, *supra* note 8, §§ 2.01, 24.01.

26. *See id.* § 2.01.

27. Pure Food & Drug Act of 1906, Pub. L. No. 59-384, § 4, 34 Stat. 768 (directing that the appropriate bureau orchestrate and supervise the examination of imported foods).

28. Food, Drug & Cosmetic Act of 1938, 21 U.S.C. § 301 (1994).

the American people [by] enforc[ing] FDA laws and regulations . . . ."[29] Under this mandate, the FDA has numerous legal and equitable powers of enforcement, including prosecution, "inspection, detention and refusal of entry."[30] The FDC Act directs the FDA to refuse to admit into the country any article that appears to be in violation of the Act.[31] A number of provisions in the FDA Regulatory Procedural Manual discuss issues surrounding imports.[32] The FDA works in conjunction with the United States Customs Service to prevent adulterated foods from entering the United States.[33]

In addition to overseeing the FDA, HHS also oversees the Centers for Disease Control and Prevention (CDC).[34] The CDC works with states and private entities to provide a system of surveillance to monitor outbreaks of disease.[35] The CDC acts as a clearinghouse of information for the federal government relating to health issues and illnesses.[36]

2. The Similar Role of USDA

The USDA is responsible for ensuring the safety of meat and poultry imports.[37] The importation restrictions followed by the USDA are similar to the restrictions in place for the FDA; however, the USDA has con-

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29. The U.S. Food & Drug Administration, *FDA's Mission* (last modified Mar. 1996) <http://www.fda.gov/opacom/morechoices/mission.html>.

30. O'REILLY, *supra* note 8, § 28.01.

31. *See* 21 U.S.C. § 801 (1994).

32. *See* O'REILLY, *supra* note 8, at Supp. 45-46; United States v. Food, 2998 Cases, 64 F.3d 984 (5th Cir. 1995). Section 381 allows import refusal as a "quick and efficient means of protecting the American public from unhealthy or mislabeled foreign goods." *Id.* at 989.

33. *See, e.g.*, FDA Memorandum of Understanding with the Customs Service, 44 Fed. Reg. 53, 577 (1979).

34. *See* The Centers for Disease Control and Prevention, *About CDC* (last modified Sept. 9, 1998) <http://www.cdc.gov/aboutcdc.htm>.

35. *See* Taylor, *supra* note 3, at 19.

36. In addition to the agencies described, HHS also oversees the National Institutes of Health, Agency for Toxic Substances and Disease Registry, Indian Health Service, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Agency for Health Care Policy and Research, Health Care Financing Administration, Administration for Children and Families, and the Administration on Aging. The U.S. Department of Health and Human Services, *HHS Agencies* (last modified Mar. 18, 1998) <http://www.hhs.gov/progorg/>.

37. *See* O'REILLY, *supra* note 8, §§ 24.05, 24.10-11.

siderably more power as a result of the Federal Meat Inspection Act[38] and the Poultry Products Inspection Act.[39] These statutes give the Food Safety and Inspection Service (FSIS) of the USDA the ability to conduct field inspections of processing facilities, including those outside of the United States.[40] Through the additional legal powers at the USDA's disposal, it has proven to be a more effective regulator than FDA or HHS.

B. The Roles Played by International Institutions

The United States is a party to a number of international organizations and agreements which affect its obligations regarding trade in food products, as well as foreign policy related to food imports. Among these are the North American Free Trade Agreement (NAFTA), the World Trade Organization (WTO), and the United Nations (UN), including its subsidiary organizations.

1. The North American Free Trade Agreement

NAFTA, the most comprehensive trade agreement ever concluded, is an agreement between the United States, Canada, and Mexico.[41] NAFTA stipulates that the signatory countries agree that liberalizing trade is in their respective interests and, therefore, agree to eliminate the possibility of increased trade barriers among members.[42] The agreement contains safeguard provisions to prevent the importation of goods that could be harmful to the economies of the member nations.[43] In addition, the Agreement on Sanitary and Phytosanitary Measures allows member countries to take necessary measures for the "protection of human, animal or plant life or health in its territory, including a measure more stringent than an international standard, guideline or recommendation."[44] The only caveat to this broad provision is a limita-

38. *See* 21 U.S.C. § 601 (1994).

39. *See id.* § 451.

40. *See id.* §§ 451, 601.

41. *See* STAFF OF HOUSE COMMITTEE ON WAYS AND MEANS, 105TH CONG., OVERVIEW AND COMPILATION OF U.S. TRADE STATUTES 211 (Comm. Print 1997).

42. North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605 [hereinafter NAFTA]. The objectives of the agreement state that the signatory countries have agreed to "eliminate barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties." *Id.* at art. 102(1)(a).

43. *See id.* at art. 2101(2).

44. *Id.* at art. 712(1).

tion on each nation's ability to utilize the provision to create restrictions on trade in violation of the spirit of the agreement.[45] The legal framework that NAFTA creates, allows for a freer flow of goods between members.

