[ORAL ARGUMENT NOT YET SCHEDULED]

No. 12-5075

U.S. Court of Appeals for the District of Columbia Circuit

NICK KORETOFF, D/B/A Nick Koretoff Ranches, *et al.*,
Plaintiff-Appellants,

v.

THOMAS VILSACK, Secretary, United States Department of Agriculture,
Defendant-Appellees.

On Appeal from the United States District Court for the District of Columbia,
Case No. 1:08-CV-1558 (ESH), The Honorable Ellen Segal Huvelle

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AMICUS CURIAE BRIEF OF ALLIANCE FOR NATURAL HEALTH USA, CITIZENS FOR HEALTH & FARM TO CONSUMER LEGAL DEFENSE FUND IN SUPPORT OF PLAINTIFF-APPELLANTS URGING REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Counsel for amicus curiae certifies as follows:

1. Alliance for Natural Health USA ("ANH") is a nonprofit organization founded in 1992 to promote sustainable health and freedom of choice in healthcare through good science and good law. It is an umbrella organization with over 200,000 individual members, which include natural health advocates, natural health practitioners, and business interests in the natural health community. ANH has no parent corporation and issues no stock.

2. Amicus Citizens for Health ("CFH") is a nonprofit organization founded in 1992 to provide a voice for natural health consumers. CFH has over 130,000 members, mostly natural health consumers. CFH has no parent corporation and issues no stock.

3. Amicus Farm to Consumer Legal Defense Fund ("FTCLDF") is a non-profit corporation founded in 2007 and organized under the laws of the State of Ohio. It has no parent company and issues no stock.

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GLOSSARY OF ABBREVIATIONS

ABC: Almond Board of California

AMAA: Agricultural Marketing Agreement Act

AMS: Agricultural Marketing Service

ANH: Natural Health US

APA: Administrative Procedure Act

CFH: Citizens for Health

EPA: Environmental Protection Agency

GAP: Good Agricultural Processes

GRAS: Generally recognized as safe

HED: Health Effects Division of the Environmental Protection Agency

MSDS: Material Safety Data Sheet

PPG: Propylene glycol

PPM: Parts per million

PPO: Propylene oxide

USDA: United States Department of Agriculture

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Statutory Addendum to the Brief for Plaintiff-Appellants.

STATEMENT OF IDENTITY

1. **Alliance for Natural Health USA:** Alliance for Natural Health USA (ANH) is a non-partisan member-based nonprofit organization founded in 1992 to promote sustainable health and freedom of choice in healthcare through good science and good law. ANH's 200,000 plus members include natural health advocates, natural health practitioners, and business interests in the natural health community. It is the organization that brings together all interests in the natural health community.

ANH works to change the medical paradigm from a focus on surgery, drugs, and other conventional techniques, to an "integrative" approach incorporating functional foods, dietary supplements, and lifestyle changes. ANH believes that this integrative approach promotes better health, longer life, and reduced healthcare costs. It works through lobbying, litigation, strategic coalitions with like-minded groups, media relationships, and education campaigns.

2. **Citizens for Health**: Citizens for Health (CFH) is a non-partisan member-based nonprofit organization founded in 1992. CFH focuses on consumer health and supports the World Health Organization's definition of health, "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." To encourage society toward a system of complete health, CFH regularly advocates for consumer interests, organizes its 130,000 members

for greater impact, and informs its members of new developments in the consumer health world.

3. **Farm to Consumer Legal Defense Fund:** Farm to Consumer Legal Defense Fund (FTCLD) is a nation-wide non-profit organization dedicated to protecting and promoting sustainable, environmentally sound farming practices and direct farm-to-consumer transactions which FTCLD believes furthers the common good and general welfare of all Americans. FTCLD defends and protects the right of farmers to directly provide, and for consumers to directly obtain, unprocessed and processed farm foods. Toward this end, FTCLD provides advocacy, education, and legal services for farmers and consumers against any local, state, and federal government interference with the legal transfer of products produced and processed on the farm.

INTEREST IN CASE

The Amici believe that toxins in our food and environment play a significant role in the increase in disease and cancer seen in the U.S. The Amici also believe that consumers should have informed access to and the right to choose the food they deem most beneficial to their health. The Almond Rule undermines these goals. Due to the pasteurization mandate of the Almond Rule, almonds are now widely pasteurized with propylene oxide (PPO), a toxin and probable carcinogen; a fact not disclosed on the almond label. Additionally, under the Almond Rule, almonds labeled as "raw" are in fact heat pasteurized, diminishing their nutritional qualities, which is also not disclosed. Thus, the Amici are concerned that the Almond Rule reduces access to healthy, toxin-free food and denies informed consumer choice.

The Amici are also concerned about the effect that upholding the Almond Rule would have on the greater regulatory framework. The USDA is asserting for the first time authority under quality provisions of marketing statutes to mandate processing requirements for agricultural products. If upheld, the USDA will be able to mandate processing requirements in any agricultural product over which it has regulatory authority for marketing. This would further diminish consumer

access to important healthy, toxin-free foods, erode the consumer's right to choose, and negatively impact public health.[1]

USDA did not follow procedural requirements erected by congress in the APA and AMAA. If the Almond Rule is upheld, the Amici are concerned that the precedent will be used by USDA and other federal agencies to avoid congressional mandated procedures designed to make rulemaking a more deliberative process, to give consumers and interested parties greater input, and to prevent unnecessarily onerous regulation.

