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NOTE

THE HUMBLE ALMOND: WHY CONGRESS SHOULD INSTITUTE THE PRECAUTIONARY PRINCIPLE TO GUIDE REGULATION OF ENVIRONMENTAL TOXINS AND FOOD ADDITIVES

David Alan Nauheim[†]

I. INTRODUCTION

Imagine a world where a food consumed since biblical times¹ is deemed unsafe in its natural form, but fumigating that food with a “probable carcinogen,”² banned in most of Europe, Africa, Asia, and Canada,³ renders it “pasteurized.”⁴ Or, imagine a world where a food that has been “blanched” in 190°F water for two minutes can be labeled “raw.”⁵ This is the logic behind recent changes to the U.S. Department of Agriculture’s (“USDA”) regulation, Almonds Grown in California, 7 C.F.R. § 981 (“Rule”).⁶ This is the story of how the combined⁷ forces of the Environmental Protection

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1. “Put some of the best products of the land in your bags and take them down to the man as a gift—a little balm and a little honey, some spices and myrrh, some pistachio nuts and almonds.” *Genesis* 43:11.

2. The Environmental Protection Agency (“EPA”) considers propylene oxide a probable carcinogen. *See, e.g.*, Environmental Protection Agency, *Technology Transfer Network Air Toxics Web Site, Propylene Oxide*, <http://www.epa.gov/ttn/atw/hlthef/propoxi.html> (last accessed Nov. 3, 2007).

3. Cornucopia Institute, *Almond Fact Sheet*, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf (last visited Dec. 17, 2007).

4. *See* California Almond Board, *Almond Action Plan, Pasteurization Treatments*, <http://www.almondboard.com/files/April%202007%20Pasteurization%20treatments.pdf> (last accessed Nov. 11, 2007).

5. *Id.*

6. Specifically, the change to the rule is embodied in 7 C.F.R. § 981.442(b)(1) (September 1, 2007).

7. Various aspects of the Rule are administered by EPA, USDA, and FDA. Their jurisdictions are often concurrent and overlapping. For example, the EPA sets tolerances for pesticides, but the USDA approves their use on almonds. *See, e.g.*, Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of

Agency (“EPA”), Food and Drug Administration (“FDA”), and the USDA have deprived the people of a traditional and beneficial food, in its natural, unadulterated form, as it has been consumed for thousands of years.⁸

Recent changes to the Rule abound with logical absurdities. Does the innocuous label “pasteurized” convey to consumers that the healthy food they think they are consuming contains a probable carcinogen?⁹ If the stated purpose of the new Rule is to “reduce the potential for salmonella bacteria in almonds,”¹⁰ why does the Rule subject all almonds to pasteurization, when the risk of salmonella is already eliminated in ninety-five percent of almonds through blanching, roasting, or baking?¹¹ Does it make sense to impose a regulation on small and organic growers that is proportionally more costly for them, when they are already required to use costly salmonella avoiding techniques, which the commercial growers are not required to use?¹²

This Note will argue that the new pasteurization requirements set out in recent changes to the Rule are not rationally related to the stated purpose of the Rule, are at once over inclusive and under inclusive, pose an undue and

Certain Antimicrobial Substances, 63 FED. REG. 54,532 (Oct 9, 1998) (resolving which agency will exercise jurisdiction over PPO where jurisdiction overlaps).

8. There is a long list of traditional foods that have been consumed for thousands of years, but now must be pasteurized. Examples include milk, beer, raw cheese, eggs, spices, red meat, and vegetables. See Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 531 (1998).

9. A food that contains propylene oxide does not need to indicate this on the label, but instead may bear the innocuous title, “pasteurized.” The USDA does not consider this contrary to the Congressional Declaration of Policy for the Fair Packaging and Labeling Program which states, “Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.” 15 U.S.C. § 1451 (Nov. 3, 1966).

10. Almonds Grown in California; Outgoing Quality Control Requirements, 72 FED. REG. 15,021 (March 30, 2007).

11. A May 21, 2004 press release of the California Almond Board states that “95 percent of almonds sold undergo processing, such as blanching, roasting or baking which eliminates any potential bacteria such as Salmonella Enteritidis.” California Almond Board, California Almond Board Responds to FDA’s Consumer Advisory Regarding Raw, Natural Almonds, <http://www.almondsarein.com/AlmondLovers/nrdetail.cfm?ItemNumber=579> (May 18, 2004).

12. See, e.g., McAfee Farms and Organic Pastures Dairy, Position on the Pasteurization of Almonds, http://www.organicpastures.com/raw_almonds.html (last accessed on November 3, 2007).

unjustifiable burden on small and organic almond growers, and unjustifiably deny consumers the right to purchase the foods that they believe are healthy, safe, and nutritious. This Note will further argue that the current administrative rule-making regime lacks a guiding principle to incline agencies toward reasoned rule-making that adequately protects human health and autonomy. This Note will propose that Congress institute the “precautionary principle”¹³ as a guiding principle for regulatory rule-making that affects human health and autonomy. Section II of this Note will lay out the background in which the rule change was made. Section III will lay out the Rule and the statutes and case law that interact with the Rule. Section IV will critique the Rule. Section V will propose that Congress require food regulators to follow the precautionary principle.

II. BACKGROUND OF THE RULE

A. *Who Really Cares About Almonds?*

1. History of the Almond

Almonds have been consumed for thousands of years and are one of the world’s oldest cultivated foods.¹⁴ They are mentioned in Genesis.¹⁵ King Tutankhamen took several handfuls with him to his grave in 1352 B.C. to snack on during his journey to the afterlife.¹⁶ Explorers carried almonds for food along the Silk Road, which may explain the almond’s spread across the Mediterranean, Turkey, Iraq, Syria, and Iran.¹⁷ The Romans introduced almonds across the Roman Empire from Egypt to England.¹⁸

Almonds were first grown in California by the Franciscan Padres in the mid 1700s.¹⁹ Later, the climate of California’s Central Valley proved superior for growing almonds.²⁰ Today, California is the only state in the U.S. where almonds are grown commercially.²¹ Almonds have become a \$2

13. See *infra* note 291 and accompanying text.

14. California Almond Board, *Almonds Through the Ages, Almond History*, <http://www.almondboard.com/Resources/content.cfm?ItemNumber=636&snItemNumber=461> (last accessed Nov. 4, 2007).

15. See *supra* note 1.

16. Blue Diamond Almonds, *A Historical Reference of the Almond*, <http://www.bluediamond.com/index.cfm?navId=173> (last accessed May 3, 2009).

17. California Almond Board, *supra* note 14.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

billion industry and California boasts more than 6000 growers.²² Central California alone produces seventy-five percent of the world's almond supply,²³ which is exported to more than eighty countries.²⁴

2. Almonds: A Superfood

Almonds are one of the world's healthiest foods.²⁵ They are packed with protein.²⁶ Almonds are a good source of manganese, copper, and vitamin B2, all of which play an important role in the body's energy production.²⁷ They are rich in magnesium, phosphorus, zinc, and vitamin E²⁸ and high in favorable fatty acid and nutrients.²⁹ Studies show that almonds lower bad cholesterol, significantly reducing the risk of heart disease.³⁰ In fact, they are almost as effective at lowering cholesterol as statin drugs.³¹ Contrary to popular belief, while they are high in healthy fats, they do not cause weight gain.³² In fact, almonds, combined with a low calorie diet, can result in weight loss.³³

22. *Id.*

23. *Id.*

24. *Id.*

25. Almonds are on the list of the top 140 healthiest foods. George Mateljan Foundation, THE WORLD'S HEALTHIEST FOODS, ALMONDS, available at <http://www.whfoods.com/genpage.php?tname=foodspice&dbid=20>.

26. *Id.* A quarter cup of almonds has more protein than a typical egg. *Id.*

27. *Id.*

28. Penny M Kris-Etherton et al., *Nuts and their Bioactive Constituents: Effects on Serum Lipids and Other Factors that Affect Disease Risk*, 70 AM. J. CLIN. NUTR. 504s, 505s (1999).

29. *Id.*

30. See, e.g., Mavis Abbey et al., *Partial Replacement of Saturated Fatty Acids with Almonds or Walnuts Lowers Total Plasma Cholesterol and Low-Density-Lipoprotein Cholesterol*, 59 AM. J. CLIN. NUTR. 995 (May 1994); David J.A. Jenkins, M.D. et al., *Dose Response of Almonds on Coronary Heart Disease Risk Factors: Blood Lipids, Oxidized Low-Density Lipoproteins, Lipoprotein(a), Homocysteine, and Pulmonary Nitric Oxide, A Randomized, Controlled, Crossover Trial*, 106 CIRCULATION, J. AM. HEART ASSOC. 1327 (2002).

31. David J.A. Jenkins et al., *Direct Comparison of a Dietary Portfolio of Cholesterol-Lowering Foods with a Statin in Hypercholesterolemic Participants*, 81 AM. J. CLIN. NUTR. 380 (2005).

32. Joan Sabaté, *Nut Consumption and Body Weight*, 78 AM. J. CLIN. NUTR. 647s (2003).

33. Lower calorie diets that use almonds, rather than carbohydrates, resulted in 11% weight loss. M.A. Wien et al., *Almonds vs. Complex Carbohydrates in a Weight Reduction Program*, 27 INTL. J. OBESITY 1365 (2003).

Almond consumption at mealtime lowers the risk of diabetes and heart disease by decreasing after-meal blood sugar spikes.³⁴ Consuming almonds at mealtime also reduces oxidative damage by providing antioxidants.³⁵ One study reported that the skin of the almond alone may contain as many as thirty different flavanoids.³⁶ Almonds have been shown to reduce colon cancer in mice³⁷ and improve memory and learning in Alzheimer's transgenic mice.³⁸

3. Raw Almonds: Superior to Cooked Almonds

Under the Rule, domestically grown raw almonds will no longer be commercially available.³⁹ To appreciate the impact of this fact, one must understand the importance of raw almonds to groups like Raw Foodists,⁴⁰ vegetarians,⁴¹ and Seventh Day Adventists.⁴²

Proponents of the "Raw Food Movement," known as "Raw Foodists," believe that raw and unprocessed foods are healthier than cooked and

34. David J.A. Jenkins et al., *Almonds Decrease Postprandial Glycemia, Insulinemia, and Oxidative Damage in Healthy Individuals*, 136 J. NUTR. 2981 (2006).

35. *Id.*

36. Chung-Yen Chen, et al., *Flavonoids from Almond Skins Are Bioavailable and Act Synergistically with Vitamins C and E to Enhance Hamster and Human LDL Resistance to Oxidation*, 135 J. NUTRI. 1366, 1370 (2005).

37. Paul A. Davis et al., *Whole Almonds and Almond Fractions Reduce Aberrant Crypt Foci in a Rat Model of Colon Carcinogenesis*, 165 CANCER LETTER 27 (2001).

38. Press Release, Society for Neuroscience, *Back to Basics: Diet May Help Maintain Brain Function and Treat Brain Disorders*, (Nov. 14, 2005) http://www.sfn.org/index.cfm?pagename=news_111405 (Nov. 4, 2005).

39. Domestically grown raw almonds will not be available in the U.S. because the Rule requires that all domestic almond handlers "subject their almonds to a treatment process . . . prior to shipment to reduce potential salmonella bacteria contamination." 7 C.F.R. § 981.442(b)(1). While almonds may be labeled as raw, they will be blanched to meet the pasteurization requirements of this rule. *Id.*; see also Cornucopia Institute, *infra* note 251.

