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From the Source to the Mouth: What Can You Reasonably Expect to Find in Your Food

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FROM THE SOURCE TO THE MOUTH: WHAT CAN YOU REASONABLY EXPECT TO FIND IN YOUR FOOD?

INTRODUCTION

Traditionally, American parents trying to instill good eating habits in their children encourage them to eat raw fruit and vegetables rather than processed, sugar-loaded snacks. But while choosing natural foods for children may cut down on the annual pediatric dental bill, are we really ensuring a safe and healthy diet for our children?

In 1989, for example, as conscientious parents directed their children to drink apple and other fruit juices, it was disclosed that apples and apple products were contaminated with the cancer-causing chemical Alar.¹ Children had been exposed to a pesticide risk several hundred times greater than the Environmental Protection Agency (EPA) claimed was acceptable.² And if apples are risky, what about those purple fruit drinks containing color additives and processed foods which claim to be fortified with high potency vitamin supplements? How safe are they, and by what standards?

This Note discusses the phases of food production from the ground to the table, and the potential risks to consumers at each stage. Part I presents the federal statutory framework regarding adulterated foods. It raises the distinction between a "food" and a "food additive," and defines "adulterated" food and its corresponding tolerance levels. Part II addresses issues about the growth phase of food and accompanying pesticide use, and concludes that although recent reports regarding high exposure to carcinogenic chemicals are extremely alarming, the government is aware of the problem and is proposing major reform designed to reduce the use of chemicals in the production of the country's food. Part III looks at the food processing phase which often involves the use of additives. This section discusses the various amendments to the Federal Food, Drug and Cosmetic Act (FDCA or the Act) regarding food additives and current proposals aimed at the regulation and restriction of vitamin and nutrient supplements. Finally, Part IV analyzes strict liability, breach of implied warranty and negligence, the causes of action available to the unfortunate consumer of adulterated food. This section defines and explains the three tests applied by states to determine a food vendor's liability, and encourages the use of the "reasonable expectation" test because it promotes the fairest result for both the consumer and vendor.

1. *Id.* Auvil v. CBS "60 Minutes", 800 F Supp. 928, 930 (E.D. Wash. 1992) [hereinafter *Auvil I*].

2. *Id.* at 939.

I. FEDERAL LEGISLATION CONCERNING ADULTERATED FOOD

A. "Food" vs. "Food Additive"

The first federal statute governing food safety was the Food and Drug Act of 1906.³ The Act declared that food was "adulterated" if it contained any poisonous additive or added substance which may render it injurious to health.⁴ The concept of an "added" substance, while not explicitly defined, was understood to mean substances intentionally incorporated into food as ingredients or applied during processing.⁵

In 1938, in an effort to further ensure the purity of the nation's food supply, Congress broadened its control over toxicants in food by enacting the present FDCA.⁶ The Food and Drug Administration (FDA) is the agency which, as the designee of the Secretary of Health and Human Services, enforces the Act.⁷

The Act defines "food" as: "(1) articles used for food or drink for man or other animals, (2) chewing gum and (3) articles used for components of any such article."⁸ According to the 1938 Act, substances defined as food are presumed safe and the FDA must, in order to deem them adulterated, show that the food contains a poisonous or deleterious substance which may render it injurious to health.⁹ And if the harmful substance is not one which is added to the food, then it is not considered adulterated if the *quantity* of the substance does not ordinarily render it injurious to health.¹⁰ Thus, while both the 1906 and the 1938 Acts retained the distinction between substances that were added and those that were not, neither clearly defined what constitutes "added."¹¹

This confusion was somewhat ameliorated in 1958 with the enactment of the Food Additives Amendment.¹² The term "food additive" was defined as:

3. Act of June 30, 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug and Cosmetic Act of 1938, ch. 675, § 902, 52 Stat. 1040, 1059; *see* Burke Pest Control, Inc. v. Joseph Schlitz Brewing Co., 438 So. 2d 95 (Fla. Dist. Ct. App. 1983) (history of federal legislation of adulterated food).

4. Act of June 30, 1906, ch. 3915, 34 Stat. 768, 770 (repealed 1938).

5. Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug and Cosmetic Act*, 77 MICH. L. REV. 171, 174 (1978).

6. Federal Food, Drug and Cosmetic Act of 1938, ch. 675, § 402, 52 Stat. 1046 (codified as amended at 21 U.S.C. § 342(a) (1988)).

7. 21 U.S.C. §§ 371(a), 393 (1988).

8. 21 U.S.C. § 321(f) (1988).

9. 21 U.S.C. § 342(a)(1) (1988); *see, e.g.*, United States v. Lexington Mill and Elevator Co., 232 U.S. 399, 410-11 (1914); United States v. 29 Cartons of An Article of Food, 987 F.2d 33, 35 (1st Cir. 1993) [hereinafter 29 Cartons I].

10. Burke Pest Control, 438 So. 2d at 97.

11. *Id.*

12. Section 201 of the FDCA was enacted as part of the Food Additives Amendment of 1958, 72 Stat. 1784 (codified as 21 U.S.C. § 321(s) (1988)).

Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . .)¹³

The Food Additives Amendment, in addition to clarifying what substances are considered "added," also allocated the burden of proof for food additives quite differently than that for food.¹⁴ Section 342(a)(1) presumes food to be safe and places the burden of proving injury on the government. However, with respect to food additives,¹⁵ the Food Additives Amendment allows the FDA to "prevent the sale of products containing a food additive unless and until the processor shows that the substance, when added to food, is generally recognized as safe (in the vernacular, 'GRAS')." ¹⁶

In sum then, to be labeled a "food additive," a substance must: (1) be intended or reasonably expected to become a component of food or to otherwise affect the characteristic of food; and (2) not be GRAS. Thus, the Act creates an important distinction between "food" and "food additives" which will often be the determining factor for a plaintiff seeking redress or in determining a purveyor's liability. This distinction also significantly affects the ease with which the FDA may regulate a substance's sale.

An illustration of this critical distinction can be seen in a series of recent cases regarding black currant oil (BCO).¹⁷ BCO is often taken as a dietary supplement and can be ingested in liquid or capsule form. BCO is obtained by squeezing black currant berry seeds and is composed of a unique fatty-acid structure.¹⁸

In *United States v. 29 Cartons of . . . An Article of Food (29 Cartons I)* the government sought, on appeal, to condemn cartons of encapsulated black currant oil alleging that the oil was a "food additive" of questionable safety.¹⁹ The question before the First Circuit was

13. *Id.*

14. *See 29 Cartons I*, 987 F.2d at 35.

15. *See supra* note 9 and accompanying text.

16. *29 Cartons I*, 987 F.2d at 35 (construing S. REP. NO. 2422, 85th Cong., 2d Sess. 3 (1958), reprinted in 1958 U.S.C.C.A.N. 5300, 5301-02).

17. *See United States v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part: Viponte, Ltd. Black Currant Oil Batch No. BOOSF 039*, 984 F.2d 814 (7th Cir. 1993) [hereinafter *Two Plastic Drums*]; *29 Cartons I*, 987 F.2d at 33; *United States v. 29 Cartons, More or Less, of an Article of Food*, 792 F. Supp. 139 (D. Mass. 1992) [hereinafter *29 Cartons II*].

18. *Two Plastic Drums*, 984 F.2d at 816.

19. 987 F.2d at 35-36.

whether these capsules should be classified as a "food" or as a "food additive."²⁰

The court analyzed the components of a capsule which were pure BCO encased in a plasticizer composed of gelatin and glycerin (neither of which has any independent food value). The court stated that "a capsule serves a dual purpose as a container . . . and as a prophylactic (protecting the BCO from rancidity)."²¹

The FDA took the position that the capsules were composed of three consumable components - BCO, gelatin and glycerin, and that each of these three ingredients was subject to potential regulation as a "food additive."²² Defendant, on the other hand, argued "that the BCO contained in the seized capsule [was] itself a food . . . and that its sale in a convenient carrier medium [did] not transmogrify it into a food additive."²³

In holding that the capsules were "food" rather than "food additive," the court relied on the reasoning of a factually similar case, *United States v. Two Plastic Drums*,²⁴ which had been decided by the Seventh Circuit several months earlier. Focusing on the language of the statute, both courts held that a substance was a "food additive" if, when added to food, it effects or could be expected to effect some change in the food. The fact that a substance was a component of a multicomponent substance did not render it a food additive.²⁵ The court interpreted the phrase "becoming a component or otherwise affecting the characteristics of any food"²⁶ as targeting "only those components that 'have the purpose or effect of altering a food's characteristics.'"²⁷ Simply put, BCO was the only active ingredient in the capsules and it was not being used for its effect on glycerin or gelatin.²⁸

In a similar case, *United States v. 21 Approximately 180 KG. Bulk Metal Drums, More or Less, of an Article of Food and Drug . . .*,²⁹ the court came to the opposite conclusion, finding that the capsules in question were a food additive.³⁰ The case involved BCO capsules as well as capsules containing Evening Primrose Oil (EPO).³¹ The de-

20. *Id.* at 36.

21. *Id.* at 35.

22. *Id.* at 36.

23. *Id.*

24. 984 F.2d at 814.

25. 29 *Cartons I*, 987 F.2d at 37.

26. 21 U.S.C. § 321(s) (1988).

27. 29 *Cartons I*, 987 F.2d at 37 (quoting *Two Plastic Drums*, 984 F.2d at 818) (emphasis added).

28. 29 *Cartons I*, 987 F.2d at 38.

