

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 970**

[Doc. No. AO-FV-09-0138; AMS-FV-09-0029; FV09-970-1]

Proposed National Marketing Agreement Regulating Leafy Green Vegetables; Recommended Decision and Opportunity To File Written Exceptions to Proposed Marketing Agreement No. 970

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and opportunity to file exceptions.

SUMMARY: This recommended decision proposes the issuance of a marketing agreement (agreement) under the Agricultural Marketing Agreement Act of 1937 to cover the handling of fresh leafy green vegetables in the United States. Leafy green vegetables include lettuce, spinach, cabbage, and similar items. The proposed agreement would authorize the development and implementation of production and handling regulations (audit metrics) to reflect United States Food and Drug Administration (FDA) Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), and United States Department of Agriculture (USDA) Good Handling Practices (GHPs). The program would be voluntary, and cover both United States and imported leafy green vegetables. Signatory handlers would agree to only handle leafy green vegetables that meet the requirements of the program. The program would be financed primarily by assessments collected from signatory first handlers. A Board, whose members would be appointed by the Secretary, would administer the proposed agreement with USDA oversight. This rule also announces USDA Agricultural Marketing Service's (AMS) intention to request approval by the Office of Management and Budget for new information collection requirements to implement this program.

DATES: Written exceptions must be filed by July 28, 2011. Pursuant to the Paperwork Reduction Act, comments on the information collection burden must be received by July 28, 2011.

ADDRESSES: Written exceptions should be filed with the Hearing Clerk, United States Department of Agriculture, 1400 Independence Ave., SW., Room 1031-S, Washington, DC 20250-9200, Fax: (202) 720-9776 or via the Internet at <http://www.regulations.gov>. All exceptions should reference the docket number and

the date and page number of this issue of the **Federal Register**. Comments will be made available for public inspection in the Office of the Hearing Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>.

To the extent practicable, all documents filed with the hearing clerk also should be submitted electronically to Melissa Schmaedick at the e-mail address noted for her in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail:

Antoinette.Carter@ams.usda.gov; or Melissa Schmaedick, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 805 SW. Broadway, Suite 930, Portland, OR 97205; Telephone (503) 326-2724, Fax (503) 326-7440, or E-mail: Melissa.Schmaedick@ams.usda.gov.

Small businesses may request information on this proceeding by contacting Antoinette Carter at the address provided for her above.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Public Hearing issued on August 31, 2009, and published in the September 3, 2009, issue of the **Federal Register** (74 FR 45565); and Notice of Additional Time for Public Hearing issued on September 18, 2009, and published in the September 23, 2009, issue of the **Federal Register** (74 FR 48423).

These actions are governed by the provisions of sections 556 and 557 of title 5 of the United States Code and are therefore excluded from the requirements of Executive Order 12866.

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to the proposed marketing agreement regulating the handling of leafy green vegetables in the United States, and the opportunity to file written exceptions thereto. Copies of this recommended decision can be obtained from Melissa Schmaedick, whose address is listed above.

This recommended decision is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (48 Stat. 31, as amended; 7 U.S.C. 601-674), hereinafter referred to as the "Act", and the applicable rules of practice and procedure governing the formulation of

marketing agreements and orders (7 CFR part 900).

The proposed agreement is based on the record of a public hearing held on: September 22 through 24, 2009, in Monterey, California; September 30 through October 1, 2009, in Jacksonville, Florida; October 6, 2009, in Columbus, Ohio; October 8, 2009, in Denver, Colorado; October 14 and 15, 2009, in Yuma, Arizona; October 20, 2009, in Syracuse, New York; and October 22, 2009, in Charlotte, North Carolina.

The hearing was held to receive evidence on the proposed agreement from producers, handlers, and other interested parties. The Notice of Public Hearing was published in the **Federal Register** on September 3, 2009 (74 FR 45565).

Background

In mid-September 2006, FDA issued the first public alerts of a multi-State *Escherichia coli* (E. coli) outbreak linked to fresh spinach grown in California's Salinas Valley. The resulting recall was the largest ever for fresh leafy green vegetables. Investigations by FDA and the California Department of Health Services, in cooperation with the Centers for Disease Control and Prevention, and USDA's Animal and Plant Health Inspection Service, concluded that the E. coli contamination might have been attributed to environmental factors in the production area.

In response to this E. coli outbreak, members of the California leafy green vegetable industry initiated the establishment of a State marketing agreement for handlers of leafy green vegetables. The California Leafy Green Products Handler Marketing Agreement became effective February 10, 2007. At the time of the hearing, 99 percent of leafy green vegetables produced and handled in California were subject to the State program. In October 2007, a similar program was implemented in Arizona: The Arizona Leafy Green Products Shipper Marketing Agreement. Approximately 75 percent of the leafy green vegetables produced and handled in Arizona were being regulated under that State's program at the time of the hearing. While both the California and Arizona programs are voluntary, the requirements of these State marketing agreements are mandatory for all signatories within each respective State.

On October 4, 2007, AMS published an Advance Notice of Proposed Rulemaking (ANPR) in the **Federal Register** (72 FR 56678) in response to industry interest in the establishment of a national marketing program to address

the handling of leafy green vegetables nationwide. The ANPR explored the concept of establishing a regulatory program to reduce microbial contamination and improve product quality of leafy green vegetables available in the United States' produce market. Proposals and comments were sought from the public, particularly from producers, handlers, buyers, and sellers of leafy green vegetables.

The ANPR resulted in the submission and consideration of more than 3,500 public comments on the need and level of support for a nationwide regulatory program for GAPs, GHPs, and GMPs. These comments may be viewed at <http://www.regulations.gov> and by typing the following docket number into the search function: AMS-FV-07-0090.

On June 10, 2009, a petition for rulemaking and a request for public hearing on a proposed national agreement for leafy green vegetables were submitted to AMS. The proposal was submitted by a group of producers, handlers, and interested persons representing a cross-section of the national fresh and fresh-cut produce industry, hereinafter referred to as the "proponents" or "proponent group". The proponent group is comprised of the membership of the following organizations: United Fresh Produce Association, Produce Marketing Association, Georgia Fresh Vegetable Association, Georgia Farm Bureau, Texas Vegetable Association, Arizona Farm Bureau, Leafy Greens Council, California Farm Bureau, California Leafy Greens Products Handler Marketing Agreement, Grower-Shipper Association of Central California, Western Growers, and the Imperial Valley Vegetable Growers Association. The proponents, whose membership includes both conventional and organic producers and handlers, as well as business entities of all sizes, claim to represent a majority of the volume of leafy green vegetables produced and handled for the United States market.

In their request and at the hearing, the proponents proposed the establishment of a program that would oversee a systematic application of good agricultural production, handling, and manufacturing practices for leafy green vegetables. Proponents stated that the proposed agreement would minimize the potential for microbial contamination in production and handling systems and would improve consumer confidence in leafy green vegetables in the United States market.

Proponents supported the establishment of a voluntary program that would require mandatory compliance for its signatories under the

authority of the Act and that it be administered by USDA. Proponents explained that, if implemented, an administrative body comprised of leafy green vegetable producers, handlers, and other representatives of the leafy green vegetable industry should be established to administer the program under USDA oversight. In addition to the administrative body, proponents proposed two committees: One to assist the administrative body in the identification and development of audit metrics, and one to advise the administrative body on research and development projects administered under the program.