2. The World Trade Organization

In 1947, the original General Agreement on Tariffs and Trade (GATT) was concluded to reduce barriers to free trade between all nations of the world and to increase economic growth.[46] The GATT, like NAFTA, provides safeguard provisions that allow member countries to impose protective measures in the interest of public health.[47] National security exceptions are also grounds for protectionist measures which otherwise would be considered antagonistic to the agreement.[48] Sanitary and phytosanitary measures are also a part of the agreement, allowing protection for purposes of animal, plant, or human health.[49] However, these measures are prohibited if they are merely disguised restrictions on trade.[50] Under GATT rules, all sanitary and phytosanitary measures that are adopted must be published.[51]

In 1986, trade ministers representing 124 nations which were party to the GATT agreement met in Punta del Este, Uruguay to launch the Uruguay Round of trade negotiations. The objectives of the Round were to strengthen the world economy and increase trade.[52] The WTO was one

45. *See id.* at art. 712(6) ("No Party may adopt, maintain or apply any sanitary or phytosanitary measure with a view to, or with the effect of, creating a disguised restriction on trade between the Parties.").

46. *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, Preamble, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

47. *See id.* at art. XX(b).

48. *See id.* at art. XXI.

49. *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, art. VIII, para. 14, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS - THE LEGAL TEXTS 1 (1994), 33 I.L.M. 1125 [hereinafter Final Act].

50. *See* Bernard M. Hoekman, *Trade Laws and Institutions -- Good Practices and the World Trade Organization*, in WORLD BANK DISCUSSION PAPERS 37 (1995) (Sanitary and phytosanitary measures "[m]ay not unjustifiably discriminate between GATT Members, be more trade restrictive than required to achieve the appropriate level of protection, or be applied so as to constitute a disguised restriction on international trade.").

51. *See id.* at 38.

52. Final Act, *supra* note 49, Marrakech Declaration of Apr. 15, 1994. The

of the substantive results of this round of negotiations.[53] The WTO is an international institution with sovereign states as members. The WTO is comprised of three major trade agreements: the 1994 GATT, the Global Agreement on Trade in Services (GATS), and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[54] The major principle behind membership in the WTO is non-discrimination in the form of Most Favored Nation status (MFN).[55] MFN status between member states prevents these states from raising tariffs and duties as long as the MFN status is in place.[56] In addition, the parties to the treaty agreed to submit trade disputes concerning procedures for international trade to the WTO.[57]

3. The United Nations

The UN was established after World War II to ensure worldwide peace and security for humankind.[58] The United States joined the UN in

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Round specifically acknowledged the purpose as follows:

> Ministers salute the historic achievement represented by the conclusion of the Round, which they believe will strengthen the world economy and lead to more trade, investment, employment and income growth throughout the world. In particular, they welcome:
> -the stronger and clearer legal framework they have adopted for the conduct of international trade, including a more effective and reliable dispute settlement mechanism,
> -the global reduction by 40 percent of tariffs and wider market-opening agreements on goods, and the increased predictability and security represented by a major expansion in the scope of tariff commitments, and
> -the establishment of a multilateral framework of disciplines for trade in . . . the reinforced multilateral trade provisions in agriculture.

Id.

53. *See id.* at art. VIII. Article VIII gives the WTO a legal personality and the legal capacity necessary to exercise its functions. *See id.* Because the GATT was an agreement, and not an institution, its legal status was weak. *See id.* The primary purpose of the WTO was to address this problem. *See* Hoekman, *supra* note 50, at 3.

54. The Final Act incorporates these three agreements into the WTO regime. *See* Final Act, *supra* note 49, at art. IV.

55. *See* GATT, *supra* note 46, at art. I; Hoekman, *supra* note 50, at 4.

56. *See* Hoekman, *supra* note 50, at 4-5.

57. *See* GATT, *supra* note 46, at art. XXII-XXIII.

58. The UN charter provides that the "purpose of the organization [is] to maintain international peace and security, develop friendly relations, achieve international cooperation and be a center for harmonizing the actions of members towards these common ends." U.N. CHARTER, art. 1, paras. 1-4.

1946 and has become a party to efforts of the UN and its subsidiary organizations concerned with food safety and health. The World Health Organization (WHO) is a UN subsidiary organization established in 1945 that is concerned with health issues around the world. The WHO coordinates health-related efforts to improve the health of all people.[59] To do so, the WHO keeps data and information on disease and nutrition levels, according to region and state, throughout the world. The WHO also provides advisories to UN member nations on prevalent diseases and the probability of outbreaks. Finally, the WHO sponsors programs in less developed countries aimed at disease prevention by way of improved hygiene, immunizations, and increased nutrition levels.[60]

The Food and Agricultural Organization (FAO), created in 1945, is another UN subsidiary organization which focuses on raising nutrition levels and the standard of living throughout the world.[61] The FAO, in cooperation with the WHO, created the Codex Alimentarius Commission that is responsible for matters pertaining to the implementation of the joint FAO/WHO Food Standards Program.[62] This program was established to further the goals of the FAO and WHO by standardizing, coordinating, and continually reviewing practices in food trade.[63] By doing so, the Codex Alimentarius sets a comprehensive international standard for food safety.