29. 761 F. Supp. 180 (D. Me. 1991) [hereinafter 21 *Bulk Metal Drums*].

30. *Id.*

31. Evening Primrose Oil is made from crushed seeds of the evening primrose plant and is sold by some companies as a dietary supplement. No regulatory approval exists for EPO as a food additive as defined by the FDA. *Id.* at 183.

fendant had been distributing promotional materials claiming that the capsules helped "to prevent, treat, or cure a broad array of maladies ranging from atopic dermatitis to cancer, obesity, and schizophrenia."³² In this case, however, the defendant had combined these two oils with other vitamins, minerals and fish oil and then encapsulated the ingredients.³³

Since these capsules contained ingredients other than the pure oil, the Court found that under these circumstances, the BCO and EPO were food additives; therefore, according to the statute, the capsules were presumptively unsafe. The defendant provided insufficient information to justify approval of BCO as an additive as required by the Act and the court found that there was no regulation or exemption in effect permitting the use of BCO.³⁴ Thus, the court held that BCO was an adulterated food additive subject to condemnation.³⁵

B. "Adulterated" Food and Tolerance Levels

As previously mentioned, under the FDCA, a food is adulterated if it contains a poisonous or deleterious substance in a quantity that ordinarily renders the food injurious to health.³⁶ If the harmful substance is an added substance, then the food is deemed adulterated even without direct proof that the food could be injurious to health as long as the added substance is considered "unsafe" pursuant to section 346.³⁷ The term unsafe has been defined as "[a]ny quantity of

32. *Id.* at 182.

33. *Id.*

34. *Id.* at 185. See 21 U.S.C. § 348 (1988).

35. 21 *Bulk Metal Drums*, 761 F Supp. at 185. See also 21 U.S.C. § 334(d) (1988).

36. Food is deemed to be "adulterated"

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (other than [exceptions]) which is unsafe within the meaning of Sec. 346a(a) of this title

21 U.S.C. § 342(a). See *Young v. Community Nutrition Inst.*, 476 U.S. 974 (1986).

37. Section 346 states:

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limit so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated ..

21 U.S.C. § 346 (1988).

added poisonous or added deleterious substance, *unless* the substance is required in food production or cannot be avoided by good manufacturing practice."³⁸

Section 346 states that under circumstances where a poisonous or deleterious substance has been unavoidably added to food, the Secretary shall promulgate regulations limiting the amount of the ingredient to the extent he finds necessary to protect the public health.³⁹ A regulation pursuant to section 346 is known as a "tolerance"⁴⁰ which is defined as the maximum concentration of a substance allowed by law.⁴¹

Tolerance levels are established by a process similar to formal rule-making which includes evidentiary hearings.⁴² When appropriate, the FDA may refrain from setting tolerance levels and instead establish "action levels" which involve a less formal procedure.⁴³ In addition to protecting the consumer, establishing an action level assures the food producers that the FDA will not enforce the general adulteration provisions against them, as long as the quantity of the harmful added substance does not exceed the quantity specified by the action level.⁴⁴ In limited circumstances, the FDA will set neither tolerance nor action levels, but rather it will grant an exemption from the requirement of a tolerance.⁴⁵

In 1986, the Supreme Court wrestled with the subject of tolerance and action levels in *Young v. Community Nutrition Institute*.⁴⁶ Two public interest groups and an individual consumer brought suit against the Commissioner of the FDA alleging that, under the Act, the FDA was required to set a tolerance level for aflatoxin before allowing it to be shipped in interstate commerce.⁴⁷ Aflatoxin, a powerful carcinogen produced by a fungal mold, grows in certain foods (in this case, corn); it is indisputably poisonous and deleterious under sections 342 and 346.⁴⁸

Both parties agreed that although aflatoxin is naturally and unavoidably present in some foods, it was to be treated as "added" to food under section 346.⁴⁹ Since aflatoxin was a poisonous and deleterious substance added to food, it was potentially the subject of a toler-

38. *Young*, 476 U.S. at 977.

39. 21 U.S.C. § 346.

40. *Young*, 476 U.S. at 979.

41. *See American Grain Prod. v. Department of Pub. Health*, 467 N.E.2d 455, 460 n.5 (Mass. 1984).

42. *See generally* 21 U.S.C. § 371(e) (1988).

43. *See Young*, 470 U.S. at 977.

44. *Id.*

45. *See* 21 U.S.C. § 348 (1988) (exception for conformity with exemption or regulation).

46. *Young*, 476 U.S. at 974.

47. *Id.* at 978.

48. *Id.* at 977-78.

49. *Id.* at 978.

ance level.⁵⁰ The FDA, however, had not set a section 346 tolerance for aflatoxin, but instead had established an action level of 20 parts per billion (ppb).⁵¹

The problem arose in 1980 when the FDA stated in the Federal Register that it would not recommend regulatory action for violation of the FDCA regarding shipments of corn harvested in North Carolina, South Carolina and Virginia which contained no more than 100 ppb of aflatoxin.⁵² The notice further specified that the corn containing aflatoxin was to be used only as feed for mature, non-lactating livestock and mature poultry.⁵³ In response to this notice, plaintiffs brought suit against the Commissioner. The district court ruled that the FDA need not establish a tolerance level for aflatoxin and that the tainted corn could be allowed into interstate commerce.⁵⁴

The court of appeals reversed, claiming that the language of the statute unambiguously addressed the issue.⁵⁵ Specifically, the court interpreted the phrase "but when such substance is so required or cannot be so avoided, the Secretary *shall* promulgate regulations limiting the quantity therein"⁵⁶ as a directive to the Secretary to establish a tolerance.⁵⁷ The court further stated that the phrase "to such extent as he finds necessary" did not diminish the focal word "shall."⁵⁸

The Supreme Court reversed, holding that whether regulations were necessary to protect the public health was a determination to be made by the FDA.⁵⁹ Thus, "the FDA enjoys complete discretion not to employ the enforcement provisions of the FDC Act, and those decisions are not subject to judicial review."⁶⁰ In sum, the provisions of the Act authorize, but do not compel, the FDA to undertake enforcement activity.⁶¹

II. THE GROWTH PHASE: EXPOSURE TO PESTICIDES

Having presented the federal statutory framework for adulterated foods, we can now address issues which arise regarding the safety of food as it moves through the various stages of production.

The first phase of concern to the consumer is the risk posed by the use of pesticides during a food's growth phase. This risk was highlighted when the *New York Times* printed an article claiming that in-

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.* at 978-79.

55. *Id.* at 979.

56. 21 U.S.C. § 346 (emphasis added).

57. *Young*, 476 U.S. at 979.

58. *Id.*

59. *Id.* at 979-81.

60. *Community Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987).

61. *Heckler v. Chaney*, 470 U.S. 821, 835 (1985).

phants and children may be uniquely sensitive to pesticides.⁶² The article raised concerns similar to the CBS "60 Minutes" broadcast in 1989, which persuaded much of the public to boycott apples because some of them were sprayed with Alar.⁶³

The *New York Times* reported that children "consume more calories per unit of body weight and tend to eat fewer types of food than adults."⁶⁴ The article also stated that millions of American children receive up to thirty-five percent of their entire lifetime dose of carcinogenic pesticides by the time they are five years old.⁶⁵

Efforts to curb the use of pesticides began in the 1960's by groups advocating measures such as organic farming, but these efforts have only recently begun to receive popular support.⁶⁶ In 1985, for example, stricter pesticide regulations were presented to the House of Representatives.⁶⁷

In 1987, a National Academy of Sciences report claimed "that the nation's food supply was inadequately protected from cancer-causing pesticides."⁶⁸ Two years later, the year of the Alar alert, the National Resources Defense Council released its report *Intolerable Risk: Pesticides in Our Children's Food*.⁶⁹ However, the federal government did nothing significant to alter the pesticide regulations.⁷⁰

The *New York Times* article indicated that some major changes directed at reducing pesticide use would be enacted in the future.⁷¹ In the meantime, however, it is important to be aware of the kinds of issues which arise from the interaction of the two statutes currently governing pesticides and food: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)⁷² and the FDCA.

A. *History of FIFRA*

Over the past century, the use of pesticides to control weeds and minimize crop damage caused by insects, disease, and animals has become increasingly more important for American agriculture. While pesticide use has led to improvements in productivity, it has also led to increased risk of harm to humans and the environment.⁷³

62. Marian Burros, *U.S. Will Focus on Reducing Pesticides in Food Production*, N.Y. TIMES, June 27, 1993, at A1, A21 [hereinafter *Reducing Pesticides*].

63. See *Auvil I*, 800 F. Supp. at 942 (referring to the Feb. 26, 1989 broadcast and the ensuing boycott).

64. *Reducing Pesticides*, supra note 62, at A21.

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* (noting pesticide legislation introduced by Sen. Edward M. Kennedy and Rep. Henry A. Waxman, and support for change among industry groups).

72. 7 U.S.C. §§ 136-136y (1988).

73. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 990 (1984) (citations omitted).

