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I. Background

Over the last ten years, consumption of bottled water in the United States has increased over 200 percent and soft drink consumption has increased over 30 percent while the consumption of all other beverages (excluding municipal drinking water) has decreased.[1] In 1993, over two billion gallons of bottled water were sold.[2] Annual sales of bottled water are estimated to be in excess of $2 billion.[3] Bottled water is used as a source of drinking water by approximately 27 million individuals[4] constituting approximately one out of every 15 households.[5]

In 1991, in response to the 'Perrier incident'[6] and in recognition of the magnitude of the industry, a United States House of Representatives Subcommittee held a hearing on the purity of bottled water.[7] Findings indicated that although as much as one-

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1. *See Is Bottled Water Better?*, 103 ENVTL. HEALTH PERSPECTIVES 322 (1995).
2. *See id.*
3. *See* S. REP. NO. 104-169 (1995).
4. *See* Linda Allen and Jeannie L. Darby, *Quality Control of Bottled and Vended Water in California: A Review and Comparison to Tap Water*, 56 J. ENVT'L. HEALTH 17-22 (1994).
5. *See* S. REP. NO. 103-102 (1993).
6. *See infra* notes 48 through 52 and text accompanying notes.
7. *See* H.R. REP. NO. 102-455 (1992)

fourth of all bottled water originated from the same sources as municipal water supplies, the Food and Drug Administration (hereinafter "FDA") had placed the regulation of bottled water low on the scale of consumer protection priorities.[8] In fact, FDA regulations were so incomplete, that FDA oversight did not even ensure that bottled water met the federal drinking water standards.[9]

Shortly after the Subcommittee initiated its review of the bottled water industry, FDA announced that a major survey of bottled water products would be undertaken. That survey was completed in 1993.[10] Immediately following its completion of the survey, FDA published a proposal to establish a standard of identity for bottled water including, among other aspects, allowable contaminant levels, labeling requirements, and source designations.[11] A final rule was published in November 1995[12] and amended in March 1996.[13] The final amended standard became effective as of September 23, 1996.[14]

These standards, promulgated to ensure that bottled water is 'safe' for consumer consumption,[15] do little more than to ensure that the quality of bottled water is no worse than the quality of municipal water! It is surprising that FDA now allows individual carcinogenic contaminants to be present in bottled water that, as the Environmental Protection Agency (hereinafter "EPA") acknowledges through its regulation of public drinking water standards,[16] has the propensity to cause an excess rate of cancer of up to one-in-ten thousand individuals.[17]

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8. *See id.*
9. *See id.*
10. Unfortunately the author was unable to obtain a copy of the survey or the results of that survey. It appears that surveys were mailed to members of the International Bottled Water Association, which is the industry representative for the over 400 companies producing bottled water in the US. It is unknown whether the survey focused on chemical quality standards, 'manufacturing' practices, or labeling requirements. However, *see infra* for references to several published surveys regarding both chemical and microbiological bottled water contamination.
11. *See* 58 Fed. Reg. 393 (1993).
12. *See* 60 Fed. Reg. 57076 (1995).
13. *See* 61 Fed. Reg. 13258 (1996).
14. The Final Amended standard is codified at 21 C.F.R. Part 165.110.
15. *See supra*, note 5.
16. *See infra*, note 35.
17. *See generally*, United States Environmental Protection Agency, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATIONS MANUAL (PART B, DEVELOPMENT OF RISK-BASED PRELIMINARY REMEDIATION GOALS), Interim Final, EPA/540/1-89/002, on file with the

Carcinogenic risk is estimated by EPA as the "incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen."[18] This type of cancer risk estimation often is considered "bright line" and can be used in managing 'unacceptable' risk.[19] To place this in a somewhat different perspective, because four million persons are born each year in the United States, "[a]n individual lifetime risk of one in [one hundred thousand] associated with exposure to a substance would mean that [forty] of these [individuals, if exposed to the substance in question] might develop cancer at some point in their lifetimes if they do not die of other causes."[20]

At first blush, it appears that FDA's new bottled water quality standards are discordant with their statutory mandate as enumerated in the Federal Food, Drug, and Cosmetic Act (hereinafter "FD&C").[21] Beginning in 1958, the Food Additives Amendment of 1958 (hereinafter "FAA")[22] and its subsequent amendments[23] have been incorporated into the FD&C. The FAA established a premarket approval system for food additives, which shifted the burden of proof of safety for intentionally added substances to the proponent of the substance.[24] As a further elaboration of the general safety standard, Congress added a specific directive, named for its proponent, Congressman Delaney: "[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by

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Dickinson Journal of Environmental Law and Policy. Office of Emergency and Remedial Response, Washington, D.C., at 2.8.1 (1991), *see also*, EPA Region 10 Supplemental Risk Assessment Guidance for Superfund and Memorandum from Patricia A. Cirone, Chief, Health & Environmental Assessment Section, USEPA Region 10, Risk at MCLs (1991), on file with the *Dickinson Journal of Environmental Law and Policy*.

18. United States Environmental Protection Agency, RISK ASSESSMENT GUIDANCE FOR SUPERFUND, VOLUME I: HUMAN HEALTH EVALUATION MATERIAL (PART A), Interim Final. EPA/540/1-89/002, Office of Emergency and Remedial Response, Washington, D.C., at 8.2.1 (1989), on file with the *Dickinson Journal of Environmental Law and Policy*.

19. *See* Commission on Risk Assessment and Risk Management, RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING, Draft Report, 1996, at Chapter 5.3.

20. PETER BARTON HUTT AND RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 897(2d ed. 1991).

21. 21 U.S.C. § 301 *et. seq*. (1996).

22. *See id.* at 348(c)(3)(A), Pub. L. No. 85-929, 72 Stat. 1784 (1958).

