No. 12-5075

IN THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

NICK KORETOFF, et al.,

Plaintiffs-Appellants,

v.

TOM VILSACK, SECRETARY OF AGRICULTURE, UNITED STATES DEPARTMENT OF AGRICULTURE,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

PROOF BRIEF FOR APPELLEE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

- A. Parties and Amici. Plaintiffs-Appellants are Nick Koretoff, doing business as Nick Koretoff Ranches; John Pryor; Paula Echabarne, doing business as Mallard Bend Farms; Mark McAfee, doing business as Organic Pastures; John Bayer; James E. Bremner; and Vista Livestock Company. Defendant-Appellee is Tom Vilsack, in his official capacity as Secretary of Agriculture. The following parties, who were plaintiffs in the district court but did not appeal, have been designated as Appellees in this Court: Sam Cabal; Cynthia Lashbrook, doing business as Riverdance Farms; Dan Hyman, doing business as D & S Ranches; John Larkin, doing business as Larkin Ranch; Stepanian Farms, Inc.; Stan Barth; Leslie Barth, doing business as Stan Barth Farms; Valley Almond Huller Inc., doing business as Sherman Thomas Ranch; Michael Barnard, doing business as Barnard Organic Farms; Harmon Beckner, doing business as Beckner Farms; Hendrik Feenstra, doing business as Riverview Orchard; Purity Organics, Inc.; and Lynn Pekarek. The Alliance for Natural Health USA, Citizens for Health, and Farm to Consumer Legal Defense Fund have appeared as amici curiae in this Court.
- **B.** Rulings Under Review. Plaintiff-Appellants appeal from the district court's January 18, 2012 Memorandum Opinion and Order granting summary

judgment to the government. See Koretoff v. Vilsack, 841 F. Supp. 2d 1 (D.D.C. 2012)

(Huvelle, J.).

C. <u>Related Cases</u>. Previously, a panel of this Court affirmed in part and

reversed in part a prior order of the district court that dismissed plaintiffs' claims. See

Koretoff v. Vilsack, 614 F.3d 532 (D.C. Cir. 2010) (No. 09-5286). The panel remanded

the case to the district court for further proceedings, and plaintiffs appeal from the

final judgment entered by the district court on remand.

/s/ Michael P. Abate

Michael P. Abate

Counsel for Appellee

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* Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY

ABC Almond Board of California

AMA Agricultural Marketing Act of 1946

AMAA Agricultural Marketing Agreement Act of 1937

APA Administrative Procedure Act

USDA United States Department of Agriculture

STATEMENT OF JURISDICTION

Plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331, 1337, and 2201. Amended Compl. ¶¶ 6-7 (JA ___). The district court granted summary judgment to the government on January 18, 2012. 1/18/12 Order (JA ___). Plaintiffs filed a timely notice of appeal on March 16, 2012. Notice of Appeal (JA ___); Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

Plaintiffs challenge a 2007 rule issued by the Secretary of Agriculture that requires almonds grown in California to be treated to reduce the potential for *Salmonella* bacteria contamination. The questions presented in this appeal are:

- 1. Whether plaintiffs waived their challenges to the final *Salmonella* Rule by failing to raise any of them during the notice-and-comment period preceding its issuance.
 - 2. Whether the Salmonella Rule regulates the "quality" of almonds.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

Following two outbreaks of *Salmonella* linked to almonds, the Secretary of Agriculture ("Secretary") issued a rule requiring almond handlers to treat almonds prior to sale in order to reduce the risk of *Salmonella* bacteria contamination.

Plaintiffs, who are almond growers, challenge the *Salmonella* Rule, arguing that it

exceeds the Secretary's authority to regulate the "quality" of almonds, and was improperly issued through notice-and-comment procedures.

The district court awarded the Secretary summary judgment, finding that some of plaintiffs' claims were expressly waived; that another had been forfeited by failure to raise it during the administrative proceedings; and that the remainder lacked merit, because the Secretary had reasonably concluded that the *Salmonella* Rule was a regulation of almond "quality," and thus was permitted by statute and regulation. *See Koretoff v. Vilsack*, 841 F. Supp. 2d 1 (D.D.C. 2012). This appeal followed.

STATEMENT OF FACTS

A. STATUTORY AND REGULATORY BACKGROUND

1. The Agricultural Marketing Agreement Act

Congress enacted the Agricultural Marketing Agreement Act ("AMAA") of 1937, 50 Stat. 246 (1937), 7 U.S.C. § 601 et seq., to regulate the production and handling of agricultural commodities. The statute is intended to promote orderly marketing conditions for agricultural commodities; to "avoid unreasonable fluctuations in supplies and prices" of those commodities; and to permit the Secretary of Agriculture to establish "minimum standards of quality" and "inspection requirements" for agricultural commodities. 7 U.S.C. § 602(1)-(4).

To achieve these goals, the AMAA authorizes the Secretary to enter into "marketing agreements," and to issue "marketing orders," concerning agricultural commodities. The Secretary may enter into a voluntary marketing agreement with a

producer or handler of any agricultural commodity if doing so would tend to effectuate the declared policies of the AMAA. *See* 7 U.S.C. § 608b.

In addition, the Secretary may issue "marketing orders" that bind all handlers of specified agricultural commodities, even if they have not entered into a voluntary marketing agreement. *See id.* § 608c(1)-(2). Marketing orders apply only to handlers, and do not bind either producers or (except in circumstances not relevant here) retailers of the agricultural commodities. *See id.* § 608c(13).

The contents of a marketing order depend upon the commodity being regulated. For milk and milk products, the Act sets forth a complex system regulating the minimum prices that handlers must pay to producers for milk. *See id.* § 608c(5). For other agricultural commodities listed in § 608c(2) – including almonds – the rules for marketing orders are different.

Instead of a minimum pricing system, the Act allows the Secretary to issue marketing orders that contain terms regulating, among other things, the "grade, size, or quality" of an agricultural commodity or product of such commodity. *Id.* § 608c(6)(A)-(E). Marketing orders also may require handlers to inspect any commodity they handle during the marketing period, *id.* § 608c(6)(F); impose

"Handlers" are defined by the Act as "processors, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof specified in subsection (2) of this section." 7 U.S.C. § 608c(1). For purposes of the almond market, "to handle" means to "use almonds commercially of own production or to sell, consign, transport, ship . . . or in any other way to put almonds grown in the area of production into any channel of trade for human consumption worldwide." 7 C.F.R. § 981.16.

packaging requirements on handlers, id. § 608c(6)(H); or provide for production and marketing research, id. § 608c(6)(I). The Secretary also may establish an agency to "make rules and regulations to effectuate the terms and provisions of such order" and to "recommend to the Secretary of Agriculture amendments to such order." Id. § 608c(7)(C).

To become effective, marketing orders must be approved by a sufficient number of the producers of the relevant commodity in the production area to be regulated. 7 U.S.C. § 608c(8). The Secretary must ensure that the marketing order is favored by either two-thirds of all producers in the production area, *id.* § 608c(8)(A), or, in the alternative, by producers responsible for at least two-thirds of the volume of the commodity in the production area, *id.* § 608c(8)(B).

The marketing order also must be submitted to handlers for their approval. If handlers responsible for at least 50 percent of the volume of the commodity in the relevant production area have voluntarily signed a marketing agreement that regulates the handling of the commodity in the same manner as the marketing order, then the order becomes effective once the two-thirds requirement for producers (described above) is satisfied. *Id.* § 608c(8). An order binds *all* handlers in the production area – even those who have not signed a marketing agreement. *Id.*

The Secretary may issue a marketing order even without handler approval, however. Under § 608c(9), the Secretary may issue a marketing order approved by at least two-thirds of producers (measured either by number of producers or share of

production volume) if he determines that the handlers' failure or refusal to sign a corresponding marketing agreement "tends to prevent the effectuation of the declared policy of this chapter with respect to such commodity or product," and that "the issuance of such order is the only practical means of advancing the interests of the producers of such commodity pursuant to the declared policy." *Id.* § 608c(9)(A)-(B).

Once adopted, a marketing order remains in effect until it is terminated under the procedures set forth in the statute. *See id.* § 608c(16). Subsequent amendments to a marketing order are subject to the same procedural requirements as the original order itself. *Id.* § 608c(17)(A).

2. The California Almond Marketing Order

Since 1950, the California almond handling industry has been subject to market controls under the California Almond Marketing Order. See 7 C.F.R. §§ 981.1-981.92 ("Almond Order"). The Almond Order was approved by at least two-thirds of the producers who participated in a referendum, and was accompanied by a corresponding marketing agreement executed by handlers that processed at least 50 percent of the volume of almonds covered by the Order. See 15 Fed. Reg. 4,993, 4,993-4,994 (Aug. 4, 1950).

The Order applies only within the production area of California, where nearly 100% of all domestically produced almonds are grown. The Order is administered by the ten-member Almond Board of California ("Board"), which is composed of growers and handlers nominated by the industry and appointed by the Secretary. 7

C.F.R. §§ 981.31-981.33. The Board has the power to "make rules and regulations to effectuate the terms and provisions" of the Order, and to recommend to the Secretary amendments to the Order. *Id.* § 981.38; *see also* 7 U.S.C. § 608c(7).

In 1976, the Almond Order was amended through a formal rulemaking process that included public hearings, a producer referendum, and the execution of an amended marketing agreement by the requisite number of handlers. *See* 41 Fed. Reg. 26,852, 26,852 (June 30, 1976) (findings regarding producer and handler approval); 41 Fed. Reg. 22,075 (June 1, 1976) (proposed amendments to Almond Order). A primary purpose of the 1976 amendments was to add new provisions to the Almond Order to govern both "incoming" and "outgoing" quality control requirements for almond handlers. The amended Order does not define either the term "quality" or the term "quality control," however. *See* 7 C.F.R. §§ 981.1-.23 (definitions).

Under the incoming quality control regulation, 7 C.F.R. § 981.42(a), handlers are required to have a third-party inspection agency determine the percent of "inedible kernels" in each variety of almonds it receives, and to report that determination to the Board.² In the event that the percentage of inedible kernels exceeds two percent of the kernel weight of the almonds received, the handler must accumulate that excess amount of inedible kernels during its processing of the

² The definition of "inedible kernel" was revised by that 1976 amendment to read: "a kernel, piece, or particle of almond kernel with any defect scored as serious damage, or damage due to mold, gum, shrivel, or brown spot, as defined in the United States Standards for Shelled Almonds, or which has embedded dirt not easily removed by washing." 7 C.F.R. § 981.8.

almonds, and deliver it to the Board or a Board-approved crusher or feed manufacturer.

The amended Order also gave the Board discretion to establish additional "outgoing" quality control requirements. With the approval of the Secretary, the Board may establish "such minimum quality and inspection requirements . . . as will contribute to orderly marketing or be in the public interest," and also may "establish rules and regulations necessary and incidental to the administration of this provision." 7 C.F.R. § 981.42(b). These outgoing quality control requirements are not limited to the same characteristics that would make almonds inedible under the standards at issue in the incoming quality control requirement. The Federal Register notice promulgating the new regulation explained, for example, that the outgoing quality control provision permits the Secretary to regulate additional "quality factor[s]" of almonds, such as the levels of carcinogenic toxins produced by certain molds. *See* 41 Fed. Reg. at 22,078 ("[T]he minimum quality could apply to a quality factor, such as the level of aflatoxin, which the inspection agency . . . ordinarily does not test.").³

³ Aflatoxins are "are naturally occurring chemicals produced by certain molds" that "affect[] a number of crops, including almonds." Almond Board of California, *Aflatoxins Are a Food Safety and Business Risk*, http://www.almondboard.com/ Handlers/FoodQualitySafety/VASP/MarketRamifications/Pages/Default.aspx (last visited Aug. 13, 2012). "The main health concern of aflatoxins is their potential"

carcinogenicity." Id.