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59. *See* W.H.O. CHARTER, art. I.

60. *See* RICHARD OWEN, THE TIMES GUIDE TO WORLD ORGANIZATIONS 172-74 (1996).

61. *See id.* at 106.

62. *See id.*

63. *See* PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION, art. I (9th ed. 1995). According to the Codex Alimentarius Charter, the purpose of the Food Standards Program is:

> a. protecting the health of consumers and ensuring fair practices in the food trade;
> b. promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;
> c. determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
> d. finalizing standards under (c) above and after acceptance by governments, publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalized under (b) above, wherever this is practicable;
> e. amending published standards, after appropriate survey in the light of the developments.

Id.

III. HAZARDOUS FOODS ARE SLIPPING THROUGH THE SAFETY NET

A. The Adequacy of Current Domestic Agencies

Food safety regulation is necessary because Americans rely on imported foods to meet the demand for a wide range of food products.[64] The FDC Act provides agencies with substantial power to oversee and regulate food imports.[65] In particular, the FDA has been delegated great power in this arena.[66] Some of the FDA's broadest powers exist in its ability to restrict imports via delegation from Congress.[67] The Agency has the broad power to stop the importation of food that "appears"[68] to be adulterated.[69] Because restricting imports from entering the United States is not considered a taking,[70] and a foreign importer does not have substantial constitutional protections,[71] it is very difficult for an importer to challenge a ruling of the FDA.

The primary problem with food safety and imports, however, is the FDA's inability to inspect a large number of imports[72] and provide information on preventative measures to current and potential importers.[73] The rate of inspection for imported fruits and vegetables is estimated to

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64. *See* Taylor, *supra* note 3, at 14. "Market mechanisms work reasonably well to satisfy consumer demands for economy, convenience and choice in the food supply, but they cannot fully satisfy the very high consumer expectations for food safety." *Id.*

65. *See* O'REILLY, *supra* note 8, § 6.01.

66. *See id.* § 28.01.

67. *See* Bowman v. Retzlaf, 65 F. Supp. 265, 269 (D. Md. 1946) (affirming that Congress's power in the field of importation is absolute).

68. Goodwin v. United States, 371 F. Supp. 433, 436 (S.D. Cal. 1972).

69. Under the FDC Act, adulterated food "consists in whole or in part of any filthy, putrid, or decomposed substance, or it is otherwise unfit for food . . . or if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated." Food, Drug and Cosmetic Act, 21 U.S.C. § 342(a)(3)-(4) (1994).

70. *See* Meserey v. United States, 447 F. Supp. 548, 553 (D. Nev. 1977).

71. *See id.* at 555.

72. *See Kessler Decries Lack of Resources at Agency*, 35 FOOD CHEM. NEWS 28, 28 (1993) [hereinafter *Kessler Decries*].

73. *See* Kenton L. Harris & James B. Goding, *Problems of Sanitation Law Enforcement for U.S. Imports*, 43 FED. LAW. 27, 27 (1996) (describing general guidelines which are published by the FDA and give little guidance to importers).

be less than two percent.[74] The FDA has been reactive, rather than proactive, in fighting unhealthy imports.[75] The FDA simply lacks the necessary resources to increase its rate of inspection.[76] Furthermore, in order to maximize its inspection ability, the FDA has come to rely on expedient measures, such as electronic processing at customs.[77] This electronic process leads to a substitution of hands-on inspection for arbitrary procedural rules, resulting in an increase of adulterated foods entering the country.[78]

The FDA also fails to adequately inspect the processing facilities of overseas producers.[79] This lack of direct interaction with foreign producers results in a disservice to both consumers and producers because unacceptable food products find their way into the United States market.[80] In many instances, the FDA relies upon Memoranda of Understanding with foreign governments, which designates a foreign government responsible for its producer's exported products that are bound for the United States.[81] However, this delegation of responsibility is ineffective when the foreign government has no control or jurisdiction over the exported product.[82]

In addition to its broad enforcement powers, the FDA possesses a small, yet effective, field investigative force.[83] This field force is responsible for inspecting food imports that reach our borders to deter-

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74. *See* Taylor, *supra* note 3, at 27.

75. *See id.* at 16.

76. *See Kessler Decries*, *supra* note 72, at 28.

77. *See* O'REILLY, *supra* note 8, § 28.01 (Supp. 1998). "In 1995, 61% of shipments for which electronic data shipments were in place were cleared within minutes, thereby reducing delays in imports." *Id.* (citing FDA, FDA ALMANAC FY 1995 13 (1995)).

78. *See* Harris & Goding, *supra* note 73, at 29.