FIFRA was adopted in 1947⁷⁴ and, at first, "was primarily a licensing and labeling statute . . . [requiring] that all pesticides be registered with the Secretary of Agriculture prior to their sale in interstate or foreign commerce."⁷⁵ Originally, FIFRA also contained general information regarding labeling directions for use and warnings intended to prevent harm to people, animals and plants.⁷⁶

Congress undertook a thorough revision of FIFRA through the Federal Environmental Pesticide Control Act of 1972, because of the then increased public concern about the safety of pesticides and their effect on the environment, and the fear that existing legislation was inadequate.⁷⁷ Under this Act, FIFRA became a comprehensive statute regulating all aspects of pesticide use and the EPA was given greater enforcement authority and the responsibility for administering FIFRA.⁷⁸ "Congress also added a new criterion for registration: that the EPA determine that the pesticide will not cause 'unreasonable adverse affects to the environment.'"⁷⁹ The EPA does so by weighing the benefits of a pesticide against its risks.⁸⁰

B. *The Dual Framework of FIFRA and FDCA*

The EPA regulates the use of pesticides on food under the dual framework of FIFRA⁸¹ and FDCA.⁸² FDCA contains special provisions which regulate the occurrence of pesticides on raw food⁸³ as well as in processed food.⁸⁴ Pesticides on raw foods are specifically governed under section 342(a)(2)(B) and section 346 which allow for a tolerance or an exemption to that requirement.⁸⁵

The FDCA allows the "flow through" of pesticide residue to processed food, even if the pesticide may be carcinogenic, for pesticides which are given a tolerance or an exemption for use on a raw agricultural commodity. This is acceptable only if the concentration of the pesticide in the processed food does not exceed the concentration allowed in the raw food.⁸⁶

74. Federal Insecticide, Fungicide and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947).

75. *Ruckelshaus*, 467 U.S. at 991 (citation omitted).

76. § 2(u)(2), 61 Stat. at 165.

77. Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973, 997 (1972).

78. *Ruckelshaus*, 467 U.S. at 991-92.

79. *Id.* at 992 (citing Federal Environmental Pesticide Control Act of 1972, § 3(c)(5)(C)-(D), 86 Stat. 973, 980-81).

80. 7 U.S.C. §§ 136(a), 136(bb).

81. *Id.* at §§ 136-136y.

82. 21 U.S.C. §§ 301-393.

83. *Id.* at § 342(a)(2)(B).

84. *Id.* at § 342(a)(2)(C).

85. *See Les v. Reilly*, 968 F.2d 985, 987 (9th Cir. 1992), *cert. denied sub nom.*, *National Agr. Chemicals Ass'n v. Les*, — U.S. —, 113 S. Ct. 1361 (1993).

86. *Id.* In this case, the provisions of § 342(a)(2)(C) are delineated:

The FDCA also contains a provision known as the Delaney Clause,⁸⁷ which dictates that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. . . ."⁸⁸

1. The Delaney Clause: Distinguishing Old and New Pesticides

The Delaney Clause was enacted in 1958 and until 1970 the FDA alone implemented the provisions of the statute. In 1970, the authority to set tolerances for pesticides was transferred from the FDA to the EPA.⁸⁹ However, the FDA has maintained the authority to set tolerances for all food additives other than pesticides.⁹⁰

While the Delaney Clause, on its face, applies to all carcinogenic pesticides, in practice, many carcinogenic pesticides are not affected. The EPA distinguishes between "old" and "new" pesticides — only new pesticides (those which have yet to receive EPA approval) have had the Delaney Clause applied to them. Since 1970, when the EPA was given authority to set tolerances for foods containing pesticides, it has refused to apply the Delaney Clause to "old" pesticides ("those which the EPA originally found benign but have since been found to cause cancer").⁹¹

This conflict was addressed in 1990 in *California ex rel. Van de Kamp v. Reilly*.⁹² The plaintiffs brought suit against the EPA, arguing that the EPA's failure to apply the Delaney Clause to "old" pesticides was contrary to Congressional intent and that such failure jeopardized the public health.⁹³ The plaintiffs sought a determination requiring the EPA to apply the Delaney clause to all carcinogenic pesticides, regardless of when the chemicals were discovered to cause cancer.⁹⁴

That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title [FDCA section 408] and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title [FDCA sections 406 and 409], not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

Id.

87 21 U.S.C. § 348.

88. *Id.* at § 348(c)(3)(A).

89. See *supra* text accompanying notes 77-78.

90. *California ex rel. Van de Kamp v. Reilly*, 750 F. Supp. 433, 437 (E.D. Cal. 1990).

91. *Id.* at 434, 437.

92. *Id.* at 433.

93. *Id.* at 437.

94. *Id.* at 435.

The opinion focused primarily on whether the challenge was ripe and on whether the decision not to apply the Delaney Clause to old pesticides was a final agency action for the purposes of the Administrative Procedures Act. It is significant to note, however, that this court interpreted the plain language of the Delaney Clause to indicate mandatory application to all carcinogenic pesticides.⁹⁵

2. No De Minimis Exceptions

In *Les v. Reilly*, the Ninth Circuit continued to strictly read the Delaney Clause, finding that the EPA had no discretion to permit use of food additives once a finding of carcinogenicity is made, regardless of the degree of risk involved.⁹⁶ Here, the petitioners sought the review of a final order of the EPA permitting the use of four pesticides⁹⁷ as food additives despite the fact that they had been found to induce cancer.⁹⁸ The EPA, notwithstanding the Delaney Clause, refused to revoke the earlier regulations, claiming that although the chemicals posed a measurable risk of causing cancer, the risk was de minimis.⁹⁹

The EPA asked the court to focus on the general statutory scheme governing pesticides (which allows the use of carcinogenic pesticides on raw foods), rather than at the specific language of the Delaney Clause.¹⁰⁰ The court denied the Agency's request based on the premise that section 342(a)(2)(C) expressly coordinates the statutory scheme with the Delaney Clause by "providing that residues on processed foods may not exceed the tolerance level established for the raw food."¹⁰¹ The court further noted that the statute clearly intended that pesticides which concentrate in processed food were to be treated as food additives under the Delaney Clause.¹⁰²

The EPA further contended that the legislative history demonstrated that it was never Congress' intention to rigidly regulate pesticides (as opposed to other additives) under the FDCA food additives provisions.¹⁰³ On this point the court agreed, adding that pesticides needed to be regulated more comprehensively under FIFRA precisely for that reason.¹⁰⁴ Ultimately, the court held that there are no de minimis exceptions to the Delaney Clause and that if a pesticide resi-

95. *Id.* at 439.

96. *Les*, 968 F.2d at 988.

97. *Id.* at 987. The four pesticides at issue were: benomyl, mancozeb, phosmet and trifluralin. *Id.*

98. *Id.* at 986.

99. *Id.*

100. *Id.* at 989.

101. *Id.* See Federal Environmental Pesticide Control Act of 1972, § 3(c)(5)(C)-(D), 86 Stat. 973, 980-81.

102. *Les*, 968 F.2d at 989.

103. *Id.* at 990.

104. *Id.*

due on processed food exceeds the tolerance established for the raw food, it must be banned.¹⁰⁵

3. Fruit Alerts: Alar on Apples

Sections 346(a)¹⁰⁶ and 348¹⁰⁷ permit persons outside the EPA to request the Agency to set a tolerance for harmful pesticides. Accordingly, in *Nader v. United States Environmental Protection Agency*, the plaintiffs sought a review of the EPA's decision denying their request to revoke pesticide tolerances for daminozide.¹⁰⁸ Daminozide, a plant growth regulator used mainly on apples and sold under the name of Alar, was registered in 1963 and approved in 1968.¹⁰⁹ Alar reduces fruit disorders, increases size and firmness and allows the fruit to remain on the tree until harvest.¹¹⁰ "Alar cannot be washed off the fruit, nor will peeling remove it. The substance remains in the flesh of the apple regardless of processing procedures."¹¹¹ Scientific studies found that Alar caused cancer in certain laboratory animals,¹¹² however, the EPA Scientific Advisory Panel found these studies to be inconclusive. Therefore, rather than revoking the tolerance, it proposed to reduce the tolerance from 30 ppm to 20 ppm as an interim tolerance.¹¹³ While the EPA's proposal was pending, petitioners asked the Agency to revoke the tolerance altogether pursuant to 21 U.S.C. §§ 346(a) and 348. The EPA denied the petition and ten days later published a final regulation reducing the tolerance as they had originally proposed.¹¹⁴

The Agency stressed that the use of an interim tolerance would permit it to reassess daminozide in light of new data. No one filed an objection or requested a hearing on the rule. Sixty days later petitioners brought their suit seeking review of the denial of their petition.¹¹⁵

The court held that it lacked jurisdiction under section 346(a) because the provision grants the court of appeals jurisdiction only over orders, and states that the denial of a petition does not constitute an

105. *Id.*

106. "The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical." 21 U.S.C. § 346a(e).

107. "Any person may, with respect to any intended use of a food additive, file with the secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(b)(1). Thereafter, the Administrator must, by order, either establish a regulation or deny the petition. 21 U.S.C. § 348(c)(1)(A).

108. *Nader v. United States Envtl. Protection Agency*, 859 F.2d 747, 749 (9th Cir. 1988), *cert. denied*, 490 U.S. 1034 (1989).

109. *Id.*

110. *Id.*

111. *Auvil I*, 800 F Supp. at 930.

112. *Nader*, 859 F.2d at 749.

113. *Id.* at 748.

114. *Id.* at 750.