23. *See id.*

24. *See* Michael R. Taylor, *Food Safety Regulation* (found in FOOD TOXICOLOGY: A PERSPECTIVE ON THE RELATIVE RISKS 185 (Steven L. Taylor and Richard A. Scanlan, eds., 1989)).

man or animal."[25] As strictly interpreted by FDA and the courts, the Delaney Clause absolutely prohibits the use of any food additive found to cause cancer.[26]

Even though one application of the Delaney Clause was recently repealed as of August 3, 1996, the repeal only affects pesticide residues on processed foods; the new regulations, to be promulgated as a result of the Food Quality Protection Act (hereinafter "FQPA"),[27] still disallow, unless petitioned by FDA,[28] concentrations of pesticide contaminants that would cause an excess cancer risk greater than one-in-a-million.[29] FDA does allow carcinogens, other than pesticides, in the food supply;[30] however, these allowable carcinogens are regulated under extremely strict guidelines.[31] FDA allows ample opportunity for notice and comment prior to issuing any rule that regulates carcinogens in the food supply. Indeed, many of the historically allowable carcinogens have been intensely scrutinized, both by research and academic communities as well as by the political community.

The format of this Article is as follows: Presented first is a brief review of some of the recently codified regulations regarding labeling and source designation of bottled water as well as regulations covering the chemical quality of bottled water. Following this review, the scientific literature is culled to provide an estimate of the actual extent of bottled water contamination. A brief discussion of agency methodology to estimate carcinogenic risk precedes a discussion on the regulation of deleterious and carcinogenic substances under the FD&C.[32] A brief discussion on the regulation of environmental contaminants under FD&C as well as whether environmental contaminants would be considered as food additives, subsequently follows. The Article then concludes by querying whether the recently promulgated bottled water standards are protective of human health to the standard required under the

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25. 21 U.S.C. § 348(c)(3)(A)(1994).

26. *See* 21 U.S.C. Sec 348(c)(3)(A); 104 CONG. REC. 17415 (daily ed. Aug. 13, 1958).

27. *See* Pub. L. No. 104-170, 110 Stat. 1489 (1996).

28. *See infra* for discussion on FDA's authority to allow carcinogenic substances in food stuffs via petition for action level or tolerance.

29. *See Congress Kills Critical Support for Food Quality Law with USDA Appropriations Cut*, 38 FOOD CHEM. (August 12, 1996). This issue, namely, that of risk regulation of carcinogens in foods, is discussed further, *infra*.

30. *See infra* note 114.

31. *See Scott infra* note 111; *see also Monsanto v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979).

32. 21 U.S.C. 301 *et. seq.* (1996).

FD&C, ultimately concluding that after nearly four years of regulatory wrangling, FDA's recently codified bottled water and beverage standards do little more to protect consumers of these beverages than EPA's municipal drinking water standards do, and in some instances, FDA's regulations do not protect consumers under their statutory mandate. Are consumers of bottled water really drinking what they think they are?

II. Beverages: Bottled Water—the Final Rule

After an extensive notice and comment period lasting almost four years, FDA recently promulgated comprehensive regulations regarding the quality of bottled water.[33] Previous to this codification, bottled water was regulated under 21 C.F.R. Part 103-Quality Standards for Foods with no Identity Standards, pursuant to Section 410 of the FD&C,[34] and in conjunction with FDA-derived authority to regulate bottled water pursuant to the Safe Drinking Water Act, as amended.[35] The historical codification was the result of FDA's transfer to EPA of the jurisdiction over national drinking water standards in the 1970's, but the specific retention of FDA's authority to regulate bottled water.[36] Historical bottled water regulations focused solely on quality standards and basically deferred to EPA's chemical contaminant standards as promulgated under the Safe Drinking Water Act.[37] EPA's chemical contaminant standards are more commonly referred to as maximum contaminant levels ("MCLs");[38] these are levels of allowable contaminants in drinking water that pose 'minimal' risk.[39] Current bottled water regulations include identity and nomenclature standards, labeling requirements, and microbiological quality standards, as well as chemical contaminant standards.[40]

Label identity definitions for various sources of bottled water include, among others, 'artesian well water'[41], 'mineral water'[42], and 'spring water'.[43] Nomenclature for these types of bottled

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33. *See* 21 C.F.R. § 165.110 *et seq.*
34. 21 U.S.C. § 349 (1996).
35. 42 U.S.C. § 300f *et seq.* (1996).
36. *See* Pub. L. No. 93-523, 88 Stat. 1660 (1974).
37. *See supra* note 35.
38. Discussed in Section IV, *infra.*
39. Discussed in Section IV, *infra* and notes accompanying text..
40. *See* 21 C.F.R. 165.110(a)(1)-(a)(4) (1996).
41. *See id.*
42. *See id.*
43. *See id.*

water is due to the method used to 'capture' the groundwater and the geological configuration of where the groundwater source is located, for example, bore holes, assistance of external force to enhance natural underground pressure, and other definitions.[44] Quality requirements include both microbiological and chemical contaminant standards;[45] these standards are promulgated and amended by EPA under the Safe Drinking Water Act.[46] FDA, however, has the opportunity to reject EPA's promulgated and amended water quality standards but must "either promulgate amendments to regulations under [the] chapter applicable to bottled drinking water or publish in the Federal Register [their] reasons for not making such amendments."[47]

III. Comparison of Promulgated Standards With Detected Contaminants

In 1990, Perrier Corporation recalled its entire United States and Canadian stock of bottled water and halted its world-wide production, because of benzene contamination.[48] Levels of benzene detected in some of their bottled water ranged from 10 to 20 micrograms benzene per liter.[49] This level was (and currently is) 4 times greater than allowable levels under EPA's drinking water MCL standard for benzene.[50] Perrier Corporation noted that removal of benzene from their water source was frustrated by inadequate processing control;[51] a facility worker had failed to replace a charcoal filter used to remove certain contaminants.[52]

In response to this incident, a number of studies subsequently investigated the occurrence of bottled water contaminants. For example, Page and co-workers identified the presence of five selected volatile organic contaminants ("VOCs") in 182 samples of retail bottled waters.[53] Both petroleum, for example, benzene,