79. *See* Lorraine Woellert, *Clinton Seeks Ban of Inferior Foreign Foods*, WASH. TIMES, Oct. 3, 1997, at B1. "Currently, the inspection of produce from foreign countries is done only when those materials reach the United States." *Id.* (quoting Richard Rominger, Deputy Secretary of Agriculture).

80. *See* Harris & Goding, *supra* note 73, at 27. "The FDA appears to have a lack of harmony or understanding of the demands of normal and acceptable overseas production patterns. Consumers do not benefit from the absence of specific policy guidelines and the undue economic burdens that the resulting regulatory inconsistencies place on importers." *Id.*

81. *See id.*

82. *See id.*

83. *See* O'REILLY, *supra* note 8, § 2.03.

mine whether the imports meet our food safety standards.[84] The FDA's field force is considered "the best in the federal government for quality of investigative work and professionalism."[85] Although this field force allows the FDA to be effective in its limited capacity of inspection, the agency's overall effectiveness is stifled by the limitations on the total amount of inspections it is able to conduct.[86]

Another major domestic player, HHS, has an important role in educating the public and heightening awareness on food safety issues. In its latest effort, HHS targeted consumers as the last line of defense against foodborne diseases.[87] The program, called "Fight Bac,"[88] is a joint effort between government and the private food industry to educate the public about the dangers of foodborne diseases and the benefits of prevention.[89] Spearheaded by HHS at the President's behest,[90] the goal of Fight Bac is to combat foodborne disease.[91] The message of the campaign is that through proper hygiene and diligence on the part of consumers, many foodborne illnesses can be avoided.[92] Furthermore, not all problems result from poor production processes or the failure to protect against adulterated imports.[93] The campaign is mainly funded by private industry in the amount of $550,000.[94]

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84. *See* Taylor, *supra* note 3, at 16.

85. O'REILLY, *supra* note 8, § 2.03.

86. *See Kessler Decries*, *supra* note 72, at 28.

87. *See* Curt Anderson, *Bacteria Fighting Ads Star Globlike Villain*, NEW ORLEANS TIMES-PICAYUNE, Oct. 25, 1997, at A13.

88. "Bac" refers to the slimy cartoon character poster child featured in the education campaign. *See id.*

89. *See President's Remarks Announcing a Food Safety Initiative and Exchange with Reporters*, 33 WEEKLY COMP. PRES. DOC. 1476 (Oct. 2, 1997) [hereinafter *President's Remarks*].

90. *See id.*

91. The marketing campaign stresses the following four precautionary measures: 1) wash your hands, 2) prevent cross-contamination between various foods, 3) cook foods to the proper temperatures, and 4) refrigerate food promptly. *See* Anderson, *supra* note 87, at A13.

92. *See id.*

93. *See, e.g., id.* (Secretary of Health and Human Services Donna Shalala commenting that "[e]ven as industry and government step up their food safety activities, consumers need to understand that they are the last line of defense in assuring the safety of foods they eat").

94. *See id.*

1. A Comparison of the FDA and the USDA

The USDA is more successful than the FDA in monitoring the importation of meat and poultry into the United States. However, the USDA continues to receive occasional criticism for its inspection rate.[95] The USDA manually inspects up to 10% of meat and poultry imports.[96] In addition, the USDA has the ability and the resources to inspect meat products at their source, the site of foreign processing.[97] This allows for broad-based identification of companies and regional food handling practices and permits the agency to provide valuable information to foreign producers on what practices are unacceptable. In order to gain access to the United States market, foreign meat and poultry processors must follow USDA health and safety regulations and open their facilities to USDA inspectors.[98] The strength of the USDA is its ability to put personnel in the actual place of production, including overseas locations.[99] Because the ultimate goal of all concerned is to provide a market with acceptable, quality food products, the system is more effective because all parties have an interest in ensuring safe practices at the earliest stages of food production. In other words, under USDA jurisdiction, foreign producers are subject to inspection, they are aware of United States standards, and they have an increased chance of inspection at the border.

2. Standardization in Food Safety Practices

An additional defense implemented by regulators in the quest for food safety is the creation of universal food standards. One example is the Hazard Analysis and Critical Control Points (HACCP) which are procedures targeting the prevention of food contamination in the processing and handling of foods.[100] HACCP is a process control system for food production. It was independently created in the 1960s, however, it is constantly undergoing revisions to meet the latest technological and scientific advances.[101] HACCP requires a producer to implement a plan for

95. *See* Taylor, *supra* note 3, at 27.

96. *See id.*

97. *See id.* at 17.

98. *See* USDA, MEAT AND POULTRY INSPECTION - 1996 REPORT OF THE SECRETARY OF AGRICULTURE TO THE U.S. CONGRESS 25 (1996).

99. *See* Taylor, *supra* note 3, at 17.

100. *See id.* at 20.