115. *Id.* at 751.

order.¹¹⁶ Thus, this case exemplifies a double message conveyed by Congress to the public in its enactment of the FDCA. In theory the Act creates a number of avenues for public participation and review by appellate courts. In practice, however, section 346 states only that "the Administrator may propose the issuance of a regulation upon request of an interested person. He is not, however, required to publish the proposal, hold a hearing, or publish his reasons denying a petition."¹¹⁷ As Judge Fletcher poignantly said, "Short of language expressly precluding any review, Congress could have hardly drafted any provision more deferential to the Administrator."¹¹⁸

Another Alar alert was sounded in 1989 when the CBS television program "60 Minutes" aired a segment highly critical of the use of daminozide.¹¹⁹ The show emphasized that the potential harm posed by Alar was greatest to children, the largest consumers of apple products.¹²⁰

The credibility of the news report was bolstered by an interview with the acting EPA director, Dr. Jack Moore. Dr. Moore explained the paradoxical effect of the two-tiered application of the Delaney Clause in treating old and new pesticides.¹²¹ He confirmed that daminozide is indeed a health hazard, noting that had it been a new pesticide, under today's rigorous certification standards, it would not have been approved for use.¹²²

The television segment also included a report from the National Resources Defense Council (NRDC) regarding their findings in a study of eight cancer causing pesticides. The report claimed the risk of developing cancer was approximately 250 times what the EPA had set as an acceptable level of cancer in our population.¹²³ The central premise in their findings was that the government's methodology failed to take into account the distinct hazards faced by pre-schoolers. Pre-schoolers as a class consume more food per unit of body weight than does the adult population due to higher metabolic activity, which in turn means increased caloric requirements.¹²⁴ Children also tend to eat more fruit than adults. Considered together, these two facts reflect an inverse correlation between age and exposure to pesticides.¹²⁵

Two weeks after the interview and after re-examining the evidence, Dr. Moore "decided to start the process of banning daminozide after

116. *Id.* at 752.

117. *Id.* at 755.

118. *Id.*

119. *Auvil I*, 800 F Supp. at 930.

120. *Auvil v. CBS "60 Minutes"*, 800 F Supp. 941, 944 (E.D. Wash. 1992) [hereinafter *Auvil II*].

121. *Auvil I*, 800 F Supp. at 938.

122. *Id.* at 937-38.

123. *Id.* at 939.

124. *Auvil II*, 800 F Supp. at 943.

125. *Id.*

all."¹²⁶ But he neither declared Alar an imminent hazard nor suspended it immediately. Rather, he chose to implement a five year process of normal cancellation instead of an accelerated suspension.¹²⁷

Even though Alar was gradually banned from use, the sale and price of apples plummeted, locally and worldwide. The industry eventually recovered through a rigorous educational campaign, but during this transition period, apple growers and others dependent on the industry suffered losses totalling approximately seventy-five million dollars.¹²⁸ This case demonstrates the conflict often encountered by regulatory agencies whereby they must weigh the health risks to consumers posed by allowing continued use of a substance known to be hazardous, against the inevitable damage or destruction of a particular industry as a consequence of its abatement.

Similarly, in *National Coalition Against the Misuse of Pesticides v. Thomas*¹²⁹ the D.C. Circuit was pressed to balance health concerns against the economic concerns of the agriculture industry. This case involved imported mangoes and the use of the pesticide, ethylene dibromide (EDB). The EPA had "determined . . . that the severe impact of an EDB ban on the economies of foreign mango-producing countries and the low health risk posed by EDB justified a level of 30 [ppb] of the pesticide in the edible pulp of imported mangoes through September 30, 1987."¹³⁰ Initially, the court of appeals held that the "EPA acted arbitrarily and capriciously by . . . 'relying exclusively on concerns of foreign well being . . . without considering the factors specified as [relevant] in the FDCA.'"¹³¹ However, the court of appeals did not immediately set aside the orders. Instead, it withheld mandate for thirty days and directed the EPA to address the issue of whether the interim level of 30 ppb was justified.¹³²

On remand the EPA determined that "an interim tolerance of 30 [ppb] of EDB on mangoes until September 30, 1987, is justified, and is adequate to protect the public health, and will best serve the interest of assuring an adequate and wholesome food supply."¹³³

The court agreed with the EPA's determination that a ban of EDB could "pose a threat to the integrity of the Nation's food supply."¹³⁴ However, in a separate concurring opinion, one judge emphasized that the continuance of the tolerance for six months was justified *only*

126. *Auvil I*, 800 F. Supp. at 940.

127. *Id.*

128. *Id.* at 931.

129. 815 F.2d 1579 (D.C. Cir. 1987) [hereinafter *Nat'l Coalition I*].

130. *Id.* at 1580.

131. *Id.* (quoting *National Coalition Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 876-78 (D.C. Cir. 1987) [hereinafter *Nat'l Coalition II*]) (alteration in original).

132. *Nat'l Coalition I*, 815 F.2d at 1581.

133. *Id.*

134. *Id.* at 1582.

because revoking the tolerance in the middle of the growing season would cause severe economic harm for the foreign mango producers who had relied on the tolerance levels.¹³⁵ The decision to allow the interim tolerance level provided foreign food producers with the notice that there would not be additional extensions and that it would be prudent to switch to other non-harmful pesticides.¹³⁶

4. Conclusion

A recent *New York Times* article on the risks posed to children by the use of pesticides¹³⁷ demonstrated the government's awareness of this serious health hazard. If the proposed change in policy regarding the use of pesticides is fully carried out, the Administration claims it will be a "landmark in the history of food safety"¹³⁸ as it would substantially alter the methods of food production and the American diet.

This proposed major reform will involve the combined efforts of three governmental agencies, EPA, the FDA, and the Department of Agriculture, will create incentives for "safe pesticides," and will remove from the market those pesticides that pose the greatest risk.¹³⁹ The plan to reduce pesticide use will also incorporate "integrated pest management," a farming method using a minimum of pesticides, which in turn, increases the use of beneficial insects and crop rotation.¹⁴⁰

It has been suggested that testing for pesticides should be done on young animals whose systems are more analogous to those of children.¹⁴¹ In addition, a recommendation was made to frequently sample foods that children eat in large quantities, and to observe all exposures to pesticides, not just those from food.¹⁴²

135. *Id.* at 1583 (Green, J., concurring).

136. *Id.*

137. See *Reducing Pesticides*, *supra* note 62, at A1.

138. *Id.*

139. *Id.* at A1, A21.

140. *Id.* at A21.

141. *Id.*

142. *Id.* While no final proposals have been submitted for approval, the EPA, the FDA and the Agriculture Department are discussing the following changes which suggest a greater compromise than the original publicity indicated:

¶ Dropping the "zero risk" standard of the Delaney amendment in favor of one assuring only "negligible risk."

¶ Shifting the burden of proof on potentially dangerous pesticides, so that industry would have to prove them safe. In the meantime, the Government could begin phasing out suspect pesticides.

¶ Reorganizing pesticide regulation to speed approval of those more beneficial to human health and the environment.

¶ Permitting the Governor to change the labels governing pesticide use .

[and]

¶ [o]ffering stricter penalties against those who knowingly violate the pesticide laws.

Time will tell whether this Administration can accomplish this ambitious reform to reduce the use of chemicals in the production of the nation's food. In the interim, however, two things are certain: (1) proposals of this magnitude clearly demonstrate the government's awareness of the need to change current practices; and (2) alerting consumers to the potential health hazards caused by pesticides (especially to infants and children) will increase the pressure on the government to put into effect the reforms which they propose.

III. THE PROCESSING STAGE: FOOD ADDITIVES

A second area of consumer concern is the use of harmful food additives in the processing stage of food production. In 1958, the FDCA was amended to address this concern. The Food Additives Amendment of 1958 established a licensing scheme similar in concept to that for pesticide residues on substances intended to be used as ingredients in formulated foods.¹⁴³ It also applies to substances that become, or can reasonably be expected to become, components of food (i.e. packages which contain food).

A. *When Does a Pesticide Become an Additive*

In 1974, the Seventh Circuit, in *United States v. Ewig Brothers Co., Inc.*, held that what was unquestionably a pesticide chemical on a raw food product, could also be a food additive after processing.¹⁴⁴ The question before the court was whether residues of DDT¹⁴⁵ found in smoked fish, were food additives within the meaning of the FDCA.¹⁴⁶ The court noted that Great Lakes fishermen, unlike farmers and pesticide salespersons, had no interest in adding DDT to the environment or to the food supply, and that from the defendant's point of view, DDT was not an item which was added to their product, but rather a natural component of the fish before it was caught.¹⁴⁷

Defendants further argued that "a process, such as smoking, during which nothing new is added to [the] food, cannot 'transmogrify' a pre-existing component of a food into an additive."¹⁴⁸ The court disagreed and held that DDT found in the fish was a "food additive," not

Philip J. Hiltz, *White House Moves on Easing Food Pesticide Laws*, N.Y. TIMES, Aug. 20, 1993, at A14.

143. 21 U.S.C. § 348 (1958).

144. 502 F.2d 715, 722 (7th Cir. 1974).

145. DDT, or Dichloro-diphenyl-trichloroethane, is an insecticide widely used on crops for pest control. It is distinguishable from other insecticides as it decays slowly and is present in plants and animals. It appears in human beings as DDT remains in the body tissues of the plants and animals we consume. In 1972 the EPA banned almost all uses of DDT, but it is still used in other parts of the world. WORLD BOOK ENCYCLOPEDIA, 1991.

146. *Ewig*, 502 F.2d at 719; see also 21 U.S.C. § 321.

147. *Ewig*, 502 F.2d at 718.

