

O'Neill Institute

for National and Global Health Law

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MEMORANDUM

TO: The Produce Safety Project
DATE: June 8, 2009
RE: USDA Authority regarding produce safety

This memorandum reviews the U.S. Department of Agriculture's authority over produce safety. It provides an overview of the activities within the Agricultural Marketing Service (AMS) that may relate to the oversight of produce, in particular, produce safety.

In general, the U.S. Department of Agriculture (USDA) has no authority to enforce safety standards and take action to remove unsafe produce from the market; that authority rests with the U.S. Food and Drug Administration.¹ Numerous USDA agencies such as the Farm Service Agency (FSA), the Animal and Plant Health Inspection Service (APHIS),² and the Agricultural Marketing Service (AMS), operate as service providers for the agricultural sector (e.g., responding to farmers' financial, marketing, and trade issues, and protection of plant and animal health), rather than as bodies that enforce safety requirements. Because of their association with agriculture, these agencies do administer programs that pertain to fresh produce. This memorandum will focus on AMS, which is the agency that works most directly with fresh produce.

Agricultural Marketing Service

AMS is charged with "facilitat[ing] the competitive and efficient marketing of agricultural products."³ It does so by overseeing "commodity programs."⁴ These programs provide standardization, grading, and market news services for regulated commodities. AMS enforces

¹ See 21 U.S.C. §§ 331(b), 342.

² For example, APHIS, whose mission is to "protect the health and value of U.S. agricultural, natural and other resources," regulates genetically engineered organisms, administers the Animal Welfare Act, and carries out wildlife damage management activities. APHIS also issues permits for regulated plants and plant product imports to the U.S. (or transit through the U.S.) for consumption or propagation. In October 2008, the agency's fruits and vegetables import requirement (FAVIR) database, went online. This database is meant to serve as a public resource for customers to search for authorized fruits and vegetables, by commodity or country, and quickly determine the general requirements for their importation into the United States. APHIS, "Fruits and Vegetables Import Requirements (FAVIR) Database," <http://www.aphis.usda.gov/favir/info.shtml>; Fruits and Vegetables Import Requirements (FAVIR) Database, available at <https://epermits.aphis.usda.gov/manual/index.cfm?CFID=1127826&CFTOKEN=f1abbdacafd3d370-555AE16F-0FF3-BBD0-79EDB0EB3919DE06&ACTION=pubHome>.

³AMS, "About AMS,"

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AMSMissionStatement&rightNav1=AMSMissionStatement&topNav=AboutAMS&leftNav=&page=AboutAMSMissionStatement&resultType=&acct=AMSPW>.

⁴ AMS oversees five commodity programs: cotton, dairy, fruit and vegetable, livestock and seed, poultry and tobacco.

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=CommodityAreas&leftNav=CommodityAreas&page=CommodityAreas&acct=AMSPW>.

the Perishable Agricultural Commodities Act and the Federal Seed Act.⁵ AMS commodity programs oversee marketing agreements and orders, administer research and promotion programs, and purchase commodities for federal food programs.⁶

➤ **Marketing Agreements/Orders**

Under the Agricultural Marketing Agreement Act (AMAA),⁷ AMS has two regulatory mechanisms that can be used to develop guidelines for the food industry: marketing agreement and orders. These are legal instruments issued by the Secretary of Agriculture that “are designed to stabilize market conditions for certain agricultural commodities by regulating the handling of those commodities in interstate or foreign commerce.”⁸ As such, both instruments can impose a wide range of requirements on to growers, handlers, or processors.

The distinction between the two mechanisms is that marketing orders are binding on all “handlers” (i.e., “processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof”)⁹ of the regulated commodity in the geographic area covered by the order, while marketing agreements are binding only on those handlers who are voluntary signatories of the agreement.¹⁰ Additionally, the two instruments are independent of one another--a marketing agreement does not need to be issued for a marketing order to take effect.¹¹

Since marketing orders are mandatory for the growers of the food commodity they produce, they must be approved prior to implementation by a referendum with at least a two-thirds majority in support. The orders may include the authority to regulate the grade, size, quality, packaging, inspection, and/or volume handled of certain agricultural commodities.¹²

By contrast, marketing agreements may be entered into by growers, handlers, processors, or others engaged in the handling of any agricultural commodity or its product.¹³ The details of the agreement are developed after a formal notice and comment period through AMS. Agreements can impose the same requirements on handlers as orders; the distinction is in their voluntary nature. Signatories voluntarily agree to participate in the programs established by the agreements; however, once they agree to participate, the requirements of the agreement become binding.