101. *See id.*

producing safe food.[102] Both the FDA[103] and the USDA's FSIS[104] have implemented HACCP procedures and standards as part of their inspection protocols.[105] In addition, HACCP achieved international recognition through incorporation into several international agreements.[106]

The main strength of HACCP is its reliance on prevention based principles to achieve food safety.[107] HACCP sets concrete production guidelines, as well as standards for industry professionals to apply during inspections.[108] This allows an allocation of responsibilities to industry and the federal government that was not possible under more subjective criteria.[109] Because this benefit is limited to only a portion of the nation's food supply, the FDA's challenge is to apply these standards to all food products bound for human consumption.

B. Overlap and Lack of Cooperation Among Agencies and Organizations

The lack of a broad and comprehensive plan to implement the many food safety functions provided by the different federal and international organizations constitutes another problem with the current regulatory system.[110] A 1993 study conducted within Vice President Al Gore's National Performance Review recognized that twenty-one different federal agencies were working in the area of food safety.[111] The report high-

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102. *See id.*

103. *See* 59 Fed. Reg. 4,142 (1994).

104. *See* 60 Fed. Reg. 6,774 (1995).

105. *See* Taylor, *supra* note 3, at 20.

106. *See, e.g., id.* at 14 n.9 (stating that the Codex Alimentarius Commission has endorsed HACCP and the European Union has adopted HACCP procedures for seafood handling).

107. *See id.* at 21. "Prevention should be the fundamental tenet of any public health program. A food safety system based on systematic, science-based prevention of hazards is preferable to a system based largely on after-the-fact enforcement and correction of problems, and the HACCP provides the framework for systematically preventing food safety problems." *Id.*

108. *See id.*

109. *See id.*

110. The food safety system has been described as a "piecemeal and incomplete national and international approach to preventing [foodborne diseases]." Testimony, *supra* note 6.

111. *See* VICE PRESIDENT AL GORE, CREATING A GOVERNMENT THAT WORKS BETTER AND COSTS LESS -- REPORT OF THE NATIONAL PERFORMANCE REVIEW 101 (1993).

lighted the fragmentation of responsibilities at the federal level.[112] For instance, the FDA is responsible for the safety of seafood, fruits, and vegetables.[113] The USDA is responsible for meat and poultry.[114] The Environmental Protection Agency has jurisdiction over pesticides and food safety decisions relating to pesticides.[115] Finally, the CDC tracks foodborne disease and conducts investigations on illnesses resulting from them.[116] In addition, state and local governments frequently conduct independent investigations and set standards at the wholesale and retail levels.[117]

There is no overall institution or protocol in place that enables all the various entities to work together. This allows valuable information, which could be more effectively used in a cooperative effort, to slip through the food safety net.[118]

C. The Effectiveness of International Organizations and Agreements

International treaties and organizations exist under the theory that liberalizing trade is good for the economies of member states.[119] The NAFTA and GATT agreements stipulate that the parties agree to liber-

112. *See id.*
113. *See* Taylor, *supra* note 3, at 18-20.
114. *See id.*
115. *See id.*
116. *See id.*
117. *See id.* at 19.
118. *See* Taylor, *supra* note 3, at 19.
119. *See* GATT, *supra* note 46, Preamble.

> Recognizing that their relations in the field of trade and economic endeavor should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, developing the full use of the resources of the world and expanding the production and exchange of goods, . . . [b]eing desirous of contributing to these objectives by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce.

Id. Furthermore,

> [An agreement] such as the WTO both creates pressure for liberalizing access to markets over time in a way that may be both politically more feasible than unilateral action (by providing domestic export-oriented interests with benefits that offset to a greater or lesser extent the losses incurred by protected industries) and locks in the result.

Hoekman, *supra* note 50, at xiv.

alize trade.[120] These agreements substantially prevent United States policymakers from raising trade barriers to other member countries.[121] Additionally, with the creation of, and participation in, the WTO, the United States has committed itself to accept the jurisdiction and to adhere to determinations of the dispute settlement body of the WTO.[122] However, "[m]any of the WTO's disciplines are optional, either in the sense that members have discretion regarding the extent to which they apply (i.e., their coverage), or have a choice whether to invoke them."[123]

Both agreements provide substantial leeway for the United States to invoke protections in the name of national security and health and safety.[124] Such leeway is necessary to allow a member nation to enter into an international agreement while retaining its inherent national sovereignty.[125] However, such protections would undoubtedly meet criticism from other members to an agreement.[126]

Internationally recognized protocols like HACCP and central organizations including the FAO provide formulae, which create uniformity, for determining risks and a basis of evidence to support claims of adulteration. Although both the NAFTA and GATT agreements call for the use of scientific evidence to invoke protections,[127] neither provides

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120. *See* NAFTA, *supra* note 42, at pt. 2, cl. 3; GATT, *supra* note 46, Preamble.

121. *See generally* NAFTA, *supra* note 42; GATT, *supra* note 46 (because NAFTA and GATT commit member nations to reducing trade barriers, justifications for reducing trade are limited).

122. *See* discussion *supra* Part II.B.2.