148. *Id.* at 722.

protected by any tolerances,¹⁴⁹ and since they contained an unsafe food product, the fish were "adulterated" within the meaning of the FDCA.¹⁵⁰

A factually similar case, *National Wildlife Federation v. Secretary of Health and Human Services*,¹⁵¹ involved fish caught in the great lakes that were exposed to dioxin.¹⁵² The National Wildlife Federation (NWF) had filed an administrative petition with the FDA requesting an interim action level and a tolerance for dioxin in fish pursuant to section 346 of the FDCA.¹⁵³ The fish involved in this case were caught and consumed by sport fisherman and were not consumed by the general populace. The FDA studied data collected by the National Marine Fisheries Service and then determined the risks of cancer from such exposure.¹⁵⁴

The court stated that the FDA found that a nation-wide tolerance and interim action level were unnecessary to effectively control this problem and that an advisory warning adequately protected consumers.¹⁵⁵ The FDA concluded that the consumption of Great Lake sports fish would not result in significant dioxin exposure to the general population.¹⁵⁶ Following the Supreme Court's analysis in *Young v. Community Nutrition Institute*,¹⁵⁷ the court reiterated that the FDA clearly had the discretion not to issue a tolerance even if a deleterious or poisonous substance had been added to food and contamination was unavoidable.¹⁵⁸

The factual similarities in *Ewig* and *National Wildlife Federation* are apparent. Both cases involved fish from the Great Lakes and in both

149. Unlike fruit, vegetables and meat, tolerance levels had not been set in fish. *Id.* at 718.

150. *Id.*

151. 808 F.2d 12 (6th Cir. 1986).

152. Dioxin is any of 75 related chemicals all of which consist of carbon, chlorine, hydrogen and oxygen. Used as a weed killer, it is difficult to dispose of, as it does not break down in salt or water. WORLD BOOK ENCYCLOPEDIA, 1991.

153. *National Wildlife Fed'n*, 808 F.2d at 13.

154. *Id.* at 15.

[The] FDA concluded that most Americans do not consume Great Lakes fish frequently, and that a tolerance would not protect Great Lakes sports fishermen, the population at greatest risk. Its conclusion was based on the following factors: (1) the area of fish contamination is limited to only a part of the Great Lakes; (2) the species of fish most likely to contain dioxin constitute only a small portion of the fish in interstate commerce; (3) only consumers, such as sports fishermen, who consistently eat fish from contaminated areas are at significant risk, and a tolerance would not apply to such fish; and (4) FDA's findings indicate that although dioxin is unavoidable, the levels of dioxin in the fish most likely to contain this chemical have been decreasing in recent years.

Id. at 14.

155. *Id.* at 15.

156. *Id.*

157. *Young I*, 476 U.S. at 974.

158. *National Wildlife Fed'n*, 808 F.2d at 15.

cases the fish were rendered adulterated as a matter of law based on the fact that pesticide residue found in the fish was deemed a food additive. Yet the *Ewig* court held that a tolerance was necessary,¹⁵⁹ while the *National Wildlife Federation* court found that a tolerance was discretionary.¹⁶⁰

The divergence in these decisions was based on the FDA's assessment of the likelihood of exposure to the adulterated food.¹⁶¹ The court in *Ewig* was dealing with a processed smoked fish to be marketed nationwide. However, the court in *National Wildlife Federation* held that dioxin exposure to the general public was minimal and that setting a "tolerance for dioxin contaminated sports fish . . . would not effectively protect sports fishermen because FDA does not have the regulatory resources to control consumption of sports fish."¹⁶²

B. *Nutrients and Color Additives*

Like pesticides, dietary and nutrient additives may also render a food adulterated. Currently there are proposed regulations which intend to limit the unrestricted use of dietary supplements including vitamins, minerals and herbs in their present over-the-counter forms.¹⁶³ Under this proposal, the FDA would also prohibit potencies of dietary supplements from exceeding the levels found in food. Any supplement with higher potencies would be classified as an unsafe food additive.¹⁶⁴ However, Congress also has before it two other bills which offer alternatives assuring "the public's continued right to use dietary supplements and establish[ing] an office for dietary supplements" allowing the FDA to continue research.¹⁶⁵ One of these proposed regulations could become law,¹⁶⁶ but presently, the cases below typify issues which have arisen regarding nutrients and color additives.

In *United States v. 42/30 Tablet Bottles*, the United States sought condemnation of certain nutrients, including "Geranium Plus" capsules and "Coenzyme Q-10" capsules.¹⁶⁷ These nutrients were components of dietary supplements produced by defendants. The

159. *Ewig*, 502 F.2d at 723.

160. *National Wildlife Fed'n*, 808 F.2d at 15.

161. While both cases in this section discuss if and when a pesticide becomes a food additive, neither case was an issue under the Delaney Clause. Consistent with the EPA's refusal to apply the Delaney Clause to old pesticides, the court's focus was on whether the pesticide was a food additive, and if so, whether the FDA was required to set a tolerance.

162. *Id.*

163. Alan Cass, *Federal Agency Wants to Cut Your Vitamins*, N.Y. TIMES, Sept. 4, 1993, at A18.

164. *Id.*

165. *Id.*

166. *Id.*

167. 779 F Supp. 253 (E.D.N.Y. 1991).

complaint alleged that the dietary supplements were adulterated in that they contained unsafe food additives.¹⁶⁸

Both parties agreed that the substances in question qualify as food within the meaning of the FDCA. Defendants contended, however, that because Geranium Plus and Coenzyme Q-10 qualified as foods, they were precluded from being classified as food additives under 21 U.S.C. § 321(s).¹⁶⁹ Following the Second Circuit decision in *National Nutritional Foods Ass'n v. Kennedy*,¹⁷⁰ the court held that a substance does not gain immunity from being categorized a food additive merely because it also qualifies as a food.¹⁷¹

Claimants further contended that the intention of the Food Additive Amendment was to restrict the use of chemical substances only in the processing and preservation of food. The court agreed that although Congress' main concern was with substances used in food processing, there was nothing in the history or language of the Act that indicated Congress' intention to limit the scope of application.¹⁷² Furthermore, the court found that an examination of the legislative intent indicated that Congress meant to treat nutrients as food additives.¹⁷³ Congress did not want to leave the FDA without discretion to regulate nutrients and other natural chemicals which could be considered food additives based on their potential toxicity.¹⁷⁴

Consumer concern also focuses on color additives used to enhance the appearance of certain foods, drugs and cosmetics. The Color Additive Amendments of 1960¹⁷⁵ established an elaborate system for the regulation of color additives. The FDA, only after determining that the additive satisfies the requirements of the Delaney Clause,¹⁷⁶ publishes a listing of the additives safe for the petitioned uses.¹⁷⁷

In *Public Citizen v. Young*,¹⁷⁸ plaintiffs challenged the decision of the FDA to list two color additives, Orange No. 17 and Red No. 19, based on a quantitative risk assessment indicating that the cancer risks

168. *Id.* at 254.

169. *Id.*

170. 572 F.2d 377 (2d Cir. 1978).

171. 42/30 *Tablet Bottles*, 779 F Supp. at 254.

172. *Id.*

173. *Id.* When the Act was amended in 1976, the Senate chose not to incorporate a provision which would prohibit the FDA's ability to regulate vitamins, minerals and associated ingredients as food additives. *Id.*

174. *Id.*

175. Pub. L. No. 86-618, 74 Stat. 397 (codified at 21 U.S.C. § 376 (1988)).

176. The additive cannot be found to cause cancer. *See supra* note 87 and accompanying text.

177. *Public Citizen v. Young*, 831 F.2d 1108, 1109 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988).

178. *Id.* at 1108. This case involved color additives used in cosmetics and was questioned under the Delaney Clause. Color additives, however, must also pass muster under § 348(C)(3)(A) relating to food additives, and § 306(d)(1)(H) relating to animal drugs.

presented by these dyes were trivial.¹⁷⁹ Specifically the Court was required to determine whether the Delaney Clause for color additives was subject to an implicit de minimis exception. The Court held that there was no de minimis exception for carcinogenic dyes with trivial risks to humans.¹⁸⁰

C. *Accidental Additives*

Occasionally, courts have had to decide how to treat additives accidentally added. The general rule is that if a substance is added intentionally or incidentally it is governed by Food Additive Amendment.¹⁸¹ An intentional additive is one which is intended to be added to food, while an incidental additive is one which may reasonably be expected to become a component of food or affect its characteristics.¹⁸² However, if the substance is found to be "accidentally" added, it is governed by sections 342 and 348 of the FDCA, the poisonous and deleterious substance provision.¹⁸³

In *Natick Paperboard Corp. v. Weinberger*,¹⁸⁴ the plaintiffs, manufacturers of a paper-food packaging material, brought an action seeking relief against the seizure of its paper food-packaging materials containing more than the specified amount of polychlorinated biphenyls (PCBs).

PCBs, a group of toxic chemical compounds, are often found in industrial waste and subsequently appear in other products. If the product happens to be used for packaging food, it is not unusual for PCBs to migrate into the food unless the food is protected from such migration by an impermeable barrier.¹⁸⁵ The court of appeals classified the packaging material as a food additive because without this impermeable barrier the PCB's could reasonably be expected to result in becoming part of the food or altering its characteristics. The court stated that the FDA was not required to wait until the toxic substance contained in the packaging material actually entered the food before it could be restricted.¹⁸⁶ Thus, the court held that unsafe food additive such as PCBs in excess of 10 ppm were "adulterated foods" and as such may be seized under the FDCA.¹⁸⁷

179. *Id.* at 1109.