Proponents defined the proposed production area as the 50 States of the United States of America and the District of Columbia. It was further proposed that the agreement be financed primarily by assessments collected from signatory first handlers on the volume of leafy green vegetables handled. In addition, contributions could be received for the purposes of funding research and development activities.

As a voluntary program, proponents explained that only signatory handlers to the proposed agreement would be regulated. Signatory handlers would be required to only handle leafy green vegetables that were produced and handled in adherence to specific requirements (audit metrics) established under the proposed agreement. Proponents stated that audit metrics should be science-based, scalable, and regionally applicable in order to accommodate compliance of varying size and types of operations. Moreover, any audit metrics proposed under the program would require approval of the USDA prior to implementation.

Proponents explained that audits should be conducted by the USDA Inspection Service, or persons or organizations authorized to audit on its behalf, to verify signatory handler compliance to the proposed agreement. If implemented, proponents stated that such audits should be conducted on both domestic and imported product handled by signatory handlers.

One hundred and twenty individuals testified during the 9 days of hearings which resulted in 4,935 pages of testimony. One hundred and thirty-nine exhibits were submitted. Witnesses represented leafy green producers and handlers, and representatives from stakeholder interest groups including State and local government representatives, certified organic auditors, organic and sustainable agriculture advocacy groups, consumer advocacy groups, conservation and wildlife advocacy organizations,

academia, and others. Some witnesses supported the proposed agreement, while others opposed it or suggested modifications or changes to it.

In addition to other opponents of the proposed agreement, an opponent group comprised of member organizations of the National Organic Coalition (NOC) testified at the hearing. Members of the NOC include: Beyond Pesticides, Center for Food Safety, Equal Exchange, Food and Water Watch, Maine Organic Farmers and Gardeners Association, Midwest Organic Farmers and Gardeners Association, National Cooperative Grocers Association, Northeast Organic Dairy Producers Alliance, Northeast Organic Farming Association-Interstate Council, Organically Grown Company, Rural Advancement Foundation International-USA, and the Union of Concerned Scientists.

Witnesses opposed to the program cited several areas of concern. These included: The cost of becoming compliant and maintaining compliance with the proposed agreement; the existing proliferation of audit requirements from private sector customers, the addition of a new and potentially conflicting set of audit requirements, and "audit fatigue"; the need for science-based production and handling requirements, as well as the need for adequate peer-review of scientific studies used to establish them; potential conflicts between existing Federal, State, and local conservation, wildlife, and environmental regulations and any proposed metrics; the need for recognition of organic and other non-conventional production and handling practices in the development of audit metrics; the appropriateness and authority for USDA oversight of the proposed agreement; and, the need for a national program.

At the conclusion of the hearing, the Administrative Law Judge fixed January 13, 2010, as the due date for interested persons to file proposed findings and conclusions or written arguments based on the evidence received at the hearing. Upon a motion for extension from the proponents as well as member organizations of the National Organic Coalition, the date was extended until January 27, 2010.

Sixteen briefs were filed in total. Those submitting briefs included: Pollinator Partnership, Global Organic Specialty Source, Inc., Chiquita Brands International, Inc., Arizona Leafy Green Products Shipper Marketing Agreement, Office of the Attorney General for the State of Arizona, Episcopal Diocese of California, DNO, Inc., Duda Farm Fresh Foods, Inc., National Organic Coalition

(including Food and Water Watch, Carolina Farm Stewardship Association, and Florida Certified Organic Growers and Consumers, Inc.), Canadian Horticultural Council, Partners for Sustainable Pollination, Association of Food and Drug Officials, Massachusetts Farm Bureau Federation, Inc., Grower's Management, Inc., Western Growers,

and California Roundtable on Agriculture and the Environment.

Overview

After extensive analysis and review of the hearing record, USDA has incorporated in this recommended decision changes and revisions to the text of the proposed marketing agreement. Changes and modifications

include numerical redesignations of sections, combining of regulatory text, the addition of new provisions, and clarifications. For ease of reference in reading this recommended decision, the following table provides a summary that identifies the differences between the sections proposed in the Notice of Hearing and the sections proposed in this recommended decision.

Notice of hearing	Changes and revisions	Recommended decision
970.1	NEW	970.1
970.2	REDESIGNATED AND REVISED	970.2
970.3	REDESIGNATED AND REVISED	970.4
970.4	NEW	970.5
970.6	REDESIGNATED AND REVISED	970.6
970.7	REDESIGNATED AND REVISED	970.8
970.8	NEW	970.9
970.9	REDESIGNATED AND REVISED	970.10
970.10	REDESIGNATED AND REVISED	970.11
970.11	REDESIGNATED AND REVISED	970.12
970.12	REDESIGNATED AND REVISED	970.13
970.13	REDESIGNATED AND REVISED	970.14
970.14	REDESIGNATED AND REVISED	970.15
970.15	REDESIGNATED AND REVISED	970.16
970.16	REDESIGNATED AND REVISED	970.17
970.17	REDESIGNATED AND REVISED	970.18
970.18	NEW	970.19
970.19	NEW	970.20
970.20	REDESIGNATED AND REVISED	970.21
970.21	NEW	970.22
970.22	REDESIGNATED	970.23
970.23	REDESIGNATED AND REVISED	970.24
970.24	NEW	970.25
970.25	REDESIGNATED AND REVISED	970.27
970.26	REDESIGNATED AND REVISED	970.29
970.27	REDESIGNATED AND REVISED	970.30
970.28	NEW	970.31
970.35	REDESIGNATED AND REVISED	970.32
970.40	REDESIGNATED AND REVISED	970.33
970.41	REDESIGNATED AND REVISED	970.34
970.42	REDESIGNATED AND REVISED	970.35
970.43	REDESIGNATED AND REVISED	970.36
970.44	REDESIGNATED AND REVISED	970.37
970.45	REDESIGNATED AND REVISED	970.39
970.46	REDESIGNATED AND REVISED	970.40
970.47	REDESIGNATED AND REVISED	970.41
970.48	REDESIGNATED AND REVISED	970.42
970.49	REDESIGNATED AND REVISED	970.43
970.50	REDESIGNATED AND REVISED	970.44
970.55	REDESIGNATED AND REVISED	970.45
970.56	REDESIGNATED AND REVISED	970.46
970.57	REDESIGNATED AND REVISED	970.47
970.58	REDESIGNATED AND REVISED	970.48
970.65	REDESIGNATED AND REVISED	970.49
970.66	REDESIGNATED AND REVISED	970.50
970.67	REDESIGNATED AND REVISED	970.51
970.68	REDESIGNATED AND REVISED	970.55
970.69	REDESIGNATED AND REVISED	970.56
970.70	REDESIGNATED AND REVISED	970.57
970.71	REDESIGNATED AND REVISED	970.58
	REDESIGNATED AND REVISED	970.65
	REDESIGNATED AND REVISED	970.66
	REDESIGNATED AND REVISED	970.67
	REDESIGNATED AND REVISED	970.68
	REDESIGNATED AND REVISED	970.69
	REDESIGNATED AND REVISED	970.70
	REDESIGNATED AND REVISED	970.71

Notice of hearing	Changes and revisions	Recommended decision
970.72	REVISED	970.72
970.75	REVISED	970.75
970.80	REVISED	970.80
970.81	REVISED	970.81
970.82	REVISED	970.82
970.83	REVISED	970.83
970.85	REVISED	970.85
970.86	REVISED	970.86
970.87	REVISED	970.87
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970.89	REVISED	970.89
970.90		970.90
970.91	REVISED	970.91
970.92		970.92
970.93	REVISED	970.93
970.94		970.94
970.95	REVISED	970.95
970.96	REVISED	970.96
970.97	REVISED	970.97
970.98	REVISED	970.98
	NEW	970.99

This recommended decision takes into consideration the record of the public hearing as well as the arguments contained in the post-hearing briefs. The merits of these arguments are discussed in the findings and conclusions of this recommended decision.