3. The Salmonella Rule

In 2001, a *Salmonella* outbreak was traced back to raw almonds produced in three orchards in California. Almonds Grown in California; Outgoing Quality Control Requirements ("Final Rule"), 72 Fed. Reg. 15,021, 15,022 (Mar. 30, 2007). The particular strain of *Salmonella* was extremely unusual and had not previously been associated with contamination in a non-animal product. *Id.* In response, the Board initiated an extensive research program to better understand the occurrence of *Salmonella* in almond orchards as well as an education program for producers and handlers regarding best agricultural practices. *Id.*

In the spring of 2004, a second *Salmonella* outbreak occurred that was linked to raw almonds purchased at a particular retailer. *Id.* The strain was very similar to the one identified in 2001. One handler had been the supplier to the retailer, and the handler initiated a full recall of approximately 15 million pounds of suspected almonds. *Id.*

Later that year, the Board unanimously approved a voluntary action plan that called for the treatment of all almonds to reduce the potential for *Salmonella* contamination. *Id.*; *see also* Almond Board of California ("ABC"), Food Quality & Safety Action Plan ("Treatment Plan") (AR 1547-49; JA __). The goal of the Treatment Plan was to achieve 100% voluntary industry compliance while the Board considered a proposal for mandatory treatment regulations to be approved by the Secretary. *See* Treatment Plan, at 1 (AR 1547; JA __).

The Board then began a lengthy period of study and public debate over a mandatory treatment program. *See* February 14, 2006 ABC Letter to Industry Members (AR 556; JA __) (describing steps taken by Board to study *Salmonella* contamination and formulate a proposed treatment rule). The Board "continued to fund research on various technologies that could be used to help reduce the potential for *Salmonella* in almonds." 72 Fed. Reg. at 15,022. It also worked with academic researchers to develop a "risk assessment model" to determine the extent to which bacterial contamination should be reduced by any required treatment process. *Id.* at 15,022-23. The Board also allocated \$1 million to fund a project designed "to ensure that appropriate treatment resulted in no significant degradation of the almonds." *Id.* at 15,031.

During this process, the Board engaged in extensive public deliberations regarding a proposed treatment program. The Board discussed the issue at more than 50 public meetings, and kept members of the industry (including producers) informed of developments through quarterly newsletters, yearly conferences, and other forms of communication. *See id.* at 15,029; ABC Almond Pasteurization Education Initiative Questions and Answers, at 1 (AR 317-26; JA ___). Indeed, members of the Board's Food Quality and Safety Committee personally contacted *every handler* about the action

plan to solicit their views. *See* Draft 10 Point Justification ("Draft Justification"), at 25-26 (AR 216-17; JA ___).⁴

In August of 2006, after two years of careful consideration, the Board formally recommended to the Secretary that a mandatory treatment program be implemented under the Almond Order. The Secretary then published a proposed mandatory treatment rule in the Federal Register. *See* Almonds Grown in California; Outgoing Quality Control Requirements and Request for Approval of New Information Collection ("Proposed Rule"), 71 Fed. Reg. 70,683 (Dec. 6, 2006). The proposed rule invoked the Almond Order's outgoing quality control requirements provision as the basis for the Secretary's proposed action. *See* 71 Fed. Reg. at 70,683 (citing 7 C.F.R. § 981.42(b)).

The Secretary provided a 45-day comment period for any interested person to provide feedback on the rule. *Id.* at 70,690. Additionally, the Almond Board sent a brochure to all almond growers informing them about the publication of the Proposed Rule and urging them to submit comments. (AR 82-83; JA ___). The Secretary received eighteen comments during the comment period. *See* 72 Fed. Reg. at 15,029. Only one of the original plaintiffs in this case – who is not appealing the district court's decision – submitted a comment, but that submission did not discuss

⁴ The Draft Justification was prepared by the Almond Board's Committee on Food Quality and Safety to support the regulation the Board recommended to the USDA, and was subject to vigorous public debate. *See* Draft Justification (AR 216-17; JA ___). On September 7, 2006, the Almond Board unanimously approved the Draft Justification and forwarded it to the USDA. *See* Board Minutes (AR 188; JA ___).

any of the legal issues raised in plaintiffs' complaint. The comment merely suggested that "the consumer should have a choice to buy raw or processed almonds" and "[a] labeling requirement for non-pasteurized almonds would be acceptable to many of us." Comment of Cynthia Lashbrook (AR 47; JA __).

The Secretary issued the Final Rule on March 30, 2007 in order to "ensure that quality almonds are available for human consumption." *See* Final Rule, 72 Fed. Reg. at 15,022. The *Salmonella* Rule addressed the comments received and modified certain aspects of the rule not at issue here. *See id.* at 15,029-15,033. Like the Proposed Rule, the final *Salmonella* Rule cited the Almond Order's outgoing quality control requirements as the authority for the Secretary's action. *Id.* at 15,022 & 15,026. The Secretary also made an explicit finding that the *Salmonella* Rule "will tend to effectuate the declared policy of the Act." *Id.* at 15,033.

In approving the mandatory treatment rule, the Secretary noted that the Board had considered several alternatives to the *Salmonella* Rule, but rejected each one. For example, the Board considered taking no action, but determined that was not in the best interests of the industry or consumers because "the industry should provide consumers with a quality product" and failing to act "could be significant in terms of the financial well being of the industry should another [*Salmonella*] outbreak occur that was linked to almonds." 72 Fed. Reg. at 15,028. Similarly, the Board considered a continuation of the voluntary action plan, but decided against that course in light of survey results "indicat[ing] that not all handlers are implementing the action plan." *Id.*

Finally, the Board considered a testing plan under which almonds would be tested for *Salmonella* bacteria contamination – but not treated to reduce it – prior to shipment. The Board rejected this approach as well, noting that pathogen experts at the California Department of Health Services and University of California, Davis determined "that testing cannot be relied upon as the only measure to ensure that almonds are *Salmonella* free." *Id.* The Secretary ultimately agreed with the Board's proposal for a mandatory treatment plan, expressing concern "about the impact of another *Salmonella* outbreak linked to almonds on the industry as a whole." 72 Fed. Reg. at 15,032.

The specific requirements of the *Salmonella* Rule – which are not at issue in this litigation⁵ – are set forth in 7 C.F.R. § 981.442(b). To comply with the Rule, handlers must subject their almonds to a treatment process that achieves a minimum 4-log reduction in *Salmonella* bacteria – a decrease by a factor of 10,000 – prior to shipment. *See* 72 Fed. Reg. at 15,026; 7 C.F.R. § 981.442(b). Handlers need not treat their almonds, however, if they ship them under the "direct verifiable (DV) program" to manufacturers in the U.S., Canada, or Mexico that agree to treat the almonds, or if they ship them to locations outside of the U.S., Canada, or Mexico in containers clearly marked as unpasteurized. 72 Fed. Reg. at 15,024-25. The *Salmonella* Rule went into effect on September 1, 2007. *Id.* at 15,033.

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⁵ Plaintiffs have abandoned their claim that the *Salmonella* rule is arbitrary and capricious, *see Koretoff*, 841 F. Supp. 2d at 4 n.2, and thus the only question remaining is whether the Secretary had the authority to issue it.

A group of plaintiffs made up of almond growers, handlers, grower-handlers, and self-styled "grower-retailers" challenged the *Salmonella* Rule, arguing that it exceeded the Secretary's authority to issue outgoing quality control regulations for almonds; that his decision to issue the rule via notice-and-comment rulemaking was therefore improper; that the *Salmonella* Rule was arbitrary and capricious; that the Secretary's authority to approve quality control regulations under the Almond Order had lapsed; and that the regulation improperly regulates producers in their purported capacity as retailers. The district court initially dismissed each of plaintiffs' claims, finding that some plaintiffs failed to exhaust their administrative remedies before bringing suit, and that the remaining plaintiffs, who were almond producers not regulated by the Almond Order, had no right to challenge the *Salmonella* Rule under the AMAA. *See Koretoff v. Vilsack*, 601 F. Supp. 2d 238 (D.D.C. 2009).

The almond grower and "grower-retailer" plaintiffs appealed, and this Court affirmed in part and reversed in part. *See Koretoff v. Vilsack*, 614 F.3d 532 (D.C. Cir. 2010), *reh'g denied*, 2010 WL 5082029 (D.C. Cir. Dec. 13, 2010). The Court affirmed dismissal of the "grower-retailer" plaintiffs' claims, finding that they failed to exhaust their administrative remedies as required by the AMAA. *Id.* at 540-41. It reversed the court's dismissal of the almond grower claims, however, finding that they did not need to exhaust administrative remedies before filing suit. *Id.* at 536-40.

On remand, the district court awarded the Secretary summary judgment on the almond growers' remaining claims. *Koretoff v. Vilsack*, 841 F. Supp. 2d 1 (D.D.C. 2012). The district court first noted that plaintiffs had expressly abandoned their claim that the *Salmonella* Rule was arbitrary and capricious (Count 4). *Id.* at 4 n.2.⁶ The court also held that plaintiffs had waived Count 5 of their Amended Complaint, which alleges that the *Salmonella* Rule is void "because the Almond Order, under which the Rule was issued, was itself not lawfully promulgated." *Id.* at 4. The court noted that plaintiffs had not even responded to the government's waiver argument concerning that count of their Amended Complaint, and that, in any event, "there is no evidence in the administrative record that this claim was pressed before the USDA." *Id.* at 6.

The court then addressed plaintiffs' two remaining claims: that "the Secretary exceeded his authority under the AMAA and the Almond Order when promulgating the *Salmonella* Rule" (Counts 1 and 3), and that "the *Salmonella* Rule is void because it was promulgated by notice and comment rulemaking without a hearing and without being subject to a vote by almond producers" (Count 2). *Id.* at 4. The court declined to decide whether these arguments were waived, finding it need not do so because "the claims fail on the merits." *Id.* at 6.

⁶ The Court also noted that both it and this Court had previously held that the "grower-retailer" plaintiffs were required to exhaust their administrative remedies before filing suit to pursue the claims contained in Count 6 of the Amended Complaint. *Id.* at 4 n.2.

Turning to the merits of those claims, the court first found that the Salmonella rule was a valid exercise of the Secretary's authority under the AMAA and the Almond Order to regulate almond quality. *Id.* at 6-19. The court found that the Secretary reasonably determined that the presence of Salmonella affects the quality of almonds, because "whether almonds are contaminated by Salmonella might reasonably be deemed a 'property' or a 'characteristic' of almonds, and *Salmonella*-free almonds might constitute a 'particular class' of almonds defined by 'its excellence." *Id.* at 10 (quoting Oxford English Dictionary Online definition of the word "quality"). The court rejected plaintiffs' contrary argument that the word "quality" under the AMAA and Almond Order can only refer to an "inherent, measurable attribute of a farm product," noting that this proffered definition "differs from the dictionary definition of the word" and "would arguably make the term redundant with 'grade," in violation of the rule that separate words in a statute should not be construed in a manner that would render one of them superfluous. *Id.* at 10-11. The court also found that the sources cited by plaintiffs to support their definition of "quality" were not in the administrative record and, in many instances, were "contrary to their argument." *Id.* Finally, the court concluded that nothing about the remainder of the AMAA, or its legislative history, compelled the definition that plaintiffs put forth. *Id.* at 12. Having rejected plaintiffs' plain meaning argument, the district court found that the Secretary's reasonable interpretation of the AMAA and the Almond Order was entitled to controlling deference. *Id.* at 16-19.