180. *Id.* at 1122. Six years later, the Ninth Circuit in *Les* was faced with the same question in a pesticide case and emphatically asserted there were no de minimis exceptions to the Delaney Clause. See *supra* notes 96-105 and accompanying text.

181. See *supra* note 9.

182. See *Natick Paperboard Corp. v. Weinberger*, 525 F.2d 1103, 1107 n.9 (1st Cir. 1975), *cert. denied*, 429 U.S. 819 (1976).

183. *Gerber Foods Co. v. Fisher Tank Co.*, 833 F.2d 505, 508 (4th Cir. 1987).

184. 525 F.2d 1103 (1st Cir. 1975), *cert. denied*, 429 U.S. 819 (1976).

185. *Id.* at 1104.

186. *Id.* at 1107.

187. *Id.*

However, in *Burke Pest Control, Inc. v. Joseph Schlitz Brewing Co.*, the court found that the residue of the chemical chloropicrin left on empty beer cans was an "accidental" food additive.¹⁸⁸ In this case, an exterminator was engaged to fumigate a warehouse in which beer cans were stored and an infinitesimal amount of the fumigant remained on the cans. The court held that because Schlitz never intended to add the fumigants to its beer, the addition was accidental.¹⁸⁹

In making its determination, the court asked whether the chemical had been added either intentionally or incidentally, thereby rendering chloropicrin an additive. Since the fumigant failed both of these tests, the court held that it was governed by the FDCA provisions dealing with poisonous and deleterious substances and not one of the subsequent amendments.¹⁹⁰

D. Conclusion

The Federal Food, Drug and Cosmetic Act of 1938 and its various amendments provide comprehensive protection of food at the processing stage. Additive alerts have come and gone and currently the FDA's focus is on vitamins and mineral supplements. Critics of the more stringent proposal which would restrict use of vitamins in their over-the-counter capacity, emphasize the deluge of litigation which will result on the State and Federal levels, as well as Constitutional challenges relating to advancement of science, right to health and freedom of choice. The more moderate proposal, allowing for the public's continued use of dietary supplements while supplemental research continues is a more reasonable solution.¹⁹¹

IV. FOOD VENDOR LIABILITY

The last stage in our analysis of food safety concerns the conveyance of wholesome food from the purveyor or vendor to the consumer. As early as 1431, the common law recognized an implied warranty of merchantability in the sale of food.¹⁹² Today the Uniform Commercial Code provides for an implied warranty of

188. 438 So. 2d at 95. See also *Gerber*, 833 F.2d at 508.

189. *Id.* at 99.

190. *Id.*

191. See *supra* notes 174-77 and accompanying text.

192. *Mexicali Rose v. Superior Court*, 822 P.2d 1292, 1311 (Cal. 1992) (Arabian, J., dissenting).

merchantability in the sale of goods¹⁹³ which can be viewed as a form of strict liability.¹⁹⁴

For plaintiffs to recover under section 2-314 of the Uniform Commercial Code, they must prove that: (1) defendant was a merchant; (2) defendant sold him the goods that were not merchantable at the time of sale; (3) the lack of merchantability proximately caused plaintiff's injury; and (4) plaintiff gave timely notice of the injury to the defendant.¹⁹⁵ Furthermore, section 2-318 of the Uniform Commercial Code removes any privity requirement by providing that both express and implied warranties extend to "any person who may reasonably be expected to use, consume, or be affected by the goods and who is injured in person by breach of the warranty."¹⁹⁶

In addition to breach of implied warranty, the unfortunate consumer of adulterated food may also have a cause of action in strict products liability and negligence. There are currently three tests for common-law food vendor liability: the foreign/natural test, the reasonable expectation test and the Louisiana test. The causes of action available to the plaintiff depends on the jurisdiction where the action is brought.

Of the three tests, the two most often employed are the foreign/natural test and the reasonable expectation test.¹⁹⁷ Currently, fifteen

193. The Uniform Commercial Code provides as follows:

(1) Unless excluded or modified (§ 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.

(2) Goods to be merchantable must be at least such as

(a) pass without objection in the trade under the contract description; and

(b) in the case of fungible goods, are of fair average quality within the description; and

(c) are fit for the ordinary purposes for which such goods are used; and

(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and

(e) are adequately contained, packaged, and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any.

(3) Unless excluded or modified (§ 2-316) other implied warranties may arise from course of dealing or usage of trade.

U.C.C. § 2-314 (1980).

194. Stacy L. Mojica, Note, *Breach of Implied Warranty: Has the Foreign/Natural Test Lost Its Bite?* 20 MEM. ST. U. L. REV. 377, 379 (1990). See also J. WHITE & R. SUMMERS, UNIFORM COMMERCIAL CODE § 9-7, at 466 (3d ed. 1988).

195. Mojica, *supra* note 194, at 380.

196. JAMES A. HENDERSON & AARON D. TWERSKI, PRODUCTS LIABILITY, PROBLEMS & PROCESS 111 n.1 (2d ed. 1992).

197. See *Mexicali Rose*, 822 P.2d at 1311 (Mosk, J., dissenting). The third test, the Louisiana test, is used much less frequently than the foreign natural test and the reasonable expectation test. *Id.*

states and the District of Columbia have adopted the reasonable expectation test, evidencing a trend in the law in that direction.¹⁹⁸

A. *Three Tests for Food Vendor Liability*

1. *Foreign/Natural Test*

The foreign/natural test developed as a result of the 1936 case of *Mix v. Ingersoll Candy Co.*, where the Supreme Court of California held that while an occasional chicken bone may appear in a chicken pie, without further defect, the pie was reasonably fit for human consumption.¹⁹⁹ The *Mix* court distinguished this case from other cases which had dealt with harmful substances “unnatural” to the food and held that in order to recover, the plaintiff must show that the injury was caused by a foreign substance rendering the product unfit for human consumption.²⁰⁰ The court asserted that bones natural to the type of meat served cannot be considered a foreign substance and that it is common knowledge that chicken pies occasionally contain chicken bones.²⁰¹ Furthermore, a food vendor or restaurateur was not required in exercising due care to serve a flawless chicken pie in every instance.²⁰²

Thus, the foreign/natural test asserts that: if a substance in a manufactured food product is natural to any of the ingredients of the product, the food vendor is not liable. However, if the substance is foreign to any of the ingredients, the manufacturer, vendor, restaurateur, etc. will be liable for any harm caused by the foreign substance.²⁰³ Under this test, injured plaintiffs have failed to recover for injuries involving “a grain of corn” in corn flakes,²⁰⁴ a cherry pit in a cherry pie,²⁰⁵ a pearl in cooked oysters²⁰⁶ and chicken bones in chicken noodle soup.²⁰⁷

Critics of the test argue that the test yields inconsistent results as it fails to take into account the extent to which certain foods have been processed.²⁰⁸ Moreover, what is considered natural to a food product in its original state, would not exclude body parts and bacteria natural

198. See Mojica, *supra* note 194, at 394. Mojica recognizes 12 states that have adopted the reasonable expectations test: Alabama, Florida, Kansas, Maryland, Massachusetts, New York, Ohio, Oklahoma, Rhode Island, Texas, Washington and Wisconsin. *Id.* at 394 n.90. As this paper discusses *infra*, Illinois, North Carolina and California claim to have adopted the reasonable expectation test in 1992.

199. 59 P.2d 144, 148 (Cal. 1936).

200. *Id.* at 147.

201. *Id.*

202. *Id.* at 148.

203. *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 449 (N.C. 1992).

204. *Adams v. Great Atl. & Pac. Tea Co.*, 112 S.E.2d 92 (N.C. 1960).

205. *Musso v. Picadilly Cafeterias, Inc.*, 178 So. 2d 421 (La. App. 1965).

206. *Title v. Pontchartrain Hotel*, 449 So. 2d 677 (La. Ct. App. 1984).

207. *Roseberry v. Wachter*, 138 A. 273 (Del. Super. Ct. 1925).

208. Mojica, *supra* note 194, at 398-99.

to the product (bird claws, chicken beaks or feces, for example). Theoretically, an injury to plaintiff caused by a chicken claw or beak in a bowl of chicken soup would not violate the foreign/natural test. The problem with this test is that it is based on a seriously flawed rationale — that because a substance is natural to the food in which it is found, it is fit for human consumption.

2. The Reasonable Expectation Test

The reasonable expectation test asserts that regardless of whether a substance in a food product is natural to an ingredient, liability will lie for injuries caused by the substance where the consumer of the product would not have reasonably expected to find the substance in the product.²⁰⁹

The reasonable expectation test was first referred to in *Brown v. Nebiker*,²¹⁰ where the Iowa Supreme Court denied recovery to a plaintiff who died as a result of injuries caused by a pork chop containing a sliver of bone. The court based its holding on the fact that a consumer of certain types of meat should reasonably expect and guard against the presence of natural objects.²¹¹ The more frequently cited case of *O'Dell v. DeJeans Packing Co.* summarizes the rationale of the reasonable expectation test:

If one purchases a whole fish to bake surely he or she could "reasonably expect" to find bones in it. If one "reasonably expects" to find an item in his or her food then he guards against being injured by watching for that item. When one eats a hamburger he does not nibble his way along hunting for bones because he is not "reasonably expecting" one in the food. Likewise, when one eats processed oysters, normally one does not gingerly graze through each oyster hunting for a pearl because he is not "reasonably expecting" one in the food. It seems logical some consideration should be given to the manner in which the food is normally eaten in determining if a person can be said to "reasonably expect" an item in processed food.²¹²

When applying the reasonable expectation test a court must determine what constitutes a reasonable expectation. *O'Dell* asserts that a reasonable expectation is one "in which the occurrence is more probable than just possible."²¹³ The Restatement (Second) of Torts clarifies *O'Dell* by defining what is to be considered "unreasonably dangerous." Section 402A states that "... unreasonably dangerous, is dangerous to an extent beyond that which would be contemplated by

209. See *O'Dell v. DeJeans Packing Co.*, 585 P.2d 399, 402 (Okla. Ct. App. 1978).

210. 296 N.W. 366 (Iowa 1941).