40. Karyn Calabrese, Chicago raw food restaurateur says that "[t]he almond is the king of the nut world and a main staple for raw Foodists[.]" *Some Find Pasteurized Almonds Rule Unsavory, A Plan to Battle Bacteria Angers Organic Farmers and Raw Food Fans*, L.A. TIMES (July 2, 2007).

41. "[S]ome strict vegetarians who consume only raw foods rely on almonds to provide as much as 30% of their caloric intake, believing that they are a nutritionally superior alternative to meat in the diet." Press Release, Cornucopia Institute, *USDA Plan to "Pasteurize" Almonds Has Consumers Going Nuts: Mandate Would Require Use of Chemical Fumigant or Heat Treatment on "Raw" Almonds*, http://www.cornucopia.org/almond/Almond_News_Release.pdf (August 7, 2007).

42. For more than 130 years, Seventh Day Adventists have practiced a vegetarian diet, which includes nuts. Seventh-Day Adventists Dietetic Association, *A Position Statement on the Vegetarian Diet*, <http://www.sdada.org/position.htm> (last accessed Jan 20, 2008).

processed food.⁴³ The human body is designed to consume raw food, they argue, and many modern health problems are caused by overconsumption of cooked food.⁴⁴ They point out that digestive, metabolic, and food enzymes, which are found in raw foods, are needed to trigger, facilitate, and accelerate proper digestion and assimilation of protein and fat, so that food can be broken down and absorbed in the small intestine.⁴⁵ Food enzymes are found *only* in raw food.⁴⁶ This is because prolonged heat kills enzymes, as does cooking and pasteurization.⁴⁷ Raw food proponents point out that the standard American diet, low in raw and uncooked food, results in widespread nutrient and enzyme deficiency, leading to numerous health problems.⁴⁸

The Raw Foodists' enzyme theory finds support in the work of Dr. Weston A. Price, DDS, an early proponent of raw foods. Dr. Price travelled the world documenting how indigenous people's teeth degraded when they abandoned their traditional diets of unprocessed, unpasteurized foods. Dr. Price's research, which included stunning photographic evidence, showed that the traditional peoples whose diets included unpasteurized and unprocessed raw food had excellent jaw development and dental health, but the first generation of children to adopt the modern diet suffered malocclusion and tooth decay.⁴⁹ Dr. Price attributed this degradation to the modern diet, which was low in nutrients and devoid of raw food.⁵⁰

The research of Dr. Edward Howell, another early raw food proponent, showed how raw food starts the digestion process and reduces the body's need to produce enzymes.⁵¹ Dr. Howell found that diets comprised primarily of cooked foods resulted in shorter life span, increased illness, lowered resistance to stress of all types, enlarged pancreas, and actual shrinkage of other organs, including the brain.⁵² Dr. Howell's research also

43. "Science proves that cooking not only destroys nutrition and enzymes, but chemically changes foods from the substances we need for health into free-radicals and poisons that destroy our health!" *Welcome to Raw Food for Life*, <http://www.rawfoodlife.com/> (last accessed Jan. 20, 2008).

44. *Id.*

45. JORDAN S. RUBIN N.M.D., PH.D., *THE MAKER'S DIET* 143 (2004).

46. *Id.* at 144.

47. *Id.*

48. *Id.*

49. Weston A. Price Foundation, *Weston A. Price, D.D.S.*, <http://www.westonaprice.org/nutritiongreats/price.html> (last accessed November 4, 2007).

50. *Id.*

51. Weston A. Price Foundation, *Edward Howell, M.D.*, <http://www.westonaprice.org/nutritiongreats/howell.html> (last accessed November 4, 2007).

52. *Id.*

showed that wet-heat temperatures at 118°F and above deactivate food enzymes.⁵³ Amazingly, the body seems to be aware of this fact as foods and liquids at 117°F degrees can be touched without pain, but liquids over 118°F degrees will burn.⁵⁴ Recent research shows that cooking certain meats at high temperatures creates chemicals not present in raw meat that may increase cancer risk.⁵⁵

Simply put, heat degrades food. As Raw Foodists put it, raw foods are living foods and cooked foods are dead foods.⁵⁶ What they mean is that heat destroys food enzymes, which are necessary for digestion and absorption of nutrients. Not surprisingly, they believe that pasteurization will degrade almonds.

In fact, raw almonds may be healthier than cooked almonds. Almonds, rich in omega-3 fatty acids, are affected by heat in a way that other foods are not. Heat oxidizes the omega-3s in the almond, rendering them rancid.⁵⁷ This diminishes the benefits of the omega-3s, further decreasing the nutritional value of the almond and producing free radicals.⁵⁸ The USDA's own data shows that raw almonds, as compared to blanched almonds, have twenty-two percent more calcium, sixty-six percent more folate, and seventeen percent more fiber.⁵⁹ Not surprisingly, Raw Foodists are among the strongest critics of mandatory pasteurization.

53. *Id.* Dry heat deactivates enzymes at 150°F or above. *Id.*

54. *Id.*

55. “[H]eterocyclic amines (“HCAs”) are the carcinogenic chemicals formed from the cooking of muscle meats such as beef, pork, fowl, and fish. . . . One study conducted by researchers showed a threefold increase in the content of HCAs when the cooking temperature was increased from 200° to 250°C (392° to 482°F).” National Cancer Institute, *Heterocyclic Amines in Cooked Meats*, <http://www.cancer.gov/cancertopics/factsheet/Risk/heterocyclic-amines> (collecting authorities) (last accessed Jan. 20, 2008).

56. Mike Adams, *The Killing of California Almonds: (And Why Dead Food Leads to Dead People)*, <http://www.newstarget.com/021989.html> (last accessed November 10, 2007).

57. George Mateljan Foundation, *THE WORLD'S HEALTHIEST FOODS*, <http://www.whfoods.com/genpage.php?tname=nutrient&dbid=84> (last accessed November 10, 2007).

58. *Id.*

59. See USDA National Nutrient Database for Standard Reference, available at <http://www.nal.usda.gov/fnic/foodcomp/search/> (enter “nuts, almond”) (last accessed Jan. 18, 2008). In other categories, blanched almonds exceeded raw almonds. For example, blanched almonds have 25% more sucrose.

B. Events Which Led to the Promulgation of the Rule

In 2001, a salmonella outbreak, which was linked to non-organic raw California almonds, sickened over 100 people.⁶⁰ In 2004, one person was killed and twenty-nine were sickened in a second outbreak linked to non-organic raw almonds from Paramount Farms in California, the world's largest supplier of almonds.⁶¹ In response, the California Almond Board ("ABC")⁶² unanimously recommended mandatory pasteurization for all almonds.⁶³ The ABC cited concerns about consumer safety.⁶⁴ "[A] prerequisite was that there would be no degradation of the product," said an ABC spokesperson, adding that nutritional specialists have tested almonds pre- and post-pasteurization and have found no differences in "sensory attributes."⁶⁵

Small and organic growers point out that salmonella has never been linked to raw almonds from small or organic growers.⁶⁶ These farmers argue that the sustainable farming methods they use, including mulching rather than controlling weeds with chemicals, naturally prevent bacteria.⁶⁷ Salmonella has also never been linked to cooked almonds, which account for ninety-five percent of almonds.⁶⁸ This is because blanching, roasting, or baking eliminates potential bacteria.⁶⁹ Nonetheless, the ABC pushed for a rule that did not distinguish between small organic growers, cooked almonds, or industrial growers. The ABC's attitude is "the press does not

60. Karen Smith, *The Unusual Suspects: Foods Such as Fruits, Nuts, and Vegetables Are*, THE GLOBE AND MAIL, September 25, 2001.

61. Cornucopia Institute, Almond Fact Sheet, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf (last accessed Dec. 17, 2007).

62. While CAB would seem the proper acronym, the California Almond Board goes by the more poetic "ABC."

63. Almonds Grown In California, 72 FED. REG. 15,021, 15,036 (March 30, 2007).

64. George Raine, *Organic Almond Supporters Roast Pasteurization Plan*, S. F. CHRON. (Aug. 23, 2007).

65. *Id.* (emphasis added).

66. *See, e.g.*, McAfee Farms and Organic Pastures Dairy, Position on the Pasteurization of Almonds, http://www.organicpastures.com/raw_almonds.html (last accessed Nov. 3, 2007).

67. Raine, *supra* note 64.

68. Press Release, California Almond Board's Responds to FDA's Consumer Advisory Regarding Raw, Natural Almonds, (May 21, 2004), <http://www.almondsarein.com/AlmondLovers/nrdetail.cfm?ItemNumber=579>.

69. *Id.*

distinguish between organic and nonorganic—they just made someone sick.”⁷⁰

The ABC is a quasi-governmental entity established in 1950 to promote the “best quality of almonds” and administer the Federal Marketing Order on almonds.⁷¹ Growers must pay three cents on every pound of almonds they sell to fund the ABC.⁷² ABC makes recommendations to the USDA regarding almond regulation and selects the scientists who approve almond pasteurization requirements.⁷³

Critics say that the ABC is composed exclusively of large commercial producers and handlers and there is no representation for small and organic farmers.⁷⁴ In fact, the 2006 board of directors hailed from California’s largest growers and producers, including: Travaille and Phippen, Inc., provider of hulling and shelling services for 5000 acres of almonds;⁷⁵ Blue Diamond, the world’s largest almond coop;⁷⁶ Hilltop Ranch, Inc., “one of the California Almond Industry’s fastest growing processors;”⁷⁷ Panoche Creek Packing, “one of the largest almond handlers in the industry;”⁷⁸ Cummings-Violich, an agribusiness management firm with 7000 acres in cultivation;⁷⁹ and Golden Hills Nut Company, annual processor of thirty million pounds of almonds.⁸⁰

70. *Id.* Statement of Dave Phippen, who served as ABC president at the time ABC voted to recommend the rule.

71. What Is the California Almond Board? <http://www.almondboard.com/About/content.cfm?ItemNumber=544&snItemNumber=467> (last accessed Dec. 17, 2007).

72. What Is the California Almond Board? <http://www.almondboard.com/About/content.cfm?ItemNumber=544>. (last accessed Jan. 15, 2009). Ironically, it appears that small and organic growers are being forced to fund their own demise.

73. *Id.*

74. There are no ABC board members who characterize themselves as “small growers.” There are, however, self-described large commercial growers on the board that market “organic almonds.” See *infra* notes 75-80 and accompanying text.

75. *It Is Harvest Time and Machinery Is out in Full Force*, MODESTO BEE (Sept. 26, 2005) available at <http://www.almondboard.com/Programs/DustDetail.cfm?ItemNumber=4926> (last accessed Dec. 23, 2007).

76. California Almond Board, Board of Directors, http://www.almondboard.com/files/PDFs/ALM_6060_Almanac07lr.pdf (last accessed Dec. 12, 2007).

77. Hilltop Ranch, <http://www.hilltopranch.com> (last accessed Dec. 12, 2007).

78. Panoche Creek Packing, <http://panochecreek.com/index.php?page=home> (last accessed Dec. 12, 2007).

79. Dan Cummings, Owner and General Manager, Cummings-Violich, Inc, <http://almondboard.files.cms-plus.com/Dan%20Cummings.pdf> (last accessed Dec. 12, 2007).

80. Golden Hills Nut Co., <http://www.goldhills.com/marketing.html>. The author found no board members from small organic farms.