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44. *See* 21 C.F.R. § 165.110(a) (1996).
45. *See id.*
46. *See* 21 C.F.R. § 165.110(b) (1996).
47. 21 U.S.C. § 349(a) (1996).
48. *See* Barry Meier, *Perrier Recall Extended and Production Halted*, N.Y. TIMES, Feb. 11, 1990, at Section 1, p.5.
49. *See id.*
50. *See id.* The historic and current MCL for benzene is 5 micrograms per liter. *See* 40 C.F.R. Sec. 141.61(a).
51. *See Perrier Calls Problem More Serious Than Was Believed*, WASH. POST, February 15, 1990, at D1.
52. *See id.*
53. *See* Page *et al., Survey of Bottled Drinking Water Sold in Canada. Part 2. Selected Volatile Organic Compounds*, 76 J. AOAC INT. 26-31 (1993).

toluene, and cyclohexane, as well as chlorinated organics, such as chloroform and dichloromethane were detected with some frequency in store-bought bottled waters.[54] Of the five investigated contaminants, only dicholormethane concentrations exceeded FDA's recently codified bottled water chemical contaminant standards.[55] Dicholormethane is a known human carcinogen;[56] the high-end concentration range detected, 0.1 milligram per liter,[57] is 20 times greater than FDA's allowable level of 0.005 milligram per liter[58].

Another investigation conducted by Allen and Darby[59] has indicated that some of the VOC contaminants detected in bottled water may be a result of inadequate process control.[60] Groundwater source contamination, however, cannot be ruled out. Other bottled water surveys have investigated the occurrence of inorganic constituents.[61] Dabeka identified various inorganic constituents in bottled water including lead, cadmium, and arsenic.[62] Although it is likely that these inorganic constituents could have been introduced into the water during processing, it is possible that they are within naturally occurring levels of inorganic groundwater constituents.

In addition, studies have also indicated the facile migration of vinyl chloride, a potent known human carcinogen, from bottled water containers made from polyvinyl chloride ("PVC") into bottled water.[63] Benfenati and co-workers, for example, observed that the concentration of vinyl chloride detected in bottled water was proportional to the time after bottling.[64] After 150 days, these investigators observed that vinyl chloride migration into bottled water increased from less than 50 nanograms per liter to approximately 175 nanograms per liter, representing approximately one

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54. *See id.*
55. *See id.*
56. *See supra* note 17.
57. *See supra* note 53.
58. 21 C.F.R. § 165.110(b)(4) (1996).
59. *See* note 4, *supra.*
60. Water bottling equipment requires, among other things, the use of petroleum lubricants and chlorinated cleaning solvents. *See id.* at 17.
61. *See* Dabeka et al., *Survey of Bottled Drinking Water Sold in Canada*, 75 J. AOAC INT., at 949-953 (1992).
62. *See id.*
63. *See* E. Benfenati et al., *Migration of Vinyl Chloride into PVC-Bottled Drinking-Water Assessed by Gas Chromatography-Mass Spectrometry,* 29 FOOD. CHEM. TOXIC. 131-134 (1991).
64. *See id.*

nanogram per liter per day fluctuation. Yet FDA's bottled water allowable level of this carcinogen is 2 micrograms per liter[65], one order of magnitude greater than the amount of vinyl chloride detected in bottled water after storage for 150 days.

IV. Cancer Risk at FDA's Allowable Bottled Water Contaminant Levels[66]

FDA currently regulates bottled water contaminants at EPA's MCL standards.[67] EPA recognizes that groundwater contains 'unavoidable' anthropogenic environmental contaminants, some of which are carcinogenic. In setting MCLs, the EPA first must set a MCL goal ("MCLG"), a concentration at "which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. [EPA has authority to set MCLs] as close to the [MCLG] as is feasible."[68] EPA recognizes that there is some calculable risk associated with the MCL, both for non-carcinogenic and carcinogenic endpoints. In general, EPA regulates carcinogenic substances at the one-in-one million cancer risk level; however, EPA has the authority to set carcinogenic risk levels as low as the one-in-ten thousand level.[69] For example, exposure to a carcinogenic substance at a concentration regulated at the one-in-one million risk level would result in one excess cancer incidence (occurrence) per million persons over the background rate.

As EPA is unable (or unwilling) to prevent carcinogenic environmental contaminants from entering groundwater used for drinking water due to the 'infeasibility' of their removal (based on cost-benefit analysis), many of the MCLs set for carcinogenic substances are set at significant cancer risk levels. For example, pesticides' MCLs are commonly set at the one-in-one million cancer risk level.[70] At arsenic's MCL, however, the cancer risk for

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65. 21 C.F.R. § 165.110(b)(4) (1996)

66. The author has considerable experience with the regulatory framework surrounding agency (especially EPA) authority to set risk levels for carcinogenic substances. In this regard, many of the inferences or factual assertions are not referenced and express the general knowledge and opinion of the author, and in no way express any official agency position unless referenced.

67. *See, e.g.*, 60 Fed. Reg. 57110 (Nov. 13, 1995) (regarding Memorandum of Understanding between EPA and FDA).

68. 42 U.S.C. § 300(g)(b)(3) (1996).

69. *See* March Sadowitz and John D. Graham, *A Survey of Permitted Residual Cancer Risks*, 6 RISK: HEALTH, SAFETY & ENV'T. 17 (1995) (providing overview).

70. For published risk level values at MCLs, *see, e.g.*, EPA REGION 10 SUPPLEMENTAL RISK ASSESSMENT GUIDANCE FOR SUPERFUND; MEMORANDUM

exposure is one-in-one thousand.[71] Similarly consistent, MCLs for many of the chlorinated solvents and petroleum contaminants are set at risk levels of approximately one-in-one hundred thousand.