Violation of both of these mechanisms may result in enforcement actions filed in U.S. District courts.¹⁴ Moreover, violations may results in a suspension of program privileges, such as use

⁵AMS, “About AMS,”

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AMSMissionStatement&rightNav1=AMSMissionStatement&topNav=AboutAMS&leftNav=&page=AboutAMSMissionStatement&resultType=&acct=AMSPW>.

⁶Id.

⁷ Agricultural Marketing Agreement Act, 7 U.S.C. § 608b-c (2000).

⁸ National Agricultural Law Center, “Federal Marketing Orders and Agreements: An Overview” <http://www.nationalaglawcenter.org/assets/overviews/marketingorders.html>.

⁹ The statute reads, 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 Such persons are referred to in this title as ‘handlers.’” 7 U.S.C. § 608c(1).

¹⁰ National Agricultural Law Center, “Federal Marketing Orders and Agreements: An Overview” <http://www.nationalaglawcenter.org/assets/overviews/marketingorders.html>.

¹¹ National Agricultural Law Center, “Federal Marketing Orders and Agreements: An Overview” <http://www.nationalaglawcenter.org/assets/overviews/marketingorders.html>.

¹² 7 U.S.C. § 608c.

¹³ 7 U.S.C. § 608b.

¹⁴ 7 U.S.C. § 608a.

of the program's certification mark. Under the Perishable Agricultural Commodities Act, AMS is authorized to investigate and prosecute alleged infractions related to misbranding or mislabeling of commodity containers, which would include misuse of a certification mark developed under the agreement.¹⁵

Currently, AMS oversees orders for 22 produce commodities.¹⁶ The question at issue is whether these agreements and orders serve to "regulate" food safety – i.e. whether AMS can take action to remove "adulterated" (unsafe) commodities from the market. The language of the AMAA is clear that these programs are meant to be tools to "stabilize market conditions."¹⁷ However, in at least two existing marketing orders, safety issues are addressed because they can impact negatively on market conditions. Additionally, there is a pending proceeding regarding leafy greens that may deal with safety concerns.

- **Marketing Order 981: California Almonds**

The marketing order that regulates almonds grown in California addresses both safety and quality issues. The marketing order that governs almonds grown in California was promulgated on August 4, 1950.¹⁸ The order must be renewed every five years; the most recent referenda opened on April 24, 2009.¹⁹ The order is administered by the Almond Board of California under AMS's supervision,²⁰ which regularly proposes revisions to the existing guidelines.

One revision, promulgated in 2007, does address an issue related to food safety: it mandates the pasteurization of some almonds to reduce the potential for *Salmonella* bacteria.²¹

Eighteen comments were submitted on the proposed rule.²² Most took issue with the administrative aspects of the rule such as manufacturing processes and frequency of audits.²³ Some were concerned that the rule would have a disproportionate burden on small producers. None of the comments raised the questions of whether AMS had the authority to regulate food safety.

- **Marketing Order 983: California Pistachios**

¹⁵ 72 Fed. Reg. 56678 (October 4, 2007).

¹⁶ These are: almonds, apricots, avocados, cherries [sweet and tart], citrus [Florida and Texas], cranberries, dates, grapes, hazelnuts, kiwifruit, nectarines, olives, onions [Idaho-E. Oregon, S. Texas, Vidalia, and Walla Walla], peaches, pears [Oregon-Washington], pistachios, plums/Prunes [California and Washington], potatoes [Idaho-E. Oregon, Washington, Oregon-California, Colorado, and Virginia-North Carolina], raisins, spearmint oil, tomatoes, and walnuts. AMS, Industry Marketing and Promotion, "Marketing Order Commodity Index," <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=LinktoCurrentFruitandVegetableMarketingOrders&rightNav1=LinktoCurrentFruitandVegetableMarketingOrders&topNav=&leftNav=&page=FVMarketingOrderIndex&resultType=&acct=fvmktord>.