Material Issues

The material issues presented on the record of hearing are as follows:

1. Whether the handling of leafy green vegetables in the production area is in the current of interstate commerce or foreign commerce, or directly burdens, obstructs, or affects such commerce;
2. Whether market conditions justify a need for a Federal marketing agreement which would tend to effectuate the declared policy of the Act;
3. What the definition of the production area and the commodity to be covered by the proposed agreement should be;
4. What the identity of the persons and the activities to be regulated under the proposed agreement should be;
5. What the specific terms and provisions of the proposed agreement should be, including:
 - (a) The definition of terms used therein, which are necessary and incidental to attain the declared objectives and policy of the Act;
 - (b) Whether an administrative body should be established to assist USDA in the administration and oversight of the proposed agreement, and what the membership composition, administrative procedures, powers, and duties of that body should be;
 - (c) Whether the proposed agreement should include the authority to establish regulations and audit requirements that would apply to signatory handlers;

(d) Whether the proposed agreement should include the authority to incur expenses and establish procedures to levy assessments on signatory first handlers to obtain revenue for paying such expenses;

(e) Whether the proposed agreement should include the authority to establish signatory handler reporting and recordkeeping requirements;

(f) Whether the proposed agreement should require signatory handler compliance with all provisions of the agreement and with any regulations issued under it;

(g) Whether the proposed agreement should include the authority to establish rules, regulations, or safeguards for exemption from the requirements of the agreement;

(h) Whether the proposed agreement should include the authority to establish or provide for the establishment of research and market development projects;

(i) Whether the proposed agreement should include additional terms and conditions as set forth in § 970.85 through § 970.98 of the Notice of Hearing published in the **Federal Register** on September 3, 2009 (74 FR 45565), which are common to all agreements; and

6. What the handler sign-up process should be, and if provisions should be made for signatory handlers to discontinue participation in the program.

Findings and Conclusions

The following findings and conclusions on the material issues are based on the evidence presented at the hearing and the record thereof.

Material Issue Number 1—Current of Interstate Commerce or Foreign Commerce

The record indicates that the handling of leafy green vegetables grown in the United States, or leafy green vegetables grown outside the United States and imported by United States handlers, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Evidence is that the leafy green vegetable industry is a highly integrated, complex system of large, mid-size, and small producers delivering product to handlers, retailers, and foodservice operators nation-wide. Leafy green vegetables may be produced in one State, processed in another State, and then shipped for consumption to many States or nationally. Moreover, the product of one or more producers of varying sizes and origin may be handled by one or more handlers, also of varying size or origin.

Evidence also is that leafy green vegetables are imported, mainly from Mexico and Canada, and that such leafy green vegetables are often co-mingled with United States produced leafy green vegetables and distributed throughout the United States market. Similarly, United States produced leafy green vegetables are regularly exported, primarily to Canada. Exported leafy green vegetables may contain product produced by a variety of producers, varying in size and origin, and may be handled by one or more handlers.

For these reasons, evidence confirms that the handling of leafy green vegetables is at multiple levels of interstate or foreign commerce and has an effect on such commerce.

Industry Overview

Producers and Handlers

According to USDA Census of Agriculture data (Census) and other USDA data presented at the hearing, there were 8,216 farms that harvested 433,023 acres of leafy green vegetables specifically for the fresh market in 2007.

While data indicates that leafy green vegetable production is found in all 50 United States, evidence is that most production tends to be concentrated in the States of California, Arizona, Florida, New York, Texas, Georgia, and Colorado, and on farms that exceed the Small Business Administration (SBA) definition of a small agricultural producer. Under 13 CFR 121.201, the SBA defines "small" agricultural producers as farming operations having gross annual receipts of \$750,000 or less. This is the threshold by which USDA analyzes the impact of the proposed marketing agreement on small producer entities. Farm data by States from the 2007 Census of Agriculture (Census), unavailable from other sources, has also been used in developing the recommended decision. However, the Census defines small producers as those with annual receipts of less than \$250,000 and large producers as those with \$250,000 or more. Thus, in some of the discussion and analysis in this recommended decision, the Census data cannot be reconciled with the SBA definition for small producers.

California and Arizona are the largest producing States of leafy green vegetables, with California alone accounting for 75 percent of total United States production in 2007, and Arizona representing 15 percent of total United States production in that same year. Evidence is that the remaining 10 percent of production is spread throughout the United States and tends to be sourced by handlers from small to mid-size farms.

For such farms, leafy green vegetable production commonly only represents a portion of these diversified farms' total production. According to the hearing record, a "diversified farm" is a farming operation that produces a variety of crops or animals, or both, on one farm, as distinguished from a producer who specializes solely in the production of leafy green vegetables.

Marketing Research Association (MRA) data presented at the hearing indicates that there were approximately 1,285 handlers of leafy green vegetables in the United States in 2009. This data is published in the Blue Book Marketing Research Service Directory (Blue Book),

which can be found at <http://www.bluebook.org>.

According to the record, many small and mid-size producers also operate as handlers by way of their direct sales to consumers, foodservice operators, or retailers. Evidence is that the Blue Book likely does not account for many of these smaller producer-handler businesses because they are not directly engaged in the mainstream, conventional market. Therefore, record evidence indicates that the number of leafy green vegetable handlers in the United States that would qualify to participate as signatory handlers under the proposed agreement is more than 1,285. Record evidence is unclear, however, as to how many small producer-handler operations handling leafy green vegetables exist in the United States.

According to the record, the majority of leafy green vegetables handled in the United States are subject to seasonal contracts between producers and handlers, and these relationships are usually long-term. Typically, such contracts are prepared using quantity, weight, acreage, or price.

Any leafy green vegetable crop for sale in the market that is not covered under a contract is considered part of the cash, or "spot" market, where produce is sold for cash and delivered immediately. Small farms often sell directly to consumers at farmers' markets, roadside stands, and through community-supported agriculture (CSA) programs, as well as directly to smaller retailers and local foodservice operators. According to the record, these types of transactions are considered part of the spot market.

Evidence shows that some leafy green vegetables for the United States market are sold through produce auctions, where members of the auction maintain their membership through a contractual relationship with the auction organization. In this scenario, produce supplied by auction members is sold through the auction method, where prices obtained for the produce can fluctuate based on daily market supply and demand, and quality of produce. According to the hearing record, sales of leafy green vegetables made through a produce auction also are considered part of the spot market.