EPA, however, does not take into consideration the overall cancer risk level from exposure to more than one carcinogenic substance in drinking water. In fact, EPA's process for setting MCLs does not even take into consideration combined exposure to other environmental carcinogens such as those in air, soil, or food. Understandably, FDA's reliance on EPA's MCLs for bottled water standards places the regulation of this beverage in direct conflict with the Delaney Clause.

FDA also uses similar methodologies to assess carcinogenic risks.

> "The agency has emphasized that a one in one million level of risk, calculated by [conservative] procedures, is an 'extremely small, perhaps non-existent, theoretical risk' that 'represents a calculated statistical upper bound estimate of a conservative model' and 'does not represent a documented experience of a real expectation.' . . . According to the agency, a one in one million level of risk over a lifetime 'imposes no additional risk of cancer to the public,' and 'is consistent with the likelihood that no cancers will result[.]' . . . The agency has variously characterized a one in one million risk as represent[ing] no significant carcinogenic burden in the total diet of man,' . . . 'for all practical purposes, zero,' . . . 'the functional equivalent of no risk at all,' . . . 'so low as to be effectively no risk,' . . . assuring that 'in all probability no one will contract cancer,' [and] 'so low that there is a reasonable certainty of no harm.'"[72]

V. Regulation of Deleterious Substances Under the FD&C

FDA regulates foods containing poisonous or deleterious substances that are naturally occurring differently than foods containing those that are 'added'. A "'naturally occurring poisonous or deleterious substance' is a . . . substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination."[73] In contrast, an

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FROM PATRICIA A. CIRONE, *supra* note 17.

71. *See id.* It must be noted that the cancer risk level at arsenic's MCL is likely over estimated due to uncertainties associated with the toxicological information used to calculate risk.

72. *See* HUTT AND MERRILL, *supra* note 20, at 903-904.

73. 21 C.F.R. § 109.3(c) (1996).

"'added poisonous or deleterious substance' is . . . not a naturally occurring . . . substance. [However, w]hen a naturally occurring . . . deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase."[74]

"For simplicity, three broad groups of added food substances can be identified: (1) unintended added substances that are neither necessary nor unavoidable; (2) substances whose use is necessary in the production of food or unavoidable by good manufacturing practice; and (3) substances that become constituents of food through their intended use. The latter category includes food and color additives and pesticide residues."[75]

The statutory 'adulteration' safety standard for deleterious substances in food is contained in Section 402(a)(1) of the FD&C Act.[76] The critical distinction between naturally occurring and 'added' substances is the adulteration safety standards. Foods containing naturally occurring substances "shall not be considered adulterated . . . if the quantity of such substance . . . does not *ordinarily render it injurious* to health."[77] This is a more lenient standard than the adulteration standard for foods that contain "any poisonous or deleterious substance which *may render it injurious* to health."[78] Furthermore, utilizing statutory interpretation, the adulteration standard for foods containing either 'added' substances or 'food additives' is generally "unsafe within the meaning of Section 346 . . . [or] . . . Section 348 [, respectively]"[79] with the exception of pesticide chemicals on raw agricultural commodities, color additives, or new animal drugs.[80]

Section 346 provides that "[a]ny poisonous or deleterious substance *added* to any food . . . shall be deemed to be unsafe . . . but when such substance . . . cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein . . . to such extent as [is] necessary for the protection of

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74. *See infra* Section VII and notes accompanying text.
75. Clausen Ely, Jr., *Regulatory Distinctions Between Naturally Occurring and Added Substances in Food*" (found in FOOD TOXICOLOGY: A PERSPECTIVE ON THE RELATIVE RISKS, *supra* note 24, at 400).
76. 21 U.S.C. § 342(a)(1) (1996).
77. *Id.* (emphasis added).
78. *Id.* (emphasis added).
79. 21 U.S.C. § 342(a)(2)(A), (C) (1996).
80. *See* 21 U.S.C. § 342(a)(2)(A)(i-iv) (1996).

public health."[81]

In contrast, Section 348 of the statute indicates that any "*food additive* . . . be deemed to be unsafe"[82] unless it is in conformity with regulations prescribing the conditions under which it is safely used or it is used for investigation purposes.[83] "Food and color additives, unlike other added substances, are regulated through an elaborate premarket review and approval process, must be proven safe by the intended user and are subject to the Delaney Clause."[84]

The distinction between food additives and other substances that are merely 'added' is initially interpreted with deference to statutory language. Food additives are statutorily defined as: "any substance the intended use of which results . . . in its becoming a component . . . of any food (including any substance intended for use in producing, manufacturing, packing, . . . food;[)], . . . except that such term does not include"[85] pesticide residues on raw commodities (and post-Delaney repeal—processed foods), color additives, and other exempted substances.[86] In 1974, FDA elaborated on the differences between food additives and 'added' substances:

> "'Added' is a statutory term of art, encompassing all ingredients which are not inherent and intrinsic parts of a food . . . . The legislative history . . . identifies examples of foods naturally containing poisonous or deleterious substances and thus not subject to the 'added' provisions of section 402(a)(1) of the act. These examples are Burma beans, which contain a glucoside that yields prussic or hydrocyanic acid; . . . and coffee and tea. Except for substances whose deleterious nature is inherent to the natural state of the food, and thus similar in origin to these examples, all poisonous and deleterious components are 'added' . . . . The definition of 'food additive' . . . is not limited to intentional additives . . . . [but] includes any food substance and excludes only those substances which cannot reasonable be expected to become a component of food."[87]

Definitions of 'poisonous', 'deleterious', or 'ordinarily injurious'

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81. 21 U.S.C. § 346 (1996) (emphasis added).
82. 21 U.S.C. § 348(a) (1996) (emphasis added).
83. *See* 21 U.S.C. § 348(a)(1-2) (1996).
84. Ely, *supra* note 75.
85. 21 U.S.C. § 321(s) (1996).
86. *See* 21 U.S.C. § 321(s)(1-6) (1996).
87. 39 Fed. Reg. 42743 (1974).