USDA's Agricultural Marketing Service is also attempting to act as a food safety agency, which is not part of AMS's mission. If upheld, the Amici are concerned that the jurisdictional scheme created by Congress will be blurred, allowing USDA to avoid congressional limits on food safety regulation, e.g, the Delaney clause.

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[1] Such rules would automatically extend to many imported commodities, under 7 U.S.C. § 608e-1, which includes certain imported fruits, nuts and vegetables.

SOURCE OF AUTHORITY TO FILE

The Amici have obtained consent from all parties to file this amicus curiae brief.

/s/ David A. Nauheim
David A. Nauheim
Attorney for amici curiae

STATEMENT OF AUTHORSHIP AND FINANCIAL CONTRIBUTIONS

This brief was authored in whole by the undersigned counsel for the Amici Curiae. No party or counsel to any party has contributed money to the preparation or submission of this brief. No person, apart from the Amici, its members, or its counsel, has contributed money to the preparation or submission of this brief.

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ARGUMENT

I. The importance of raw, unpasteurized almonds

Almonds in general are one of the world's healthiest foods.[2] They have been consumed since biblical times.[3] They are packed with protein[4] and are an excellent source of manganese, copper, and vitamin B2, all of which play an important role in the body's energy production.[5] They are rich magnesium, phosphorus, zinc, and vitamin E,[6] and high in fatty acids and nutrients.[7] They are rich in healthy fats.[8] Almond skins alone may contain as many as thirty different flavanoids.[9]

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[2] 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 (last accessed June 30, 2012).

[3] "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 (NIV).

[4] *See infra note* 2. A quarter cup of almonds has more protein than a typical egg. *Id*.

[5] *Id*.

[6] 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).

[7] *Id.*

[8] Joan Sabaté, *Nut Consumption and Body Weight,* 78 AM. J. CLIN. NUTR 647S (2003).

[9] 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).

Raw almonds are particularly important to a variety of groups, most notably, "raw foodists" (proponents of a raw foods diet),[10] and vegetarians.[11] They believe that raw almonds are healthier than cooked almonds. According to USDA's own data, raw almonds, as compared to blanched almonds (which are only minimally cooked), have significantly more calcium, iron, potassium, fiber, manganese, and vitamin E.[12]

While all almonds contain omega 3 fatty acids, in cooked almonds, heat oxidizes the omega 3's, rendering them rancid,[13] diminishing the antioxidants, and

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[10] 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).

[11] 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) (last accessed June 30, 2012) [hereinafter "*Almond Fact Sheet*"].

[12] *See* USDA National Nutrient Database for Standard Reference, available at http://ndb.nal.usda.gov/ndb/foods/list (enter "almond" and compare data for NDB No.12061 (almonds) to NDB 12062 (blanched almonds) (last accessed July 4, 2012). In some categories, blanched almonds are equal to or in some cases exceed raw almonds.

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

producing free radicals.[14] Raw foodists therefore oppose any application of heat to raw almonds.

Raw foodists also object that heat destroys enzymes in raw almonds.[15] They point out that certain 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.[16] Raw foodists believe that cooked food diets correlate with shorter life span and increased illness.[17]

Raw foodists and vegetarians turn to raw almonds as an important non-animal source of nutrients[18] and alternative to traditional foods. They grind raw almonds into flour for all kinds of preparations, such as almond milk and almond "burgers,"[19] and derive as much as 30% of their daily protein from them.[20] Almond

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[14] *Id*.
[15] "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 June 30, 2012).
[16] JORDAN S. RUBIN N.M.D., PH. D., THE MAKER'S DIET 143 (Siloam 2004).
[17] *Id*.
[18] *Id*.
[19] Mike Adams, *Almond Growers Sue USDA to Halt Mandatory Chemical Fumigation of Raw Almonds*, http://www.naturalnews.com/024132_USDA_the_food.html (last accessed June 30, 2012).
[20] *Id*.

milk and almond cheese are important alternative to those who must avoid gluten and casein.[21]

Prior to the Almond Rule, there was a lucrative market centered on raw domestic almonds, which benefited both consumers and producers. Under the Almond Rule, raw almonds must be pasteurized either with PPO or treated with some form of heat. Accordingly, virtually all domestic almonds are either tainted with a probable carcinogen or not truly raw.[22] Consequently, consumers have turned to imported raw almonds, which are exempted by the Almond Rule. The Almond Rule, therefore, has effectively destroyed the lucrative market for domestic raw almonds.

The Almond Rule mandates the pasteurization of virtually all domestic raw almonds.[23] PPO fumigation is used on the majority of almonds, because it is the

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[21] E.g. The Gluten Free Cooking School, *The Gluten Free, Casein Free Diet – Milk Substitutions*, http://www.glutenfreecookingschool.com/archives/the-gluten-free-casein-free-diet-milk-substitutions (last accessed June 30, 2012).