Finally, the court rejected plaintiffs' argument that the Secretary improperly issued the *Salmonella* Rule through notice-and-comment rulemaking. The court held that "all of the procedural protections plaintiffs seek – a hearing and almond producers' right to vote on the Rule – apply only if the *Salmonella* Rule is an amendment to the Almond Order, and not a requirement promulgated pursuant to the authority in the Order's outgoing quality control provision." *Id.* at 19. Because the *Salmonella* rule was issued pursuant to existing authority in the Order, the court held, no hearing or producer referendum was required.

SUMMARY OF ARGUMENT

- I. Plaintiffs have waived all of the claims presented in their complaint. It is undisputed that none of the appellants here submitted a comment to the agency during the relevant rulemaking process. This Court may affirm the district court's grant of summary judgment on this basis alone, without reaching the merits of plaintiffs' claims.
- II. Plaintiffs' claims lack merit in any event. Although this case arises under a complex statutory and regulatory scheme, it turns on a simple question: whether the Secretary reasonably determined that *Salmonella* bacteria contamination affects the "quality" of almonds intended for human consumption. If so, then a measure designed to prevent *Salmonella* contamination falls squarely within the Secretary's existing authority to establish "minimum quality and inspection requirements" that

"will contribute to orderly marketing [of almonds] or be in the public interest," 7 C.F.R. § 981.42(b), and was properly issued through notice-and-comment procedures.

The Secretary's interpretation of this authority under the Almond Order is entitled to controlling weight unless it is plainly erroneous or inconsistent with the regulation. The Secretary's view that the authority to regulate commodity "quality" includes the authority to issue the *Salmonella* Rule easily withstands scrutiny under this standard. It is consistent with the dictionary definition of the word "quality"; gives meaning to the different language and function of the Order's "incoming" and "outgoing" quality control provisions; and accords with the Secretary's contemporaneous understanding of the authority when it was created.

Plaintiffs nevertheless argue that the Secretary's interpretation of quality control regulation is entitled to no deference, but their arguments rest on an unduly narrow definition of the term "quality" that is not supported by any relevant statute, regulation, or case law. Plaintiffs fare no better in arguing that the *Salmonella* Rule is inconsistent with the AMAA itself. Like the Almond Order, that statute permits the Secretary to issue marketing orders regulating almond "quality," and the Secretary's interpretation of that term is entitled to deference for all of the reasons just discussed.

Finally, plaintiffs are incorrect in arguing that formal rulemaking was required to promulgate the *Salmonella* Rule. As they concede, informal notice-and-comment rulemaking may be used to issue rules pursuant to existing rulemaking authority in a marketing order. This claim therefore adds nothing to their arguments that the

Salmonella Rule exceeded the Secretary's authority under the AMAA and the Almond Order, and it should be rejected for the same reasons.

STANDARD OF REVIEW

This Court reviews the district court's grant of summary judgment *de novo*.

Nat'l Mining Ass'n v. Kempthorne, 512 F.3d 702, 707 (D.C. Cir. 2008).

ARGUMENT

I. PLAINTIFFS HAVE WAIVED ALL OF THEIR CLAIMS BY FAILING TO RAISE ANY OF THEM DURING THE RULEMAKING PROCEEDING.

A party seeking judicial review of an agency rule issued through notice-and-comment rulemaking may raise only those issues that they presented to the agency during the relevant administrative process. *See Lake Carriers' Ass'n v. EPA*, 652 F.3d 1, 7 (D.C. Cir. 2011) (per curiam); *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1148-50 (D.C. Cir. 2005). Indeed, "[i]t is well established that issues not raised in comments before the agency are waived and this Court will not consider them." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002) (per curiam).

This rule extends to legal as well as factual claims. *Id.; see also Orion Reserves Ltd.*P'ship v. Salazar, 553 F.3d 697, 707 (D.C. Cir. 2009) (party waived statute of limitations defense by failing to raise it in administrative proceedings). This well-settled principle serves two complementary purposes: to ensure that courts are not called upon to "review"... a substantive claim that has never even been presented to the agency for

its consideration," and to guarantee "[s]imple fairness" to administrative agencies. *Advocates for Highway & Auto Safety*, 429 F.3d at 1150 (internal quotation marks omitted); *see also State of Ohio v. EPA*, 997 F.2d 1520, 1528-29 (D.C. Cir. 1993) (discussing purposes of waiver doctrine as applied to legal challenges).

It is undisputed that none of the appellants submitted a comment during the relevant administrative proceeding. Indeed, only one of the original plaintiffs – who is not an appellant here – submitted a comment, and it did not raise *any* of the claims at issue in this litigation. Rather, this plaintiff suggested only that "the consumer should have a choice to buy raw or processed almonds" and stated that "[a] labeling requirement for non-pasteurized almonds would be acceptable to many of us."

Comment of Cynthia Lashbrook (AR 47; JA ___). The agency responded to this comment, noting that it does not have authority under the AMAA to impose labeling requirements at the consumer level. 72 Fed. Reg. at 15,032. Plaintiffs do not take issue with that response in this litigation.

In light of plaintiffs' failure to raise any of their claims during the notice and comment proceeding, the district court correctly concluded that they waived the argument in Count 5 of their complaint. *See Koretoff*, 841 F. Supp. 2d at 6. That claim alleged that the rulemaking authority provided by the Almond Order lapsed in 1996 when, for the first time, a requisite number of almond handlers did not sign a voluntary marketing agreement that regulated almonds in the same manner as the Almond Order. *See* Amended Complaint ¶ 89 (JA __).

Plaintiffs do not dispute the district court's finding that neither they nor any other person presented this claim to the agency during the rulemaking. Instead, they try to resurrect Count 5 on a new and different premise, by alleging that the Secretary failed to include certain findings in the 2007 *Salmonella* Rule that they believe were required by statute. *See* Pls. Br. 63-64 (discussing 7 U.S.C. § 608c(9)). But that is not the claim they were found to have waived. Indeed, that argument directly undercuts Count 5 of their complaint, because the premise of this new argument is that the Secretary *did make* the findings plaintiffs believe to be required by the AMAA when the handlers effectively withdrew their consent for the Almond Order in 1996. *See* Pls. Br. 63 ("The Secretary made an 'only practical means' determination for the 1996 amendments, but he did not do so (and has not done so) for the 2007 almond processing rule . . .").7

In addition, plaintiffs waived the claims contained in Counts 1, 2, and 3 of their complaint, which allege that the *Salmonella* Rule was not a regulation of almond quality and thus exceeded the Secretary's authority and should have been promulgated through formal rulemaking. *See* Amended Compl. ¶¶ 74-85 (JA ___). Although the district court declined to decide whether these claims were properly preserved, this

⁷ Plaintiffs' recast Count 5 is no different in substance than Count 2, which argues that the Secretary was required to use the formal rulemaking procedures contemplated by 7 U.S.C. § 608c(8)-(9) before amending the Almond Order in 2007. As explained *infra*, that claim fails because the *Salmonella* Rule was not an amendment to the Order, but rather a quality control measure issued pursuant to the Secretary's existing authority in 7 C.F.R. § 981.42(b).

Court may affirm the grant of summary judgment based upon any ground presented in the record – or, in this instance, *not* presented. *See, e.g., Jones v. Bernanke*, 557 F.3d 670, 676 (D.C. Cir. 2009) (affirming grant of summary judgment based on alternative statute of limitations defense).

As noted, it is undisputed that none of these plaintiffs suggested during the rulemaking that *Salmonella* contamination has no bearing on the "quality" of an almond intended for human consumption. The district court nevertheless found that the claims might have been preserved because a *different* commenter "question[ed] the authority to impose [a treatment requirement] through this rulemaking," and because, "in issuing the *Salmonella* Rule, USDA responded by stating that it was 'implementing this rulemaking action under the quality control authority contained in the [Almond Order]." *Koretoff*, 841 F. Supp. 2d at 6 (quoting AR 55 [JA __] and 72 Fed. Reg. at 15,031).

This single, passing reference to the Secretary's authority to issue the *Salmonella* rule is not sufficient to preserve plaintiffs' specific claims, which turn on disputes about the scope of the Secretary's rulemaking authority that were never presented to the agency. *See Lake Carriers' Ass'n*, 652 F.3d at 7 (finding petitioners' argument waived where "petitioners' comments on the draft [vessel permit] did not contain *any* of the textual arguments they now raise"); *Ohio*, 997 F.2d at 1550 ("[T]his minimal reference to the contiguity issue is so tangential to the principal thrust of the comment that it cannot fairly be said to have been presented to EPA for resolution."). Nor, for

that matter, is the government's waiver argument overcome by the Board's statement in July 2005 that informal rulemaking may be used to promulgate a treatment rule, see Koretoff, 841 F. Supp. 2d at 6; that document predated the Proposed Rule by 18 months, and plaintiffs had a duty to bring that issue to the Secretary's attention if they disagreed with the Board's interpretation of the Secretary's rulemaking authority and planned to challenge the Salmonella Rule on this basis.

Plaintiffs offer no reason why they could not have raised the claims in their complaint in comments on the Proposed Rule. Had they done so, the Secretary could have explained even more fully why his interpretation of the outgoing quality control regulation is reasonable. Having failed to raise any of these issues, plaintiffs are in no position to complain, as they do, that agency is merely advancing "litigation arguments, derived from but not disclosed in its 2007 almond processing rulemaking." Pls. Br. 55. All of their claims should be dismissed for failure to preserve them.

PLAINTIFFS' CLAIMS LACK MERIT IN ANY EVENT. II.

Even if they were properly before this Court, plaintiffs' remaining claims would lack merit, as the district court properly concluded. Counts 1, 2, and 3 all rest on the flawed premise that Salmonella bacteria contamination has no impact on the "quality" of almonds intended for human consumption.

- A. The District Court Properly Deferred to the Secretary's Reasonable Interpretation of His Authority Under the Almond Order and the Complex Statutory Scheme He Administers.
 - 1. The Secretary Reasonably Determined That the *Salmonella* Rule Falls Within His Authority to Approve "Outgoing" Quality Control Regulations Under 7 C.F.R. § 981.42(b).
- a. The Secretary issued the *Salmonella* Rule pursuant to the authority granted to him by the Almond Order to establish "outgoing" quality control requirements for processed almonds, 7 C.F.R. § 981.42(b). *See* 72 Fed. Reg. at 15,022. That authority has existed since 1976, when the Almond Order was amended through a successful producer referendum and the adoption of a corresponding marketing agreement by a sufficient number of handlers. *See* 41 Fed. Reg. at 26,852. The central question in this case is thus whether the *Salmonella* Rule was a proper exercise of the Secretary's authority to approve "such minimum quality and inspection requirements . . . as will contribute to orderly marketing or be in the public interest." 7 C.F.R. § 981.42(b).