have also been judicially interpreted with disappointing and ambiguous results. Many of the judicial interpretations indeed appear to be dependent on whether the substance is 'added' or 'naturally occurring.' The current authoritative safety standard for 'added' substances, as initially enumerated by the Supreme Court in 1914,[88] is that the term 'may render injurious to public health' is construed as indicating (in the negative) that a food containing an added substance is not 'injurious' to public health, "[i]f it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, [even] though having a small addition of poisonous or deleterious ingredients . . . . This is the plain meaning of the words."[89]

As is understandable, additional judicial interpretations have been used to clarify this holding. For example, in a preeminent case,[90] the United States Court of Appeals for the Tenth Circuit affirmed a district court holding that even after FDA banned diethylstilbestrol ("DES"),[91] a known human carcinogen, minute levels of the 'added' substance (as residue) did not 'render' meat 'adulterated' nor 'injurious' to public health under the Federal Meat Inspection Act ("FMI").[92] The district court, however, indicated that the term 'adulterated' could be defined differently in regards to the FD&C and the FMI statutes, even though the definition of adulteration in both statutes was identical.[93] In an earlier case,[94] caffeine was held by the Supreme Court to be an 'added' substance in soft drinks and whether it met the 'may render injurious' standard was a question of fact for the jury.[95] Another court held that arsenic, present as a contaminant in a color additive, was an 'added' substance but that FDA failed to establish that the quantity was sufficient to render the food injurious.[96]

These judicial constructions of 'added' substances, and whether these 'added' substances meet the standard of 'may render injurious' demonstrate the limits of this construction. There are

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88. United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).
89. *Id.* at 411.
90. United States v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds, etc., 516 F. Supp. 321 (D.Kan. 1981), *aff'd* 726 F.2d 1481 (10th Cir. 1984).
91. *See id.*
92. *See id.*
93. *See id.* at 328-329.
94. United States v. Forty Barrels and Twenty Kegs, 241 U.S. 265 (1916).
95. *See id.* at 289-90.
96. *See* W.B. Wood Mfg. Co. v. United States, 286 F. 84 (7th Cir. 1923).

many judicial holdings finding that 'added' substances are deleterious.[97] It appears that the key issue of whether an 'added' substance may render a food injurious' is determined by the quantity of the 'added' substance in the food.[98]

In contrast to 'added' substances, it appears that the 'ordinarily injurious' safety standard for naturally occurring toxicants is even more lenient than for all other types of food substances. In an early case, one court held that shell fragments, as naturally occurring, were not of sufficient 'character' (i.e. toxicity) to render a food 'ordinarily injurious'.[99] In the most recent leading case, the court held that amygdalin, occurring naturally in apricot kernels, is a non-added substance and is not 'ordinarily injurious' despite the fact that it might be toxic to those who consume unusually large amounts of the substance.[100]

The distinction between adulteration safety standards for 'added' and naturally occurring substances is most succinctly summarized by Justice Wisdom:

> If a substance is deemed 'added', then the [FDA] need show only that it '*may render* (the food) injurious to health' in order to regulate . . . [it]. The 'may render' standard has been interpreted to mean that there is a reasonable possibility of injury to the consumer . . . . If, however, a substance is considered 'not-added', the [FDA] must go further, and show that the substance would '*ordinarily render* (the food) injurious to health', before it can [be] regulate[d]." (emphasis added)[101]

VI. The Delaney Clause and Tolerances for Added Deleterious Substances

Since 1958, the FAA and its subsequent amendments[102] have been incorporated into the FD&C. The FAA established a premarket approval system for food additives, which shifted the burden of proof of safety for intentionally added substances to the

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97. *See infra* notes 101; *see also* Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38 (D.C. Cir. 1982); United States v. Boston Farm Center, Inc., 590 F.2d 149 (5th Cir. 1979).

98. *See* United States v. Commonwealth Brewing Corp., 1938-1964 F.D.L.I. Jud.Rec. 310 (D.Mass. 1945).

99. *See* United States v. 1232 Cases American Beauty Brand Oysters, 43 F. Supp 749 (W.D. Miss. 1942).

100. *See* Millet, Pit and Seed Co., Inc. v. United States, 436 F. Supp. 84, 88 (E.D. Tenn. 1977).

101. United States v. Anderson Seafoods, Inc., 622 F.2d 157, 158 (5th Cir. 1980).

102. Pub L. No. 85-929, 72 Stat. 1784 (1958).

proponent of the substance.[103] As a further elaboration of the general safety standard, Congress added the specific directive, named for its proponent, Congressman Delaney, that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal".[104] As strictly interpreted by FDA and the courts, the Delaney Clause absolutely prohibits the use of any food additive found to cause cancer.[105]

The definition of cancer, however, has been judicially and administratively reviewed over the years. For example, just two years after the enactment of the Delaney Clause, the President's Scientific Advisory Committee Panel on Food Additives reported that:

> [the] definition of a carcinogen . . . requires discretion in its interpretation because so many variables enter into a judgment as to whether a particular substance is or is not carcinogenic . . . . It is essential that [administrative] discretion . . . [, on classifying a substance as a carcinogen, is] . . . based on the most informed and expert scientific advice available.[106]

It is not within the scope of this article to further discuss how a substance is classified as a carcinogen by FDA.[107]

In addition, historically, there have been some limited legislative attempts to overturn the Delaney Clause's rigid characteristics. Two well known legislative attempts to regulate food additives include the DES Proviso,[108] which allows carcinogenic animal feed additives if there is no detectable residue remaining in the edible portions of the meat, and the Saccharin Study and Labeling Act of 1977,[109] which placed a moratorium on FDA action to ban saccharin.[110]

More recently, the Delaney Clause has been challenged on the

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103. *See* Michael R. Taylor, *Food Safety Regulation* (found in FOOD TOXICOLOGY: A PERSPECTIVE ON THE RELATIVE RISKS, *supra* note 24, at 185).