[22] Since the Almonds Rule only applies to California almonds, consumers can still buy truly raw unpasteurized that are grown in other states or imported.

[23] Almonds Grown in California, 7 C.F.R. § 981.442(b) (May 24, 2007). As noted by the district court, a nascent almond industry is emerging in Washington State to satisfy the demand for unpasteurized raw almond market that was previously met by almond growers like the Plaintiffs.

most cost effective means of pasteurization.[24] Due to organic standards, organic almonds will undergo the more expensive process of steam pasteurization.[25]

A. Propylene oxide fumigation

The Amici are particularly concerned about PPO pasteurization. PPO is a volatile, colorless, extremely flammable chemical with an ether-like odor.[26] It is used in the production of polyurethane foam, polyester resins, hydraulic fluid, drugs, and antifreeze.[27] It has its own Material Safety Data Sheet ("MSDS"), with a long list of unpleasant symptoms that can arise from inhalation, contact with skin, or ingestion.[28] The MSDS provides for protective measures in handling, including full body personal protective equipment, solvent-proof gloves, clothing, hats,

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[24] *Almond Fact Sheet*. With PPO, almonds can be treated in bulk in a fumigation chamber, whereas steam pasteurization occurs on the processing line. Almond Board of California, February 8, 2006 letter to EPA at 4, available at http://www.regulations.gov/ (enter Docket ID # EPA-HQ-OPP-2005-0253-0034).

[25] 72 Fed. Reg. 15021, 15023; *Almond Fact Sheet*; Almond Board of California, Almond Pasteurization, The Food Safety System, http://www.almondboard.com/Consumer/Documents/Pasteurization_Sheet%205.22.09.pdf (March 30, 2009).

[26] PPO converts to propylene glycol (PPG) when it is combined with water. PPG is used to manufacture the products referenced above. Dow Chemical Company, Propylene Glycols, http://www.dow.com/PublishedLiterature/dh_006e/0901b8038006e13c.pdf (last accessed July 31, 2012).

[27] *Id*.

[28] Material Safety Data Sheet: Propylene Oxide, https://fscimage.fishersci.com/msds/19910.htm (last accessed July 1, 2012) [hereinafter "*PPO MSDS sheet*"].

aprons, boots and vapor-proof goggles.[29] It is on the state "right to know" lists of California, New Jersey, Pennsylvania, Minnesota, Massachusetts.[30]

EPA considers PPO a probable carcinogen.[31] The Department of Health and Human Services says that PPO is reasonably anticipated to be a human carcinogen.[32] The State of California calls it a "known carcinogen."[33] Prolonged exposure poses a possibility of individual organ or organ system damage, and affects the central nervous system.[34] It is considered an air pollutant under the Clean Air Act, and a Hazardous Substance under the Clean Water Act.[35]

PPO is known to cause cancer in animals.[36] The Department of Transportation considers PPO a hazardous material and sets special requirements

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[29] *Id.* § 8.
[30] *Id*. § 15.
[31] EPA, *Technology Transfer Network Air Toxics Web Site*, *Propylene Oxide*, http://www.epa.gov/ttn/atw/hlthef/prop-oxi.html (last accessed July 1, 2012).
[32] U.S. Dept. of Health and Human Services, National Toxicology Program, REPORT ON CARCINOGENS,12TH ED, PROPYLENE OXIDE, available at http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/PropyleneOxide.pdf (2011) (accessed July 1, 2012).
[33] *PPO MSDS* § 11.
[34] U.S. Dept. of Health and Human Services, National Toxicology Program, REPORT ON CARCINOGENS,12TH ED, PROPYLENE OXIDE, available at http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/PropyleneOxide.pdf (2011) (accessed July 1, 2012).
[35] *PPO MSDS sheet* § 15.
[36] *Id*. § 11.

for marking, labeling, and transporting this material.[37] The Clean Air Act lists PPO as a Hazardous Air Pollutant.[38] The Occupational Safety and Health Administration sets the Permissible Exposure Limit at 100 ppm.[39] The National Institute for Occupational Safety and Health sets the Immediately Dangerous to Life and Health Level for PPO at 400 ppm.[40] Its use in food is banned in most of Europe, Africa, Asia, and Canada.[41]

While EPA currently allows PPO to be used for almond pasteurization,[42] it has attempted *twice* to ban it in the past. In 1996 EPA found that PPO did, in fact, "induce cancer" within the meaning of the Delaney clause, and announced its intention to revoke PPO's "Food Additive Regulation."[43] Under protest by PPO

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[37] *Id*.
[38] *Id*.
[39] Office of Safety and Health Administration, Propylene Oxide, http://www.osha.gov/dts/chemicalsampling/data/CH_265000.html (last accessed July 2, 2012).
[40] 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 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).
[41] *Almond Fact Sheet*. *See also* 72 Fed. Reg at 15031 in which the AMS acknowledges that PPO use in food is prohibited in the E.U. and Canada.
[42] Propylene Oxide; Tolerances for Residues, 40 C.F.R. § 180.491 (Dec. 6, 2007).
[43] EPA Revocation of Pesticide Food Additive Regulations, 61 Fed. Reg. 11994, 11998. (March 22, 1996).