Production

USDA data presented at the hearing indicates that the value of leafy green vegetables grown for the United States fresh and fresh-cut market was \$2.5 billion in 2008. The majority of United States leafy green vegetable production is accounted for by three lettuce crops

(head, leaf, and romaine), spinach, and fresh cabbage. Of the 2008 production value, lettuce crops accounted for 79 percent, cabbage accounted for 15 percent, and spinach accounted for 7 percent, for a total of 81 percent. Other minor fresh leafy green vegetable crops, such as collards, escarole, endives and specialty varieties of kale, are produced regionally and seasonally. Evidence is that these crops are produced widely across the United States and are generally available throughout the year. Since 1997, United States production of major fresh leafy green vegetables has grown by almost 25 percent.

Major Fresh Leafy Green Vegetable Crops

At the time of the hearing, head lettuce production was estimated at 5.3 billion pounds. Even though head lettuce's average share of United States lettuce production has declined from an average of 77 percent during 1996 to 1998, to 56 percent from 2006 to 2008, head lettuce continues to represent the majority of total leafy green vegetable production in the United States. Iceberg lettuce is harvested year-round in California. Of the other States with large production of head lettuce, Arizona harvests in the winter, New Jersey harvests in the spring and fall, and Colorado harvests in the summer.

According to 2007 Census data, 1,158 farms harvested head lettuce from nearly 167,000 acres. Although the farms harvesting head lettuce were spread over 48 States, only three States reported harvesting more than 1,000 acres: California (118,676 acres), Arizona (39,187 acres), and Colorado (2,268 acres).

USDA statistical evidence presented at the hearing indicates that demand for lettuce has shifted away from head lettuce to romaine and other varieties of leaf lettuce. Leaf and romaine lettuce production from major States increased 125 percent between 1990 and 1999, and an additional 42 percent between 2000 and 2009. Total production of leaf and romaine lettuce for 2009 was estimated at 3.9 billion pounds accounting for 42 percent of United States lettuce production. Leaf and romaine lettuce are harvested year-round in California. Arizona is the other main producer of these lettuces in the winter. According to 2007 Census record data, 2,891 farms in all 50 States harvested leaf lettuce from approximately 59,000 acres. For romaine lettuce, the figures are 87,000 acres harvested from 1,057 farms in 49 States.

According to the hearing record, demand for fresh spinach resulted in

average production increases of over 6 percent per year since 1990, with production from major States estimated to have reached 513 million pounds in 2009. According to the 2007 Census, 1,121 farms in all 50 States harvested spinach for the fresh market from almost 30,000 acres. In 2007, the top producers of spinach for the fresh market were California (harvesting 18,000 acres), Arizona (harvesting 3,600 acres), Texas (harvesting 2,200 acres), Colorado (harvesting 1,900 acres), and New Jersey (harvesting 1,500 acres). These States accounted for 94 percent of the fresh spinach acreage. Seasonal production data indicates that California harvests spinach throughout the year. Arizona and Texas harvest in the winter, Colorado harvests in the summer, and New Jersey harvests in the spring and fall.

Production increases for fresh cabbage have been significantly less than for lettuce and spinach over the past 20 years, but do indicate a steady increase in demand for fresh cabbage. Production averaged 2.3 billion pounds in the 1990s, 11 percent higher than the average for the 1980s. For the 10-year period between 2000 and 2009, fresh cabbage production in major States averaged 2.4 billion pounds, 4 percent higher than the 1990s average.

In 2007, 88 percent of harvested cabbage acreage was for fresh use. In 2007, the top 5 State producers of cabbage for the fresh market were California (harvesting 14,000 acres), New York (harvesting 10,300 acres), Florida (harvesting 9,800 acres), Texas (harvesting 6,800 acres), and Georgia (harvesting 6,600 acres), and accounted for 67 percent of United States total fresh cabbage production. Other States that produce large quantities of fresh cabbage include North Carolina, Wisconsin, and Arizona. According to the 2007 Census, 3,986 farms in all 50 States harvested cabbage for the fresh market from approximately 71,000 acres. Of the States with large production of fresh cabbage, Florida, Georgia, and Texas harvest in the winter and spring, California harvests year round, and New York harvests in the summer.

Minor Fresh Leafy Green Vegetable Crops

The 2007 Census included limited data for the following leafy green vegetables for the United States market: Chinese cabbage, escarole & endive (data combined), kale, and mustard greens.

According to hearing record evidence, there were a total of 618 farms growing Chinese cabbage on a total of 11,471

acres in 2007. The top producing States for Chinese cabbage include California (harvesting 5,593 acres on 111 farms), Florida (harvesting 3,206 acres on 40 farms), New Jersey (harvesting 981 acres on 27 farms), Texas (harvesting 517 acres on 7 farms), and Hawaii (harvesting 271 acres on 53 farms).

For escarole and endive, the 2007 Census numbers reported for national acreage and numbers of farms are 3,169 and 132, respectively. The top producing States for these crops are California (harvesting 1,974 acres on 28 farms), New Jersey (harvesting 546 acres on 32 farms), Florida (harvesting 402 acres on 7 farms), Ohio (harvesting 164 acres on 4 farms), and New York (harvesting 75 acres on 13 farms).

For kale, the 2007 Census numbers reported for national acreage and numbers of farms are 3,784 and 946, respectively. The top producing States for these crops are California (harvesting 1,077 acres on 96 farms), North Carolina (harvesting 363 acres on 64 farms), Texas (harvesting 214 acres on 13 farms), Colorado (harvesting 84 acres on 12 farms), and Ohio (harvesting 76 acres on 28 farms).

For mustard greens, the 2007 Census numbers reported for national acreage and numbers of farms are 7,013 and 848, respectively. The top producing States for these crops are California (harvesting 1,902 acres on 87 farms), Georgia (harvesting 1,585 acres on 36 farms), South Carolina (harvesting 581 acres on 35 farms), Texas (harvesting 470 acres on 61 farms), and Michigan (harvesting 308 acres on 29 farms).

Consumption

According to the hearing record, annual per capita lettuce consumption in the United States was 21 pounds in the 1960s, 24 pounds in the 1970s, and 25 pounds in the first half of the 1980s. Since the late 1980s, lettuce consumption has averaged about 30 pounds per person, an increase of 40 percent compared to the 1960s. The type of lettuce consumed has changed over this period of time. Historically, head lettuce has accounted for the majority of national leafy green vegetable consumption. While still representing the majority of leafy green vegetable production volume, evidence is that consumer demand for head lettuce is slowly shifting toward other leafy green vegetable crops. Evidence is that demand is shifting to leaf lettuce, romaine, spinach, and specialty crops.

Consumption of head lettuce decreased from 23.5 pounds per person in 2000 to 16.9 pounds per person in 2008. At the same time, consumption of leaf and romaine lettuce increased from

8.4 pounds per person in 2000 to 11.1 pounds per person in 2008. Consumption of spinach peaked in 2005 at 2.3 pounds per person, and has remained at most 15 percent below peak consumption since the E. coli outbreak in 2006. Average per capita consumption of spinach was forecasted at 1.6 pounds per person for 2009. Cabbage consumption has remained steady since 2004, oscillating from 8.1 pounds per person in that year to 7.8 pounds per person in 2005–06 to 8.2 pounds per person in 2009.