104. 21 U.S.C. § 348(c)(3)(A) (1996).

105. *See, e.g.*, 21 U.S.C. Sec. 348(c)(3)(A); 104 Cong. Rec. 17415 (Aug. 13, 1958); *Monsanto*, *supra* note 31; *Scott infra* note 111; *Public Citizens, infra* note 114.

106. President's Scientific Advisory Committee, REPORT OF THE PANEL ON FOOD ADDITIVES (May 1960), reprinted in 106 CONG. REC. 153809 (daily ed. July 1, 1960).

107. For a discussion on how FDA classifies carcinogenic substances, *see* Hutt and Merrill, *supra* note 20, at 295.

108. 21 U.S.C. § 348(c)(3)(A) (1996).

109. Pub. L. No. 95-203, 91 Stat. 1451 (1977).

110. *See id.*

grounds of the *de minimis* risk potential (short hand for *de minimis non curat lex* ["the law does not concern itself with trifles"]). For example, the United States Court of Appeals for the Sixth Circuit held that a carcinogenic impurity in a color additive was not considered a 'food additive' nor was the color additive *in toto* carcinogenic in animals.[111] Since the *Scott* decision, recognized as one of the first "*de minimis*" cases,[112] the FDA has approved more than 30 color additives and indirect food additives that contain a variety of trace carcinogenic 'impurity' constituents.[113] Three years after the *Scott* decision, FDA published in the Federal Register its rationale for allowing a carcinogenic dye, D&C Orange No. 17, to be used in external applications even though the dye was assessed to be carcinogenic.[114] FDA again relied on the *de minimis* argument.[115] In response to the listing, however, the United States Court of Appeals for the District of Columbia Circuit held that "the Delaney Clause . . . does not contain an implicit *de minimis* exception for carcinogenic dyes with trivial risks to humans."[116]

Following this decision and denial of *certiorari* by the Supreme Court, FDA disapproved the color additive involved in the litigation.[117]

There is one additional methodology that FDA can utilize to possibly 'allow' carcinogenic substances into the food supply. Section 406 of the FD&C[118] gives FDA authority to promulgate 'tolerance levels' for unavoidable added deleterious substances.[119] This section can be used similarly to Section 406a of the FD&C, which allows FDA to promulgate tolerance levels for pesticide residues on raw agricultural commodities.[120] Historically, tolerance levels have been set for many of the more well recognized, unavoidable, 'added', environmental contaminants and is discussed in greater detail *infra*.

Tolerance-setting under Section 406 of the FD&C is subject to

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111. *See* Scott v. Food and Drug Administration, 728 F.2d 322 (6th Cir. 1984).
112. *See* Hutt and Merrill, *supra* note 19, at 944.
113. *See id.* at 922.
114. *See* 51 Fed. Reg. 28331, 28334 (Aug. 7, 1986); Public Citizens v. Young, 831 F.2d 1108, 1110 (D.C. Cir. 1987).
115. *See Young* at 1111.
116. *Id.* at 1122.
117. *See* 53 Fed. Reg. 26766 (1988).
118. 21 U.S.C. § 346 (1996).
119. *See id.*
120. *See* 21 U.S.C. § 346a (1996).

'formal' rulemaking requirements.[121] Formal rulemaking involves evidentiary hearings, notice (publication in the Federal Register), and comment periods. To minimize the time commitment necessary to set formal tolerances, FDA has adopted "action levels" as a more flexible means of regulating unavoidable contaminants in food. Action levels have also been set for a variety of environmental contaminants[122]; however, in response to a Supreme Court decision[123] and the remanded case,[124] FDA published a notice in the Federal Register emphasizing that action levels do not have the force of law and that FDA is not bound by them.[125] However, FDA emphasized that it also has the authority to take action against a product that is contaminated below the action level and to refrain from action against products that violate action levels, depending on the circumstances of each case.[126]

The Delaney Clause historically banned the use of food additives (as pesticide chemical residues) in certain processed, ready-to-eat foods, if they could be shown to induce cancer, but only if they concentrated in the ready-to-eat food at levels above the acceptable tolerance level set for the pesticide on the raw agricultural commodity that was the basis for the processed food.[127]

On August 3, 1996, however, one application of the Delaney Clause was repealed by the Food Quality Protection Act (hereinafter FQPA).[128] Specifically, the FQPA "allows FDA, which sets food additive regulations for processed foods, and EPA, which sets tolerances for raw foods, to use the same risk-based practices for setting [these standards]."[129] The law, as initially interpreted, "established a uniform, risk-based standard for pesticide residues in foods. Specifically, it requires EPA to set 'tolerances' for pesticide

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121. *See* 21 U.S.C. § 371(e) (1996).
122. *See infra* Section VII and notes accompanying text.
123. Young v. Community Nutrition Inst., 476 U.S. 974 (1986).
124. Community Nutrition Inst. v. Young, 818 F.2d. 943 (D.C. Cir. 1987).
125. *See* 53 Fed. Reg. 5043 (1988).
126. *See id.*
127. *See House Approves Delaney Reform Bill*, 24 PEST. TOXIC CHEM. NEWS (24 July 1996).
128. *See* 110 Stat 1489, Public Law 104-170 (1996).
129. *See supra* note 127. However, "[a]s one FDA expert pointed out, the passage of [the FQPA] did not affect the Delaney clause at all. Pesticides were merely removed from any association with the clause (found in the [FD&C]), and, ironically, pesticides were never specifically part of the clause's provisions." *See Congress Kills Critical Support for Food Quality Law with U.S.D.A. Appropriations Cut*, 38 FOOD CHEM. (Aug. 12, 1996).

residues in foods at levels determined to be 'safe,' i.e., in order to achieve 'reasonable certainty of no harm.' The House Commerce Committee Report accompanying the legislation indicates that Congress intends EPA to impose a 'negligible risk' standard under this law, defined as no greater than a one-in-a-million lifetime risk."[130] Of course, FDA (and possibly EPA) will promulgate regulations in accordance with the interpretation of the FQPA, and courts will likely entertain whether their interpretation is correct.