Under longstanding principles of administrative law, the Secretary's interpretation of this regulatory authority "must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotation marks omitted); *see also Auer v. Robbins*, 519 U.S. 452, 461 (1997); *Orion Reserves*, 553 F.3d at 707; *Fabi Const. Co., Inc. v. Sec'y of Labor*, 508 F.3d 1077, 1080-81 (D.C. Cir. 2007). Indeed, "[a]n agency's interpretation of its own regulation merits even greater deference than its interpretation of the statute that it administers." *Buffalo Crushed Stone, Inc. v. Surface*

regulatory program." Thomas Jefferson Univ., 512 U.S. at 512 (internal quotation marks

omitted).

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As the district court concluded, the Secretary's interpretation of the outgoing quality control regulation easily merits the deference it is due. *See Koretoff*, 841 F. Supp. 2d at 17. Indeed, it is difficult to quarrel with the Secretary's conclusion that the Rule "will help ensure that quality almonds are available for human consumption" by "provid[ing] for a mandatory program to reduce the potential for *Salmonella* bacteria in almonds." 72 Fed. Reg. at 15,022. Common sense alone dictates that almonds infected with potentially lethal bacteria cannot be considered a "quality" product in any sense of the word.

The Oxford English Dictionary confirms this intuition. As the district court noted, "quality" is there defined to mean "[a]n attribute, property; a special feature or characteristic,' or '[a] particular class, kind, or grade of something, as determined by its character, esp[ecially] its excellence." *Koretoff*, 841 F. Supp. 2d at 10 (quoting Oxford English Dictionary ("OED") Online⁸); *see also* OED Online (defining "quality" as "the standard or nature of something as measured against other things of a similar kind; the degree of excellence possessed by a thing"). This definition comfortably

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⁸ Available at http://www.oed.com/view/Entry/155878 (last visited Aug. 22, 2012).

accommodates the *Salmonella* Rule, because "whether almonds are contaminated by *Salmonella* might reasonably be deemed a 'property' or a 'characteristic' of almonds, and *Salmonella*-free almonds might constitute a 'particular class' of almonds defined by 'its excellence." *Koretoff*, 841 F. Supp. 2d at 10.

The reasonableness of the Secretary's interpretation is further demonstrated by the structure and history of the regulation. The regulation provides for two separate types of quality control requirements: one for "incoming" almonds received by a handler, and another for "outgoing" almonds processed by a handler. The incoming quality control regulation provides detailed and prescriptive rules governing how a handler is to determine the percentage of incoming almonds that meet the definition of "inedible kernel," and what the handler must do with any percentage of inedible kernels that exceed the allowable limit. *See* 7 C.F.R. § 981.42(a).

In contrast, the outgoing quality control requirement uses broad and permissive language; it allows the Board to propose, and the Secretary to approve, "such minimum quality and inspection requirements applicable to almonds to be handled or to be processed into manufactured products, as will contribute to orderly marketing or be in the public interest." *Id.* § 981.42(b). As the district court correctly held, reading these two provisions together "yields the conclusion that the Secretary

⁹ Even this "incoming" quality control regulation is not limited to the "inherent" characteristics of almonds, as plaintiffs repeatedly assert. It also regulates "damage due to mold" and "embedded dirt not easily removed by washing." 7 C.F.R. § 981.8.

provided the Board with specific instructions regarding permissible incoming quality control provisions and allowed it to exercise more discretion, if necessary, with regard to outgoing quality control provisions." *Koretoff*, 841 F. Supp. 2d at 18.

The Secretary's contemporaneous understanding of the 1976 amendments confirms that § 981.42(b) was indeed intended to provide additional flexibility in regulating outgoing almond quality. The Secretary noted that the outgoing quality control provision was to be used as a contingency, in the event that "the incoming regulation should prove inadequate for industry needs." 41 Fed. Reg. at 22,078. The Secretary also explained that the outgoing quality control provision was not limited to the quality concerns that would suffice to make an almond inedible, which were the focus of the incoming quality control regulation. For example, the outgoing quality control regulation "could apply to a quality factor, such as the level of aflatoxin, which the inspection agency . . . ordinarily does not test" when determining the percentage of inedible kernels in a sample of almonds. 41 Fed. Reg. at 22,078. Aflatoxins are not an inherent characteristic of almonds that makes them inedible; rather, they "are naturally occurring chemicals produced by certain molds" that "affect[] a number of crops, including almonds." Almond Board of California, Aflatoxins Are a Food Safety and Business Risk.¹⁰

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¹⁰ Available at http://www.almondboard.com/Handlers/FoodQualitySafety/VASP/MarketRamifications/Pages/Default.aspx (last visited Aug. 22, 2012).

Indeed, even plaintiff agrees that "The Board was also authorized . . . to adopt quality control rules for 'outgoing' almonds by identifying undesirable attributes (such as aflatoxin) in addition to inedible attributes defined in Grade Standards at the time." Pls. Br. 20 (emphasis added). This concession is fatal to their case, for there is no basis to conclude almond quality is affected by "undesirable attributes" like toxins, but not bacteria. At a minimum, the Secretary's interpretation is reasonable and must be given the deference it is due. See Koretoff, 841 F. Supp. 2d at 18 (citing Devon Energy Corp. v. Kempthorne, 551 F.3d 1030, 1037 (D.C. Cir. 2008)).

b. Despite the ordinary meaning of the word "quality," the text and structure of the Almond Order's quality control regulations, and the contemporaneous understanding of the Secretary's authority to issue outgoing quality control requirements, plaintiffs suggest that the Secretary's interpretation of this regulation is entitled to no deference whatsoever. Their arguments lack merit.

Plaintiffs contend that there is "simply no principled way to read the 1976 Almond Order amendment as providing authority for the 2007 processing rule," Pls. Br. 60, because "quality attributes subject to Marketing Order limitations had consistently involved inherent farm product attributes for 40 years prior to the 1976 amendment (and for 30 years thereafter)." Pls. Br. 59. But plaintiffs appear to have invented this definition out of whole cloth, and provide no citation to any provision of the AMAA or Almond Order that supports this narrow view of an almond's "quality." *See Koretoff*, 841 F. Supp. 2d at 10 n.12 (plaintiffs have neither "proffered a

precise definition for the word [quality]" nor "cited any sources . . . where one might be found"). Moreover, as noted above, plaintiffs concede that almond quality *is* affected by the presence of aflatoxin, Pls. Br. 20, which is not an inherent attribute of almonds. Especially in light of this concession, there is no basis for concluding that the Secretary's interpretation of § 981.42(b) is "plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ.*, 512 U.S. at 512 (internal quotation marks omitted).

At times, plaintiffs also appear to be arguing that the Secretary had no authority to require handlers to take affirmative steps to treat almonds as a means of regulating their quality. *See, e.g.*, Pls. Br. 33, 49, 51, 60. If that is indeed their argument on appeal, it has been forfeited because it differs from the contentions pressed in plaintiffs' summary judgment motion or decided by the district court. *See Potter v. Dist. of Columbia*, 558 F.3d 542, 550 (D.C. Cir. 2009) ("It is well settled that issues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal." (internal quotation marks omitted)).

In any event, this argument lacks merit. Nothing in the Almond Order (or the AMAA for that matter) limits the means by which the Secretary may ensure the quality of almonds intended for human consumption. On the contrary, the Almond Order contemplates that handlers will often have to take affirmative steps to ensure quality control of their almonds beyond simply determining whether their almonds comply with various grade or inspection standards. *See, e.g.*, 7 C.F.R. § 981.42(a)

(requiring handlers to pay for testing by outside inspection agency; report the test results to the Board; collect any excess percentage of inedible kernels; and deliver those excess kernels to the Board or a Board-accepted crusher, feed manufacturer, or feeder). Moreover, the Order gives the Board, with the approval of the Secretary, the authority to "establish rules and regulations necessary and incidental to the administration of this provision." 7 C.F.R. § 981.42(b). In this case, the Board exercised that authority only after considering numerous alternatives to a treatment requirement, each of which was rejected as ineffective. *See* 72 Fed. Reg. at 15,028.

2. The Secretary Reasonably Determined That the Salmonella Rule Is Consistent with the AMAA.

Plaintiffs additionally argue that the *Salmonella* Rule is inconsistent with the AMAA. The Act permits the Secretary to issue Marketing Orders that regulate, among other things, the "grade, size, or quality" of agricultural commodities. 7 U.S.C. § 608c(6)(A)-(E). Like the Secretary's interpretation of the Almond Order, his interpretation of this statutory text is entitled to deference under the principles set forth in *Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). Accordingly, the Secretary's interpretation of any ambiguities in the AMAA is entitled to deference if it "is based on a permissible construction of the statute." *Id.* at 843.

a. The Secretary's interpretation of the AMAA is entitled to deference for the same reasons as his interpretation of the Almond Order; both the statute and the regulation concern the "quality" of agricultural products, and the Secretary's

interpretation of that term is eminently reasonable in this context. *See Koretoff*, 841 F. Supp. 2d at 17 (plaintiffs' regulatory and statutory challenges to the *Salmonella* Rule fail for the same reasons). Indeed, it is telling that plaintiffs do not allege that the Almond Order's quality control regulation is in any way inconsistent with the AMAA. They simply argue that the *Salmonella* Rule is not a quality control regulation, and thus is impermissible under both the statute and regulations.

This claim lacks merit. As the district court noted, the AMAA, like the Almond Order, does not define the meaning of the word "quality." *Koretoff*, 841 F. Supp. 2d at 10. Nor does that word have an unambiguous meaning that forecloses the Secretary's reasonable interpretation. *Id.* And although plaintiffs spend some twenty pages of their brief attacking the district court's conclusion that the word has no unambiguous meaning in this statute, *see* Pls. Br. 36-56, they once again "have not proffered a precise definition for the word, nor have they cited any sources (*i.e.*, decisions, statutes, dictionaries, or articles dealing with agricultural sciences or regulations) where one might be found." *Koretoff*, 841 F. Supp. 2d at 10 n.12. Indeed, plaintiffs do not even take issue with the dictionary definition of the word "quality" relied upon by the district court, even though that court held that "to the extent that plaintiffs have put forward a definition." *Id.* at 10.

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b. In an attempt to demonstrate that the word "quality" in the AMAA can refer only "to inherent attributes of the commodity," Pls. Br. 37, plaintiffs invoke numerous statutes, cases, and regulations. None advances their case, however.

Plaintiffs begin by arguing that in Walter Holm & Co. v. Hardin, 449 F.2d 1009, 1011 (D.C. Cir. 1971), this Court held that the "grade, size, or quality" language of § 608c was "designed solely to reduce the quantities of [the commodity] entering the market." Pls. Br. 37 (alteration in original). Plaintiffs are mistaken. The quoted language from Walter Holm was not a characterization of the Secretary's authority to regulate commodity quality under the AMAA, but rather a description of the particular regulations at issue in that case, which "d[id] not relate to quality." Walter Holm, 449 F.2d at 1011 (emphasis added). Moreover, that case was about the Secretary's authority to impose import restrictions on certain specified kinds of foreign produce under 7 U.S.C. § 608e-1, not his power to issue marketing orders regulating commodity quality under \ 608c(6). 11

Plaintiffs next argue that the word "quality" can only be interpreted as a synonym for a commodity's agricultural "grade," which is generally determined according to detailed regulations issued by the Secretary. See Pls. Br. 40-41. This contention is rebutted by the text of the statute itself, however. The AMAA permits

¹¹ Section 608e-1 does not allow the Secretary to regulate the quality of almonds imported into the United States. It is therefore beside the point that the Secretary has not issued rules prohibiting the importation of untreated almonds. See Pls. Br. 28 (noting that "foreign producers . . . may continue to meet U.S. consumer demand for unprocessed raw almonds").

the Secretary to issue marketing orders regulating the "grade, size, or quality" of agricultural products, 7 U.S.C. § 608c(6)(A)-(E) (emphasis added), and to interpret "quality" to mean "grade" would violate the principle that "courts should disfavor interpretations of statutes that render language superfluous." Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253 (1992) (cited in Koretoff, 841 F. Supp. 2d at 11). Moreover, this argument also is rebutted by plaintiffs' own brief, which repeatedly acknowledges that the Secretary may "devise Marketing Order quality limits in the absence of grade standards, or at variance from grade standards," and has in fact done so. Pls. Br. 41; see also Pls. Br. 14 n.17.