C. *Pasteurization: What is Propylene Oxide?*

Fumigation with propylene oxide (“PPO”) is the least expensive and most common means of pasteurization.⁸¹ PPO is a volatile, clear, colorless, extremely flammable liquid with an ether-like odor.⁸² It is irritating to the respiratory system, harmful to skin, irritating to eyes, harmful if swallowed, and may cause heritable genetic damage.⁸³ Prolonged exposure poses a possibility of individual organ or organ system damage and affects the central nervous system.⁸⁴ PPO’s Material Safety Data Sheet (“MSDS”)⁸⁵ provides a long list of unpleasant symptoms that can arise from inhalation, contact with skin, or ingestion.⁸⁶ The MSDS also provides for protective and cleanup measures for accidental release, handling, and storage. For example, where there is potential for dermal contact, full body personal protective equipment must be worn including solvent-proof gloves, clothing, hats, aprons, boots and vapor-proof goggles.⁸⁷ Where PPO air concentrations are twenty ppm or greater, a full face self-contained breathing apparatus is required.⁸⁸ These areas must be placarded to indicate the presence of PPO.⁸⁹

PPO is used in the production of polyurethane foam, polyester resins, hydraulic fluid, drugs, antifreeze, and in fumigation chambers for the sterilization of foods.⁹⁰ It is also used in thermobaric weapons.⁹¹ PPO was once used as an additive in stock car racing fuel, but is now banned due to health concerns.⁹²

81. Press Release, Cornucopia Institute, *Almond Fact Sheet*, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf (last accessed Jan. 20, 2008).

82. Material Safety Data Sheet: Propylene Oxide, <https://fscimage.fishersci.com/msds/19910.htm> (last accessed Dec. 18, 2007).

83. *Id.*

84. *Id.* at 7.

85. An MSDS is documentation supplied by manufacturers of dangerous chemicals to the user, which provides important information for the chemicals safe and legal use. 29 C.F.R. § 1910.1200(g)(1) (Jan. 10, 2008).

86. See Material Safety Data Sheet: Propylene Oxide, *supra* note 82 at 2-4.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. Nationmaster.com, Encyclopedia, Thermobaric, <http://www.nationmaster.com/encyclopedia/Thermobaric> (last accessed Sept. 5, 2008).

92. 2007 NHRA Nostalgia Rulebook 2 <http://www.nhra.com/2007/images/Museum/2007NostalgiaSupplement.pdf>.

PPO is “known to cause cancer” in the state of California.⁹³ It is not permitted for food use in most of Europe, Africa, Asia, and Canada.⁹⁴ The Department of Health and Human Services says that PPO is reasonably anticipated to be a human carcinogen.⁹⁵

Further, PPO is known to cause cancer in animals.⁹⁶ Administering PPO to animals by inhalation induced hemangiomas or hemangiosarcomas of the nasal cavity of mice, increased the incidences of papillary adenomas in rats, and increased the incidences of adrenal pheochromocytomas and peritoneal mesotheliomas.⁹⁷ When administered by gavage to female rats, PPO produced an increase in the incidence of local tumors, primarily squamous cell carcinomas of the forestomach.⁹⁸ When administered by subcutaneous injection to female mice, PPO increased the incidence of local tumors, mainly fibrosarcomas.⁹⁹

The Department of Transportation considers PPO a hazardous material and sets special requirements for marking, labeling, and transporting this material.¹⁰⁰ The Clean Air Act lists PPO as a Hazardous Air Pollutant.¹⁰¹ The Emergency Planning and Community Right-To-Know Act requires reporting of spills in excess of 100 pounds, and Threshold Planning of quantities over 10,000 pounds.¹⁰² The Occupational Safety and Health Administration sets the Permissible Exposure Limit at 100 ppm.¹⁰³ The National Institute for Occupational Safety and Health sets the Immediately Dangerous to Life and Health Level for PPO at 400 ppm.¹⁰⁴ And, of course,

93. See *supra* note 81, at 9. Ironically, while PPO is “known” to be a carcinogen in California that is the state where almonds are to be fumigated with PPO.

94. Cornucopia Institute, *Almond Fact Sheet*, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf (accessed Dec. 17, 2007).

95. U.S. Dept. of Health and Human Services, National Toxicology Program, REPORT ON CARCINOGENS, 11TH ED., PROPYLENE OXIDE, available at <http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s155prop.pdf>.

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. PPM stands for parts per million. Permissible Exposure Limits are enforceable permissible exposure limits to protect workers against the health effects of exposure to hazardous substances. See Office of Safety and Safety Administration, PERMISSIBLE EXPOSURE LIMITS (PELs), <http://www.osha.gov/SLTC/pel/index.html> (last accessed Dec. 23, 2007).

104. This is the level at which an atmospheric concentration of a toxic, corrosive, or asphyxiant substance that poses an immediate threat to life or would cause irreversible or

the EPA allows PPO to be used to “pasteurize” almonds to a surface residue of 300 ppm.¹⁰⁵

III. THE RULE

A. “Handlers shall subject their almonds to a treatment process”

The Rule requires that handlers “subject their almonds to a treatment process . . . prior to shipment to reduce potential salmonella bacteria contamination.”¹⁰⁶ There are exceptions for growers who sell their own almonds at their own roadside stand¹⁰⁷ and so that growers can ship untreated almonds to verified processing facilities for treatment.¹⁰⁸

Almonds must be treated by a process identified as effective by an FDA “letter of determination” or by acceptance of the Technical Expert Review Panel (“TERP”).¹⁰⁹ The members of the TERP are chosen by the ABC board of directors.¹¹⁰ Thus far, the FDA has issued letters of determination for PPO fumigation, oil roasting, blanching, and for a moist heat process.¹¹¹ TERP has recommended steam and moist heat for acceptance.¹¹² PPO fumigation is the most cost effective means of pasteurization and therefore the most common.¹¹³

B. *The Delaney Clause: Are Carcinogens Permitted in Our Food?*

Whether a carcinogen is permitted in food depends on whether it is deemed an “additive” or a “pesticide.” If a carcinogen is deemed an additive, it is never permitted; but if a carcinogen is deemed a pesticide, it is allowed if it is found to be “safe.” The Federal Food, Drug and Cosmetic Act (“FFDCA”) regulates “adulterated” foods.¹¹⁴ Adulterated food means

delayed adverse health effects or would interfere with an individual’s ability to escape from a dangerous atmosphere. Hazardous Waste Operations and Emergency Response, 29 C.F.R. § 1910.120 (April 3, 2006).

105. Propylene Oxide; Tolerances for Residues, 40 C.F.R. § 180.491 (Dec. 6, 2007).

106. Almonds Grown in California, 7 C.F.R. § 981.442(b) (May 24, 2007).

107. 7 C.F.R. § 981.13.

108. 7 C.F.R. § 981.442(b)(6).

109. 7 C.F.R. § 981.442(b)(1).

110. So much for independence. California Almond Board, Almond Safety Research Update: October 2005, http://almondboard.files.cms-plus.com/PDFs/Almond%20Safety%20Research%2010-20-05%20_2_.pdf (last accessed Dec. 18, 2007).

111. 72 FED. REG. 15,021, 15,023.

112. *Id.*

113. Cornucopia Institute, Almond Fact Sheet, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf (last accessed Dec. 17, 2007).

114. Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 (1938).

any food containing an unsafe food additive.¹¹⁵ A food additive is considered unsafe unless there is a specific regulation permitting its use.¹¹⁶ Under the so-called Delaney Clause of the FFDCa, no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.¹¹⁷ Even if an additive presents a *de minimis* cancer risk, its use is banned by the Delaney Clause.¹¹⁸

PPO is known to cause cancer in animals and considered a probable human carcinogen by the EPA.¹¹⁹ So how under the Delaney Clause can it be used to fumigate almonds? The EPA is employing a 1996 loophole in the Delaney Clause that established a lower standard for pesticides.¹²⁰ By treating PPO as an “insecticidal fumigant” rather than an additive, the EPA avoids the stringent Delaney Clause standard.¹²¹ Surprisingly, when almonds are fumigated in PPO for four hours in a de-pressurized vacuum chamber at 140°F, it does not become an “additive” in the EPA’s narrow interpretation of the term.¹²² But the EPA’s interpretation of “additive” seems inconsistent with Congress’s broad definition. Congress defined “additive” as:

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 intended for use in . . . processing, preparing, treating, packaging, transporting, or holding food; and . . . any source of radiation intended for any such use[.]¹²³

115. FFDCa, Adulterated Foods, 21 U.S.C. § 342(a)(2)(c) (2005).

116. FFDCa, Food Additives, 21 U.S.C. § 348(a) (1984).

117. Delaney Clause, 21 U.S.C. § 348(c)(3)(A) (1962).

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

119. *See supra* notes 91-97 and accompanying text.

120. In 1996 Congress amended the Delaney Clause to provide an exemption for pesticides that fell below a certain tolerance level. *Tolerance and Exemptions for Pesticide Chemical Residues*, 21 U.S.C. 346a(1)(A) (1998).

121. *See Delaney Clause, supra* note 117. While the regulations for food additives (21 U.S.C. §348) prohibit the use of any additive “found to induce cancer when ingested by man or animal[.]” the regulations governing pesticide residue (21 U.S.C. 346(a)) contain no such blanket prohibition.

122. California Almond Board, *Almond Pasteurization Using Propylene Oxide (PPO)*, Standard Operating Procedure 1-2 (SOP) (Oct. 2004) <http://www.almondboard.com/files/PPOSOP-FINAL.pdf> (last accessed Dec. 17, 2007).

123. FFDCa, Definitions, 21 U.S.C. § 321(s) (Sept. 27, 2007).

Where Congress has spoken directly to an issue, the agency must give effect to the unambiguously expressed intent of Congress.¹²⁴

Considering Congress's definition of "additive," it appears that PPO is an additive in multiple respects. For example, when food is fumigated in a chemical for four hours, that chemical "may reasonably be expected to result, directly or indirectly, in its becoming a component"¹²⁵ Also, PPO is used in the "treating, preparing and processing" of almonds, which would make it an "additive" within the broad definition of additive in the FFDCA.¹²⁶ PPO also would fit the definition of additive because it "affects the characteristics" of almonds since it creates an acknowledged cancer risk and kills bacteria.¹²⁷

On the other hand, if PPO is deemed a pesticide, it would be regulated under the looser standards of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and the Food Quality Protection Act ("FQPA").¹²⁸ FIFRA defines antimicrobial pesticide as "a pesticide that . . . is intended to . . . disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms."¹²⁹ PPO clearly fits this definition. But which definition should control, additive or pesticide?

This question was addressed by the FDA and USDA in a joint policy statement.¹³⁰ Recognizing that the regulatory scheme applicable to PPO would depend on whether it was characterized as an additive or pesticide, they concluded that the determination would turn on *where* the application of PPO was made.¹³¹ If PPO was applied in a food processing facility, it would be treated as an additive under FFDCA and thus subject to the

124. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984). See also, ERNEST GELLHORN, et al., *ADMINISTRATIVE LAW AND PROCESS IN A NUTSHELL* 81 (5th ed. 2006).

125. This language is from the FFDCA's expansive definition of additive. 21 U.S.C. § 321(s).

126. This language also comes from the FFDCA's definition of additive. *Id.*

127. If PPO did not "affect the characteristics of almonds," it would not be used!

128. EPA, PROPYLENE OXIDE – REVISED HED RISK ASSESSMENT FOR REREGISTRATION ELIGIBILITY DECISION 5, <http://www.regulations.gov/fdmspublic/component/main> (enter document ID: EPA-HQ-OPP-2005-0253-0002) (posted Sept. 26, 2005) (last accessed Dec. 17, 2007).

129. 7 U.S.C. § 136(mm)(1)(A) (1996).

130. *Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances*, 63 FED. REG. 54,532 (Oct 9, 1998).

131. *Id.* at 54,537.