VII. Regulation of Environmental Contaminants Under the FD&C

Whether environmental contaminants, if they are deemed to be deleterious, are regulated as 'naturally occurring' or as 'added' is somewhat difficult to ascertain. Additionally, there is some ambiguity as to how a carcinogenic environmental contaminant that is present in a food substance, and which could possibly be construed as 'naturally occurring', is or will be regulated, especially in light of the partial repeal of the Delaney Clause and FDA's continual partial recognition of the *de minimis* exception for impurities associated with food additives.

First there is the issue of whether an environmental contaminant is considered a "naturally occurring substance" or as a "food additive." The authoritative case on point is *United States v. Anderson Seafoods, Inc.*[131] Here Judge Wisdom stated that "where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an added substance."[132] In this case, the court explained that although swordfish may contain natural mercury, "if a[n additional] *de minimis* amount of mercury [that is present in the food] is shown to result from industrial pollution, then all of the metal in the fish is treated as an added substance."[133] It is worth noting that in *Andersen*:

> following the district court's decision and before the Court of Appeals ruled, FDA announced . . . that it would adopt [an] action level . . . determined by the district court to be safe . . . [this action level was less than the level of mercury contamination in the fish] . . . . The agency also stated that it

130. PIPER & MARBURY L.L.P., *Food Quality Protection Act Enacted*, 5 MARYLAND ENV. LAW LETTER (September 1996).
131. 622 F.2d 157 (5th Cir. 1980).
132. *Id.* at 161.
133. *Id.* at 159.

> would adhere to its own definition of an 'added' substance in 21 C.F.R. § 106.3 pending the court of appeals' [sic] decision but it has not amended that definition even after the Fifth Circuit rejected it as too broad.[134]

The FDA's definition of an 'added' substance is interpreted in its negative definition of 'naturally occurring': "an inherent natural constituent of a food [that] is not the result of *environmental, agricultural, industrial, or other contamination.*"[135] Specifically, on the particular issue of the definition of an 'added' substance, Judge Wisdom also once noted that if FDA utilized the definition in the regulation,[136] "[u]nder the rule, mercury in swordfish tissue deriving from the mercury naturally dissolved in sea water would be an added substance . . . however, we agree with the . . . term 'added' as used in Section 342(a)(1) [which] means artificially introduced, or attributable in some degree to the acts of man."[137] The definition of 'added', especially with respect to environmental contaminants, is therefore still somewhat uncertain.

From the *Anderson* holding, however, it appears that an 'environmental contaminant', such as an inorganic constituent, will be considered an 'added' substance and regulated as a food additive. Furthermore, it appears that an 'added' environmental contaminant will also be subject to the Delaney Clause if the additive is considered a carcinogen. Contrast, however, the *Anderson* holding with the regulation of aflatoxin, a potent liver carcinogenic byproduct of certain molds that grow especially well in peanuts and corn. In proposing a tolerance level for aflatoxin, FDA determined that the carcinogen was an *'added' substance.*[138] FDA initially proposed to set a tolerance level for this carcinogen, under Section 406 of the FD&C, based on an agricultural economic cost-benefit analysis.[139] However, after a formal risk assessment was conducted by FDA, as well as other agency and judicial events, FDA merely issued an action level for the carcinogen in certain foods.[140] However, the only formal FD&C Section 406 tolerance

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134. HUTT AND MERRILL, *supra* note 20, at 295.
135. 21 C.F.R. § 109.3(c) (1996) (emphasis added).
136. 21 C.F.R. § 109.3
137. Anderson, *supra* note 101, at 160.
138. *See* 39 Fed. Reg. 42748 (1974) (emphasis added).
139. *See id.*
140. *See* HUTT AND MERRILL, *supra* note 19, at 906-907. Action levels have also been set for carcinogenic nitrosamines in malt beverages and rubber baby bottle nipples, as well as for residues of a variety of carcinogenic pesticides in foods. *See* 45 Fed. Reg. 39341 (1980); 48 Fed. Reg. 57014 (1983); 52 Fed. Reg.

ever established was for PCBs in food and food packaging.[141]

It appears that when considering naturally occurring carcinogens, FDA sometimes adopts a fairly conservative position, especially where a major food market is not adversely impacted. For example, in 1960, FDA prohibited the use of safrole, a known animal carcinogen, as an ingredient in root beer and other soft drinks.[142] However, when the issue of FDA's authority to prohibit or condemn sassafras tea was determined, the agency contended that sassafras bark, used to make sassafras tea, was a food and contained an unsafe food additive.[143] The case was never tried because the claimant, over the government's objections, successfully moved to withdraw its claim.[144] However, the FDA's claim on sassafras raises another problem. The carcinogen safrole is also a natural constituent of a number of other food substances, including nutmeg. Nutmeg, although not a food that can be eaten alone, has a wide variety of food applications. Since the withdrawal of the sassafras tea case:

> the agency has not sought to ban natural food products containing carcinogenic constituents. Although FDA has quietly ignored carcinogenicity studies relating to long-established food products, it has consistently taken the position that a substance found to be carcinogenic in test animals cannot be regarded as GRAS, although a substance containing a carcinogenic constituent can be regarded as GRAS, . . . [however,] on occasion, FDA has banned synthetic [carcinogenic] chemicals that are identical to natural constituents of food.[145]

Compare FDA's prohibition of safrole, a naturally occurring substance affecting a relatively minor food industry niche, with FDA's allowance of aflatoxin, a naturally occurring substance affecting major food industry groups such as nuts and grains. With the regulation of aflatoxin, as indicated in congressional hearings, FDA realized the disproportionate impact on certain food industries that strict prohibition of this carcinogen would cause.

18025 (1987).