Plaintiffs do not advance their attack on the Secretary's interpretation by surveying "the history of related farm product quality legislation preceding the AMAA, farm cooperative marketing practices incorporated by the AMAA, and judicial decisions to which Congress responded in writing the AMAA." Pls. Br. 41-42. Plaintiffs' discussion of the statutes that predated the AMAA does not illuminate the supposedly "clearly understood farm product trade meaning" of the word "quality" as used in these agricultural statutes. Pls. Br. 44. Nor does Congress's decision to allow farmer cooperatives illustrate a plain meaning of that term, as plaintiffs suggest (*see* Pls. Br. 44-46). Likewise, judicial interpretations of other statutes do not demonstrate the unambiguous meaning of the word "quality" in the AMAA. *See* Pls. Br. 46 (citing *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)).

Plaintiffs are equally wide of the mark in suggesting that cases interpreting the Secretary's authority to issue milk marketing orders under \ 608c(5) of the AMAA shed light on the definition of "quality" as it appears in \S 608c(6) of the Act. See Pls. Br. 47-50. As the district court found, these milk pricing cases are inapposite. Koretoff, 841 F. Supp. 2d at 13-15. In both *Zuber v. Allen*, 396 U.S. 168, 179 (1969), and *Blair v*. Freeman, 370 F.2d 229, 234-35 (D.C. Cir. 1966), the relevant question was whether the inclusion of a "nearby differential" in the calculations of the blended price of milk was consistent with the text and purpose of \(608c(5), \) which permits only specified exceptions to the general rule that all producers should receive a uniform price for their fluid milk. Similarly, in *Smyser v. Block*, 760 F.2d 514 (3d Cir. 1985), the issue was whether a milk marketing order could allow handlers to claim a "transportation credit" not specifically contemplated by § 608c(5) of the AMAA. In all three cases, the courts concluded that the price adjustments at issue were neither authorized by nor consistent with the detailed milk pricing scheme established by Congress, and that allowing these adjustments would undermine the paramount purpose of 608c(5) – providing a uniform price to all milk producers.

Here, by contrast, the question is whether "the Secretary reasonably determined that the *Salmonella* Rule regulates the 'quality' of almonds pursuant to 7 U.S.C. § 608c(6)(A)," *Koretoff*, 841 F. Supp. 2d at 15 – authority that already exists in the statute. Under § 608c(6), the Secretary has far "broader leeway . . . to fashion marketing orders" for non-dairy commodities than for milk marketing orders

governed by the detailed provisions of § 608c(5), which were dispositive in the cases plaintiffs cite. *Koretoff*, 841 F. Supp. 2d at 14; *see also Koretoff*, 614 F.3d at 544 & n.5 (Henderson, J., dissenting in part) (noting that "[m]ilk is *sui generis*" and "is far more extensively regulated under the Act than the other covered commodities"). Moreover, the *Salmonella* Rule is entirely consistent with the purpose of the AMAA, which is intended to ensure "a 'minimum standard[] of quality' for almonds trafficking in interstate commerce so as to 'effectuate [their] orderly marketing." *Koretoff*, 841 F. Supp. 2d at 15 (quoting 7 U.S.C. § 602(3)).

It is similarly beside the point that Congress has frequently amended the AMAA without altering the provisions that allow the Secretary to issue marketing orders regulating the "grade, size, or quality" of certain agricultural products. *See* Pls. Br. 50-53. Those amendments do not reveal anything about Congress's understanding of the meaning of the words left untouched in the statute.

Finally, plaintiffs err by suggesting that the definition of "quality" that appears in 7 C.F.R. § 51.2(p) has any relevance to this case. *See* Pls. Br. 53. As an initial matter, that regulation was cited nowhere in plaintiffs' summary judgment papers below, and thus their reliance on it has been waived. *See Potter*, 558 F.3d at 550. Moreover, that regulation does not interpret provisions of the AMAA or the Almond Order. Rather, it was issued pursuant to the separate rulemaking authority granted under the Agricultural Marketing Act ("AMA") of 1946, 7 U.S.C. § 1621 *et seq.* And it does not undermine the Secretary's interpretation in any event. The regulation makes

clear that the term "quality" under the AMA is determined by all of the inherent properties and attributes of a commodity that combine to determine "its relative degree of excellence." 7 C.F.R. § 51.2(p). There can be no serious doubt that almonds contaminated with *Salmonella*, like those containing certain toxins, are less "excellent" than uncontaminated almonds.

3. The Secretary's Interpretation of the word "Quality" is Not Inconsistent With Prior Agency Positions.

Relying entirely on materials outside the administrative record, plaintiffs argue that the Secretary's interpretation of his authority to issue quality control regulations conflicts with the agency's purported view that it has no authority to regulate food "safety." *See* Pls. Br. 54; *Koretoff*, 841 F. Supp. 2d at 10-11 (noting that materials cited in support of plaintiffs' food safety argument are not in administrative record). This resort to extra-record materials only underscores that plaintiffs failed to raise any of their claims during the relevant administrative proceeding.

As the district court found, this argument is meritless. Indeed, the materials cited by plaintiffs *support* the Secretary's interpretation of his authority to issue quality control regulations under the AMAA and the Almond Order. In the Congressional testimony cited by plaintiffs (Pls. Br. 54-55), the agency consistently noted that it "considers the absence of harmful pathogens or toxins to be a characteristic of higher *quality* products." *Koretoff*, 841 F. Supp. 2d at 11 (quoting 2009 Congressional Testimony of Agricultural Marketing Service ("AMS") Administrator) (emphasis

added); see also id. ("Under federal marketing orders, USDA considers food safety to be a quality characteristic of regulated fruit, vegetable, and specialty crops, and that the absence of harmful pathogens or toxins is a characteristic of higher quality products." (quoting 2007 Congressional testimony of AMS Administrator)).

Nor do plaintiffs provide any logical reason why this Court should draw a rigid dividing line between the concepts of food quality and food safety. From a consumer standpoint, measures that make a commodity safer – such as regulating the level of toxins or bacteria – are usually perceived as increasing its quality. Indeed, this is the very reason why the Board and the Secretary believe the rule to be in the industry's best interests; should another outbreak of *Salmonella* occur that is linked to almonds, many consumers will likely stop buying them, with devastating effect on the industry.

Plaintiffs err in suggesting that the Fifth Circuit drew such a distinction between food quality and food safety in *Supreme Beef Processors v. USDA*, 275 F.3d 432 (5th Cir. 2001). That case arose under the Federal Meat Inspection Act – not the AMAA – and presented the question of whether the language of that statute permitted the Secretary to regulate the levels of *Salmonella* in meat received by a processing plant, or merely permitted the Secretary to regulate *Salmonella* contamination that occurred during the meat's processing. The resolution of that question had nothing to do with a purported distinction between food "quality" and food "safety," as the district court correctly held. *See Koretoff*, 841 F. Supp. 2d at 16.

В. Because the Salmonella Rule Was Issued Pursuant to the Existing Authority in the Almond Order, the Secretary Was Not Required to Follow the Formal Rulemaking Procedures Necessary to Amend that Order.

Plaintiffs' final argument – that the Secretary was required to use formal rulemaking procedures to enact the Salmonella Rule – is merely derivative of their other claims and fails for the same reasons. Even plaintiffs agree that "[r]ules to implement existing Marketing Order provisions" are "not subject to a hearing or producer approval, but follow ordinary notice and comment rulemaking." Pls. Br. 9-10; see also Koretoff, 614 F.3d at 539 n.3 ("Because such rules [issued under § 981.42(b)] are not amendments to the Order, no producer referendum was held before promulgation of the salmonella rule."). Thus, if this Court concludes that the Salmonella Rule is a valid exercise of the Secretary's authority to establish outgoing quality control requirements under the existing Almond Order, plaintiffs' claim may be summarily rejected. See Koretoff, 841 F. Supp. 2d at 19 ("[A]ll of the procedural protections plaintiffs seek – a hearing and almond producers' right to vote on the Rule – apply only if the Salmonella Rule is an amendment to the Almond Order, and not a requirement promulgated pursuant to the authority in the Order's outgoing quality control provision, 7 C.F.R. § 981.42(b).").

Plaintiffs' citations to \(608c(9)\)'s formal rulemaking procedures are therefore beside the point. See Pls. Br. 62-64. That statute would apply when a marketing order is first adopted (if not accompanied by a voluntary marketing agreement), or when the

Order is itself amended, *see id.* § 608c(17), but has no application to informal rulemakings conducted under the terms of an *existing* Order. And as plaintiffs concede, the rulemaking authority granted by the Order was itself validly promulgated by formal rulemaking procedures. *See* Pls. Br. 58 ("[T]he 1976 quality control provision was promulgated, as a Marketing Order amendment, by formal adjudicatory-process rulemaking governed by 5 U.S.C §§556-557.").

C. The Treatment Process Required by the *Salmonella* Rule is Not At Issue in this Litigation.

Plaintiffs have expressly waived their claim that the terms of the *Salmonella* Rule are arbitrary and capricious, arguing only that the Rule exceeds the Secretary's authority to issue quality control requirements and, thus, was invalidly promulgated through informal notice-and-comment procedures. *See* Pls. Br. 31 n.58 ("Growers admittedly waived their fourth cause of action"); *Koretoff*, 841 F. Supp. 2d at 4 n.2 (finding express waiver of arbitrary and capricious claim). That claim may not be pressed on appeal by plaintiffs' *amici* who object, among other things, to the treatment processes that have been approved by the Board, and to the Secretary's decision not to exempt almonds grown by "organic" producers from the *Salmonella* Rule.

As a general rule, this Court will "not entertain arguments not raised by parties." *Narragansett Indian Tribe v. Nat'l Indian Gaming Comm'n*, 158 F.3d 1335, 1338 (D.C. Cir. 1998); *Michel v. Anderson*, 14 F.3d 623, 625 (D.C. Cir. 1994) (same). That rule should apply with even greater force here, where the plaintiffs have expressly

abandoned the claim. *Cf. Eldred v. Reno*, 239 F.3d 372, 378 (D.C. Cir. 2001) (court should not address argument of *amicus* that "is rejected by the actual parties to this case"), *aff'd sub nom. Eldred v. Ashcroft*, 537 U.S. 186 (2003).¹²

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

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increase almond quality and contribute to their orderly marketing, *see* 7 U.S.C. § 602(1), (3), (4), not to increase the price of almonds, which it does not regulate.