¹⁷ Agricultural Marketing Agreement Act, 7 U.S.C. § 608b-c (2000).

¹⁸ AMS, Industry Marketing and Promotion, "Marketing Order 981: California Almonds," at <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=FVMarketingOrderIndexAlmonds>.

¹⁹ 74 Fed. Reg. 7830 (February 20, 2009).

²⁰ Almond Board of California, What We Do, available at <http://www.almondboard.com/About/content.cfm?ItemNumber=544&snItemNumber=467>.

²¹ 72 Fed. Reg. 15034, 15036 (March 20, 2007); codified at 7 C.F.R. 981.442.

²² 71 Fed. Reg. 70683.

²³ 72 Fed. Reg. 15029, 15033.

Similarly, the marketing order that regulates pistachios grown in California also addresses both safety and quality issues. In addition to addressing the grade, quality, size, and reporting requirements of in-shell and shelled pistachios, the order requires testing for aflatoxin,²⁴ one of a group of mycotoxins produced by the molds *Aspergillus flavus* and *Aspergillus parasiticus*, which can be spread in improperly processed and stored nuts, dried fruits and grains.²⁵ The marketing order explicitly sets a maximum acceptable level of aflatoxin in any given pistachio shipment.²⁶

As was the case with almonds, the comments submitted on the proposed pistachio marketing order did not challenge AMS's authority to set requirements for aflatoxin.

- **Recent Proposal for a "Handling Regulations for Leafy Greens Under the Agricultural Marketing Agreement Act of 1937"**

There are currently two Leafy Green Products Handler Marketing Agreements (LGMA) in effect, one in California and another in Arizona. California implemented the statewide marketing agreement in 2007 after the *E.coli* O157:H7 outbreak linked to contaminated spinach.²⁷ Signatories to the state agreement certify that the production, handling, shipment, and sale of leafy green products they handle are compliant with commodity specific food safety guidelines adopted as best practices under the agreement.²⁸ The best practices and its guidelines are designed to minimize the risk of pathogenic contamination. Compliance with the best practices is verified by agricultural inspection agencies under contract with the administrative Board established under the agreement.²⁹

In October 2007, AMS released an advanced notice of proposed rulemaking (ANPR) on "Handling Regulations for Leafy Greens Under the Agricultural Marketing Agreement Act of 1937." The ANPR proposed to establish a voluntary, national marketing program to address the handling of fresh and fresh-cut leafy green vegetables, similar to the state marketing agreement in California.³⁰ AMS was careful to note in the ANPR that the authorities and regulations under this rule would not supplant those of FDA.³¹

Under the proposed rule, growers may voluntarily enter into the agreement, but once entered, signatories would be required to comply with the agreement's regulations. The agreement would specify "Best Practices" for minimizing the risk of pathogenic contamination of leafy

²⁴ AMS, Industry Marketing and Promotion, "Marketing Order 983: California Pistachios," at <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=FVMarketinOrderIndexPistachio>.

²⁵ 7 C.F.R. § 983.4.

²⁶ 7 C.F.R. § 983.38(a). On May 5, 2009, AMS submitted a recommended decision to the marketing order that would allow general authority for aflatoxin regulations in the order language, and provide authority to issue rules and regulations through the informal rulemaking process to implement specific regulations and procedures. Currently, the order provides authority for regulation of aflatoxin levels in pistachios, and specific regulatory requirements such as sampling, testing, and certification are also included. The order provisions allow for modification of the regulatory requirements by issuing rules and regulations through the informal rulemaking process. Essentially, this would allow the order more discretion to revise aflatoxin regulations. Exceptions to the proposed revisions must have been received by June 4, 2009.

²⁷ See "FDA Warning on Serious Foodborne E. coli O157:H7 Outbreak" FDA News (September 14, 2006) <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html>; see also LGMA, About LGMA, available at <http://www.caleafygreens.ca.gov/about/lgma.asp>.

²⁸ See "LGMA accepted Food Safety Practices" and "Audit Information" under LGMA, Resources, available at <http://www.caleafygreens.ca.gov/members/resources.asp>.

²⁹ Id.

³⁰ 72 Fed. Reg. 56678, 56680 (October 4, 2007).