141. *See* 21 C.F.R. § 109.15 and § 109.30 (1996).
142. *See* 25 Fed. Reg. 12412 (1960).
143. *See* HUTT AND MERRILL, *supra* note 19, at 327.
144. *See id.*
145. *Id.* at 950.

VIII. Regulation of Environmental Contaminants in Bottled Water[146]

As it appears from the foregoing discussion, carcinogenic environmental contaminants contained in foodstuffs, if defined as either 'added' or 'naturally occurring', should be regulated under fairly strict guidelines, that is, comply with the Delaney Clause if considered an 'additive', demonstrate, at the minimum, *de minimis* risk if considered as 'naturally occurring,' or have a tolerance or action level set for them under proper notice and comment administrative procedures. Similarly, non-carcinogenic environmental contaminants contained in foodstuffs should also be regulated according to the 'may' or 'ordinarily' render injurious standard, depending on whether the contaminant is considered as, respectively, 'added' or 'naturally occurring'.

FDA's bottled water chemical quality standards are set for 67 substances;[147] these substances are defined as 'contaminants' within the regulation and are comprised of 21 organic (VOC) contaminants such as petroleum and chlorinated solvent substances, 29 pesticides and other 'synthetic' organic contaminants, and 17 inorganic contaminants.[148] Nine of these contaminant standards have been 'stayed' pending further agency investigation.[149]

Of the 21 organic contaminants, undeniably anthropogenic, that are allowed in bottled water, 12 are carcinogenic. These include benzene, carbon tetrachloride, tetrachloroethylene ("PERC"), trichloroethylene ("TCE"), and vinyl chloride, among others. Similarly, carcinogenic 'synthetic' organic contaminants and pesticides are anthropogenic by their inherent purpose and definition. Of the 29 'synthetic' organic contaminants and pesticides listed under 21 C.F.R. Part 165.110, approximately 20 percent of these are considered as carcinogenic. The total cancer risk that an individual would incur drinking bottled water over their lifetime, if all carcinogenic organic, 'synthetic' organic, and pesticide contaminants were present in bottled water at their regulated (allowable) standards, is approximately three-in-ten thousand. This clearly presents a greater carcinogenic risk than would be allowable under

146. The listing or determination of carcinogenic substances as well as the cancer risks associated with their ingestion in water is interpreted using EPA's Region 10 Supplemental Risk Assessment Guidance document, *supra* note 16.

147. *See* 21 C.F.R. Part 165.110

148. *See id.*

149. *See* 61 Fed. Reg. 13258 (1996).

any FDA standard discussed in this Article.

FDA also currently sets bottled water chemical quality standards for 17 inorganic constituents, two of which are carcinogenic. Unlike the organic contaminants, there could be some question regarding the anthropogenic nature of inorganic substances in groundwater. That is, natural groundwater does contain low levels of naturally occurring inorganic constituents that are leached from the earth's natural underground mineral formations, over millions of years, into groundwater. The extent to which anthropogenic processes and causes add inorganic contaminants to the naturally occurring mineral content of groundwater is somewhat unknown. Relying, however, on the *Anderson* decision, one could argue that any anthropogenic addition of an inorganic substance to groundwater that is bottled would constitute an additive under FD&C and thereby fall under more stringent safety standards such as 'may render it injurious' or the Delaney Clause for carcinogens.

Regardless of how one construes whether these inorganic constituents are considered as 'naturally occurring' or 'added', the carcinogenic risk posed by the two inorganic carcinogens, arsenic and beryllium, at their allowable bottled water standards, is one-in-one thousand, and two-in-ten thousand, respectively.[150]

Not only are bottled water chemical quality standards set for carcinogens, but standards are also set for noncarcinogens. Adverse effects caused by noncarcinogenic toxicants are somewhat differently measured. Standards are set based on the propensity to adversely effect the body.[151] Understandably, pesticides, by their nature, are toxic. Certainly, pesticides and other organic and inorganic contaminants, at allowable levels in bottled water, 'may render' or even 'ordinarily render' the water injurious to one's health, as was identified by the *Anderson* court.[152]

IX. Conclusion

Although FDA took approximately four years to promulgate regulations regarding bottled water quality, after a Congressional Committee identified the need for these regulations, the chemical quality standards portion of these newly codified regulations do

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150. For a discussion of arsenic's cancer risk, *see* note 71 and text accompanying note.

151. Such effects include: causing internal bleeding, *see* 45 Fed. Reg. 39341 (1980); kidney failure, *see* 48 Fed. Reg. 57014 (1983); or other effects, *see* 52 Fed. Reg. 18025 (1987).

152. *See* notes 101, 137 and 138, *supra*, and text accompanying notes.

little more than adopt EPA's groundwater contaminant standards. Unfortunately, EPA's mandate to protect public health is not as rigorous as FDA's. For example, EPA's regulation of carcinogenic drinking water contaminants at the one-in-ten thousand cancer risk level (and higher in some instances) may be adequate for EPA's statutory mandate; however, it is not adequate for FDA's statutory mandate. Even if the Delaney Clause is fully repealed for all food additives, the newly-enacted FQPA indicates that carcinogenic food additives would still likely be regulated at a 'negligible cancer risk' standard, currently defined as no greater than the one-in-one million cancer risk level.

It is obvious from the *Anderson* holding that environmental contaminants are to be construed as 'food additives.' Whether this will be overruled by the Supreme Court remains to be ascertained. Regardless, even if environmental contaminants are considered as 'naturally occurring,' the current cancer and noncancer risk levels, resulting from the newly codified bottled water chemical quality standards, would still likely be considered as to great, even under the more relaxed 'naturally occurring' safety standards. The only way that the current levels would be acceptable, is for FDA to promulgate, after proper notice and comment, legally enforceable tolerance levels or questionably enforceable action levels for each contaminant regulated in bottled water.

It is apparent that FDA's new bottled water quality standards are discordant with the Delaney Clause, even as partially repealed by the Food Quality Protection Act, and certainly discordant with FDA's statutory mandate. Are consumers of bottled water really drinking what they think they are?