registrant Aberco, Inc.,[44] EPA reversed itself, setting a permissible residue level for PPO at 150 ppm.[45] 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."[46] For example it reasoned that only 3% of almonds would be treated under the rule. Furthermore, EPA estimated that from the time of fumigation until the time the nuts reached the consumer (18 days), the off-gassing would cause the PPO residue level to drop from 150 ppm to 3.3 ppm.[47]

Notably, these assumptions are no longer valid. By December of 2007, over 68% of almonds were being treated with PPO,[48] as compared to 3% assumed by the EPA in 1996.[49] Additionally, the approved residue level is now 300 ppm—twice the 1996 level. And finally, EPA assumes that the residue level will diminish significantly through off-gassing before almonds reach the consumer. However,

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[44] EPA's reversal was in response to a petition by Aberco, Inc. Propylene Oxide; Pesticide Tolerance, 61 Fed. Reg. 25152 (May 20, 1996).
[45] *Id.*
[46] This assumption is no longer valid because the majority of almonds that go directly into consumer hands are treated with PPO. *Id*.
[47] *Id*.
[48] In 2006 before pasteurization was mandatory, 68% of almonds were pasteurized with PPO. Now that pasteurization is mandatory, presumably that number is much higher. Almond Board of California, Pasteurization Treatments (Dec. 2007), http://www.almondboard.com/Handlers/Documents/Pasteurization-Treatments.pdf (last accessed July 12, 2012) [hereinafter "Almond Board of California, *Pasteurization Treatments*"].
[49] Almond Board of California, *Pasteurization Treatments*.

once almonds reach 300 ppm, they are sealed to prevent salmonella recontamination.[50] Sealing almonds prevents off-gassing, negating EPA's assumption.

In 2005, for a second time, the EPA attempted to ban PPO. A 2005 FDA memo stated that, "the cancer dietary risk estimates for propylene oxide are *above* HED's[51] level of concern. . . . A critical exposure contribution analysis for propylene oxide indicates that nutmeat commodities account for the largest percentage of dietary risk for the general population."[52] 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.[53]

Again, Aberco objected, urging that EPA use a different method to calculate PPO's cancer risk.[54] Aberco contended that PPO converts to propylene glycol

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[50] "[E]very effort is made to prevent the nuts from being exposed to ambient air to prevent re-contamination." Almond Board of California, February 8, 2006 letter to EPA, available at http://www.regulations.gov/ (enter Docket ID # EPA-HQ-OPP-2005-0253-0034).
[51] HED refers to the Health Effects Division of the EPA.
[52] EPA, Propylene Oxide – Revised HED Risk Assessment for Reregistration Eligibility Decision (RED) Document, http://www.regulations.gov (enter: Document ID EPA-HQ-OPP-2005-0253-0002 at p.8 (September 26, 2005).
[53] *Id*. at 9.
[54] Aberco, Registrant Correction Phase: Propylene Oxide (PPO) Preliminary Risk Assessment (PRA) for Reregistration Eligibility Documents (RED), Phase I, http://www.regulations.gov/ (enter document ID EPA-HQ-OPP-2005-0253-0006) (posted Sept. 29, 2005).

(PPG) in the human stomach, a chemical which is deemed Generally Recognized as Safe ("GRAS").[55] Under Aberco's approach, PPO came in under HED's level of concern.[56] Aberco's comment was followed by thirty-seven other comments in support of Aberco from lobbyists and users of PPO, and one comment opposed.[57]

The Amici are skeptical of Aberco's approach. They are not comforted by the fact that PPO may convert to PPG in the stomach. The same mechanism would occur in the stomachs of rats, which were fed PPO in the Dunkleberg study.[58] And yet there was in an increase of stomach tumors in rats feed PPO, indicating that the conversion of PPO to PPG in the stomach, if it occurs, does not vitiate the cancer concern.[59]

Moreoever, PPG, the conversion product of PPO, is not benign. Ingestion of PPG "may cause gastrointestinal tract irritation, affect behavior/central nervous system (CNS depression, general anesthetic, convulsions, seizures, somnolence, stupor, muscle contraction or spasticity, coma), brain (changes in surface EEG), metabolism, blood (intravascular hemolysis, white blood cells - decreased

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[55] *Id*. at 3.
[56] Aberco argued that the EPA ignored hydrolysis of PPO in the stomach. *Id*. at 8.
[57] All comments available at http://www.regulations.gov/ (enter Docket ID # EPA-HQ-OPP-2005-0253).
[58] The Dunkleberg study is a study discussed and criticized in Aberco's comment in which rats were fed with PPO. *See infra note* 56.
[59] *Id*. at 68.

neutrophil function), respiration (respiratory stimulation, chronic pulmonary edema, cyanosis), cardiovascular system (hypotension, bradycardia, arrhythmias, cardiac arrest), endocrine system (hypoglycemia), urinary system (kidneys), and liver."[60]

Furthermore, the Amici are concerned that EPA's assumption about off-gassing are not valid. EPA reasons that PPO residue level decreases before reaching the consumer due to off-gassing.[61] ABC estimates that almonds "typically" spend 3-7 days in off-gassing room in order to reach 300 ppm residue level.[62] However, there is no mechanism to ensure or monitor whether this critical off-gassing actually occurs. Between 2004 and 2006, almond processors have increased PPO pasteurization from processing 25%[63] to 68%.[64] The Amici are skeptical as to whether they are allowing the amount of off-gassing that ABC claims, undermining an important assumption by EPA.