Leafy Green Vegetable Imports and Exports

According to data submitted into evidence, the United States is the second largest producer of leafy green vegetables in the world, accounting for roughly 22 percent of global production in 2009. China is the world's largest leafy green vegetable producer, with a world market share equal to 51 percent in 2008.

Witnesses explained that United States leafy green vegetable producers compete on both a domestic and international level with foreign leafy green producers. Since 2002, Mexico has been the largest exporter of leafy green vegetables to the United States, followed by Canada, Peru, and Israel. In 2006, Mexico exported 118 million pounds of leafy green vegetables to the United States. During the same period, Canada, Peru, and Israel exported 52 million pounds, 1.2 million pounds, and 365,000 pounds, respectively. In 2006, the United States exported slightly less than 12 percent of its leafy green vegetable production.

Even though China consumes the majority of its leafy green vegetable production, witnesses stated that China is the main competitor to United States leafy green vegetable exports to Asian markets. Although Japan and India both are top ten global producers of leafy green vegetables, neither country exports more than 0.1 percent of the leafy green vegetables that they produce.

Mexico is the largest producer of leafy green vegetables in Latin America and was the ninth largest global producer in 2006. Its proximity to the United States market makes Mexico a competitor in both the United States and Mexican markets, in addition to other Latin American markets. Witnesses also explained that some of the leafy green vegetables from Mexico are produced by United States companies operating in both countries.

Major producers and exporters in the European Union are Spain and Italy. Both Spain and Italy produced approximately 2 million pounds of leafy

green vegetables annually from 2000–2006. Total exports from Spain and Italy average 45 percent and 10 percent of their respective leafy green vegetable production.

Record evidence from the hearing illustrates that the handling of United States grown leafy green vegetables is multi-State, regional, national, and international in scope. Within the United States, the handling of leafy green vegetables in one State exerts an influence on all other handling of leafy green vegetables within the production area. Additionally, the handling of imported fresh leafy green vegetables also impacts interstate commerce and foreign commerce. Record evidence is that imported leafy green vegetables are widely distributed throughout the United States market alongside domestic leafy green vegetables. Moreover, record evidence is that sometimes imported product is commingled with domestic product prior to its distribution in United States markets. Thus, the evidence shows that the handling of leafy green vegetables for the United States market, whether the leafy green vegetables are produced domestically or imported, is in the current of interstate and foreign commerce and directly affects such commerce.

Material Issue Number 2—The Need for a National Leafy Green Vegetable Marketing Agreement

The record evidence demonstrates that there is a need for the proposed program to regulate the handling of leafy green vegetables, and that such a program would improve quality by minimizing the occurrence of microbial contamination of those vegetables. If implemented, the proposed program would provide for the establishment of audit metrics and verification audits of all product handled by signatory handlers within the United States. Any audit metrics developed under the proposed program would reflect FDA good agricultural practice guidelines (GAPs) and FDA fresh product manufacturing regulation (GMPs). Any regulation would also take into account leafy green vegetable industry stakeholder interests and concerns regarding varying production and handling environments across the nation. Furthermore, the proposed program would assist in stabilizing market conditions if a contamination event were to occur, and would increase consumer confidence in the quality of leafy green vegetables.

While participation in the proposed program would be voluntary, any handler becoming a signatory to the

agreement would be subject to mandatory compliance. The proposed program would also cover any imported leafy green vegetables handled by signatory handlers. According to record evidence, foreign producers and handlers doing business with signatory handlers would be required to meet equivalent audit metrics as in effect for the domestic industry.

USDA Inspection Service would serve as the primary auditing authority to conduct verification audits under the proposed program. USDA Inspection Service would also have the authority to designate other entities approved or recognized by USDA to conduct audits on its behalf.

According to the hearing record, there are no national, mandatory food quality or safety regulations for the growing and handling of fresh leafy green vegetables. There are, however, FDA guidelines that are commonly used by leafy green vegetable producers and handlers in their development of private or customer-driven food safety plans. These guidelines are: The “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (1998), and the “Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables” (2008). According to the hearing record, these guidelines jointly comprise what are referred to as “Good Agricultural Practices” or “GAPs”. In 2009, FDA published a draft set of commodity specific guidelines for leafy green vegetables, the “Commodity Specific Food Safety Guidelines for Lettuce and Leafy Greens Supply Chain”. These guidelines have not been finalized yet and, therefore, are not being actively used in the industry.

Mandatory FDA regulation does exist for manufacturers of fresh-cut leafy green vegetables. Manufacturers alter leafy green vegetables from their fresh form into a fresh-cut form. FDA regulations regarding the manufacturing of fresh-cut leafy green vegetables are found in 21 CFR Part 110. According to the record, these regulations are commonly referred to as Good Manufacturing Practices (GMPs).

The AMS, in partnership with State departments of agriculture, offers a voluntary, audit-based program that verifies adherence to the two FDA guidelines identified above. Under AMS’s Good Agricultural and Good Handling Practices Audit Verification Programs, the FDA GAPs guidelines are divided into two specific programs: GAPs verification audits, which examine farm practices, and Good Handling Practices (GHPs), which concentrate on packing facilities, storage

facilities, and wholesale distribution centers. The AMS programs are not mandatory. However, according to the hearing record, many commercial purchasers of leafy green vegetables require their vendors to be audited under one of the above mentioned programs.

There are two State programs that have been established specifically for the purpose of regulating the handling of fresh leafy green vegetables. These programs are found in California and Arizona.

The California Leafy Green Products Handler Marketing Agreement became effective February 10, 2007. Record evidence indicates that, at the time of the hearing, 99 percent of leafy green vegetables produced and handled in California were subject to the State program. In October 2007, a similar program was implemented in Arizona: The Arizona Leafy Green Products Shipper Marketing Agreement. Evidence is that approximately 75 percent of the leafy green vegetables produced and handled in Arizona were being regulated under that State’s program at the time of the hearing. While both the California and Arizona programs are voluntary, the requirements of these State marketing agreements are mandatory for all signatories within each respective State.

Proponents of the proposed agreement stated that a national program would allow for the coordination of audit verifications for all fresh leafy green vegetables at a national level and would allow for continuity of product quality as it moves between States.

While proponents acknowledged that leafy green vegetable GAP and GHP programs have been designed and implemented in cooperation with the USDA Inspection Service in two States (Arizona and California), they argued that the development of a national program was necessary. Proponents stated that a national program would minimize the potential for contamination of fresh leafy green vegetables in all States where they were produced or handled, not just California and Arizona. According to the record, participation in the two State programs represents roughly 99 and 75 percent of production in California and Arizona, respectively, but participation of production outside of those two States is inconsistent and limited. Proponents explained that producers and handlers who currently undergo GAP or GHP audit verifications outside of the States of California and Arizona primarily do so either electively or at the request of their buyers.

Proponents explained that a fresh leafy green vegetable may be grown in one State, shipped to another State for washing and preliminary handling, and then shipped to a third State for further processing and packaging prior to that product reaching consumers. For this reason, proponents stated that consistency in good agricultural and handling practices were needed in all States in which leafy green vegetables are grown or handled. Proponents stated that national coordination of such practices is needed to maintain the integrity of product quality, including minimizing the potential for microbial contamination.