123. Hoekman, *supra* note 50, at xii.

124. *See* discussion *supra* Part II.B.1-2. See also the legislation enacted by the U.S. Congress in 1994 implementing the U.S. accession to the WTO, providing that U.S. law will prevail over any conflicting provision with the Uruguay Round or determination by the WTO. *See* Legislation Implementing the Uruguay Round of Trade Negotiations § 102(a), 19 U.S.C. § 3512 (1994).

125. *See* Hoekman, *supra* note 50, at 14. "Safeguard provisions are often critical to the existence and operation of trade liberalizing agreements, as they function as both insurance mechanisms and safety valves." *Id.*

126. *See, e.g.*, Brian Knowlton, *Clinton Sounds Food Safety Alarm*, INT'L HERALD TRIB., Oct. 3, 1997, at A1 (reporting the reaction of Mexican officials to President Clinton's proposed legislation).

127. *See* Jeffery Atik, *Science and International Regulatory Convergence*, 17 NW. J. INT'L L. & BUS. 736, 737 (1996-97) ("The WTO accords and NAFTA now require that health regulations have a scientific basis and result from a risk assessment.").

much guidance as to what that evidence should be.[128] Each agreement allows for the member states to invoke their own respective protocols.[129] In both agreements, there is an absence of a rule-making body to set regulatory standards as they develop.[130] This absence needs attention because increased acceptance of international protocols will help eliminate conflict as divergence in standards decreases.

International organizations such as the UN, FAO, and WHO aid the United States by assisting in setting international standards and supplying information on food safety to producers in lesser developed countries. For instance, Codex Alimentarius Standards for food safety, published by the FAO, are now broadly recognized.[131] The WHO can assist the United States regulatory agencies, especially the CDC, because it tracks information on regional disease and makes it available on a worldwide basis.[132] Further, the WHO increases awareness on food safety issues worldwide.[133] However, international institutions, including the WHO, are often criticized for failing to issue specific standards and enforcing their guidelines.[134] This tendency to criticize derives from the institutions' status as advisory which leaves them lacking substantive authority over their member nations.[135]

D. Political And Economic Considerations

In addition to the international obligations undertaken by the United States, the tremendous consumer demand for imported foods makes it politically infeasible to restrict the importation of the diverse supply of food products.[136] As consumers have come to expect diversity in their local markets, per capita consumption of a variety of imported products has increased from ten percent to sixty percent.[137] On the other hand,

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128. *See id.*
129. *See id.* at 737-39.
130. *See id.*
131. *See* discussion *supra* Part II.B.3.
132. *See* Paul Magnusson et al., *Eating Scared*, BUS. WK., Sept. 8, 1997, at 30.
133. *See id.* "[T]he World Health Organization is ringing alarm bells about 'emerging' foodborne diseases because of the globalization of the food supply." *Id.*
134. *See* Hoekman, *supra* note 50, at xii.
135. *See id.*
136. *See supra* note 17.
137. *See* Kraul, *supra* note 7, at D1 (reporting statistics of the USDA).

public criticism is leveled against international trade agreements.[138] Congress reacts to this criticism by attempting to curtail the President's authority to unilaterally negotiate trade agreements.[139]

1. President Clinton's Proposed Legislation

On October 2, 1997, President Clinton announced "an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States."[140] Specifically, the President's plan would provide the FDA with sweeping new authority over food produce imports.[141] President Clinton said he would boost next year's FDA budget for foreign-food inspections by approximately twenty-four million dollars.[142] The proposed legislation would require Customs to refuse entry to any food product originating in a country which does not have food safety systems which are "on par" with that of the United States.[143] The proposal calls on HHS and the USDA to develop safety system guidelines on growing, processing, shipping, and selling produce within the next year.[144] The strength of this proposal is that it gives the FDA additional resources and manpower to proactively inspect foreign production facilities to ensure their compliance with United States' standards.[145]

A criticism of the President's proposal is that it will harm the foreign

138. *See supra* note 17. Testimony on Capitol Hill related to the President's fast track authority to negotiate trade agreements has been critical of NAFTA on the grounds that free trade is a safety issue for the nation. *See* Richard A. Ryan, *Mom Says NAFTA is Safety Issue*, DET. NEWS, Sept. 10, 1997, at B3 (citing Sue Doneth, mother of a student in Michigan who contracted Hepatitis A from tainted strawberries from Mexico).

139. *See* John E. Yang, *Lacking Support, Clinton Postpones 'Fast Track' Vote*, WASH. POST, Nov. 10, 1997, at A1.

140. The White House, Office of the Press Secretary, Food Safety Fact Sheet, available in 1997 WL 605922, Oct. 2, 1997 [hereinafter Food Safety Fact Sheet].

141. *See* Knowlton, *supra* note 126, at A1.

142. *See* Woellert, *supra* note 79, at B8.

143. *See* Food Safety Fact Sheet, *supra* note 140.