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[60] *PPO MSDS sheet*, § 11, http://www.sciencelab.com/msds.php?msdsId=9927239 (last accessed July 4, 2012).
[61] 61 Fed. Reg. 25152.
[62] Almond Board of California letter to USDA, February 8, 2006 at 7.
[63] *Id*. at 5.
[64] Almond Board of California, *Pasteurization Treatments*.

Nevetheless, EPA adopted Aberco's approach and determined that dietary risk of cancer was "below HED's level of concern"[65] and currently PPO is approved at a residue level up to 300 ppm.[66]

Under the circumstances, consumer concern about PPO is reasonable. While EPA may consider the cancer risk of PPO to be negligible, consumers are entitled to be skeptical.

> [T]here are many possible reasons why a government agency might fail to find real health risks, including inadequate time and budget for testing, insufficient advancement of scientific techniques, insufficiently large sampling populations, pressures from industry, and simple human error.

Int'l Dairy Foods Assoc. v. Amestoy, 92 F.3d 67, 77 (2d Cir. 1996) (Judge Pierre Leval dissenting). Judge Leval also pointed out the government's poor track record in determining product safety, noting that between 1976 and 1985 51.5% of drugs approved by the FDA turned out to have previously unknown serious side effects or were withdraw from the market altogether. *Id*. "[A] government agency's conclusion regarding a product's safety, reached after limited study, is not a guarantee and does not invalidate public concern . . . ." *Id*.

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[65] 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/ at 2 (enter document ID EPA-HQ-OPP-2005-0253-0057) (posted June 30, 2006).

[66] 40 C.F.R. § 180.491.

These concerns are magnified when the agency fails to conduct a searching analysis but rather defers to the industry's conclusions and desires, as USDA did in this case. This also heightens the importance of conducting a formal hearing on the Almond Rule, as argued below.

Unfortunately, FDA has not mandated that almonds fumigated with PPO be labeled accordingly. Most consumers are not aware of the risk the USDA has chosen for them. Consequently, consumers are not given an informed choice whether to avoid this toxin and are unknowingly consuming a probably carcinogen. Ironically, the Almond Rule allows unpasteurized California almonds to be exported, so long as the container is labeled "unpasteurized." 7 C.F.R. § 981.442(b). Thus, foreign consumers are given an informed choice while U.S. consumers are not. Many consumers, given a choice, would presumably risk a bout of salmonella, which generally induces temporary nausea, over the risk of contracting cancer, which is rarely a temporary inconvenience.

B. Steam pasteurization of organic raw almonds

The Amici also object to heat pasteurization of raw almonds. Organic raw almonds are pasteurized with steam heat. As shown above, heating raw almonds diminishes many of the almond's beneficial qualities. Additionally, almonds that have been treated with heat are, quite simply, no longer truly raw; they are, in the

view of many consumers—cooked. Unfortunately, FDA permits almonds that have been pasteurized with steam to be labeled as "raw."[67] Not only is this misleading, but it also denies consumers an informed choice to buy truly raw almonds.

While USDA may disagree with claims by raw foodists and others about the superiority of raw unpasteurized almonds, that misses the point: they are entitled to their opinions. They have the right, in the view of the Amici, to choose the food that *they* deem most beneficial.

II. The Almond Rule does not comply with mandated Congressional standards

A. The Almond Rule is contrary to the legislative policy declared by Congress in section 602 of the AMAA

The AMAA mandates that the USDA act in the interest of consumers, as distinct from producers. 7 U.S.C. § 602. The Almond Rule, however, conflicts with consumers' interests; this court should take note that the mandated hearing AMS evaded was the optimal place for consumers to assert their interests. Section 602 states in pertinent part:

> It is declared to be the policy of Congress–
> . . .

[67] Almond Board of California, Pasteurization Sheet http://www.almondboard.com/Consumer/Documents/Pasteurization_Sheet%205.22.09.pdf (last accessed July 8, 2012).

> (2) *To protect the interest of the consumer* by (a) approaching the level of prices which it is declared to be the policy of Congress to establish in subsection (1) of this section by gradual correction of the current level at as rapid a rate as the Secretary of Agriculture deems to be in the public interest and feasible in view of the current consumptive demand in domestic and foreign markets, and (b) authorizing no action under this chapter which has for its purpose the maintenance of prices to farmers above the level which it is declared to be the policy of Congress to establish in subsection (1) of this section.
>
> . . .
>
> (4) Through the exercise of the powers conferred upon the Secretary of Agriculture under this chapter, to establish and maintain such orderly marketing conditions for any agricultural commodity enumerated in section 608c(2) of this title as will provide, *in the interests of producers and consumers*, an orderly flow of the supply thereof to market throughout its normal marketing season to avoid unreasonable fluctuations in supplies and prices.