¹² For that same reason, this court also should decline to address *amici*'s argument that the *Salmonella* Rule conflicts with the purposes of the AMAA because it artificially increases the prices of untreated almonds, which must now be imported. *See Amici* Br. 16. That argument is meritless in any event. The Rule's purpose is to

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 9,795 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/ Michael P. Abate
MICHAEL P. ABATE

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2012, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system, which constitutes service on all parties under the Court's rules.

I further certify that I caused 8 paper copies of this brief to be filed with the Court.

s/ Michael P. Abate

MICHAEL P. ABATE

ADDENDUM

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EXCERPTS OF AGRICULTURAL MARKETING AGREEMENT ACT OF 1937

7 U.S.C. § 602

Declaration of policy; establishment of price basing period; marketing standards; orderly supply flow; circumstances for continued regulation

It is declared to be the policy of Congress--

- (1) Through the exercise of the powers conferred upon the Secretary of Agriculture under this chapter, to establish and maintain such orderly marketing conditions for agricultural commodities in interstate commerce as will establish, as the prices to farmers, parity prices as defined by section 1301(a)(1) of this title.
- (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.
- (3) Through the exercise of the powers conferred upon the Secretary of Agriculture under this chapter, to establish and maintain such production research, marketing research, and development projects provided in section 608c(6)(I) of this title, such container and pack requirements provided in section 608c(6)(H) of this title1 such minimum standards of quality and maturity and such grading and inspection requirements for agricultural commodities enumerated in section 608c(2) of this title, other than milk and its products, in interstate commerce as will effectuate such orderly marketing of such agricultural commodities as will be in the public interest.
- (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.
- (5) Through the exercise of the power conferred upon the Secretary of Agriculture under this chapter, to continue for the remainder of any marketing season or marketing year, such regulation pursuant to any order as will tend to avoid a

disruption of the orderly marketing of any commodity and be in the public interest, if the regulation of such commodity under such order has been initiated during such marketing season or marketing year on the basis of its need to effectuate the policy of this chapter.

7 U.S.C. § 608b

Marketing agreements; exemption from anti-trust laws; inspection requirements for handlers not subject to agreements

- (a) In order to effectuate the declared policy of this chapter, the Secretary of Agriculture shall have the power, after due notice and opportunity for hearing, to enter into marketing agreements with processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof, only with respect to such handling as is in the current of interstate or foreign commerce or which directly burdens, obstructs, or affects, interstate or foreign commerce in such commodity or product thereof. The making of any such agreement shall not be held to be in violation of any of the antitrust laws of the United States, and any such agreement shall be deemed to be lawful: Provided, That no such agreement shall remain in force after the termination of this chapter.
- (b)(1) If an agreement with the Secretary is in effect with respect to peanuts pursuant to this section--
 - (A) all peanuts handled by persons who have not entered into such an agreement with the Secretary shall be subject to inspection to the same extent and manner as is required by such agreement;
 - (B) no such peanuts shall be sold or otherwise disposed of for human consumption if such peanuts fail to meet the quality requirements of such agreement; and
 - (C) any assessment (except with respect to any assessment for the indemnification of losses on rejected peanuts) imposed under the agreement shall--
 - (i) apply to peanut handlers (as defined by the Secretary) who have not entered into such an agreement with the Secretary in addition to those handlers who have entered into the agreement; and
 - (ii) be paid to the Secretary.

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(2) Violation of this subsection by a person who has not entered into such an agreement shall result in the assessment by the Secretary of a penalty equal to 140 percent of the support price for quota peanuts multiplied by the quantity of peanuts sold or disposed of in violation of subsection (b)(1)(B) of this section, as determined under section 1445c-3 of this title, for the marketing year for the crop with respect to which such violation occurs.

7 U.S.C. § 608c Orders

(1) Issuance by Secretary

The Secretary of Agriculture shall, subject to the provisions of this section, issue, and from time to time amend, orders applicable to processors, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof specified in subsection (2) of this section. Such persons are referred to in this chapter as "handlers". Such orders shall regulate, in the manner hereinafter in this section provided, only such handling of such agricultural commodity, or product thereof, as is in the current of interstate or foreign commerce, or which directly burdens, obstructs, or affects, interstate or foreign commerce in such commodity or product thereof. In carrying out this section, the Secretary shall complete all informal rulemaking actions necessary to respond to recommendations submitted by administrative committees for such orders as expeditiously as possible, but not more than 45 days (to the extent practicable) after submission of the committee recommendations. The Secretary is authorized to implement a producer allotment program and a handler withholding program under the cranberry marketing order in the same crop year through informal rulemaking based on a recommendation and supporting economic analysis submitted by the Cranberry Marketing Committee. Such recommendation and analysis shall be submitted by the Committee no later than March 1 of each year. The Secretary shall establish time frames for each office and agency within the Department of Agriculture to consider the committee recommendations.

(2) Commodities to which applicable

Orders issued pursuant to this section shall be applicable only to (A) the following agricultural commodities and the products thereof . . . or to any regional, or market classification of any such commodity or product: Milk, fruits (including filberts, almonds, pecans and walnuts but not including apples. If the Secretary determines that the declared policy of this chapter will be better achieved thereby (i) the commodities of the same general class and used wholly or in part for the same purposes may be combined and treated as a single commodity and (ii) the portion of

an agricultural commodity devoted to or marketed for a particular use or combination of uses, may be treated as a separate agricultural commodity. All agricultural commodities and products covered hereby shall be deemed specified herein for the purposes of subsections (6) and (7) of this section.

(3) Notice and hearing

Whenever the Secretary of Agriculture has reason to believe that the issuance of an order will tend to effectuate the declared policy of this chapter with respect to any commodity or product thereof specified in subsection (2) of this section, he shall give due notice of and an opportunity for a hearing upon a proposed order.

(4) Finding and issuance of order

After such notice and opportunity for hearing, the Secretary of Agriculture shall issue an order if he finds, and sets forth in such order, upon the evidence introduced at such hearing (in addition to such other findings as may be specifically required by this section) that the issuance of such order and all of the terms and conditions thereof will tend to effectuate the declared policy of this chapter with respect to such commodity.

* * *

(6) Terms--Other commodities

In the case of the agricultural commodities and the products thereof, other than milk and its products, specified in subsection (2) of this section orders issued pursuant to this section shall contain one or more of the following terms and conditions, and (except as provided in subsection (7) of this section), no others:

(A) Limiting, or providing methods for the limitation of, the total quantity of any such commodity or product, or of any grade, size, or quality thereof, produced during any specified period or periods, which may be marketed in or transported to any or all markets in the current of interstate or foreign commerce or so as directly to burden, obstruct, or affect interstate or foreign commerce in such commodity or product thereof, during any specified period or periods by all handlers thereof.

- (B) Allotting, or providing methods for allotting, the amount of such commodity or product, or any grade, size, or quality thereof, which each handler may purchase from or handle on behalf of any and all producers thereof, during any specified period or periods, under a uniform rule based upon the amounts sold by such producers in such prior period as the Secretary determines to be representative, or upon the current quantities available for sale by such producers, or both, to the end that the total quantity thereof to be purchased, or handled during any specified period or periods shall be apportioned equitably among producers.
- (C) Allotting, or providing methods for allotting, the amount of any such commodity or product, or any grade, size, or quality thereof, which each handler may market in or transport to any or all markets in the current of interstate or foreign commerce or so as directly to burden, obstruct, or affect interstate or foreign commerce in such commodity or product thereof, under a uniform rule based upon the amounts which each such handler has available for current shipment, or upon the amounts shipped by each such handler in such prior period as the Secretary determines to be representative, or both, to the end that the total quantity of such commodity or product, or any grade, size, or quality thereof, to be marketed in or transported to any or all markets in the current of interstate or foreign commerce or so as directly to burden, obstruct, or affect interstate or foreign commerce in such commodity or product thereof, during any specified period or periods shall be equitably apportioned among all of the handlers thereof.
- (D) Determining, or providing methods for determining, the existence and extent of the surplus of any such commodity or product, or of any grade, size, or quality thereof, and providing for the control and disposition of such surplus, and for equalizing the burden of such surplus elimination or control among the producers and handlers thereof.
- (E) Establishing or providing for the establishment of reserve pools of any such commodity or product, or of any grade, size, or quality thereof, and providing for the equitable distribution of the net return derived from the sale thereof among the persons beneficially interested therein.
- (F) Requiring or providing for the requirement of inspection of any such commodity or product produced during specified periods and marketed by handlers.

* * *

- (H) providing a method for fixing the size, capacity, weight, dimensions, or pack of the container, or containers, which may be used in the packaging, transportation, sale, shipment, or handling of any fresh or dried fruits, vegetables, or tree nuts: Provided, however, That no action taken hereunder shall conflict with the Standard Containers Act of 1916 (15 U.S.C. 251-256) and the Standard Containers Act of 1928 (15 U.S.C. 257-257i);7
- (I) establishing or providing for the establishment of production research, marketing research and development projects designed to assist, improve, or promote the marketing, distribution, and consumption or efficient production of any such commodity or product, the expense of such projects to be paid from funds collected pursuant to the marketing order: Provided, That with respect to orders applicable to almonds... such projects may provide for any form of marketing promotion including paid advertising and with respect to almonds. . . may provide for crediting the pro rata expense assessment obligations of a handler with all or any portion of his direct expenditures for such marketing promotion including paid advertising as may be authorized by the order and when the handling of any commodity for canning or freezing is regulated, then any such projects may also deal with the commodity or its products in canned or frozen form: Provided further, That the inclusion in a Federal marketing order of provisions for research and marketing promotion, including paid advertising, shall not be deemed to preclude, preempt or supersede any such provisions in any State program covering the same commodity.

* * *

(7) Terms common to all orders

In the case of the agricultural commodities and the products thereof specified in subsection (2) of this section orders shall contain one or more of the following terms and conditions:

- (A) Prohibiting unfair methods of competition and unfair trade practices in the handling thereof.
- (B) Providing that (except for milk and cream to be sold for consumption in fluid form) such commodity or product thereof, or any grade, size, or quality thereof shall be sold by the handlers thereof only at prices filed by such handlers in the manner provided in such order.

- (C) Providing for the selection by the Secretary of Agriculture, or a method for the selection, of an agency or agencies and defining their powers and duties, which shall include only the powers:
 - (i) To administer such order in accordance with its terms and provisions;
 - (ii) To make rules and regulations to effectuate the terms and provisions of such order;
 - (iii) To receive, investigate, and report to the Secretary of Agriculture complaints of violations of such order; and
 - (iv) To recommend to the Secretary of Agriculture amendments to such order.

No person acting as a member of an agency established pursuant to this paragraph shall be deemed to be acting in an official capacity, within the meaning of section 610(g) of this title, unless such person receives compensation for his personal services from funds of the United States. There shall be included in the membership of any agency selected to administer a marketing order applicable to grapefruit for canning or freezing one or more representatives of processors of the commodity specified in such order.