For example, the California Leafy Green Products Handler Marketing Agreement does not cover lettuce or leafy green vegetables grown outside of California. It does not have the authority to send inspectors to audit growers or handlers in another State. Therefore, if a handler who is based in California receives product from outside the State, that product may not be required to meet the GAPs or GHPs. According to the proponents, the development of a national GAP and GHP program for leafy green vegetables based on FDA guidelines would foster consistency in agricultural and handling practices across all States.

Proponents explained that FDA-based GAPs and GHPs provide general guidance on critical steps within the growing, harvesting, transportation, cooling, packing, and storage of fresh produce where food safety might be compromised. FDA guidelines alert producers and handlers to critical areas within the production and handling of fresh leafy green vegetables that present potential for microbiological contamination. FDA guidelines do not, however, describe the actions that need to be taken by producers or handlers within their individual businesses to meet the guidance benchmark. Proponents explained that guidance of this kind is established in the form of "audit metrics".

For example, FDA guidelines state that mechanical or machine harvest has become increasingly prevalent and that this activity leads to increased surface contact exposure of leafy green vegetables with components of the harvest machinery. FDA guidelines identify surface contact in mechanical harvesting as a critical step. One of the guidelines offered by FDA to reduce the potential for contamination at this critical step includes establishing appropriate measures that reduce, control, or eliminate the potential introduction of human pathogens at the cut surface during and after the

mechanical harvest operation. Under the proposed program, audit metrics would be developed to identify actions that would meet this guideline, such as equipment cleaning schedules and requirements for harvest workers to use gloves or other protective clothing.

According to proponents, if the proposed program were implemented, its administrative body would have authority to recommend "audit metrics". Witnesses explained that audit metrics are standards or steps within a production or handling system at which some action or measure should be taken to minimize the potential for microbial contamination. The standards or steps within a production or handling system at which action or measures are taken are also referred to as "control points" of a "process control". It was further explained that any "audit metrics" established under the proposed program would represent a set of auditable standards or requirements within a process control that would allow an auditor to determine if a producer or handler is in compliance with the program.

While proponent witnesses supported the need for a uniform verification audit program, they also supported the development of a program that recognizes differences among producers and handlers across regions in the production area. For example, differences in water sources, geography, climate, or size of operation could require slight variations in the types of actions needed to be taken for a producer or handler to be compliant under the proposed program.

It also was argued that the proposed agreement should allow for the development of audit metrics that are reflective of current industry practices and are scientifically-based. According to the record, standardization of production and handling audit metrics would result in increased efficiencies and reduced costs related to multiple buyer-specific requirements. Proponents explained that usage of current industry practices was important for two reasons. First, current practices for organic handling operations are likely different from conventional handling operations. However, the audit metric established for each respective type of handling operation should result in both operations meeting the FDA guidelines and complying with the proposed program.

Secondly, proponents advocated that audit metrics be supported by current scientific research accepted within the professional and academic scientific community. Proponents stated that the proposed program would positively

address the increasingly common practice among fresh produce buyers to develop their own food safety requirements for producers and handlers. According to the hearing record, these requirements often differ from buyer to buyer, resulting in a complex web of private standards that producers and handlers need to adhere to in order to sell their product.

Implementation of these varied requirements is costly to the producer and handler, and is often redundant. Moreover, many witnesses testified that some buyer requirements are not scientifically justified and, in turn, have led to production and handling practices that challenge existing industry technology or are contra-indicated to findings of current scientific research.

To this end, proponents expressed the importance of including input from stakeholder groups including, but not limited, to organic producers and handlers, small businesses, and natural resource interest groups. Additionally, proponents stated that members of the professional and academic community should be represented in the audit metric development process.

Proponents argued that because the handling of imported fresh leafy green vegetables impacts domestic commerce, foreign product handled by signatories should also be regulated. As discussed in Material Issue 1, imported leafy green vegetables are widely distributed throughout the United States market alongside domestic leafy green vegetables. Moreover, record evidence shows that imported product can be commingled with domestic product prior to its distribution in United States markets.

Witnesses explained that if microbial contamination were to occur during the growing or handling of foreign leafy green vegetables imported by United States handlers and consumed by United States consumers, the United States fresh leafy green vegetable industry would suffer economic losses regardless of the origin of the contaminated product. Witnesses stressed the importance of having a Federally-regulated program through which the industry could stabilize any negative market impacts, and proactively address consumer confidence with regard to domestically handled leafy green vegetables, if such an event were to occur.

According to the hearing record, the regulation of imported product handled by signatory handlers would ensure that both domestic and foreign product was held to the same, or equivalent, good agricultural and handling practices. This would allow for consistency of

product quality among participants of the proposed program.

Proponents stated that it is critical for the industry to improve and ensure the safety and quality of leafy green vegetables. The relationship among quality, consumer demand, and producer returns was demonstrated at the hearing. Furthermore, the correlation between product quality and the absence of microbial contamination was clearly defined.

Witnesses testifying at the hearing used the example of the September 2006, multi-state outbreak of *E. coli* linked to fresh spinach grown in California's Salinas Valley. According to the record, the resulting recall was the largest ever for the fresh leafy green vegetable industry. Investigations by FDA and the California Department of Health Services, in cooperation with the Centers for Disease Control and Prevention, and USDA Animal and Plant Health Inspection Service, concluded that *E. coli* contamination might have been attributed to environmental factors in the production area.

Witnesses who were impacted by the recall stated that consumer demand for fresh spinach dropped by more than 60 percent immediately following FDA's public alerts. Witnesses also explained that after the contamination had been linked to California, consumer consumption of spinach remained at record lows regardless of the State within which it was produced. According to record evidence, consumer demand for spinach remains below pre-2006 levels.

Proponents used the 2006 *E. coli* outbreak, and the subsequent damage to consumer confidence and demand for leafy green vegetables, to demonstrate that a contamination event in one State can impact industry participants nationwide. Witnesses stressed the need to have a regulatory system in place as a means of minimizing the potential for future contamination events. Witnesses also expressed the usefulness of having a Federally regulated program to facilitate the rapid identification and containment of contamination events if they occur. Proponents explained that such a national program would safeguard consumers, as well as provide the leafy green vegetable industry with a mechanism to address potential loss of consumer confidence in product quality.

According to record evidence, USDA has several programs—namely the Qualified Through Verification and the GAPs and GHPs Audit Verification Programs—that provide independent verification that growers and handlers

are following FDA's guidance and commodity-specific best practices.

Proponents further stated that USDA and FDA have an established working relationship on food quality programs. For example, AMS offers the GAPs and GHPs Fresh Produce Audit Verification Program, a voluntary, audit-based program for the fresh produce industry based on the FDA's "Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", and also coordinates Inspection Service audits under both the California and Arizona leafy green vegetable marketing agreements.

Witnesses in favor of USDA oversight also cited the history of interagency cooperation. As an example, witnesses at the hearing referred to the USDA and FDA co-sponsorship of the National Advisory Committee on Microbiological Criteria for Foods by the Food Safety and Inspection Service, along with other Federal agencies such as the Centers for Disease Control and Prevention.