7 U.S.C. § 602 (2), (4) (emphasis added).

The Court should note that the declared policy of section 602(2) solely protects consumers while the policy of 602(4) protects both consumers and producers. This is a clear indication that Congress considers the interests of consumers and producers to be distinct, even if they overlap at times, and that the AMAA mandates that the USDA protect the interests of consumers.

The Almond Rule is contrary to the policy stated in section 602 because it reduces the competition in the raw and unpasteurized almond market. At first glance, the Almond Rule may seem to eliminate the raw and unpasteurized almond market, but that is not true from the consumer perspective.

While the Almond Rule virtually prohibits domestic raw and unpasteurized almonds from sale and distribution, it does not prohibit foreign, imported raw and unpasteurized almonds. Essentially, the Almond Rule acts as an inverse tariff, protecting foreign raw and unpasteurized almond producers at the expense of domestic producers. So, the consumer still has access to raw and unpasteurized almonds, only at an artificially inflated price, which is contrary to the stated policy of Congress in section 602 of the AMAA.

Section 602(2)(b) contemplates this situation directly and denies the USDA any authority to act in this way: ". . . authorizing no action under this chapter which has for its purpose the maintenance of prices to farmers above the level which it is declared to be the policy of Congress to establish in subsection (1) of this section[, establishing orderly market conditions.]" The Almond Rule is therefore directly contrary to the stated policy of the AMAA.

B. Section 608c(9) of the AMAA

The Amici agree with Plaintiffs that the Secretary was required under section 608c(9) to find that (1) the Rule was the *only practical means* of advancing the interests of producers; and (2) that the handlers refusal to agree to the order tends to prevent the effectuation of the declared policy of the AMAA.

The district court refused to consider the plaintiffs' section 608c(9) argument under the waiver doctrine because it was not raised during notice and

comment. However, the Secretary's section 608c(9) finding is made when a rule is promulgated, which occurs after notice and comment—how can commenters object to something that occurs *after* notice and comment? Accordingly, the Court should reject the district court's application of the waiver doctrine and consider the growers section 608c(9) argument.

It is uncontested that the Secretary did not make the finding required by section 608c(9). Accordingly, the Almond Rule must fail as a matter of law. Congress intended to constrain the discretion of the Secretary. If the Secretary ignores section 608c(9), then he is exceeding his authority.

Moreover, there are numerous practical ways in which USDA could have minimized the effect of the Almond Rule on the small almond growers that catered to raw organic almond market, while still protecting consumers from salmonella. The Secretary could have exempted almonds from organic growers. The application of the Almond Rule to almonds from raw organic almond growers cannot be justified. There has *never* been a salmonella outbreak linked to an organic almonds producer. Organic almond growers are already required to utilize Good Agricultural Practices ("GAP").[68] GAP is short for a list of best practices recommended by the ABC to protect almonds by targeting the main sources of

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[68] 7 C.F.R. subpart C, Organic Production and Handling Requirements.

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.[69]

Salmonella can be better prevented by utilizing GAP in the orchard, rather than by pasteurization. Pasteurization is an attempt to mitigate the problem, not address the cause.[70] When it comes to salmonella, the orchard is the "weakest link" in the chain from producer to consumer.[71] Additionally, organic California almond growers must also comply with the more stringent California Organic Products Act of 2003. 7 Cal. Code § 110810 et seq. Given that raw organic almond producers are *already* implementing the more expensive and labor intensive state and federal methods, and that there has never been a salmonella outbreak linked to organic producers, there is simply

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[69] Anna Belle Peevey, *New Pasteurization Regulations Have Raw Food Growers Heated,* ALAMEDA TIMES-STAR, (Dec. 2, 2007). *See also* 72 Fed. Reg. 15022.
[70] " 'The mode of industrial agriculture,' [one organic farmer] said, 'is that instead of addressing the cause, they deal with the problems.' " *Id*.
[71] Linda Romander, *Almond Orchard Food Safety Link*, 27 WESTERN FARM PRESS 17, (Aug. 6, 2005).

not adequate justification for mandating the additional expense and burden of pasteurization on organic growers.[72]

For non-organic growers, following GAP is voluntary.[73] If USDA has authority to mandate pasteurization, as it claims, it could have mandated it only for almonds produced by non-organic growers. Or, even more narrowly, USDA could have applied the Almond Rule only to almonds produced by non-organic growers that do not use GAP—after all, these are the growers who pose the biggest risk and from whom salmonella has been linked in the past.

Alternatively, the USDA could have exempted unpasteurized almonds from the Almond Rule so long as they were marketed with a label warning consumers of the risks. A voluntary label as a condition of exemption avoids USDA's concern that it does not have consumer product labeling authority. This approach has been

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[72] USDA did conduct a Regulatory Flexibility analysis when promulgating the Rule, which included a discussion of the effect of the Rule on small businesses, as required by the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. §601. 72 Fed. Reg. 15032. However, it failed to consider the impact of the Rule on the small organic almond growers complained of in this lawsuit by the plaintiffs: that the Rule unnecessarily ends the lucrative market for unpasteurized, toxin-free raw California almonds.