211. *Id.* at 371.

212. *O'Dell*, 585 P.2d at 402.

213. *Id.*

the ordinary customer/consumer who purchased it, with the ordinary knowledge common to the community as to its character."²¹⁴

3. Louisiana Test

The third test evolved in the state of Louisiana. This civil law state employs a two-pronged inquiry. If an injury is caused by a foreign substance in a food product, the manufacturer or vendor is subject to strict liability and the analysis stops.²¹⁵ If, however, the injury causing substance is natural to the product or its ingredients, the manufacturer may be liable *only* if the presence of the substance resulted from his negligence in the manufacture of the product.²¹⁶ In sum, if the substance is foreign, the defendant is held strictly liable and if the substance is natural the defendant may be found negligent. Under the Louisiana test there can be no cause of action in breach of implied warranty if the substance is natural to the product.²¹⁷

In 1964, the Louisiana Court of Appeals applied this two-pronged test in *Musso v. Picadilly Cafeterias, Inc.*,²¹⁸ a case in which the plaintiff brought an action for personal injuries caused by biting on a cherry pit contained in a slice of cherry pie. Because the pits were natural to the cherries, the plaintiff was unable to sue for breach of warranty.

In deciding the negligence action, the court found that the defendant restaurant keeper who customarily looked for and removed pits was not negligent if an occasional pit went undetected and happened to end up in a pie.²¹⁹ The court applied the standard of "reasonableness" to determine negligence, requiring that a restaurant use the same degree of care that a "reasonably prudent man skilled in culinary art, would use in selection and preparation of food for his own table."²²⁰

Under this analysis the foreign/natural test is employed to determine whether the food could be deemed unfit as a matter of law, but the negligence standard of "reasonableness" is used to determine whether a defendant could be liable in negligence for an injury producing substance that was natural to the food served.²²¹

214. RESTATEMENT (SECOND) OF TORTS § 402A cmt. 1 (1965).

215. See *Mexicali Rose*, 822 P.2d at 1300.

216. *Id.*

217. *Id.* at 1299.

218. 178 So. 2d at 421.

219. *Id.* at 428.

220. *Id.* at 427.

221. See *Title*, 449 So. 2d at 680; *Mexicali Rose*, 822 P.2d at 1300.

B. *Current Cases: Nibbling Away at the Foreign Natural Test*

The following three 1992 cases are illustrative of the shift in the law away from the foreign/natural test and towards the reasonable expectation test.

1. *Jackson v. Nestle-Beich, Inc.*²²²

In May 1988, plaintiff purchased a sealed can of Katydids, chocolate covered pecan and caramel candies manufactured by Nestle, and as plaintiff bit into her candy she broke a tooth on a pecan shell embedded in the chocolate.²²³ She subsequently filed a complaint asserting breach of implied warranty and strict products liability against Nestle.²²⁴

Nestle moved for, and was granted, summary judgment on the basis of the foreign/natural test. However, on appeal, the lower court's decision was reversed. The appellate court asserted a preference for the underlying rationale of the reasonable expectation test which de-emphasizes the naturalness element, and instead, focuses on the reasonable expectations of the consumer.²²⁵ The court rejected the reasoning of the foreign/natural test as relying on the untrue premise that consumers know (or should know) that prepared food products could contain any ingredient natural to it.²²⁶ The court reasoned that the naturalness of a harmful ingredient of a food product is merely "one factor to be considered in determining whether the presence of the ingredient breached a warranty or rendered the product unreasonably dangerous."²²⁷

Appealing to the Supreme Court of Illinois, Nestle argued that the appellate decision failed to recognize that "perfection in removing naturally occurring substances is impossible on each and every occasion" and that they "should be exempted from strict liability due to the difficulty of eliminating such matter."²²⁸ Nestle further argued that the Illinois courts should adopt the Louisiana test, but the court declined this invitation, agreeing with the plaintiff that the Louisiana approach resembles the outmoded doctrine of *caveat emptor*.²²⁹

Ultimately, the Supreme Court of Illinois affirmed the appellate court's decision to adopt the reasonable expectation test and in so doing noted three factors that it took into consideration when applying strict liability to Nestle: (1) "the customer's reasonable expectation as

222. 589 N.E.2d 547 (Ill. 1992).

223. *Id.* at 548.

224. *Id.*

225. *Id.* at 548-49.

226. *Id.*

227. *Id.* at 549.

228. *Id.* at 549-50.

229. *Id.*

to the contents of the food products";²³⁰ (2) the fact "[t]hat Nestle actually processes the ingredients in its product before placing it in the stream of commerce and thereby has some opportunity to discover and eliminate . . . risk[s] of injury";²³¹ and (3) the fact that "Nestle's product lacks the social utility of those products which justifies their exemption from such liability."²³²

The court added that a manufacturer, such as Nestle, could avoid strict liability by placing an adequate warning to the consumer on the product's container stating the possibility of risk or injury posed thereby.²³³ In conclusion, the court explained that even if it agreed with the defendant that its product merits classification as an unavoidably unsafe product, the court would still subject the defendant to strict liability due to the absence of a warning of the unavoidable risk of injury it posed.²³⁴

2. *Goodman v Wenco Foods, Inc.*²³⁵

This case involved an injury to the plaintiff's teeth which occurred when he bit down on a small bone lodged in a hamburger purchased at Wendy's Old Fashioned Hamburgers (Wendy's).²³⁶ Plaintiff brought actions in negligence and breach of implied warranty of merchantability against Wendy's and against the Greensboro Meat Supply Company (GMSC) which supplied the hamburger meat to Wendy's.

The plaintiff "introduced into evidence a copy of Wendy's' grinding specifications for its meat suppliers, which required that chopped meat be 'free from bone or cartilage in excess of 1/8 inch in any dimension that is ossified' prior to grinding and packing."²³⁷ The owner of GMSC was called as a witness for the plaintiff. He elaborated on GMSC's meat inspection criteria and the guidelines used in considering whether bone fragments were considered a defect.²³⁸ He explained that meat was not routinely inspected after the grinding

230. *Id.* at 550.

231. *Id.* at 551.

232. *Id.*

233. *Id.* at 552.

234. *Id.* (citing RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965) ("an unavoidably unsafe product is not defective or unreasonably dangerous when properly prepared and accompanied by proper directions *and warning*")).

235. 423 S.E.2d 444 (N.C. 1992).

236. *Id.* at 446 (the triangular bone was 1/16th to 1/4 inch long thick and 1/2 inch long).

237. *Id.* at 447.

238. *Id.* The owner presented a chart which indicated that "minor" defects were those less than 1/2 inch in any dimension and that "insignificant" defects were those less than 1/4 inch wide, were flexible or crumbled easily. If a sample unit of 30 pounds contained more than five minor fragments, it was considered a "major" defect.

process but rather that Wendy's employed a strict random inspection of meat which occurred several times a week.²³⁹

In determining whether the bone in the hamburger was a breach of implied warranty, the Supreme Court of North Carolina relied on the case *Coffer v. Standard Brands, Inc.*²⁴⁰ In *Coffer*, a breach of implied warranty claim was brought by a plaintiff whose tooth had been broken on a shell contained in a jar of nuts.²⁴¹ Under the foreign/natural test, no liability would lie, but the *Coffer* court added another dimension to the analysis. The court emphasized the quantity of such substance and whether it could be classified as injurious to health, not the naturalness or the reasonableness of the substance's presence.²⁴²

The *Goodman* court concluded that "the modern and better view is that there may be recovery, notwithstanding the injury-causing substance's naturalness to the food, if because of the way the food is processed, or the nature, size or quantity of the substance, or both, a consumer should not reasonably have anticipated the substance's presence."²⁴³ Thus, the court held that a jury could reasonably determine the meat to be of such a nature and the bone in the meat of such size, that a consumer should not reasonably have anticipated the bone's presence.²⁴⁴ This decision marked North Carolina's displacement of the foreign/natural test and its preference for the reasonable expectation test.

With regard to the cause of action in negligence, the court looked at the North Carolina Food, Drug and Cosmetic Act,²⁴⁵ which prohibits "the manufacture, sale, delivery, holding or offering for sale of any food . . . that is adulterated."²⁴⁶ The language of the North Carolina statute follows the FDCA and deems a food adulterated when: "It bears or contains any poisonous or deleterious substance which may render it injurious to health."²⁴⁷

The court was persuaded by the evidence at trial that Wendy's had exercised due care in the preparation of its hamburgers by the use of its grinding process and that, by itself, the fact that there was a bone in the hamburger did not create an inference that Wendy's was negligent in its inspection of hamburgers.²⁴⁸ The court did not want to place

239. *Id.*

240. 226 S.E.2d 534 (N.C. Ct. App. 1976).

241. *Goodman*, 423 S.E.2d at 450.

242. *Id.*

243. *Id.* at 451.

244. *Id.* at 452.

245. North Carolina Food Drug and Cosmetic Act, N.C. GEN. STAT. §§ 106-124 (1988).

246. *Id.* at §§ 106-122(1).