Delaney Clause.¹³² If it was applied on a raw agricultural commodity it would remain a FIFRA pesticide and thus the 1996 FQPA loophole to the Delaney clause would apply.¹³³

What is the rationale for treating a chemical differently based on the location of its application? While the policy statement is vague on this question, the answer seems to be simply regulatory efficiency.¹³⁴ This does not seem to provide a satisfying explanation for why location should be the determinative factor in determining whether PPO is regulated as an additive or pesticide. Whether PPO is applied in a processing facility or a handling facility, almonds receive the same amount of PPO; yet PPO applied in a processing facility is considered an additive, and PPO applied in an almond handling facility is considered a pesticide.¹³⁵ It is not clear why it should make a difference whether almonds are fumigated in a food processing facility or an almond handling facility.

C. Regulation of Propylene Oxide as a Pesticide Under the Food Quality Protection Act

1. The Food Quality Protection Act of 1996 (“FQPA”)

After the passage of the FQPA, pesticides ceased to be regulated under the Delaney Clause, which forbade any pesticide known to “induce cancer when ingested by man or animal”¹³⁶ Instead, under FQPA, a pesticide would be permitted if there was “a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue”¹³⁷ If a pesticide was deemed “unsafe,” it would still violate the Delaney Clause and not be permitted.¹³⁸ Thus, because PPO was considered a pesticide, after 1996 the question became whether PPO was “safe” and if so, what residue tolerance would be permitted?

2. EPA Finds that Propylene Oxide Violates the Delaney Clause, Then Reverses Under Industry Pressure

In 1996, the EPA asked this question and found that PPO *did*, in fact, “induce cancer” within the meaning of the Delaney Clause, and therefore

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. 21 U.S.C. § 348(c)(3)(A).

137. 21 U.S.C. § 346a(b)(2)(A)(ii).

138. 21 U.S.C. § 346a(a)(1).

was not “safe.”¹³⁹ It announced its intention to revoke PPO’s “Food Additive Regulation,” which had previously permitted its use.¹⁴⁰ Even though PPO was treated under the new looser pesticide loophole, it still could not be deemed “safe” within the meaning of the FQPA.¹⁴¹

Predictably, sellers and users of PPO rallied against the decision.¹⁴² Responding to industry pressure, the EPA reversed itself, setting a permissible residue level for PPO at 150 ppm.¹⁴³ The EPA reasoned that “nuts treated with propylene oxide are not sold directly to consumers but are intended to be added to foods that may be further processed.”¹⁴⁴ The EPA further reasoned that if PPO levels were limited to 150 ppm,¹⁴⁵ by the time the nuts got to the consumer, the level of PPO would drop to 3.3 ppm due to off-gassing.¹⁴⁶ Such a level would produce a cancer risk of three in one million, which the EPA characterized as a “negligible risk.”¹⁴⁷

139. “EPA, in general, interprets ‘induces cancer’ to mean: The carcinogenicity of a substance in animals is established when administration in an adequately designed and conducted study or studies results in an increase in the incidence of one or more types of malignant . . . neoplasms in treated animals compared to untreated animals maintained under identical conditions except for exposure to the test compound.” EPA Revocation of Pesticide Food Additive Regulations, 61 FED. REG. 11,994, 11,998. (Mar. 22, 1996).

140. A Food Additive Regulation allows an additive to be used up to a certain residue “tolerance” level. PPO’s tolerance level was 300 ppm. However, after the EPA’s *de minimis* rule was struck down, the EPA was forced to re-evaluate its pesticide regulation and concluded that PPO violated the Delaney Clause. *Id.* at 12008.

141. Any additive “found to induce cancer when ingested by man or animal” is not “safe” under the FQPA. 21 U.S.C. § 348(c)(3)(A).

142. “All of the comments received in response to this notice of filing supported the issuance of the proposed tolerance.” Propylene Oxide; Pesticide Tolerance, 61 FED. REG. 25,152 (May 20, 1996).

143. *Id.* at 25, 153.

144. This assumption is no longer valid because under the new rule, *all* domestic almonds must be pasteurized, and PPO fumigation is the most common method of pasteurization. See Press Release, Cornucopia Institute, *Almond Fact Sheet*, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf at 2 (last accessed Jan. 20, 2008).

145. Ppm means parts per million.

146. Propylene Oxide; Pesticide Tolerance, 61 FED. REG. 25,152 (May 20, 1996). The EPA admitted that more research was needed on off-gassing. *Id.* The ABC recommends that almonds be ventilated from two to five days after fumigation. California Almond Board, *supra* note 122. But during the harvest time crunch, when a handler is processing millions of pounds of almonds, is there any evidence that handlers are ventilating their almonds sufficiently? This author found none. This is one reason why the off-gassing data seems somewhat questionable.

147. *Id.*

In other words, under conservative estimates, only three out of one million people will get cancer in their lifetimes from PPO in almonds. With the current US population at 300 million, a PPO residue limit of 150 ppm could result in approximately 900 cancer cases.¹⁴⁸ When we combine this information with the current mandatory pasteurization rule, there is a staggering disproportionality: only one person has ever died (and 129 sickened) from salmonella poisoning linked to almonds,¹⁴⁹ but to prevent this from happening again, the EPA allows, and the USDA mandates, a pasteurization process that may result in 900 incidences of cancer.

The rationale behind the EPA's 1996 acceptance of PPO is no longer valid. No longer is PPO use limited to almonds that are merely components of other foods bound for further processing and not sold directly to consumers. Furthermore, while the use of PPO in 1996 was justified based on mitigating salmonella risk, today PPO is used on cooked almonds, which *do not* pose a salmonella risk.¹⁵⁰ While PPO might be justified to prevent the salmonella risk posed by non-organic raw almonds, it cannot be similarly justified when used on cooked almonds.¹⁵¹ Yet nonetheless, large producers like Blue Diamond and Paramount Farms use it nonetheless on their cooked almonds.¹⁵² In fact, the majority of almonds today are fumigated with PPO, even though ninety-five percent of them are cooked and pose no salmonella risk.¹⁵³

148. Today the limit is 300 ppm. See 40 C.F.R. § 180.491 (2007).

149. See *supra* notes 60-61 and accompanying text.

150. "Ninety-five percent of almonds sold undergo processing, such as blanching, roasting or baking which eliminates any potential bacteria such as *Salmonella* Enteritidis." Press Release, California Almond Board, California Almond Board Responds to Recall Regarding Raw, Natural Almonds, <http://www.almondboard.com/News/pressreleasedetail.cfm?ItemNumber=582> (May 18, 2004).

151. Heat kills salmonella. See *id.*

152. See Dale Kasler, *Almond Treatment Urged After Last Year's Recall*, http://web2.westlaw.com/find/default.wl?fn=_top&rs=WLW8.10&rp=%2ffind%2fdefault.wl&mt=LawSchoolPractitioner&vr=2.0&sv=Split&cite=2005+WLNR+8705790 (first published in SACRAMENTO BEE, June 1, 2005) (noting that Paramount Farms had announced pasteurization of all almonds before delivery); Anna Belle Peevey, *New Pasteurization Requirements Have Raw Food Growers Heated 2*, <http://www.cornucopia.org/2007/12/new-pasteurization-regulations-have-raw-food-growers-heated> (first published in ALAMEDA TIMES-STAR, Dec. 2, 2007) (noting that Blue Diamond began pasteurizing all of its almonds with PPO in 2001).

153. Cornucopia Institute, *Almond Fact Sheet 2*, http://www.cornucopia.org/almond/Almond_Fact_Sheet.pdf; Press Release, California Almond Board, California Almond Board Responds to Recall Regarding Raw, Natural Almonds, <http://www.almondboard.com/News/pressreleasedetail.cfm?ItemNumber=582> (May 18, 2004).

3. EPA Finds That Cancer Risk From Dietary Sources of PPO Exceed the Health Effects Division's ("HED") Level of Concern; Then Reverses Under Industry Pressure

In 2005, for a second time, the EPA concluded that propylene oxide should not be used, and for a second time, it reversed under industry pressure.¹⁵⁴ A 2005 FDA memo stated that "the cancer dietary risk estimates for propylene oxide are above HED's level of concern."¹⁵⁵ Using two different models, the risk of cancer was found to be either 1.3 in 100,000 or 1.5 in every 100,000, either of which exceeded acceptable levels.¹⁵⁶

In response, industry lobbyist Aberco submitted a public comment urging that the EPA use a different method to calculate PPO's potential cancer risk.¹⁵⁷ Under Aberco's approach, PPO came in under HED's level of concern.¹⁵⁸ Aberco's comment was followed by thirty-seven other comments in support of Aberco from lobbyists and users of PPO, and one comment opposed.¹⁵⁹

The EPA agreed, adopting Aberco's approach and revising its finding to state, "modified cancer slope factor results in dietary risk below HED's

154. EPA, PPO REVISED RISK ASSESSMENT 1, <http://www.regulations.gov/search/index.jsp> (enter Document ID: EPA-HQ-OPP-2005-0253-0002 (posted Oct. 18, 2005) (last accessed Dec. 18, 2007).

155. *Id.* at 52.

156. The FDA used a Dietary Exposure Evaluation Model ("DEEM") and a Health and Lifetime model to estimate excess lifetime risk estimates. *Id.* at 53.

157. Aberco, Registrant Correction Phase: Propylene Oxide Preliminary Risk Assessment for Reregistration Eligibility Documents, <http://www.regulations.gov/search/index.jsp> (enter document ID: EPA-HQ-OPP-2005-0253-0006) (published Sept. 29, 2005).

158. EPA, PROPYLENE OXIDE: RESPONSE TO PUBLIC COMMENTS ON THE HED RISK ASSESSMENT FOR PROPYLENE OXIDE 2, <http://www.regulations.gov/fdmspublic/component/main> at 2 (enter document ID EPA-HQ-OPP-2005-0253-0057) (posted June 30, 2006); Aberco argued that the EPA ignored hydrolysis of PPO in the stomach. Aberco, Registrant Correction Phase: Propylene Oxide Preliminary Risk Assessment for Reregistration Eligibility Documents 2, <http://www.regulations.gov/search/index.jsp> (enter document ID: EPA-HQ-OPP-2005-0253-0006) (published Sept. 29, 2005).

159. All comments available at <http://www.regulations.gov/fdmspublic/component/main> (enter Docket ID: EPA-HQ-OPP-2005-0253). Negative comment states: "this product has the following negative effects on our world: known carcinogen, development toxicant, gastrointestinal toxicant, neurotoxicant, reproductive toxicant, respiratory toxicant, skin toxicant. . . . [I]t is clear that what is going on now is simply poisoning the earth and negatively affecting the health of the peoples of america [sic] and this world." See Document ID: EPA-HQ-OPP-2005-0253-0060.

level of concern.”¹⁶⁰ Today, PPO may be used to fumigate almonds up to a residue concentration of 300 ppm.¹⁶¹

D. The Mislabeled, Food Labeling Act

The Rule raises two questions with regard to the Food Labeling Act: (1) When an almond is fumigated for four hours at 140°F in a vacuum chamber with a probable carcinogen, must the label reflect this fact?; and (2) When a raw almond has been subjected to 190°F water for two minutes, can that almond still be labeled as raw? Not surprisingly, the answer to both questions is probably no.

One would think that a Food Labeling Act (“FLA”) would require a label to accurately reflect the contents and condition of the food within.¹⁶² However, the Misbranded Food provision of the FLA is offended only if a label is false or misleading in a “material respect.”¹⁶³

Congress has not squarely addressed whether materiality in the FLA “pertains only to safety concerns or whether it also includes consumer interest.”¹⁶⁴ When Congress has not spoken directly to an issue in a statute, an agency has discretion in its construction of the statute, so long as the agency’s construction is faithful to the statute’s plain meaning, based on a permissible construction of the statute, and reasonable and consistent with the statutory scheme and legislative history.¹⁶⁵ The question is, does FDA’s interpretation of “material” pass this test?