[73] *See* Almond Board of California, Good Agricultural Practices Minimize Food Safety Risks, http://www.almondboard.com/Growers/GAPS/Pages/default.aspx (last accessed July 12, 2012).

successfully implemented by FDA with unpasteurized fruit juices.[74] There is no principled reason why it could not have been done with almonds.

Yet another approach, the Secretary could have instituted a salmonella inspection program for non-organic raw almonds; a practical option given that these almonds represent a very small percentage of the domestic market. Inspection is squarely within the Secretary's authority. If tainted almonds were discovered, the Secretary could take the appropriate actions. This is a viable option because domestic raw almonds represent 1.5% of the total almond production.[75]

Or, USDA could take the approach that it has proposed for preventing salmonella in Leafy Greens, which were also the source of a salmonella outbreak. 76 FED. REG. 24292. Under that proposed rule, the USDA would promulgate voluntary GAP guidelines, and signatory handlers would only process leafy greens from growers who practice GAP. The proposed rule covers both domestic and imported leafy greens. *Id*. If such an approach is viable with leafy greens to prevent salmonella while protecting the interests of small businesses and consumers, there is no principled reason why it would not be viable with almonds.

The section 608c(9) determination, discussed above, is akin to the narrowly

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[74] 21 C.F.R. §101.17(g),

[75] Almond Board of California, February 8, 2006 letter to EPA, available at http://www.regulations.gov/ (enter Docket ID # EPA-HQ-OPP-2005-0253-0034).

tailored standard of strict scrutiny. The Almond Rule is not narrowly tailored at all. There are other practical means of protecting the consumer and producer interest in preventing a salmonella outbreak, which are less onerous than the Almond Rule. Given the myriad of practical, proven, less onerous, options open to USDA, the Almond Rule does not satisfy the standards mandated by Congress. By allowing USDA to hide behind the waiver doctrine, the district court failed to enforce the congressionally mandated standards. The congressional policy behind the AMAA and the strict standards mandated therein cannot be realized if they are not enforced by rigorous judicial review. The Court should therefore invalidate the Almond Rule and reverse the district court.

III. Upholding the Almond Rule would have broad implications for food regulation

The Amici agree with the Plaintiffs that since 1935 USDA has interpreted "quality" as used in section 608c(6) as authorizing it to establish minimum standards for the inherent attributes of marketable farm products. With the Almond Rule, AMS now claims, for the first time, that the authority to set minimum quality standards enables it to mandate how farm products are processed. If the Almond Rule is upheld, it will enable USDA to mandate processing requirements on every agricultural product that it regulates.

The Amici agree with Plaintiffs that the Secretary's interpretation of the section 608c(6) is impermissible. That section directs that a marketing order shall contain at least one of a list of enumerated conditions and terms *and no others*. One of those conditions that an order may contain is "grade, size, or quality." This would allow USDA to mandate that almonds be free from salmonella,—a quality. However, there is a critical difference between stating what qualities marketable almonds must have, and mandating a processing requirement.

Words have meaning. Quality refers to an inherent feature.[76] The Secretary may not ignore the plain meaning of the word quality. *TVA v. Hill*, 437 U.S. 153, 173 (1978). Furthermore, the limiting phrase—no others—clearly indicates that Congress did not intend for USDA to expand its powers beyond the enumerated list of terms and conditions. The Secretary's authority under section 608C(6) should therefore be interpreted narrowly.

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The Amici are concerned that if the Secretary's newly asserted authority to mandate processing of agricultural products is upheld, it will open the door to USDA pasteurization mandates, under the guise of "quality" standards, for every agriculture product that it regulates: dairy, fruit, vegetables, nuts, livestock, seed, and poultry. This will further diminish consumer access to important healthy,

[76] Quality, Merriam Webster online edition, http://www.merriam-webster.com/dictionary/quality (last accessed July 4, 2012).

toxin-free foods, erode the consumer's right to choose, and negatively impact public health.

Some products, like lettuce and spinach, which cannot tolerate any heat, may instead be irradiated, a deleterious process that the Amici are concerned about. While currently all irradiated foods are labeled, a rule change proposed by the FDA would not mandate labeling unless the irradiation "cause[d] a material change in a food's characteristics."[77] The FDA has also proposed to allow irradiated foods to be labeled with the term: "pasteurized."[78]

One can imagine a world in which it is virtually impossible for a consumer to find toxin-free *whole foods* in their natural form that have not undergone some kind of government mandated processing. The Amici are concerned about the effect on the consumer's right to choose as well as the public health effects of such a diet. The Amici are also concerned that USDA will begin mandating other deleterious agricultural process, for example chemical pesticides.

Additionally, the Amici are also concerned that upholding the Almond Rule will undermine the Delaney Clause, which Congress enacted to protect consumers from potentially cancerous additives in food. The Delaney Clause provides that no

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[77] Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16,291, 16,294 (FDA proposed Apr. 4, 2007).