Witnesses opposed to the proposed program, as well as those who voiced the need for revisions to the proponents' proposal, expressed apprehension over the ability of program administrators to collaborate with stakeholder interest groups. Specifically, witnesses were concerned that the development and recommendation process of audit metrics would not take into consideration differences between conventional and organic production and handling practices, as well as scale of business operations. Other areas of particular concern noted during the hearing include topics such as conservation practices and natural resource management.

These witnesses also explained that regulatory jurisdiction over some of these topics is shared by multiple Federal, State, and local government agencies, and stated the need to include representatives from these regulatory agencies in the audit metric development process. It was argued that their involvement would mitigate the potential for conflicting requirements being placed on producers or handlers that are subject to multiple sets of standards and compliance issues.

Some witnesses opposed to the proposed program expressed concern that its implementation would lead to further proliferation of private sector standards. These critics argue that the current California and Arizona State programs have had little positive impact on the reduction of private standards in those States since their implementation.

While many witnesses testified at the hearing that a relationship between

product quality and food safety does exist, some stated that a regulatory program would be better placed under FDA oversight, or perhaps under a system of State regulatory programs.

Critics of USDA oversight of such a program stated that USDA lacks the scientific expertise needed for the development and implementation of a science-based regulatory program for food safety. Critics also explained that their understanding of the mission of AMS is to facilitate the marketing of agricultural products and therefore should not be involved in the oversight of quality as it relates to food safety issues. These witnesses stated that monitoring of food safety is not relevant to food quality and should not be included under the purview of marketing and market stability.

Others witnesses stated that individual State departments of agriculture would be better equipped at addressing the particular needs and unique characteristics of their producer and handler constituents. Witnesses in favor of State regulatory programs argued that the implementation of a national program would result in a "one-size fits all" Federal regulatory program. These witnesses believe that regulation would be developed to reflect the agricultural practices of regions producing the most volume of leafy green vegetables to the detriment of regions producing less volume.

Lastly, concerns were raised during the hearing process and in the post-hearing briefs submitted over the development process of any audit metrics applied to foreign production or handling operations. Witnesses also raised questions over the proposed agreement's ability to recognize foreign GAPs, GHPs and GMPs programs, foreign auditing services, or independent third-party auditing services currently in operation both domestically and internationally.

Based on hearing record evidence, USDA concludes that there is a need for a national program to regulate the handling of leafy green vegetables. The evidence supports that the proposed program would allow a uniform baseline of regulation to be proficiently administered throughout the complex and diverse leafy green vegetable industry. The proposed program should allow for participation and compliance among the diverse community of growing and handling operations across the United States.

Through the proposed program, leafy green vegetable industry stakeholders could work cooperatively together to develop and recommend a uniform, auditable, science-based food quality

verification program. Furthermore, audit oversight conducted by the USDA Inspection Service or USDA approved or recognized entities in coordination with current FDA guidelines, would benefit the industry and would be in the best interest of consumers. Finally, the proposed agreement would tend to effectuate the declared policy of the Act.

Material Issue Number 3—Definition of Leafy Green Vegetables and Production Area

The proposed agreement should provide for the definition of the commodity and the area that would be regulated. Terms related to the commodity to be covered by the proposed agreement, such as “fresh” and “fresh-cut” should also be defined.

Leafy Green Vegetables

The proponents testified that leafy green vegetables are short-lived herbaceous plants that are eaten raw. Most leafy green vegetables are produced in raised beds that are either directly seeded or transplanted with plugs (immature plants). Leafy green vegetables produced for fresh market production are harvested either as single leaves or as whole plants. Some types of leafy green vegetables, such as chard, kale, mizuna, and baby leaf lettuce may be harvested multiple times in a crop year. Record evidence pertaining to the leafy green vegetables included in the definition follows.

Arugula, a member of the *Brassicaceae* family of plants, has three species that are used for human consumption: the annual species—*Eruca sativa* (domesticated) and *Eruca sativa vesicaria* (L.) Cav. (wild-type); perennial species—*Diplotaxis tenuifolia* (L.) DC; and a polyploidy perennial *Diplotaxis muralis* (L.) DC. Arugula is a low-growing annual that is commonly called rocket, roquette (French), rughetta, and rucola (Italian). If arugula is marketed as a single commodity, it is usually bunched and packed into cartons in the field. Arugula that is for the fresh-cut market is shipped from the field to the processing facility in bulk containers.

According to record evidence, arugula produced in Arizona is primarily produced for value-added packaged salad mixes. In this example, the plants are not thinned after sprouting and are harvested as immature arugula. This differs from producers in New Jersey, who generally harvest, wash, and bundle their crop, and sell it as a single commodity at local produce auctions in wholesale units of 24 bunches per crate. Record evidence indicates that small producers who produce arugula

generally sell their crop in bunches directly to customers at farmers’ markets.

Cabbage, one of the most consumed vegetables in the world, is a member of the *Brassica oleracea* species (*Capitata* Group) of the family *Brassicaceae*. Cabbage is produced year-round in all 50 States. A mature head of cabbage generally weighs 3–5 pounds, depending on the variety. Cabbage produced for the fresh market is harvested by hand and packed 18–24 heads per carton.

Chard (*Beta vulgaris* var. *cicla*) is a member of the *Amaranthaceae* family of plants that is commonly called Swiss chard in the United States. It is the same species as beetroot. Stems of the chard plant vary from white to red and yellow depending on the variety. If only mature leaves are harvested, chard will continue to be productive for up to a year. Leaves are typically bunched in the field during harvest. Immature or baby leaves may be added to packaged salad mixes.

Cilantro (*Coriandrum sativum*) is an annual herb in the family *Apiaceae* that is also called Chinese or Mexican parsley in the United States. In Florida, cilantro is produced for the fresh-cut market between late September and May, whereas in California it is produced year-round. Hand-harvested cilantro is sold in bunches tied with a rubber band or twist tie. Conventional packing is 30 bunches in 10 pound boxes.

There are three major cress species known in North America: Garden cress, Upland cress, and watercress. All are members of the family *Brassicaceae*. Garden cress (*Lepidium sativum*), also called peppergrass, pepper cress, or pepperwort, is a fast-growing plant. Introduced to the United States from China, it is botanically related to mustard and watercress and is sometimes referred to as an herb. Garden cress is commonly used in salads as a “baby green”. Upland cress (*Barbarea verna*) is native and grows wild in the southeast; it is often called creasy greens, highland creasy, or creasy salad. Watercress (*Nasturtium officinale*, *N. microphyllum*) is a fast-growing aquatic or semi-aquatic perennial plant. It is thought to be one of the oldest known leafy green vegetables consumed by humans.

Dandelion is produced commercially in the United States from two species, *Taraxacum officinale* and *Chichorium intybus*, both belonging to the *Asteraceae* family. A perennial herbaceous plant, dandelions are native to North America and produced as weeds worldwide. Dandelion use as a

fresh leafy green is growing in popularity.

Endivia is a new variety of forced red chicory that is a cross between Belgian endive and two varieties of radicchio—Chioggia and Verona.