Currently, the FDA treats a fact as “material” only when it relates to an increased risk to consumer safety as defined by the FDA.¹⁶⁶ If there is an

160. EPA, PROPYLENE OXIDE: RESPONSE TO PUBLIC COMMENTS ON THE HED RISK ASSESSMENT FOR PROPYLENE OXIDE 2, <http://www.regulations.gov/fdmspublic/component/main> at 2 (enter document ID: EPA-HQ-OPP-2005-0253-0057) (posted June 30, 2006).

161. 40 C.F.R. § 180.491 (2007). It is not clear how or why the residue concentration limit was changed from 150 ppm to 300 ppm. Finding no record of this change in the Federal Register, this author made a Freedom of Information Act (“FOIA”) request to the FDA. In response, the FDA produced a memorandum. However, this author cannot discern from that memorandum how or why the residue concentration level was changed. That memorandum is on file with Liberty University Law Review.

162. The Congressional declaration of policy for the Food Labeling Act states, “[i]nformed consumers are essential to the fair and efficient functioning of a free market economy.” Fair Packaging and Labeling Program, 15 U.S.C. § 1451 (1967).

163. FFDC, Misbranded Food, 21 U.S.C. § 343(a) (Jan 1, 2006).

164. *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166, 178 (D.C. Cir. 2000).

165. *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-43 (1984).

166. *Alliance for Bio-Integrity*, 116 F.Supp.2d at 179 (“Thus, without a determination that . . . food[s] pose inherent risks . . . to consumers, or differ in some material way. . . , the

increased risk to consumers and consumers would likely want to know about the difference, then labeling is appropriate.¹⁶⁷ “If, however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceive the product as different.”¹⁶⁸ Of course whether or not a chemical constitutes an increased risk to consumer safety is determined by the agency.¹⁶⁹ This gives the FDA great latitude in labeling policy, and whatever its decision, it will receive deferential review because the reasoning behind labeling decisions are “characterized by scientific and technological uncertainty.”¹⁷⁰

The FDA has not spoken to whether fumigating almonds in a probable carcinogen or cooking “raw” almonds in 190°F water for two minutes are material facts that must be disclosed on the label. Yet considering the FDA’s treatment of irradiated foods, genetically modified foods, and pasteurized fruit juices, all signs point to no.

In 1986, the FDA mandated labeling of irradiated food on the basis of consumer interest alone, despite noting that there was “no concern about the safety of such treatment at the doses provided by [the] rule.”¹⁷¹ However today, the FDA claims that it does not have authority under the FDCA to mandate labeling solely on the basis of consumer interest.¹⁷² Therefore, in

FDA is without authority to mandate labeling.”); *accord*, Food Labeling; Protein Products; Warning Labeling, 49 FED. REG. 13,679, 13,686 (Apr. 6, 1984) (“In FDA’s opinion, the risk associated with such a consumer misunderstanding is significant and the ... warning statement is therefore necessary.”). While this is the current FDA view, the FDA has not always held this view. *See infra* note 172.

167. *Alliance for Bio-Integrity*, 116 F.Supp.2d at 179.

168. *Id.* This quotation comes out of *Alliance for Bio-Integrity*, but the court’s use of “id.” makes it unclear who is being quoted.

169. In some instances, an agency declares that they are not aware of any evidence of risk, *when some of the research showing risk was done by the agency itself!* *See Mercola, infra* note 176.

170. *Environmental Defense Fund v. Costle*, 578 F.2d 337, 339 (D.C. Cir. 1978).

171. *Irradiation in the Production, Processing, and Handling of Food* 51 FED. REG. 13,376, 13,388 (1986).

172. This marks a stark contrast to current FDA policy. Currently, the FDA claims that it does not have the legal authority to mandate labeling on the basis of consumer interest alone. *See, e.g., Stauber v. Shalala*, 895 F.Supp. 1178, 1193 (W.D. Wis. 1995). However, in 1986 the FDA argued vigorously that the FDCA *did* give it authority to mandate labeling on the “abstract worth of the information” and “whether consumers view such information as important and whether the omission of label information may mislead a consumer.” *See Irradiation in the Production, Processing, and Handling of Food*, 51 FED. REG. 13,376, 13,388. The FDA cites as examples its mandated labeling of bleached and bromated flour, enriched or fortified orange juice made from concentrate, potato chips made from

2007 the FDA proposed to only require labeling in cases where irradiation causes a material change in the sensory, nutritional, or functional properties of food.¹⁷³ Under that proposal, even when labeling is required, the FDA will allow firms to petition to use the innocuous term “pasteurized” rather than irradiated.¹⁷⁴ The FDA reasoned that while past labeling policy focused on conveying to consumers whether a food had been processed, today the focus is on the *results* of the processing rather than the processing itself.¹⁷⁵ In deciding that irradiated foods in themselves do not present an increased risk to consumers, apparently the FDA discounted a substantial amount of research on the dangers of irradiated food—including research conducted by the FDA itself.¹⁷⁶

The FDA does not require special labeling for genetically modified foods (“GMO”).¹⁷⁷ It reasons that while many consumers are concerned about the long-term effects of GMOs, the FDA is not aware of “any data or other information that would form a basis for concluding that the fact that a food . . . was produced using bioengineering is a material fact that must be disclosed [under the FDCA].”¹⁷⁸ Again it seems that a substantial amount of

dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish. *Id.* Therefore, the FDA’s current claim—that it does not have the legal authority under the FDCA to mandate labeling solely on the basis of consumer interest—rings hollow. More likely, the FDA does have the legal authority, but for policy reasons or political reasons, it does not choose to. *See also* Robert Streiffer & Alan Rubel, *Genetically Engineered Animals and the Ethics of Food Labeling* in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 68 (2007); Thomas O. McGarity, *Consumer Sovereignty, Federal Regulation, and Industry Control in Marketing and Choosing Food in the United States*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 139 (2007). *But see* Fred H. Degnan, *Biotechnology and the Food Label*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 27 (2007).

173. FDA, Irradiation in the Production, Processing and Handling of Food, 72 FED. REG. 16,291 (2007).

174. *Id.* at 16,291. This is ironic because in 1996, the FDA concluded that using the term “pasteurization” to label irradiated food “probably would be misleading.” Irradiation of Meat Food Products, 64 FED. REG. 72,150, 72,158 (1999).

175. *Id.* at 16,295.

176. For a compilation of negative irradiation research, including one 1968 FDA study where irradiated food caused internal bleeding in rats, see Dr. Joseph Mercola, *The Problems with Irradiated Food: What the Research Says*, http://www.mercola.com/article/irradiated/irradiated_research.htm (last accessed Dec. 18, 2007).

177. 66 FED. REG. 4839. Genetically modified foods are sometimes referred to as GMOs. A GMO is an organism created by the introduction, removal, or suppression of genes using DNA manipulation technology. Forest Genetics Counsel of British Columbia, www.for.gov.bc.ca/hti/fia/GRMGlossary.htm (last accessed Oct. 10, 2008).

178. 66 FED. REG. 4839, 4840.

negative research failed to penetrate the FDA's "awareness."¹⁷⁹ Nevertheless, the FDA provides guidance for "voluntary labeling . . . to ensure that labeling is truthful and not misleading."¹⁸⁰ While it may seem surprising that the FDA would put the truthfulness or misleading nature of labeling in the hands of the labeler, an agency's decision not to enforce a statute is generally committed to that agency's absolute discretion.¹⁸¹

The FDA's "concern" for the "confusion" of consumers is also reflected in its labeling policy on pasteurized and unpasteurized fruit juices. Here, the FDA reasoned that juices should not be labeled "unpasteurized" because:

FDA was not aware of the extent to which consumers understand the terms "pasteurized" and "unpasteurized." Thus, the agency is concerned that without effective consumer education, labeling untreated juice products as simply "unpasteurized" may not only have relatively little meaning to consumers but could even cause *confusion*. For example, some consumers, for example, may select unpasteurized juice believing that such juice is superior to pasteurized juice in that it is less processed.¹⁸²

Information should be kept from consumers lest it "confuse" them, causing them to make the "wrong" choice.

If the FDA determines that irradiation of food, genetic modification of food, or the non-pasteurization of fruit juice is not a material fact that needs to be disclosed to the customer, then PPO fumigation and cooking of raw almonds are probably not either. Further, information about PPO or pasteurization might "confuse" consumers, causing them to erroneously conclude that a chemical free unprocessed food might be a healthier choice. And consumers who believe they are purchasing "raw" almonds might be "confused" by a label that indicates that their "raw" almonds have been cooked. Judging from this history, the words "propylene oxide" will probably not appear on almond labels any time soon.¹⁸³

179. See, e.g., Yasmine Phillips, *New Health Alert on GM Foods*, WEST AUSTRALIAN NEWSPAPERS, LTD. November 12, 2007 ("After working with more than 30 scientists over two years, Mr. Smith has pinpointed 65 health risks he says are directly and indirectly linked with genetically engineered food.").

180. 66 FED. REG. 4839.

181. *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

182. Food Labeling: Warning and Notice Statements; Labeling of Juice Products, 63 FED. REG. 20,486, 20,488 (Apr. 24, 1998) (emphasis added, irony intended).

183. Ironically, if you are transporting propylene oxide, you must meet federal labeling requirements. See, e.g., 49 C.F.R. § 172.328 (October 1, 2005). Also ironic is the fact that there is a labeling requirement for unpasteurized almonds being shipped to processors in Canada, the U.S., or Mexico. See 7 C.F.R. § 981.442(b)(6)(i) (July 25, 2008).

E. Is the Rule Susceptible to Judicial Review?

Judicial review of administrative agencies is governed by the Administrative Procedure Act (“APA”).¹⁸⁴ In most instances, courts give agency decisions considerable deference.¹⁸⁵ However, when an agency’s action is contrary to the express will of Congress, no deference is given and agencies are susceptible to reversal.¹⁸⁶

When a court reviews agency actions under the APA, the reviewing court must hold an agency’s actions unlawful if they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.¹⁸⁷ The reviewing court must conduct a “substantial inquiry” and determine whether the agency acted within the scope of its authority, “whether the decision was within the small range of available choices,” and whether it could have “reasonably believed that there was no feasible alternative.”¹⁸⁸ The court must also consider “whether the decision was based on a consideration of the relevant factors, and whether there has been a clear error of judgment.”¹⁸⁹ The inquiry into the facts is to be “searching and careful.”¹⁹⁰ However the court should not substitute its judgment for that of the agency.¹⁹¹

If Congress has spoken directly to the issue at hand, the agency must give effect to the unambiguously expressed intent of Congress.¹⁹² If, however, Congress has not directly addressed the issue at hand, the question for the court is “whether the agency’s answer is based on a permissible construction of the statute.”¹⁹³ The agency’s construction need not be the only permissible construction, or the construction favored by the court.¹⁹⁴ Where Congress has made an explicit delegation of power, agency

184. 5 U.S.C. § 706. (Sept. 6, 1966).

185. “We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.” *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984).

186. “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43.

187. *Id.* This is not an exhaustive list of judicial review authority granted by the APA, but includes those elements that are relevant to the Rule.

188. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 403 (1971).

189. *Id.* at 416.

190. *Id.*

191. *Id.*

192. *See* 5 U.S.C. § 706.

193. *Chevron*, 467 U.S. at 843.