247. *Id.* at §§ 106-129.

248. *Goodman*, 423 S.E.2d at 453.

defendants in the precarious position of having to insure the absolute perfection of their food.²⁴⁹

With regard to the claims of negligence and breach of implied warranty against GMSC, the court held that unlike Wendy's, GMSC did not proffer evidence at trial which demonstrated due care in its grinding regulations. The Court, therefore, held that GMSC failed to sustain its burden as movant for summary judgment.²⁵⁰

3. *Mexicali Rose v. Superior Court*²⁵¹

In *Mexicali Rose*, the plaintiff, Jack Clark, a customer at petitioner's restaurant, sustained throat injuries when he swallowed a one inch long chicken bone in his enchilada.²⁵² He brought an action for damages based on theories of negligence, breach of implied warranty and strict liability.²⁵³ Before reaching the Supreme Court of California, the court of appeals had held that under the principal of *stare decisis* the foreign/natural test must be followed.²⁵⁴

On appeal, the plaintiff argued that "the foreign-natural test draws an arbitrary line of liability, . . . and unfairly exonerates the restaurateur [sic] from all liability simply because the injury producing substance happens to be 'natural' to the food served."²⁵⁵ Plaintiff further asserted that due to advances in modern technology over the past fifty-five years it should now be easier to safeguard against bones being left in food than it was in 1936 (when *Mix* was decided), and therefore defendant should be held liable.²⁵⁶

Finally, plaintiff contended that the foreign/natural test should be replaced by the reasonable expectation test²⁵⁷ and that defendant should be held:

- (i) liable in negligence for their failure to exercise reasonable care in the preparation of the food, (ii) liable for violating California's statutory implied warranty because a chicken bone in a chicken enchilada renders the latter unfit for human consumption . . . and (iii) strictly liable because the food item was "defective."²⁵⁸

249. *Id.* (citing *Norris v. Pig 'n Whistle Sandwich Shop, Inc.*, 53 S.E.2d 718, 722 (Ga. 1949)).

250. *Goodman*, 423 S.E.2d at 458.

251. 822 P.2d 1292 (Cal. 1992). As discussed *supra*, *Mexicali Rose* is an important case because it refers to and discusses the evolution of all three of the tests for food vendor liability. See *supra* note 197 and accompanying text.

252. *Id.* at 1294.

253. *Id.*

254. *Id.* (relying on *Mix*, 59 P.2d at 144).

255. *Id.*

256. *Id.*

257. *Id.*

258. *Id.* (citing RESTATEMENT (SECOND) OF TORTS, § 402A, cmt. 1 (imposing strict liability when food is "dangerous beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to the community as to its characteristics"))).

The California Supreme Court purportedly agreed with the plaintiff that a reasonable expectation test is applicable in this context and that it comports with the jurisdiction's development of tort law.²⁵⁹ The court, however, put significant limitations on the reasonable expectation test, which resulted in a holding that limits a plaintiff's claim to a cause of action in negligence (clearly echoing the Louisiana rule).²⁶⁰ The *Mexicali Rose* court offered the following interpretation of the reasonable expectation test:

[(1)] If the injury producing substance is natural to the preparation of the food served, it can be said that it was reasonably expected by its very nature and the food can not be determined unfit or defective. [The injured party] in such a case has no cause of action in strict liability or implied warranty. If, however, the presence of the natural substance is due to a restaurateur's [sic] failure to exercise due care in food preparation, the injured patron may sue under a negligence theory. [(2)] If the injury-causing substance is foreign to the food served, then the injured patron may also state a cause of action in implied warranty and strict liability. . . . [T]he trier of fact will determine whether the substance (i) could be reasonably expected by the average consumer and (ii) rendered the food unfit or defective.²⁶¹

As this explanation clearly demonstrates, the majority in *Mexicali Rose* did theoretically reject the straight foreign/natural test. But while they asserted that they had replaced it with the reasonable expectation test, they had merely created a camouflage of the Louisiana test.²⁶²

Judge Mosk stated in his dissent that he found the majority rule "bizarre in application to mass producers and distributors of processed food, irrational in differentiating between natural and unnatural contaminants and unfair in saddling the objectively unreasonable - and truthful consumer with costs he or she had no way of protecting against."²⁶³ Judge Mosk was also critical of the majority's suggestion that courts across the country had moved away from the strict foreign/natural test and that now the Louisiana rule represented the majority view.²⁶⁴ As Judge Mosk pointed out, in fact, no other jurisdiction had adopted the Louisiana standard,²⁶⁵ and that until the *Mexicali Rose* majority adopted it, it had remained unique to that state.²⁶⁶

259. *Mexicali Rose*, 822 P.2d at 1294.

260. *Id.* at 1307 (Mosk, J., dissenting).

261. *Id.* at 1303.

262. *Id.* at 1307-08 (Mosk, J., dissenting).

263. *Id.* at 1305.

264. *Id.* at 1307-08 (Mosk, J., dissenting).

265. *Id.* at 1308.

266. *Id.*

C. Conclusion

As these cases demonstrate, the reasonable expectation test is the only test which assures consumers of food the same protection afforded consumers of other products. While the foreign/natural distinction is a relevant consideration, it should not be controlling, nor should its results bar further analysis. Similarly, the Louisiana test which limits a cause of action to negligence, unfairly insulates food vendors from being held liable for implied breach of warranty and strict liability.

The trend in the majority of jurisdictions has been to replace the foreign/natural test with the reasonable expectation test. An illustrative example is found in *Zabner v. Howard Johnson's, Inc.*²⁶⁷ which states that "[t]he 'foreign-natural' test as applied as a matter of . . . law does not recommend itself to us as being logical or desirable."²⁶⁸ The foreign/natural test while focusing on the naturalness of the substance to the product loses sight of the fact that warranty of fitness of food was a rule of liability imposed as a matter of public policy in the interest of protecting health and safety.²⁶⁹ Viewed in this light, why would it matter if an injury was caused by a chicken bone or a similar sized piece of metal wire?²⁷⁰

The fact that a product contains only ingredients natural to it does not necessarily render it fit for human consumption. With the exception of *Coffer*,²⁷¹ very few courts discuss the *amount* of the deleterious substance as being an important consideration. Moreover, the central flaw in the foreign/natural test is that it totally ignores the nature of the natural injury producing substance. Surely a consumer who bit into a chicken patty sandwich only to discover himself munching on a chicken claw should be able to pursue a cause of action in breach of implied warranty or strict liability. The dissenting opinion of Judge Mosk in *Mexicali Rose* states very bluntly and accurately, "We started a wild goose chase . . . when this Court declared in 1936 that when the injury is caused by an object which *is natural* to the food being served, there can be no liability."²⁷²

The Louisiana test, is basically a two-pronged test with all of the flaws inherent in the foreign/natural test. Only Louisiana (and now California) have adopted this standard which limits plaintiff's cause of action to negligence.²⁷³ By disallowing implied breach of warranty and strict liability as causes of action the courts seem to ignore the intention of the Uniform Commercial Code in adopting these provi-

267. 201 So. 2d 824 (1967).

268. *Id.* at 826.

269. *Mexicali Rose*, 822 P.2d at 1306 (Mosk, J., dissenting).

270. *Id.*

271. 226 S.E.2d at 538.

272. *Mexicali Rose*, 822 P.2d at 1306 (Mosk, J., dissenting).

273. *Id.* at 1308.

sions, which was that the injured plaintiff would *not have to prove negligence*.²⁷⁴

So long as there is a foreign/natural dispositive component or prong to any test it will yield arbitrary results. It is illogical to base a decision on this distinction, as an unanticipated natural object may cause as much harm as a foreign object in food.²⁷⁵

The reasonable expectation test, by allowing plaintiffs to benefit from strict liability and breach of implied warranty, yields more equitable results than any version of the foreign natural test. The courts in *Nestle-Beich* and *Goodman* represent jurisdictions which clearly have adopted the reasonable expectation test. These decisions indicate that the trend is moving away from the foreign/natural test and gravitating toward greater reliance on jury perceptions of the reasonable consumer's expectations.²⁷⁶

This Note has presented a panoramic view of the issues raised and risks posed to consumers in the various stages of food production. Simultaneously, it has attempted to convey to the wary consumer that government is not only aware of these concerns, but more importantly, has been and is currently actively seeking to remedy them.

The current administration, by bringing together the Environmental Protection Agency, the Food and Drug Administration and the Department of Agriculture, is addressing the risks of pesticides posed during the growth of food and is determined to employ less chemically intense techniques. Similarly, the Federal Food, Drug and Cosmetics Act and its various amendments has and will continue to provide comprehensive protection of food at the processing stage. The final concern of the innocent consumer is that food which is conveyed be fit for human consumption. As courts continue to reject the problematic foreign/natural test in favor of the reasonable expectation test, the consumer's right to wholesome food is increasingly broadened and remains consistent with one medieval lawyer's observation that "it is ordained that none [shall] sell corrupt victuals."²⁷⁷

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274. See Mojica, *supra* note 194, at 407.

275. *Mexicali Rose*, 822 P.2d at 1307 (Mosk, J., dissenting).

276. Alan J. Lazarus, *Products, General Liability, and Consumer Law*, 28 TORT and INSURANCE L. J. 354, 356 (1993).

277. *Mexicali Rose*, 822 P.2d at 1311 (Arabian, J., dissenting) (quoting Y.B. Hen. VI, f. 53(b)(1431)).