³¹ 72 Fed. Reg. 56678.

greens. These Best Practices would be aligned with principles developed in cooperation with the industry, those within FDA's non-binding *Guide to Minimize Microbial Food Safety Hazards in Fresh Fruits and Vegetables*, and other FDA-issued guidance.³²

Once AMS verifies compliance, through verification audits, members would obtain a distinguishing mark for their leafy green products.³³ Although not described in detail, the audits would probably be similar to those described above (e.g., checklists and score sheets). Federal (or federal-state) inspection programs would conduct verification audits to ensure that handlers are in compliance. Violation of requirements may disqualify a non-compliant handler from using the distinctive mark for a pre-determined period of time.

Comments to the ANPR are available online.³⁴ Although some federal agencies submitted comments, interestingly, FDA apparently did not.³⁵ Comments from federal and state agencies, and concerned consumers organizations did not address the issue of whether AMS was within its legislative authority to promulgate such a regulation.³⁶ The pertinent question for many of the respondents was not whether AMS has the legal authority to regulate produce safety in this manner, but whether it should.

Primarily, the issue was raised whether a marketing agreement is an appropriate mechanism for produce safety regulation. The Consumers Union argued that marketing agreements (and orders) "were designed to establish and maintain orderly marketing conditions for regulated commodities, not to ensure the safety of those commodities."³⁷ The Center for Science in the Public Interest (CSPI) noted that AMS's proposed marketing agreement may circumvent FDA's authority to legitimately regulate produce safety.³⁸

Additionally, the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Commerce (through the National Marine Fisheries Services) wrote of their concerns about environmental degradation as a result of the order. Both comments noted that in the aftermath of the California agreement, individual buyers and handlers (e.g., chain grocery stores and fast food chains) exceeded the requirements of the agreement. EPA commented "that many of these practices are not scientifically based, and have unintended consequences to the environment."³⁹

³² FDA, "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," available at <http://www.cfsan.fda.gov/~dms/prodqui4.html#ch10> (February 2008).

³³ 72 Fed. Reg. 56679.

³⁴ Comments are available at <http://www.regulations.gov> – Docket # FV07-962-1.

³⁵ Comments were submitted by the National Ocean Service of the U.S. Department of Commerce and the U.S. Environmental Protection Agency. The Massachusetts's Department of Agricultural Resources also submitted a comment.

³⁶ Although this is speculation, the respondents may not have raised jurisdictional questions because AMS was explicit in the ANPR that the authorities and regulations under this rule would not supplant those of FDA. Additionally, perhaps relevant parties were waiting for a proposed rule before raising such questions.

³⁷ ConsumersUnion.org, "Comments of Consumers Union," available at http://www.consumersunion.org/pub/core_food_safety/005238.html.

³⁸ Sarah Klein, Food Safety Staff Attorney, CSPI, "Re: Comments on Handling Regulations for Leafy Greens Under the Agricultural Marketing Agreement Act of 1937 (Docket No. AMS-FV-07-0090; FV07-962-1 AN)" (December 3, 2007).

³⁹ Alexis Strauss, Director, Water Division, U.S. Environmental Protection Agency, "RE: Handling Regulations for Leafy Greens Under the Agricultural Marketing Agreement Act of 1937 [Docket No. AMS-FV-0090; FV07-962-1 AN]" (November 29, 2007).

Currently, AMS does not plan to move on the ANPR until they receive an official submission (proposed agreement) from the industry.⁴⁰ The Western Growers Association in California is working closely with AMS to draft an agreement.⁴¹

➤ **Fresh Produce Audit Verification Program**

In addition to the marketing orders and agreements discussed above, AMS also offers on a fee-for-service basis a "Fresh Produce Audit Verification Program."⁴²

It is common for the retail and food service industry to use third-party auditors to verify that their suppliers are in conformance to specific agricultural best practices. AMS has offered such services to the produce industry since 1999. AMS, in partnership with state departments of agriculture, offers a voluntary, audit based program that verifies adherence to the recommendations made in the Food and Drug Administration's (FDA) *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.⁴³ In this capacity, AMS also provides examples of checklists and score sheets for both USDA and the client. As noted, participation in the audit program is voluntary, and is a fee-based service. Fees are based on the time required to conduct the audit, the volume of commodity inspected, and the travel expenses of the auditor.⁴⁴

In this program, AMS offers inspections at two "points": 1) a Shipping Point Inspection (SPI), and 2) a Terminal Market Inspection (MKT). Inspections are conducted by an approved local fresh fruit and vegetable inspection office.⁴⁵ The program serves as a quality-assurance check for suppliers, not a formal check on food safety.⁴⁶ The audit does not require sampling for

⁴⁰ Call with Antoinette Carter, AMS Marketing Specialist (April 20, 2009).