194. *Id.*

regulations are given “controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.”¹⁹⁵ Where the delegation of power is implicit, the agency’s construction of the statutory provision need only be reasonable.¹⁹⁶ Considerable weight and deference should be given to an agency’s statutory construction when decisions involve conflicting policies, or more than ordinary knowledge of the subject matter.¹⁹⁷ A court must also give deference to agency choices that reflect a reasonable accommodation of conflicting policies committed to the agency by statute.¹⁹⁸

In sum, agency decisions are difficult to overturn. While there are many legal arguments against the Rule, most would probably not survive the deferential review afforded agencies. The exception is, however, an argument that the Rule contravenes the unambiguously expressed will of Congress.¹⁹⁹ Such an argument would have the strongest chance of success, because if a court determines that an agency is acting contrary to the unambiguously expressed will of Congress, it will not give the agency judicial deference.²⁰⁰

Considering the broad definition that Congress gave the term “additive” in the FFDCA, the USDA’s choice to treat PPO as a pesticide appears to be contrary to the unambiguously expressed will of Congress.²⁰¹ And because where “the intent of Congress is clear . . . the court . . . must give effect to the unambiguously expressed intent of Congress,”²⁰² if a court, in fact, found that the USDA’s treating PPO as a pesticide was contrary to the express intent of Congress, it would overturn the designation, and PPO would be regulated as an additive.²⁰³ And since PPO is known to induce cancer in animals, the Delaney Clause would operate to forbid its use in food.²⁰⁴

The decision to pasteurize all domestic almonds would be harder to overturn, since the USDA would receive deferential review in this area. It would be upheld unless it was arbitrary or capricious. The argument here is

195. *Id.*

196. *Id.* at 844.

197. *Id.*

198. *Id.* at 845.

199. *See* 5 U.S.C. § 706.

200. *Id.*

201. *See supra* notes 125-27 and accompanying text.

202. *Chevron*, 467 U.S. at 842-43.

203. This reasoning applies to the use of PPO for pasteurization, and not, for example, in the field.

204. 21 U.S.C. § 348(c)(3)(A).

that the Rule is not rationally related to the ends of preventing salmonella because it applies to all almonds, when less than five percent of almonds—the non-organic raw almonds—actually pose a significant salmonella risk. The stated rationale for the Rule, the argument would run, is merely pretext. The real reason behind the Rule is that the big growers and handlers want to crush the growing market share of the small and organic growers. A more narrowly tailored approach, the challenger would argue, would be to focus on non-organic raw almonds, which are the source of the salmonella problem. And the proper solution would be mandating Good Agricultural Practices, not pasteurization, which are more effective at preventing salmonella than pasteurization.²⁰⁵

Challenging the lack of a PPO labeling requirement would be difficult because Congress has made an implicit delegation of power to the regulators by not defining “material.”²⁰⁶ The agency would, therefore, receive deferential review. The lack of a PPO labeling requirement, however, could be challenged by arguing that the presence of PPO is a material fact under the FDA’s own definition.²⁰⁷ A fact is material, according to the FDA, if it relates to an increased risk to consumer safety.²⁰⁸ Since PPO is an acknowledged cancer risk, it *does* pose an increased risk to consumer safety and thus constitutes a material fact requiring labeling.

Challenging the FDA’s policy allowing almonds to be labeled as “raw,” when they are in fact cooked, would be equally difficult. While labeling a cooked almond as raw is clearly misleading, it does not constitute a “material fact” as it is defined by the FDA because it does not present an increased health risk. Since the FDA would receive deference here, and since an agency’s decision not to enforce a statute is generally afforded absolute discretion, a challenge here would likely fail.²⁰⁹

IV. CRITIQUE OF THE RULE

The stated purpose of the Rule is to protect the consumer. But are safety concerns really just a pretext to benefit the big growers and handlers?

205. See *Chevron*, 467 U.S. at 843.

206. See *supra* notes 163-64 and accompanying text.

207. The FDA, not the EPA, would regulate labeling of almonds.

208. Food Labeling; Protein Products; Warning Labeling, 49 FED. REG. 13,679 (April 6, 1984).

209. See *supra* notes 192-98 and accompanying text.

A. Rule Favored by Large Almond Producers and Handlers; Condemned by Small and Organic Growers, Consumers, and Proprietors of Raw Almonds

The large growers uniformly favor the Rule. Almonds are a \$2 billion industry,²¹⁰ and no one wants the bad press and diminished sales that another salmonella outbreak might bring, even though previous outbreaks have had no impact on demand.²¹¹ Dave Phippen, former chairman of the ABC, says that “[w]ith an outbreak we would have a blemish on the California almond name whether organic or not.”²¹² The ABC also cites the need to “ensure that consumers are provided with safe, wholesome food products, free from potentially harmful levels of bacteria that can cause illness, without compromising the almond qualities and attributes that consumers expect and appreciate.”²¹³

Almond handlers are downright ebullient about the new Rule. Handlers have invested hundreds of thousands of dollars in pasteurization equipment and expect to make hundreds of thousands in profit.²¹⁴ “It’s awesome,” said one handler. “We’ve invested quite a lot of money in this to get it up and running. It means a lot to us.”²¹⁵

Small almond growers complain that “they have lost tens of thousands of dollars in sales, experienced higher than expected processing costs, and are seeing store shelves now carrying foreign almonds where their product used to be on display. Some worry that they may go out of business.”²¹⁶ They complain that the Rule is a “ploy by the big outfits, the big handlers, to

210. California Almond Board, *The Almond Almanac*, 2007 <http://www.almondboard.com/trade/content.cfm?ItemNumber=529&snItemNumber=459&tnItemNumber=851> at 40 (last accessed Dec. 18, 2007).

211. Loretta Kalb, *Salmonella Recall Doesn't Hurt Almond Sales*, SACRAMENTO BEE (June 8, 2004).

212. *Id.* Mr. Phippen, in his statement, implicitly acknowledges that the rule is *not* needed to prevent salmonella outbreaks among the small and organic growers.

213. Press Release, California Almond Board, *Mandatory Almond Pasteurization Implementation Moves Forward*, <http://www.almondboard.com/News/pressreleasedetail.cfm?ItemNumber=25615> (August 1, 2007).

214. Robert Rodriguez, *Almond Processors Oppose Delay of Program, Board Proposes that USDA Bump the Sept. 1 Start Date for Mandatory Pasteurization to March 1*, SACRAMENTO BEE (August 7, 2007).

215. Dennis Pollock, *Sept. 1 Start to Pasteurize Raw Almonds is Affirmed, Madera Nut Processor Is Pleased USDA Rejects Bid to Delay Implementation*, SACRAMENTO BEE (August 22, 2007). The handler quoted invested \$1,000,000 in pasteurization equipment.

216. Cornucopia Institute, *Update on Almond Pasteurization, USDA Weighing Compromise Proposal*, <http://cornucopia.org/index.php/update-on-almond-pasteurization/> (last accessed Dec. 20, 2007).

drive the small guy out of business.”²¹⁷ They point out that small and organic almond growers, which primarily focus on the raw almond market, will be disadvantaged because consumers of raw organic almonds, including purveyors of foods that include raw organic almonds as a component, are being forced to buy from Italy, Spain, and Turkey.²¹⁸ They are turning to imported almonds because the Rule requires domestic almonds to be either blanched (rendering them cooked), or fumigated with PPO (rendering them not organic).²¹⁹ The Rule does not require pasteurization of imported almonds.²²⁰

Critics also complain that the small growers cannot afford the expense of pasteurization.²²¹ The cost of a typical steam treatment line ranges from \$525,000 to \$800,000.²²² The cost of a propylene oxide chamber ranges from \$500,000 to \$1,250,000.²²³ Outsourcing pasteurization, critics complain, could cost small growers four to five times more than what an industrial-scale producer would pay because processors charge flat rates.²²⁴ Transportation costs required by outsourcing pasteurization are also cited as a concern.²²⁵

B. Eight Reasons Why the Rule Does Not Reflect Sound Policy

1. The Rule is Over-Inclusive

Salmonella is only a concern in raw almonds.²²⁶ This is because heat eliminates the threat of salmonella in cooked almonds.²²⁷ Thus, ninety-five

217. George Raine, *Organic Almond Supporters Roast Pasteurization Plan*, S. F. CHRON. (Aug. 23, 2007).

218. *Id.*

219. *Id.*

220. 7 C.F.R. § 981.

221. *Id.*

222. “This rule provides for a mandatory program to reduce the potential for Salmonella bacteria in almonds.” 72 FED. REG. 15,021, 15,022.

223. *Id.* at 15,026.

224. Press Release, Cornucopia Institute, USDA Plan to “Pasteurize” Almonds Has Consumers Going Nuts: Mandate Would Require Use of Chemical Fumigant or Heat Treatment on “Raw” Almonds, http://www.cornucopia.org/almond/Almond_News_Release.pdf (August 7, 2007).

225. *Id.*

226. Press Release, California Almond Board, California Almond Board Responds to Recall Regarding Raw, Natural Almonds, <http://www.almondboard.com/News/pressreleasedetail.cfm?ItemNumber=582> (May 18, 2004).

227. “Ninety-five percent of almonds sold in the United States undergo processing, such as blanching, roasting or baking which eliminates any potential bacteria such as *Salmonella* Enteritidis.” *Id.*

percent of almonds sold in the United States, because they are cooked, pose no threat of salmonella.²²⁸ If there is no salmonella risk, then there is no reason to pasteurize.²²⁹ Yet, cooked almonds and raw almonds alike must be pasteurized.²³⁰ For this reason alone, the Rule is over-inclusive.

However, the Rule is also over-inclusive because it applies to growers of raw organic almonds, as well as non-organic raw almonds. Non-organic raw almond growers use raw manure for fertilizer,²³¹ a practice not recommended by the ABC,²³² but not forbidden.²³³ Using raw manure makes almonds susceptible to salmonella.²³⁴ The only two salmonella outbreaks linked to almonds both originated from *non-organic* raw almond growers.²³⁵

In contrast, the stringent farming techniques *required* of organic farmers prevent raw manure from being used with crops.²³⁶ Furthermore, the sustainable farming techniques used by organic growers, which include mowing and mulching rather than controlling weeds by chemical herbicide applications, naturally prevent the spread of harmful bacteria more effectively.²³⁷ As one grower put it, “[a]n organic farming system fosters

228. *Id.*

229. The only justification given for pasteurization is salmonella prevention. No salmonella risk, no justification.

230. With minor exceptions discussed *supra* in notes 107-108 and accompanying text, “handlers shall subject their almonds to a treatment process or processes prior to shipment to reduce potential Salmonella bacteria contamination . . .” 7 C.F.R. § 981.442(b)(1).

231. Anna Belle Peevey, *New Pasteurization Regulations Have Raw Food Growers Heated*, ALAMEDA STAR TIMES (Dec. 2, 2007).

232. Linda Romander, *Almond Orchard Food Safety Link*, WESTERN FARM PRESS (Aug. 6, 2005).

233. The ABC’s Food Quality and Safety Program is *voluntary*. See *Almond Board of California Food Quality and Safety Program*, http://www.almondboard.com/files/PDFs/FQSP_GAPs.pdf (last accessed Jan. 20, 2008).

234. “Use of raw animal manure that has not been treated significantly increases the risk of microbiological contaminants.” *Id.* at 29.

235. See McAfee Farms and Organic Pastures Dairy, *supra* note 12.

236. “Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles.” The National Organic Program, *Production and Handling, Subpart C – Organic Crop, Wild Crop, Livestock, and Handling Requirements, Crop Production*, <http://www.ams.usda.gov/nop/NOP/standards/ProdHandPre.html> (last accessed Jan. 20, 2008).