144. *See id.*

145. *See* Woellert, *supra* note 79, at B8. "By looking more carefully at the land-management practices, the farming practices, the fertilization, the water supplies at [sic] each of these areas, it's possible to look at the public-health issues in a particular country and then to realize how best one can minimize the risks and maximize the benefits." *Id.*

trade environment, alienating importers and damaging the United States' credibility in light of a multitude of trade liberalizing agreements.[146] During his press conference on the issue, the President defended his proposal on the ground that it does not require foreign producers to meet any standards that United States producers are not mandated to follow, and that the more important issue is the safety of the American public.[147] Another criticism of the President's proposal is that it amounts to a political reaction to current events, and is simply an opportunity to garner support for the passage of "fast track" legislation.[148] However, the Administration has an active enforcement record on food safety and related issues going back to 1993.[149] This record indicates a genuine interest in these matters.

The President's proposal is problematic because it fails to fill the largest gap in the food safety net. Within the proposal, there is no specific requirement for an increase in the number of imports that are subject to FDA inspection. Employing additional inspectors to conduct inspections of foreign production facilities is essential. However, without

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146. *See, e.g.*, Knowlton, *supra* note 126, at A1 (reporting an interview with Mexican farm official Luis Cardenas). "It is very clear to us that behind all this are economic interests that want to prevent Mexican vegetables from entering the U.S." *Id.*

147. *See, e.g.*, *President's Remarks*, *supra* note 89 ("I don't want to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick.").

148. *See, e.g.*, Editorial, *America, The World's Food Policeman*, ROANOKE TIMES & WORLD NEWS, Oct. 13, 1997, at A8.

149. Since 1993, President Clinton's administration's record on food safety issues includes the following activities: GORE, *supra* note 111 (Vice President's National Performance Review results); Safe Drinking Water Act of 1996, 42 U.S.C. § 300(f) (1994 & Supp. II); Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996); *Administration Announces New Initiative to Improve the Safety of the Nation's Food Supply*, Food Safety Fact Sheet, *supra* note 140 (reporting an initiative in May 1997 to improve the nation's farm supply by increasing surveillance, response, and education); *President Announces New Early Warning System to Gather Information on Foodborne Diseases*, *id.* (reporting an early warning system to gather data to stop foodborne disease outbreaks quickly); *President Clinton Announces New Regulations*, *id.* (reporting new regulations for meat and poultry inspections in July 1996); *Administration Issues New Rules to Ensure Seafood Safety*, *id.* (reporting new rules on seafood safety in Dec. 1995); *CDC Embarks on Strategic Program to Detect, Prevent, and Control Emerging Infectious Disease Threats*, *id.* (reporting a prevention program to control emerging infectious disease threats).

a specific and mandated measure of the number of additional inspectors or the goals the FDA is trying to reach, there is no guarantee that inspections will increase.

Another defect in the Clinton proposal is that it fails to identify existing standards that foreign countries should meet in order to be classified as "on par" with the United States system.[150] While the President delegates responsibility for identifying specific standards to HHS,[151] the development of these standards will be enveloped in the political process. Special interest groups will lobby for rules which will allow their imports to meet the "on par" requirement or will lobby for standards that will close the door completely to specific imports.[152]

2. The Benefits of Free Trade Outweigh the Drawbacks

In light of the public's strong criticism of free trade,[153] it is necessary to look at the reasons for, and benefits of, a global free trading system. "A liberal trade regime is a crucial input into the creation [and maintenance] of a viable, competitive private sector."[154] There are three major benefits to free trade for the United States. First, free trade allows the standard of living for United States consumers to increase because of a greater food supply and decreased food costs.[155] Second, free trade allows for the laws of comparative advantage to apply to the United States economy, thus making it more efficient and productive.[156] Third, the United States is able to establish and maintain a working relationship with foreign states which is beneficial to the United States economy and the stability of the world order.[157] The only time protectionism becomes a valid argument is when national security is at issue. National security issues may include threats to the health and safety of individual citizens.[158] However, before invoking national security as a ground for protectionism, it is necessary to ensure that the costs to society of re-

150. *See Forbidden Fruit*, *supra* note 17, at A22.
151. *See* Woellert, *supra* note 79, at B8.
152. *See* Hoekman, *supra* note 50, at xi.
153. *See supra* note 17.
154. Hoekman, *supra* note 50, at 1.
155. *See* MELVYN KRAUSS, HOW NATIONS GROW RICH 4 (1997).
156. *See id.* "[T]he standard of living of the nation's citizens is higher when the nation specializes its production in certain goods, exports these goods, and imports others than when it tries to achieve self-sufficiency in all goods." *Id.*
157. *See* Taylor, *supra* note 3, at 33.
158. *See id.*

ductions in free trade do not outweigh the benefits of the protection being sought.

IV. THE FOOD SAFETY NET REQUIRES MENDING

There are four ways that the federal government can work to reduce foodborne diseases via imported food products. These measures include increasing the inspections of imported foods, creating a government task force to integrate the system, ensuring science-based food safety standards, and increasing public awareness.