- (D) Incidental to, and not inconsistent with, the terms and conditions specified in subsections (5), (6), and (7) of this section and necessary to effectuate the other provisions of such order.
- (8) Orders with marketing agreement

Except as provided in subsection (9) of this section, no order issued pursuant to this section shall become effective until the handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping the commodity or product thereof covered by such order) of not less than 50 per centum of the volume of the commodity or product thereof covered by such order which is produced or marketed within the production or marketing area defined in such order have signed a marketing agreement, entered into pursuant to section 608b of this title, which regulates the handling of such commodity or product in the same manner as such order, except that as to citrus fruits produced in any area producing what is known as California citrus fruits no order issued pursuant to this subsection shall become effective until the handlers of not less than 80 per centum of the volume of such commodity or product thereof covered by such order have signed such a marketing agreement: Provided, That no order issued pursuant to this subsection shall

be effective unless the Secretary of Agriculture determines that the issuance of such order is approved or favored:

- (A) By at least two-thirds of the producers who (except that as to citrus fruits produced in any area producing what is known as California citrus fruits said order must be approved or favored by three-fourths of the producers), during a representative period determined by the Secretary, have been engaged, within the production area specified in such marketing agreement or order, in the production for market of the commodity specified therein, or who, during such representative period, have been engaged in the production of such commodity for sale in the marketing area specified in such marketing agreement, or order, or
- (B) By producers who, during such representative period, have produced for market at least two-thirds of the volume of such commodity produced for market within the production area specified in such marketing agreement or order, or who, during such representative period, have produced at least two-thirds of the volume of such commodity sold within the marketing area specified in such marketing agreement or order.

(9) Orders with or without marketing agreement

Any order issued pursuant to this section shall become effective in the event that, notwithstanding the refusal or failure of handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping the commodity or product thereof covered by such order) of more than 50 per centum of the volume of the commodity or product thereof (except that as to citrus fruits produced in any area producing what is known as California citrus fruits said per centum shall be 80 per centum) covered by such order which is produced or marketed within the production or marketing area defined in such order to sign a marketing agreement relating to such commodity or product thereof, on which a hearing has been held, the Secretary of Agriculture determines:

(A) That the refusal or failure to sign a marketing agreement (upon which a hearing has been held) by the handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping the commodity or product thereof covered by such order) of more than 50 per centum of the volume of the commodity or product thereof (except that as to citrus fruits produced in any area producing what is known as California citrus fruits said per centum shall be 80 per centum) specified therein which is produced or marketed within the production or marketing area specified therein tends to

prevent the effectuation of the declared policy of this chapter with respect to such commodity or product, and

- (B) That the issuance of such order is the only practical means of advancing the interests of the producers of such commodity pursuant to the declared policy, and is approved or favored:
 - (i) By at least two-thirds of the producers (except that as to citrus fruits produced in any area producing what is known as California citrus fruits said order must be approved or favored by three-fourths of the producers) who, during a representative period determined by the Secretary, have been engaged, within the production area specified in such marketing agreement or order, in the production for market of the commodity specified therein, or who, during such representative period, have been engaged in the production of such commodity for sale in the marketing area specified in such marketing agreement, or order, or
 - (ii) By producers who, during such representative period, have produced for market at least two-thirds of the volume of such commodity produced for market within the production area specified in such marketing agreement or order, or who, during such representative period, have produced at least two-thirds of the volume of such commodity sold within the marketing area specified in such marketing agreement or order.

(10) Manner of regulation and applicability

No order shall be issued under this section unless it regulates the handling of the commodity or product covered thereby in the same manner as, and is made applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held. No order shall be issued under this chapter prohibiting, regulating, or restricting the advertising of any commodity or product covered thereby, nor shall any marketing agreement contain any provision prohibiting, regulating, or restricting the advertising of any commodity, or product covered by such marketing agreement.

* * *

(13) Retailer and producer exemption

- (A) No order issued under subsection (9) of this section shall be applicable to any person who sells agricultural commodities or products thereof at retail in his capacity as such retailer, except to a retailer in his capacity as a retailer of milk and its products.
- (B) No order issued under this chapter shall be applicable to any producer in his capacity as a producer.

* * *

(16) Termination of orders and marketing agreements

- (A)(i) Except as provided in clause (ii), the Secretary of Agriculture shall, whenever he finds that any order issued under this section, or any provision thereof, obstructs or does not tend to effectuate the declared policy of this chapter, terminate or suspend the operation of such order or such provision thereof.
 - (ii) The Secretary may not terminate any order issued under this section for a commodity for which there is no Federal program established to support the price of such commodity unless the Secretary gives notice of, and a statement of the reasons relied upon by the Secretary for, the proposed termination of such order to the Committee on Agriculture, Nutrition, and Forestry of the Senate and the Committee on Agriculture of the House of Representatives not later than 60 days before the date such order will be terminated.
- (B) The Secretary shall terminate any marketing agreement entered into under section 608b of this title, or order issued under this section, at the end of the then current marketing period for such commodity, specified in such marketing agreement or order, whenever he finds that such termination is favored by a majority of the producers who, during a representative period determined by the Secretary, have been engaged in the production for market of the commodity specified in such marketing agreement or order, within the production area specified in such marketing agreement or order, or who, during such representative period, have been engaged in the production of such commodity for sale within the marketing area specified in such marketing agreement or order: Provided, That such majority have, during such representative period, produced for market more than 50 per centum of the volume of such commodity produced for market within the production area specified in such marketing agreement or order, or have, during such representative period, produced more than 50 per

centum of the volume of such commodity sold in the marketing area specified in such marketing agreement or order, but such termination shall be effective only if announced on or before such date (prior to the end of the then current marketing period) as may be specified in such marketing agreement or order.

- (C) Except as otherwise provided in this subsection with respect to the termination of an order issued under this section, the termination or suspension of any order or amendment thereto or provision thereof, shall not be considered an order within the meaning of this section.
- (17) Provisions applicable to amendments
 - (A) Applicability to amendments

The provisions of this section and section 608d of this title applicable to orders shall be applicable to amendments to orders.

* * *

EXCERPTS OF CALIFORNIA ALMOND MARKETING ORDER

7 C.F.R. § 981.8 Inedible kernel.

Inedible kernel means a kernel, piece, or particle of almond kernel with any defect scored as serious damage, or damage due to mold, gum, shrivel, or brown spot, as defined in the United States Standards for Shelled Almonds, or which has embedded dirt not easily removed by washing. This definition may be modified by the Board with the approval of the Secretary: Provided, That the Board shall submit any recommendation for modification to the Secretary not later than August 1.

7 C.F.R. § **981.16** To Handle

To handle means to use almonds commercially of own production or to sell, consign, transport, ship (except as a common carrier of almonds owned by another) or in any other way to put almonds grown in the area of production into any channel of trade for human consumption worldwide, either within the area of production or by transfer from the area of production to points outside or by receipt as first receiver at any point of entry in the United States or Puerto Rico of almonds grown in the area of production, exported therefrom and submitted for reentry or which are reentered free of duty. However, sales or deliveries by a grower to handlers, hullers or other processors within the area of production shall not, in itself, be considered as handling by a grower.

7 C.F.R. § **981.42** Quality control.

(a) Incoming. Except as provided in this paragraph, each handler shall cause to be determined, through the inspection agency, and at handler expense, the percent of inedible kernels in each variety received by him and shall report the determination to the Board. The quantity of inedible kernels in each variety in excess of two percent of the kernel weight received, shall constitute a weight obligation to be accumulated in the course of processing and shall be delivered to the Board, or Board accepted crushers, feed manufacturers, or feeders. The Board, with the approval of the Secretary, may change this percentage for any crop year, may authorize additional outlets, may exempt bleaching stock from inedible kernel determination or obligation and may establish rules and regulations necessary and incidental to the administration of this provision, including the method of determining inedible kernel content and satisfaction of the disposition obligation. The Board for good cause may waive

portions of obligations for those handlers not generating inedible material from such sources as blanching or manufacturing.

(b) Outgoing. For any crop year the Board may establish, with the approval of the Secretary, such minimum quality and inspection requirements applicable to almonds to be handled or to be processed into manufactured products, as will contribute to orderly marketing or be in the public interest. In such crop year, no handler shall handle or process almonds into manufactured items or products unless they meet the applicable requirements as evidenced by certification acceptable to the Board. The Board may, with the approval of the Secretary, establish different outgoing quality requirements for different markets. The Board, with the approval of the Secretary, may establish rules and regulations necessary and incidental to the administration of this provision.

7 C.F.R. § 981.442 Quality Control

- (a) Incoming. Pursuant to § 981.42(a), the quantity of inedible kernels in each variety of almonds received by a handler, including almonds of his own production, shall be determined and disposed of in accordance with the provisions of this paragraph.
 - (1) Sampling. Each handler shall cause a representative sample of almonds to be drawn from each lot of any variety received. The sample shall be drawn before inedible kernels are removed from the lot, or the lot is processed or stored by the handler. For receipts at premises with mechanical sampling equipment and under contracts providing for payment by the handler to the producer for sound meat content, samples shall be drawn by the handler in a manner acceptable to the Board and the inspection agency. The inspection agency shall make periodic checks of the mechanical sampling procedures. For all other receipts, including but not limited to field examination and purchase receipts, accumulations purchased for cash at the handler's door or from an accumulator, or almonds of the handler's own production, sampling shall be conducted or monitored by the inspection agency in a manner acceptable to the Board. All samples shall be bagged and identified in a manner acceptable to the Board and the inspection agency.
 - (2) Variety. For the purpose of classifying receipts by variety to determine a handler's disposition obligation, "variety" shall mean that variety of almonds which constitutes at least 90 percent of the lot: Provided, That lots containing a combination of Butte and Padre varieties only, shall be classified as "Butte—Padre", regardless of the percentage of each variety in the lot. If no variety constitutes at least 90 percent of the almonds in a lot, the lot shall be classified as "mixed":

Provided further, That if the variety or varieties of almonds in a lot are not identified, the lot shall be classified as "mixed", regardless of the percentage of each variety in a lot.

- (3) Analysis of sample. Each sample shall be analyzed by or under the surveillance of the inspection agency to determine the kernel content and the proportion of inedible kernels in the sample. The inspection agency shall prepare a report for each handler showing, by variety, the total adjusted kernel weight received by handler, the inedible kernel weight and any other information as the Board may prescribe. The report shall cover the handler's daily receipt or the handler's total receipts during a period not exceeding one week, and shall be submitted by the inspection agency to the Board and the handler.
- (4) Disposition obligation.
 - (i) Beginning August 1, 2006, the weight of inedible kernels in excess of 0.50 percent of kernel weight reported to the Board of any variety received by a handler shall constitute that handler's disposition obligation. For any almonds sold inshell, the weight may be reported to the Board and the disposition obligation for that variety reduced proportionately.
 - (ii) If a sufficient sample is not available for any lot of almonds, the handler may establish and substantiate, to the satisfaction of the Board, the received weight, the edible and inedible kernel weights, and the adjusted kernel weight by providing sufficient information as the Board may prescribe. If the handler is only able to establish and substantiate the approximate received weight, an inedible disposition obligation of 10 percent of such received weight may be applied, upon agreement between the Board and the handler.
- (5) Meeting the disposition obligation. Each handler shall meet its disposition obligation by delivering packer pickouts, kernels rejected in blanching, pieces of kernels, meal accumulated in manufacturing, or other material, to crushers, feed manufacturers, feeders, or dealers in nut wastes on record with the Board as accepted users. Handlers shall notify the Board at least 72 hours prior to delivery: Provided, That the Board or its employees may lessen this notification time whenever it determines that the 72 hour requirement is impracticable. The Board may supervise deliveries at its option. In the case of a handler having an annual total obligation of less than 1,000 pounds, delivery may be to the Board in lieu of an accepted user, in which case the Board would certify the disposition lot and report the results to the USDA. For dispositions by handlers with mechanical sampling equipment, samples may be drawn by the handler in a manner acceptable

- (6) Inedible almonds unfit for processing. All lots received from growers as "inedible almonds unfit for processing," shall be exempt from the requirements of paragraphs (a)(1) and (3) of this section, but shall be disposed of in their entirety (other than as pickouts), as provided in paragraph (a)(5) of this section. Disposition of these lots shall not be credited toward the disposition obligation of paragraph (a)(4) of this section. If a grower sells or ships inedible almonds to a person other than a handler, the grower thereby becomes a handler and subject to all the requirements of this paragraph.
- (7) Accepted Users. An accepted user's eligibility shall be subject to the following criteria:
 - (i) Completion of an application with the Board for accepted user status;
 - (ii) Submission of a business data sheet to the Board; and
 - (iii) The accurate and prompt submission of ABC Form 8 Part B to the Board for each lot of almonds received, supported by a public weighmaster weight certificate issued at the request of the accepted user at the time of receipt.
 - (iv) The Board may deny or revoke accepted user status at any time if the applicant or accepted user fails to meet the terms and conditions of § 981.442, or if the applicant or accepted user fails to meet the terms and conditions set forth in the accepted user application (ABC Form 34).