237. Press Release, USDA Plan to “Pasteurize” Almonds Has Consumers Going Nuts: Mandate Would Require Use of Chemical Fumigant or Heat Treatment on “Raw” Almonds.

biodiversity and creates an environment where salmonella cannot survive.”²³⁸ The efficacy of the organic farmer’s technique is evidenced by the fact that there has never been a salmonella incident linked to organic almonds.²³⁹ Since organic growers are already required to follow stringent farming techniques that prohibit the use of raw manure, the justification behind pasteurizing non-organic raw almonds does not support pasteurizing organic raw almonds.

2. The Rule is Under-Inclusive

The Rule does not require imported raw almonds to be pasteurized, only domestic raw almonds. Now that truly raw organic domestic almonds are not available, consumers are turning to imported almonds.²⁴⁰ The Rule, therefore, does not eliminate raw unpasteurized almonds from the food supply—it only prevents American farmers from supplying them.

3. Good Agricultural Practices, Not Pasteurization, is the Most Effective Way to Prevent Salmonella

Salmonella is better prevented by utilizing Good Agricultural Practices (“GAP”) in the orchard, rather than by pasteurization. Pasteurization is an attempt to address the problem, not the cause.²⁴¹ GAP is short for a list of best practices recommended by the ABC to protect almonds by targeting the main sources of almond contamination: poor quality water or poor moisture management that favors microbial growth; failure to properly compost manure fertilizer if used (manure is not recommended); the presence of fecal material from wild animals, livestock, or pets; and poor human hygiene practices.²⁴²

For non-organic growers, following GAP is voluntary.²⁴³ While the occurrence of salmonella in almonds is very rare,²⁴⁴ the most effective place

Cornucopia Institute http://www.cornucopia.org/almond/Almond_News_Release.pdf (Aug. 6, 2007).

238. *Id.*

239. *Id.*

240. George Raine, *Organic Almond Supporters Roast Pasteurization Plan*, S. F. CHRON. (August 23, 2007).

241. “ ‘The mode of industrial agriculture,’ [one organic farmer] said, ‘is that instead of addressing the cause, they deal with the problems.’ ” Peevey, *supra* note 231.

242. Romander, *supra* note 232.

243. *Almond Board of California Food Quality and Safety Program*, http://www.almondboard.com/files/PDFs/FQSP_GAPs.pdf 1 (last accessed Jan. 20, 2008).

244. Press Release, California Almond Board, California Almond Board Responds to Recall Regarding Raw, Natural Almonds. http://www.almondboard.com/News/pressrelease_detail.cfm?ItemNumber=582 (May 18, 2004).

to prevent it is in the orchard, not by pasteurization. When it comes to salmonella, the orchard is the “weakest link” in the chain from producer to consumer.²⁴⁵ In fact, if producers do not follow GAP, pasteurization may not be enough to prevent salmonella.²⁴⁶ While most growers follow GAP, some do not.²⁴⁷ Mandatory pasteurization may even cause growers to become complacent in implementing GAP due to a false sense of security provided by pasteurization. Pasteurization could therefore increase, rather than decrease, the risk of salmonella.

4. The Rule Creates a Greater Risk Than It Prevents

The EPA’s current estimate of cancer incidence from dietary PPO consumption is four in ten million.²⁴⁸ Under that estimate, with the current U.S. population swelling above three hundred million, it is possible that over one hundred people will get cancer from consuming PPO fumigated almonds. Most people who contract salmonella, experience diarrhea, fever, and abdominal cramps for four to seven days, and recover without treatment.²⁴⁹ Considering that only one person has ever died from salmonella linked to almonds, a regulation that may cause over one hundred incidences of cancer cannot be justified. Especially when ninety-five percent of the almonds that may be pasteurized with PPO are cooked and therefore do not even pose a salmonella risk.²⁵⁰

245. Romander, *supra* note 232.

246. According to Linda Harris, Cooperative Extension specialist in microbial food safety, Department of Food Science and Technology, UC-Davis, “[i]f a handler receives almonds from growers or hullers and shellers who did not practice GAPs and GMPs (good manufacturing practices), a pasteurization process that provides a five-log reduction of bacteria such as Salmonella may not be sufficient to eliminate all contamination[.]” *Id.*

247. *Id.*

248. It was 1.3 in 100,000 or 1.5 in every 100,000, but then changed to 4 in 10,000,000, the current number, following pressure from industry lobbyist Aberco. *See supra* notes 154-61, and accompanying text. For the current post Aberco risk assessment level, *see*, EPA, PROPYLENE OXIDE: RESPONSE TO PUBLIC COMMENTS ON THE HED RISK ASSESSMENT FOR PROPYLENE OXIDE; PC CODE 042501; DP BARCODE; 329650, <http://www.regulations.gov/fdmspublic/component/main> at 2 (enter document ID: EPA-HQ-OPP-2005-0253-0057) (posted June 30, 2006).

249. Centers for Disease Control and Prevention, WHAT IS SALMONELLOSIS? http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm (last accessed Jan. 20, 2008).

250. *See* California Almond Board, *supra* note 11.

5. The Rule Unjustifiably Denies Consumers the Right to Choose the Foods They Deem Most Beneficial

Consumers should be able to choose whether they would rather take a risk with salmonella or cancer. The Rule was promulgated in the name of protecting consumers—but no consumers demanded protection. In fact, the Rule was pushed by the big growers and handlers, and received only eighteen public comments—none of which came from consumers.²⁵¹ Now that consumers have become aware of the Rule, *half of all comments coming in to the Secretary of Agriculture are on almonds.*²⁵²

Many health-conscious consumers do not want their almonds fumigated with PPO or their raw almonds cooked.²⁵³ But the Rule deprives consumers of this choice.²⁵⁴ This is particularly worrisome to Raw Foodists and vegetarians, some of whom rely on almonds to provide up to thirty percent of their caloric intake, believing that they are a nutritionally superior alternative to meat.²⁵⁵ Raw foods are also a religious concern to some, including Seventh-Day Adventists.²⁵⁶

6. The Rule Creates an Undue and Unjustifiable Burden on Small and Organic Growers

Techniques used by some commercial growers of non-organic raw almonds, such as use of raw manure, make their almonds susceptible to salmonella contamination.²⁵⁷ In contrast, organic growers of raw almonds are required to use more stringent techniques, and are not permitted to use raw manure with their almonds.²⁵⁸ Yet while they are the least likely to be

251. Press Release, Cornucopia Institute, USDA Plan to “Pasteurize” Almonds Has Consumers Going Nuts: Mandate Would Require Use of Chemical Fumigant or Heat Treatment on “Raw” Almonds, http://www.cornucopia.org/almond/Almond_News_Release.pdf (August 6, 2007).

252. Press Release, Cornucopia Institute, Update on Almond Pasteurization, USDA Weighing Compromise Proposal <http://cornucopia.org/index.php/update-on-almond-pasteurization/> (last accessed Jan. 20, 2008).

253. Reed Fujii, *Almond Growers Tasked To Treat Nuts To Kill Pathogens*, THE RECORD, STOCKTON CA. (April 11, 2007).

254. Unless you happen to live in California near a small organic farmer who sells his own unpasteurized almonds in a roadside stand.

255. Cornucopia Institute, *supra* note 252.

256. *Id.* Arguing that the almond rule violates the Establishment Clause or the Religious freedom act would probably fail because, “neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion or the Religious Freedom Restoration Act.” *Alliance for Bio-Integrity*, 116 F. Supp. 2d 166, 179.

257. *See supra* notes 231-35 and accompanying text.

258. *See supra* notes 236-39 and accompanying text.

the sources of salmonella, organic raw almond growers bear the largest burden from the Rule. This is because, in addition to their more costly farming techniques, flat rates charged by many handlers mean that growers who produce fewer almonds will pay proportionally higher costs to have their almonds pasteurized.²⁵⁹ These growers present the lowest risk of salmonella, yet the Rule imposes the greatest burden on them. It is unfair to impose a disproportionate burden on organic raw almond growers, who *already* are required to do more and spend more to avoid the problem, when it is the non-organic growers who pose the greatest risk of salmonella.

7. The Rule is Reactionary

Regulators have tremendous rulemaking power that can have powerful effects on industries and consumers. They should not wield these powers on a whim, but based on meaningful metrics. There are 40,000 reported cases of salmonella poisoning per year and unreported cases may number as much as thirty times more.²⁶⁰ The Centers for Disease Control and Prevention estimate that approximately 400 people die each year from salmonella.²⁶¹ How can the USDA justify a rule that results in the pasteurization of over one billion pounds of almonds a year, denies consumers the choice to buy unpasteurized almonds, and puts a probable carcinogen into the food supply, in response to *130 illnesses and one death*? What response to the other 39,870 illnesses and 599 deaths? A more meaningful threshold is needed to prevent arbitrary use of regulatory power.

8. Designating Propylene Oxide as a Pesticide Contravenes the Unambiguous Intent of Congress

Where Congress has spoken directly to an issue, an administrative agency must give effect to the unambiguously expressed intent of Congress.²⁶² PPO appears to meet Congress's broad definition of

259. Because many handlers charge a flat rate, small growers may wind up paying up to four or five times than industrial-scale producers. Press Release, Cornucopia Institute, USDA Plan to "Pasteurize" Almonds Has Consumers Going Nuts: Mandate Would Require Use of Chemical Fumigant or Heat Treatment on "Raw" Almonds, http://www.cornucopia.org/almond/Almond_News_Release.pdf (August 7, 2007).

260. Centers for Disease Control and Prevention, HOW COMMON IS SALMONELLOSIS?, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm#How%20common%20is%20salmonellosis (accessed Dec 20, 2007).

261. *Id.*

262. *Chevron U.S.A., v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984).

additive.²⁶³ Yet the USDA regulates PPO as an insecticide based on the location of where it is applied.²⁶⁴ This decision appears to be based solely on administrative convenience, as there is no conceivable reason (the USDA gave none) why location of application relates to whether PPO is a pesticide or an additive.

V. PROPOSAL

A. *Premise Behind Proposal: U.S. Regulation of Environmental Toxins Needs Improvement*

The leader of the Free World leads the Western World in preventable disease.²⁶⁵ With disease, establishing causation is problematic, but there is strong circumstantial evidence that the U.S.'s regulation of environmental toxins, including the kind we ingest in our food, needs improvement.²⁶⁶ The U.S. has a history of willingly accepting new technologies, while regarding traditional foods with suspicion.²⁶⁷ This attitude correlates with rising rates of disease. In contrast, Europe, which favors traditional foods, less processing, and takes a skeptical view toward new technology, enjoys lower rates of disease.²⁶⁸

Rates of diseases that are closely associated with environmental toxins are rising at alarming levels.²⁶⁹ The data supports a strong inference that we are moving in the wrong direction. The U.S. ranks forty-second in life expectancy, down from eleventh decades ago.²⁷⁰ In the U.S., from 1950, the

263. See *supra* note 124-28 and accompanying text.

264. See *supra* note 130-36 and accompanying text.

265. Nicholas Timmins, *US Leads on Deaths From Treatable Disease*, FIN. TIMES, (Jan 8, 2008).

266. See, e.g., Samuel S. Epstein, M.D., THE STOP CANCER BEFORE IT STARTS CAMPAIGN: HOW TO WIN THE WAR ON CANCER 14, available at http://www.preventcancer.com/press/pdfs/Stop_Cancer_Book.pdf, The Cancer Prevention Coalition (2003), citing twelve examples of Congress, FDA, OSHA, and EPA failing to warn the public about epidemiological evidence on a wide range of avoidable and involuntary risk factors or causes of cancer.

267. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 526. Most of Europe tops the US for life expectancy. See *supra* note 265 and accompanying text.

268. *Id.*

269. See *infra* notes 271-81.

270. Stephen Olemacher, *41 Nations Top US Life Expectancy*, SEATTLE TIMES, (Aug. 12, 2007). Some use these statistics to argue for universal health care. This Note focuses on the factors that cause disease. Health care focuses on what to do once disease is contracted. As long as we continue to allow the presence of disease causing environmental toxins in our

beginning of the synthetic chemical revolution,²⁷¹ to 2001 the incidence for all types of cancer increased by eighty-five percent.²⁷² Since 1950, skin melanoma is up 690%; thyroid cancer is up 258%; Non-Hodgkin's lymphoma is up 249%; liver and intrahepatic cancer is up 234%; and kidney and renal pelvis cancer is up 182%.²⁷³

Non-cancer diseases are also on the rise. Fourteen years ago, autism affected one in 10,000 children.²⁷⁴ Today, that number has grown to an astonishing one in 150.²⁷⁵ Research now shows that Attention Deficit Hyperactivity Disorder may be linked to chemical additives in food.²⁷⁶ Dementia in the elderly is growing at epidemic rates.²⁷⁷ "Pediatric asthma rates are reaching epidemic proportions."²⁷⁸ "Toxic chemicals linked to developmental disorders, thyroid problems, and cancer have been found in the breast milk of mothers."²⁷⁹ Up thirty-one percent since 1981, one in eight

food and environment, health care will not reduce the incidence of disease. Health care only relates to survival rates.

271. New technology introduced in the 1940's called thermal and catalytic cracking allowed scientists through molecular splicing and recombination to produce any chemical they wanted. By the 1950's the U.S. produced 50-billion pounds of new synthetic chemicals. By the late 1980s, we produced 500 billion pounds. Most of these chemicals have never been tested for toxic, carcinogenic, or environmental effects. Randall Fitzgerald, *THE HUNDRED-YEAR LIE: HOW TO PROTECT YOURSELF FROM THE CHEMICALS THAT ARE DESTROYING YOUR HEALTH* 30-31 (Penguin Group 2007).

272. *Id.* at 31. This figure is age-adjusted, which means that the increase is not explained by people living longer.

273. *Id.*

274. See, e.g., Michael Szpir, *Tracing the Origins of Autism: A Spectrum of New Studies*, 114(7) ENVIRONMENTAL HEALTH PERSPECTIVES A412, (2006), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?pubmedid=16835042> (last accessed Jan. 23, 2008). Some scientists credit the increase to increased awareness of autism, or of the diagnostic criteria, but other say it is too soon to say. *Id.* While scientists disagree on the importance of genetic versus environmental factors in causing autism, an increase in incidents of autism, and not merely reporting, would argue in favor of environmental factors. *Id.* at A413. Little research has been done. *Id.* There are, however, cases that have been "clearly linked" to environmental insults. *Id.*

275. *Id.*

276. Claudia Wallis, *Hyper Kids? Check their Diet*, TIME MAG. Vol. 170, Issue 13, 68 (Sept. 24, 2007).

277. Medical Devices and Surgical Technology Week, *1 In 7 Americans Over Age 70 Has Dementia*, MED. DEVICES & SURGICAL TECH. WK. 332 (Nov. 18, 2007).

278. Immunotherapy Weekly, *Research from the University of Tennessee Has Provided New Data on Asthma in Children*, IMMUNOTHERAPY WKLY. 14 (Jan. 3, 2007).

279. Patti Truant, *Toxic Chemicals Making Their Way into Mother's Breast Milk*, NATION'S HEALTH, Vol. 25, Issue 9, 19 (November 11, 2005). This is a study of mothers in the U.S. and Canada.

babies are born premature; a “silent epidemic” and a sign that *something* is wrong, say advocates.²⁸⁰ In a recent study on the presence of environmental toxins in blood, all thirty participants have had high levels of toxic substances, including phthalates, bisphenol-A, and polybrominated diphenyl ethers, or PBDEs.²⁸¹

Pasteurization and the sterile Western diet may be to blame for the recent epidemic in asthma and allergies. The “Hygiene Hypothesis” holds that it is the *lack* of exposure to the natural environment teeming with hostile bacteria and parasites that cause our body to have exaggerated responses to things like peanuts, shrimp, and ragweed.²⁸² Interestingly, populations of undeveloped countries are not suffering from the industrialized world’s allergy epidemic.²⁸³ The correlation between overly sterile diets and poor health would seem to counsel against widespread pasteurization of foods.

We are often told that a given chemical is not dangerous, because the dose is so small. However, sometimes small doses are dangerous. For example, five parts per billion of polychlorinated biphenyls (“PCB”) is enough to cause permanent brain damage to a fetus in the womb.²⁸⁴ The “danger is in the dose” rationale also fails to consider how a chemical will react with the myriad other chemicals we have in our body.²⁸⁵ For example, one study showed how two or more chemicals in combination could increase overall toxic effects, even when there was a separation of 200 days between one chemical being added and the next.²⁸⁶ Another study showed how monosodium glutamate (“MSG”) combined with common artificial colors and chemicals typically found in a child’s bloodstream after a snack, interact to interfere with normal development of nerve cells, increasing the toxic effect of the chemical alone by seven times.²⁸⁷ Furthermore, much of the chemical onslaught we ingest cannot be rapidly metabolized by our

280. Kevin Lamb, *Pay Now, Later for Increase Premie Births*, DAYTON DAILY NEWS E3 (Oct. 25, 2005).

281. These chemicals have been linked to birth defects, infertility, and learning disabilities. William Hathaway, *Be Afraid of What Your Made of, Study Says*, THE HARTFORD COURANT A1 (Nov. 9, 2007).

282. Jerry Adler et al., *The Allergy Epidemic: We’ve Conquered Most Childhood Infections but Reactions to Everyday Substances Pose a New Threat*, NEWSWEEK MAG. Vol. 142, Issue 12, 50-57 (Sept. 22, 2003).

283. *Id.*

284. Randall Fitzgerald, THE HUNDRED-YEAR LIE: HOW TO PROTECT YOURSELF FROM THE CHEMICALS THAT ARE DESTROYING YOUR HEALTH 27 (2007).

285. *Id.* at 30-31.

286. *Id.* at 36.

287. *Id.* at 37. For a list of similar alarming studies about the dangerous of chemical synergies see *Id.*

livers and kidneys, accumulating inside of us, eventually impairing our health.²⁸⁸

In short, the U.S. population is experiencing wide-ranging increases in health problems. While admittedly, there are many factors and causality is hard to establish, when disease increases, and genetics have not changed, there is a strong inference that environmental factors are to blame. Our permissive regulation of environmental toxins²⁸⁹ almost certainly contributes to those environmental factors. At the very least, the wide-ranging increase in disease argues that more caution is warranted before we proliferate more chemicals into our bodies, our food, and our environment.

B. U.S. Administrative Agencies Should Follow the Precautionary Principle

As the almond rule demonstrates, federal regulators are not immune to manipulation by big business and are quite capable of creating policies that do more harm than good. In part, this is because Congress has not given agencies a guiding principle that would incline agencies toward more reasoned and less reactionary regulation.

The precautionary principle may be a solution to that omission. It is a moral and political risk management principle used in European food and environmental law to ensure that when faced with scientific uncertainty, regulatory action (or inaction) does not do more harm than good.²⁹⁰ While a definitive statement of the precautionary principle has yet to be developed, the author suggests the following version for the regulation of environmental toxins and food additives:

If there is insufficient scientific evidence to prove beyond a reasonable doubt that a proposed environmental toxin or food additive will not adversely affect human health, that substance should not be approved, or if it is approved, products containing that substance should be conspicuously labeled, and an unadulterated alternative should be permitted.²⁹¹

288. *Id.* at 28-29.

289. "Ninety-five percent of all chemicals have never undergone testing for their toxicity or environmental impact." Mark Shapiro, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS, WHO'S AT RISK AND WHAT'S AT STAKE FOR AMERICAN POWER 132 (2007).

290. Shawn Kolitch, *The Environmental and Public Health Impacts of U.S. Patent Law: Making the Case for Incorporating a Precautionary Principle*, 36 ENVTL. L. 221 (2006).

291. This articulation of the precautionary principle is not derived from any particular source and is purely a product of the author.

Critics of the precautionary principle argue that it is paralyzing, “forbidding inaction, stringent regulation, and everything in between because all societal decisions, including the decision not to act at all, entail risks of harm.”²⁹² One critic offers the following illustration:

Global warming *may* occur, resulting in a broad range of potential harms. Here, many environmental activists call for a drastic reduction in the emission of greenhouse gases, pursuant to the Precautionary Principle. However, reducing greenhouse gas emissions would entail stunning economic costs, diverting money from many health programs and putting at risk the lives of countless world citizens.²⁹³

Indeed the result suggested in the illustration—putting lives at risk to fund global warming mitigation—would be absurd; but the precautionary principle does not have to be carried to absurdity. Any principle, carried to its logical extreme, yields absurd results. But the principle can be applied with judgment and discretion, and not, thereby, yield absurd results.

If the precautionary principle articulated above were applied to the almond issue, one of two things would happen: The USDA would forbid the use of PPO in food, because of the uncertainty regarding its safety, as much of the rest of the world has done.²⁹⁴ Or, if PPO were to be allowed, products containing it would be labeled, and consumers who are concerned about carcinogens would have the information and the freedom to choose the food that they believe is most beneficial to them. Consumers would have the information and the autonomy to choose between a salmonella risk and a cancer risk. Such a result would better protect the liberty of consumers and entrepreneurs.²⁹⁵ Should not important choices with such profound effect on our liberty be in the hands of people, rather than the government?

292. James M. Taylor, *Liberal Academic Shoots Down Precautionary Principle*, THE HEARTLAND INSTITUTE (July 1, 2002) available at <http://www.heartland.org/Article.cfm?artId=902>. Cass Sunstein is a well-known professor at the University of Chicago School of Law.

293. *Id.*

294. See Cornucopia Institute, *supra* note 94 and accompanying text.

295. The application of the precautionary principle to food regulation would also allow for the return of raw milk, raw butter, and raw cheese—formerly known as milk, cheese, and butter.

VI. CONCLUSION

One who did not have a stake in the almond controversy might simply conclude, “Oh well, . . . just eat something else.” But almonds are only the latest on a long list of foods that are not permitted in their natural, unadulterated form.²⁹⁶ The “pasteurize everything” movement is gaining steam. Where will chemical-adverse consumers get their food if regulators do not leave the door open to alternatives?

The Rule discussed in this Note injures liberty in three ways: (1) It deprives consumers of the opportunity to choose the food they believe is most beneficial to them; (2) it places a probable carcinogen in the food supply that may destroy a person’s health, a necessary condition for enjoying liberty; and (3) it limits the freedom of entrepreneurs to offer the goods that they believe their consumers demand. It is just one example of how regulators have too much power and too much discretion. Congress should institute the precautionary principle as a guiding dictate for regulators, so that their regulations will not do more harm to human health, liberty, and autonomy, than good.²⁹⁷

296. Natural butter, milk, and cheese are the most prominent examples. *See supra* note 8 and accompanying text.

297. At the time of publication, a case was pending in the U.S. District Court for the District of Columbia filed by a group of almond growers and handlers challenging the validity of the Rule. *Koretov v. Schaeffer*, No. 1:2008cv01558 (D.C.C. filed Sept. 9, 2008).