A. Increase Inspections

The most practical way to reduce the risk of adulterated products entering the United States market is to increase the amount of food imports that are subject to inspection by the FDA.[159] This approach will serve two purposes. It will increase the number of exclusions of adulterated foodstuffs and it will serve as a deterrent for importers who knowingly attempt to get adulterated foods through Customs under the existing *de minimus* inspection system. Therefore, the FDA should maximize its current opportunity to increase inspections and, at the very least, attempt to meet the more successful inspection rate of the USDA.

B. Create a Federal Task Force to Integrate Existing Agencies

The federal government needs to integrate the objectives of the numerous federal agencies. In order to do this, a task force should be created composed of individuals from the various organizations that oversee food safety. These agencies include the FDA, the USDA, Customs, the EPA, and the CDC. The purpose of the task force should be to identify the overall objectives of the federal government and to identify ways in which these objectives can be met. Responsibilities should then be assigned to the various agencies on all issues currently lacking oversight. This would ensure that duplication of efforts is minimal.

In addition, the task force should investigate ways that each agency can work with existing international organizations, such as the WHO, to utilize existing data to which the United States is privy. This information, which includes regional outbreaks of disease and agricultural issues in specific countries, will help the federal government develop

159. *See id.* A starting point for the FDA would be to match the ten percent import inspection rate of the USDA. *See id.*

policies to prevent foodborne illnesses.

C. Ensure Science-Based Food Safety Standards

Any policy to prevent adulterated products from entering the United States' market should rely on existing standards which are founded upon scientific principles.[160] Standards currently in use by the FDA and the USDA's FSIS for domestic producers should be applied to foreign imports. This will ensure safety and prevent political interests from affecting the standards that apply to foreign producers.[161] Use of reliable and existing food safety protocols will legitimize any policy advocated by the United States Government and serve to defend against criticism by foreign governments of protectionist actions.

Additionally, United States negotiators should require that internationally recognized safety protocols, such as HACCP, are integrated into existing trade agreements on sanitary and phytosanitary measures, as well as any forthcoming trade agreements. This approach will appropriately set the expectations of parties to an agreement and avoid future conflicts. Use of standardized measures will also result in regulatory convergence, which will create additional economic benefits to nations.[162]

D. Increase Programs Aimed Toward Public Education

The risks to our food supply caused by foodborne diseases threaten our national security because these risks are a drain on our economy and a health risk to our citizens. Therefore, international programs should be developed which focus on public information campaigns targeted to producers in less developed countries. These programs should provide

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160. "Where scientific justification is present, national competence to regulate is hardly diminished." Atik, *supra* note 127, at 758.

161. *See* Hoekman, *supra* note 50, at xi. "Careful design of institutions and procedures is very important to [ensure the] . . . policy formation process is not captured by special interests." *Id.*

162. *See, e.g.*, Atik, *supra* note 127, at 752.

> The dynamics of globalization often . . . urge regulatory convergence. Harmonizing standards encourages the development, production and exchange of goods and services across borders. Where standards are consistent, greater economies of scale are available to producers, some of which are passed on to consumers. From the point of view of free trade, diverging regulation creates an economic drag.

Id.

information to food producers on internationally accepted food safety standards and protocols.[163]

Finally, the last and best line of defense against foodborne disease must rest with the individual who is ultimately going to consume the imported product. American consumers have begun to rely on the safety of products they buy at their local supermarkets.[164] This reliance has led to a national memory lapse regarding safe food preparation and proper hygiene when handling food. Additional domestic education programs, such as the "Fight Bac" campaign, need to be implemented on a federal and local scale, enlightening consumers to the risks of foodborne disease.[165] Providing preventive measures on how to avoid illness should remain a policy goal of the federal government.[166]

V. CONCLUSION

Protecting consumers against the risk of foodborne diseases arising from imported foods is increasingly important due to the rapid increase in food imports in the last five years and the growing reliance of American consumers on imported foods. The issue is one that regulators must consider immediately because the risks include a continuing increase in foodborne illnesses and the possibility of adverse effects on our nation's trade relations and policies. It is clear from the state of our nation that the benefits of free trade have far outweighed any deleterious effects caused by foodborne illnesses. Therefore, regulators must proceed with the utmost caution in walking the fine line between protecting the consumer and creating detrimental effects on the United States economy or alienating our partners in the global marketplace.

James Robert Burke

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163. "If people grasp food safety hazards by the way food is handled and prepared, confidence in food safety can be enhanced." Taylor, *supra* note 3, at 28.

164. *See* O'REILLY, *supra* note 8, § 1.02.

165. *See* Taylor, *supra* note 3, at 25.

166. *See id.*

> Improving the food safety practices of consumers and commercial food handlers with regard to such basic matters as hand washing, proper food storage, and cooking would go a long way toward reducing the risk of foodborne illnesses. Food safety education is not a panacea and cannot substitute for other food safety measures, but it should be a major component of society's public health program to reduce foodborne illness.

Id.