⁴¹ Contact person at Western Growers is Hank Giclas, (949) 863-1000.

⁴² AMS, Grading, Certification, and Verification, "Fresh Produce Audit Verification Program," <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=GAPGHPAuditVerificationProgram>.

⁴³ Id.

⁴⁴ AMS, Grading, Certification, and Verification, "Fresh Products Inspections - Destination Market Inspection Fees,"

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=InspectionFees&rightNav1=InspectionFees&topNav=&leftNav=&page=FreshFVGradingFees&resultType=&acct=freshgrdcert>.

⁴⁵ AMS, Grading, Certification, and Verification, "Address List of Fresh Fruit and Vegetable Inspection Offices,"

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=RequestanInspection/ContactanOffice&rightNav1=RequestanInspection/ContactanOffice&topNav=&leftNav=&page=Federal/StateGradingContacts&resultType=&acct=freshgrdcert>. There are seven parts to the audit: 1)

Farm Review; 2) Field Harvest and Packing Activities; 3) House Packing Facility; 4) Storage and Transportation; 5) Traceback; 6) Wholesale Distribution Center/Terminal Warehouses (6a – Traceback for Wholesale Distribution Center/Terminal Warehouses); and 7) Preventative Food Security Procedures. *Id.* Each section includes a list of questions, and each question has a maximum number of points receivable. To receive a passing score on any given section, a producer must receive at least 80% of the total points receivable. For example, Part 1 of the audit has 165 total possible points; to pass, a supplier must receive at least 132 points.

⁴⁶ The distinction between food safety and food quality is more clearly explained in the joint U.N. FAO/WHO report, "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems" (2003), available at <http://www.fao.org/docrep/006/Y8705E/Y8705E00.HTM>. "Food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. It is not negotiable. Quality includes all other attributes that influence a product's value to the consumer. This includes negative attributes such as spoilage, contamination with filth, discoloration, off odours and positive attributes such as the origin, colour, flavour, texture and processing method of the food. This distinction between safety and quality has implications for public policy and influences the

common contaminants, and asks only broad questions that are related to safety. For example, for the question “[pr]ior to loading, conveyances are required to be clean,” a response of “yes” is worth 10 points.⁴⁷

Conclusion

FDA, not AMS, has the legal authority to regulate produce safety. In recent testimony before Congress, the Acting AMS Administrator reiterated this fact, stating that “FDA is the federal agency with primary responsibility for the food safety of fruits and vegetables. . . . AMS is not a food safety agency.”⁴⁸ He went on to explain that AMS marketing orders and agreements do occasionally address safety-related issues because “[t]he presence or absence of harmful pathogens, toxins, or other contaminants is considered a quality characteristic.”⁴⁹ Regarding the proposed National Marketing Agreement for Leafy Greens, the Acting Administrator emphasized that any under such an agreement “would be consistent with FDA guidance and regulations requirements” and that “[a]ny product deemed an immediate threat to public health by USDA inspection would be reported by USDA to FDA.”⁵⁰

nature and content of the food control system most suited to meet predetermined national objectives.”
Id. at 3.

⁴⁷ AMS, Grading, Certification, and Verification, Question 6-44, “USDA Good Agricultural Practices & Good Handling Practices Audit Verification Checklist” at 22,
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5050869>.

⁴⁸ David R. Shipman, Acting Administrator, Agriculture Marketing Service, USDA, testifying before the House Committee on Agriculture, Subcommittee on Horticulture and Organic Agriculture, 111th Cong. 1st sess., May 14, 2009, p. 1, <http://agriculture.house.gov/testimony/111/h051409/Shipman.pdf>.

⁴⁹ Id. at 8.

⁵⁰ Id. at 11.