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- (v) The eligibility of accepted users shall be reviewed annually by the Board. Handlers will not receive credit towards their disposition obligations pursuant to paragraph (a)(4) of this section for lots where the difference between the weight of the lot reported by the inspection agency on ABC Form 8 and the weight of the lot reported on the public weighmaster weight certificate exceeds 2.0 percent.
- (b) Outgoing. Pursuant to § 981.42(b), beginning September 1, 2007, and except as provided in § 981.13 and in paragraph (b)(6) of this section, handlers shall subject their almonds to a treatment process or processes prior to shipment to reduce potential Salmonella bacteria contamination in accordance with the provisions of this section.
 - (1) Treatment process. Treatment processes shall utilize technologies that have been determined to achieve in total a minimum 4-log reduction of Salmonella bacteria in almonds, pursuant to a letter of determination issued by the Food and Drug Administration (FDA), or acceptance by a scientific review panel as identified by the Board (Technical Expert Review Panel or "TERP"). Such panel shall be approved at least annually by the Board prior to the beginning of each crop year, or as needed during the crop year.
 - (2) On-site versus off-site treatment. Handlers shall subject almonds to a treatment process or processes prior to shipment either at their handling facility (on-site), or at an off-site treatment facility located within the production area. Transportation of almonds by a handler to an off-site treatment facility shall not be deemed a shipment.
 - (3) Validation by process authorities. Handlers shall only use, or transport their almonds to off-site treatment facilities that use treatment processes that have been validated by a Board-approved process authority. Treatment technology and equipment that have been modified to a point where operating parameters such as time, temperature, or volume change, shall be revalidated.
 - (i) Validation means that the treatment technology and equipment have been demonstrated to achieve in total a minimum 4-log reduction of Salmonella bacteria in almonds. Validation data prepared by a Board-approved process authority must be submitted to and accepted by the TERP for each piece of equipment used to treat almonds prior to its use under the program.

- (ii) A process authority is a person that has expert knowledge of appropriate processes for the treatment of almonds as defined in paragraph (b)(1) of this section, and meets the following criteria:
 - (A) Knowledge about the equipment used for the treatment process;
 - (B) Experience in conducting appropriate studies to determine the ability of the equipment to deliver the appropriate treatment (such as heat penetration or heat distribution); and
 - (C) Able to determine that sufficient data has been gathered to identify the critical factors needed to ensure the quality of the final product.
- (iii) Process authorities may be employees of the entity for which they are conducting validation. The Board shall provide process authorities specific protocols and parameters for treatment processes that are FDA determined or TERP accepted.
- (iv) Process authorities must submit an initial application to the Board on ABC Form No. 51, "Application for Process Authority for Almonds," and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, the applicant may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved applicants with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file.
- (v) The TERP may revoke any approval for cause. The TERP shall notify the process authority in writing of the reasons for revoking the approval. Should the process authority disagree with the TERP's decision, he/she may appeal the decision in writing to the Board, and ultimately to USDA. A process authority whose approval has been revoked must submit a new application to the TERP and await approval.
- (4) Compliance and verification. In accordance with the requirements of this paragraph, handlers shall utilize either an on-site verification program (traditional), or an audit-based verification program to ensure that their almonds have been subjected to a treatment process to reduce Salmonella bacteria prior to shipment. Each handler may decide which verification program would be the most cost-effective for his or her operation.

- (i) By May 31, each handler shall submit to the Board a Treatment Plan for the upcoming crop year. A Treatment Plan shall describe how a handler plans to treat his or her almonds, and must address specific parameters as outlined by the Board for the handler to ship almonds. Such plan shall be reviewed by the Board, in conjunction with the inspection agency, to ensure it is complete and can be verified, and be approved by the Board. Almonds sent by a handler for treatment to an off-site facility affiliated with another handler shall be subject to the approved Treatment Plan utilized at that facility. Handlers shall follow their own approved Treatment Plans for almonds sent to an off-site facility that is not affiliated with another handler.
- (ii) Handlers utilizing an on-site verification program shall cause the inspection agency to verify that their Treatment Plans have been followed, and that their almonds have been subjected to a treatment process that has been validated by a Board-approved process authority. Such handlers shall submit, or cause to be submitted, a verification report to the Board. The inspection agency must physically observe the treatment process to issue such report.
- (iii) Handlers utilizing an audit-based verification program shall be subject to periodic audits conducted by the inspection agency. The inspection agency shall provide copies of the audit report to the Board. Handlers who do not comply with an audit-based verification program shall be required to revert to an on-site verification program.
- (iv) Interhandler transfers of almonds may or may not be treated prior to transfer. Handlers receiving untreated almonds from another handler shall be responsible for treating the product. Handlers receiving treated almonds from another handler must have procedures outlined in their Treatment Plan addressing how the integrity of the treated almonds will be maintained. In all instances involving interhandler transfers, the receiving handler shall be responsible for ensuring that the almonds are treated prior to shipment and maintaining documentation to that effect.
- (v) An off-site treatment facility that does not handle almonds, pursuant to § 981.16, shall provide access to the inspection agency and Board staff for verification of treatment and review of treatment records. A treatment process at an off-site treatment facility that has been validated by a Board approved process authority is deemed to be approved by the Board for handler use. The Board may revoke any such approval for cause. The Board shall notify the off-site treatment facility of the reasons for revoking the approval. Should the off-site facility disagree with the Board's decision, it may appeal the decision in

writing to USDA. Handlers may treat their almonds only at off-site treatment facilities that have been deemed to be approved by the Board.

- (5) Records. Handlers shall maintain records and documentation that will be subject to audit by the Board for the purpose of verifying compliance with this section. Records must be maintained for two full years following the end of the crop year, and must identify lots from the point of treatment forward to the point of shipment by the handler. Lot identification shall also provide the ability to differentiate treated from untreated product. Off-site treatment facilities that do not handle almonds pursuant to § 981.16, shall maintain treatment records for 2 full years following the end of a crop year and make such records available to the Board.
- (6) Exemptions. Handlers may ship untreated almonds under the following conditions. For purposes of this section, container means a box, bin, bag, carton, or any other type of receptacle used in the packaging of bulk almonds.
 - (i) Handlers may ship untreated almonds for further processing directly to manufacturers located within the U.S., Canada or Mexico. This program shall be termed the Direct Verifiable (DV) program. Handlers may only ship untreated almonds to manufacturers who have submitted ABC Form No. 52, "Application for Direct Verifiable (DV) Program for Further Processing of Untreated Almonds," and have been approved by the TERP. Such almonds must be shipped directly to approved manufacturing locations, as specified on Form No. 52. Such manufacturers DV users must submit an initial Form No. 52 to the Board and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved applicants with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file. The TERP may revoke any approval for cause. The TERP shall notify the manufacturer in writing of the reasons for revoking the approval. Should the manufacturer disagree with the TERP's decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A manufacturer whose approval has been revoked must submit a new application to the TERP and await approval. The Board shall issue a DV User code to an approved manufacturer. Handlers must reference such code in all documentation accompanying the lot and identify each container of such almonds with the term "unpasteurized." Such lettering shall be on one outside principal display panel, at least $\frac{1}{2}$ inch in height, clear and legible. If a third party is involved in the transaction, the handler must provide sufficient

documentation to the Board to track the shipment from the handler's facility to the approved DV user. While a third party may be involved in such transactions, shipments to a third party and then to a manufacturing location are not permitted under the DV program. Approved DV Users shall:

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- (A) Subject such almonds to a treatment process or processes using technologies that achieve in total a minimum 4–log reduction of Salmonella bacteria as determined by the FDA, accepted by the TERP, or established by a process authority approved in accordance with and subject to the provisions and procedures of paragraph (b)(3) of this section. Establish means that the treatment process and protocol have been evaluated to ensure the technology's ability to deliver a lethal treatment for Salmonella bacteria in almonds to achieve a minimum 4–log reduction;
- (B) Identify the manufacturing locations where treatment will occur;
- (C) Have their treatment technology and equipment validated by a Board-approved process authority, and provide documentation with their DV application to verify that their treatment technology and equipment have been validated by a Board-approved process authority. Such documentation may include, but not be limited to, a letter from such process authority certifying the validation. Such documentation shall be sufficient to demonstrate that the treatment processes and equipment achieve a 4–log reduction in Salmonella bacteria. Treatment technology and equipment that have been modified to a point where operating parameters such as time, temperature, or volume change, shall be revalidated;
- (D) Have their technology and procedures verified by a Board-approved DV auditor to ensure they are being applied appropriately. A DV auditor may not be an employee of the manufacturer that he/she is auditing. DV auditors must submit a report to the Board after conducting each audit. DV auditors must submit an initial application to the Board on ABC Form No. 53, "Application for Direct Verifiable (DV) Program Auditors," and be approved by the TERP. Should the applicant disagree with the TERP's decision concerning approval, it may appeal the decision in writing to the Board, and ultimately to USDA. For subsequent crop years, approved DV auditors with no changes to their initial application must send the Board a letter, signed and dated, indicating that there are no changes to the application the Board has on file. The TERP may revoke any approval for cause. The TERP shall notify the DV auditor in writing of the reasons for revoking the approval. Should the DV auditor disagree with the TERP's

decision, it may appeal the decision in writing to the Board, and ultimately to USDA. A DV auditor whose approval has been revoked must submit a new application to the TERP and await approval;

- (E) Maintain all records regarding validation and verification of treatment methods, processing, and product traceability. Such records shall be retained for two years and shall be made available for review by the Board; and,
- (F) Ship any almonds which will not be treated to a handler, to another approved DV user, to locations outside the U.S., Canada, and Mexico (containers must remain identified with the term "unpasteurized"), as specified in § 981.442(b)(6)(i), or dispose of such almonds in non-edible channels.
- (ii) Handlers may ship untreated almonds directly or through a third party to locations outside the U.S., Canada, and Mexico, provided that each container of such almonds is identified with the term "unpasteurized." Such lettering shall be on one outside principal display panel, at least ½ inch in height, clear and legible. If a third party is involved in the transaction, the handler must provide sufficient documentation to the Board to track the shipment from the handler's facility to the importer in the foreign country.
- (7) Other restrictions. The provisions of this section do not supersede any restrictions or prohibitions regarding almonds grown in California under the Federal Food, Drug and Cosmetic Act, or any other applicable laws or regulations or the need to comply with applicable food and sanitary regulations of city, county, State or Federal agencies.