[78] *Id.* at 16295. Ironically, FDA has argued in the past that this would be misleading.

additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.[79] Even if an additive presents a *de minimis* cancer risk, its use is banned by the Delaney Clause.[80] The Delaney Clause governs the Food and Drug Administration, which historically has been the agency that regulates food additives. If the Almond Rule had been promulgated by the FDA it could be challenged under the Delaney Clause. However, since it was promulgated by USDA, the Delaney Clause is not applicable.[81] If the Almond Rule is upheld, it will weaken the protections that Congress enacted to protect consumers from carcinogens and probable carcinogens.

The Delaney Clause is based on a principle that today is known as the precautionary principle, which holds that if there is insufficient evidence to prove that an unnatural substance will not adversely affect human health, that substance should not be allowed. The Delaney Clause put consumer interest above the interests of industry. While USDA claims that the Almond Rule promotes

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[79] Delaney Clause, 21 U.S.C. § 348(c)(3)(A) (1962) ("[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal[.]").
[80] *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987).
[81] USDA has argued that the Delany Clause should be amended. USDA, Does the Delaney Clause of the U.S. Food and Drug laws prevent human cancers? http://openagricola.nal.usda.gov/Record/IND20416595 (last accessed July 4, 2012).

consumer safety, what it fails to consider is that the consumers have a greater interest in avoiding cancer than salmonella. In reality, the Almond Rule favors the concerns of industry over those of consumers and small almond organic growers.

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The Amici are also concerned about the USDA lack of concern regarding the consumer's right to make an informed choice to choose the foods they deem most beneficial. By mandating pasteurization of all almonds, when lesser measures would have sufficed, the USDA has paternalistically denied consumers the right to an informed choice. This kind of government paternalism should be frowned upon, especially when it comes to something as important as health. In *44 Liquormart*, the Court struck down a state law that prevented liquor stores from advertising their prices.[82] The Court reasoned that:

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> The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. *That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products*: . . . "Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented."[83]

The principle that courts should be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good is equally applicable here.

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[82]. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996)
[83] *Id.* at 503-04 (emphasis added) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

IV. The Importance of Formal Hearing Procedures

The Amici are also concerned that USDA did not follow formal hearing procedures, as required by the AMAA. Although consumers can be greatly impacted by marketing orders, as seen here, they do not have standing to challenge them. *Block v. CNI*, 467 U.S. 340 (1984). Formal rule making, therefore, presents an important forum in which consumer interest can be protected, a stated goal of the AMAA. Formal hearing procedures allow consumers, health advocates, and other interested parties to test the assertions of a rule's proponents, including the right of cross-examination that was absent here. 7 U.S.C. §§ 608c(4), (5); 7 C.F.R. § 900.1 et seq. (USDA rules of practice).

Furthermore, formal rulemaking is conducted by an unbiased decision maker that does not have a financial interest in the outcome. Here, while in theory USDA was the decision maker, as a practical matter, the decision was made by the Almond Board of California. The USDA virtually made no findings itself—it merely recited the findings of the Almond Board of California. This is problematic because the members of the Almond Board of California are not an "unbiased decision maker" and they do have a direct financial stake in the outcome of the Almond Rule. This is because the Board is dominated by the interests of the large industrial almond growers—*six* out of ten seats on the Almond Board of California

are controlled by Blue Diamond, the largest almond cooperative.[84] It is unsurprising, therefore, that Board would recommend a Rule that is favorable to Blue Diamond, but anathema to the interests of small organic almond growers. The appearance of bias in promulgating the Almond Rule raises due process concerns.[85]

Even more concerning, USDA has a track record of allowing industry special interests to corrupt the self-regulated marketing order model. A dramatic example of this can be found in *U.S. ex re. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325 (E.D. California 1995).

In order to provide consumers an adequate voice in rulemaking, in order to provide a forum that eliminates the concern of bias and financial interests, and in order to ensure that the interests of all parties are adequately considered, the Court should hold that formal rule hearing procedures must be followed.

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[84] Plaintiffs' Statement of Material Fact p.9 m.15.

[85] *Gibson v. Berryhill*, 411 U.S. 564, 579 (1973) ("It is sufficiently clear from our cases that those with substantial pecuniary interest in legal proceedings should not adjudicate these disputes. . . . It has also come to be the prevailing view that '[m]ost of the law concerning disqualification because of interest applies with equal force to . . . administrative adjudicators.' ") (internal citations omitted). For a summary of the case law concerning due process and biased decision makers see *Haas v. County of San Bernadino*, 27 Cal. 4th 1017, 1029-1032, 45 P.3d 280 (Cal. 2002).

CONCLUSION

For the reasons stated above, the Court of Appeals should reverse the ruling of the district court.

Respectfully submitted this 13th day of July, 2012.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,885 words, excluding the parts of the brief that are exempted by FRAP 32(a)(7)(B)(iii) and Circuit Rule 32(a)(1).

2. This brief complies with the typeface requirements of FRAP 32(a)(5) and the type style requirements of FRAP 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman type style.

Dated this 13th day of July, 2012.

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CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2012, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the D.C. by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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