Endive (*Cichorium endivia*) is a leafy green belonging to the large *Asteraceae* family. There are two main varieties of endive, curly endive, or frisee (var. *crispum*), and escarole (var. *latifolia*). The leaves from endive are harvested by hand and tied in bunches before being packed into cartons. Belgian endive (*Cichorium intybus* var. *foliosum*) is also known as witloof in the United States.

Kale is a member of the *Brassica oleracea* species (*Acephala* Group) with common varieties of green kale, red kale, red Russian kale, and Lacinto or dinosaur kale. At harvest, two cuttings may generally be taken from one seeding. If harvested as an immature leaf, kale is often co-mingled with other immature or baby leaf variety leafy green vegetables in salad mixes. Mature kale is typically cooked prior to eating. However, witnesses testified that mature kale is often used on salad bars for decoration, so it comes into contact with other leafy green vegetables in that context.

Lettuce (*Lactuca sativa*) is produced in all 50 States and is highly perishable. Lettuce crops include head, leaf, and romaine. Common varieties of head lettuce (*Lactuca sativa* var. *capitata*) are iceberg (also called crisphead) and butterhead (also called Boston, bibb, buttercrunch, or Tom Thumb). During harvesting in Arizona and California, outer leaves are stripped from the lettuce heads before boxing. Head lettuce sold fresh is boxed 24 heads to a carton—either naked or film-wrapped. Head lettuce that will be further processed is shipped in bulk to the processing facility where it is washed, cored, shredded, and/or cut and packaged as ready-to-eat products. Leaf lettuce (*Lactuca sativa* var. *crispa*) has steadily grown in popularity in the United States in the past 15 years. Common leaf lettuce varieties are red leaf, green leaf, and baby leaf or salad/spring mix. At harvest, leaf lettuce is generally naked packed 24 to a carton. Romaine lettuce (*Lactuca sativa* var. *longifolia*), also called Cos lettuce, is generally loosely packed.

Mâche (*Valerianella locusta*) is a small annual plant of the family *Valerianaceae*. It is also called corn salad, Lewiston cornsalad, lamb’s lettuce, lamb’s tongue, field lettuce, field salad, rapunzel, and fetticcio.

Parsley (*Petroselinum crispum*) is a biennial green leaf herb that is a member of the family *Apiaceae*. Parsley

is available in two varieties—curly leaf and Italian or flat leaf. Parsley is harvested by cutting 1.5–2 inches above ground so that re-growth may occur, allowing for three to four cuttings per planting.

Radicchio, a type of chicory (*Cichorium intybus* var. *foliosum*), is a member of the family *Asteraceae*. Sometimes called Italian chicory, varieties of radicchio are named after the regions of Italy from which they originate. The most common variety of radicchio found in the United States is Radicchio di Chioggia. Other lesser known varieties available are Radicchio di Treviso, Tardivo, and Radicchio di Castelfranco. In Italy, radicchio is often grilled or roasted, but in the United States it is most often used as a colorful addition to leafy green salad mixes. The United States also imports radicchio from Italy and Chile.

Spinach (*Spinacia oleracea*) is a hardy leafy green vegetable that is produced in all 50 States. There are several different varieties of spinach that are classified according to leaf shape and texture. Varieties include savoy, which has wrinkled leaves, semi-savoy, and varieties with smooth or flat leaves. Savoy types are sold mainly for fresh market uses, while types with smooth or flat leaves are used mainly for processing. The growing season varies by location, and leaves may be cut as often as four times during a crop year. Spinach is sold in bunches or as loose leaf in cellophane packaging to food service and retail outlets.

Tat soi (*Brassica rapa* var. *rosularis*, *Narinosa* group) is an Asian leafy green vegetable and a member of the *Brassicaceae* family.

Winter purslane (*Claytonia perfoliata*) is a member of the *Portulacaceae* family. Also known as Cuban Spinach and Miner's lettuce, winter purslane is an annual plant.

Proponents and other witnesses testified that they believe this is a comprehensive list of the leafy green vegetables produced in the United States and available in the market. However, new varieties of lettuces and other leafy greens appear in the market on an annual basis. Those varieties would be covered by the proposed agreement. Similarly, witnesses testified that “baby leaf” or “baby greens” are a seed variety that is to be harvested and marketed as a vegetable, rather than being an immature version of a leafy green vegetable. These varieties would also be covered by the program. The definition of leafy green vegetables should be revised to clarify that all varieties of the listed items would be covered.

Some witnesses supported adding mustards and herbs to the proponents' definition. However, record evidence does not support extending program coverage to those items. Proponents testified, for example, that mustards were not included in the definition of leafy green vegetables because they are normally cooked prior to consumption.

The proponents supported including “spring mix” in the definition of leafy green vegetables. However, the record evidence is that spring mix is not a single commodity, but a mixture of a variety of leafy green vegetables. Proponents and other witnesses testified that there is no universal, standard ingredient blend for spring mix. A spring mix typically includes, but is not limited to, arugula, chard, cress, lettuce, and radicchio. It also includes baby leaf items such as cress, dandelion, endiga, mache, mizuna, tat soi, and winter purslane. While the list of leafy green vegetables includes most items commonly used in a spring mix, signatory handlers who produce a spring mix would need to ensure that all ingredients of their spring mix are produced and handled in accordance with the terms of the proposed agreement.

The proposed agreement is intended to cover all mixes (such as spring mix and other salad blends) of leafy green vegetables. The definition of leafy green vegetables is revised to clarify this point by adding a new paragraph (b). In a related matter, sometimes salad mixes contain items that are not leafy green vegetables, such as carrots or dressings. These items would not be covered by the agreement. Such language is being added to the definition of leafy green vegetables as a new paragraph (c). (This provision appeared in § 970.8 of the proponents' proposal, but that section of the proposed agreement is being deleted as unnecessary.)

Some witnesses stated that the program should apply only to fresh-cut leafy green vegetables. These witnesses cited that there is a different safety risk for leafy green vegetables produced for fresh-cut versus the fresh market. Other witnesses with generally the same viewpoint stated that the list of leafy green vegetables presented by the proponents was too broad and should provide an exception for leafy green vegetables that require cooking.

Based on hearing record evidence, all leafy green vegetables included in the proposed definition that are handled by signatory handlers and that are intended for human consumption in the fresh form (whether fresh-cut or not) should be covered under the proposed agreement. Record evidence

demonstrates that the movement of leafy green vegetables from producers to handlers is fluid and that oftentimes it is difficult to anticipate what the end use of a harvested field will be. Moreover, record evidence supports that the opportunity for microbial contamination exists throughout the industry at the production, harvesting, handling and processing stages. Therefore, coverage of all leafy green vegetables, whether in their fresh or fresh-cut form, is necessary and is in the best interest of consumers.

Regarding witness requests to exempt leafy green vegetables that require cooking prior to human consumption, this exemption is unnecessary as the proposed program would only cover leafy green vegetables intended for consumption in their raw or uncooked form. This is because the process of cooking is identified as a “kill step” in food safety guidelines and is believed to eliminate contamination.

Lastly, the record evidence supports the authority for the Board, with the approval of the Secretary, to add and remove leafy green vegetables from the definition as deemed necessary. This authority would enable the program to adapt and change to the needs of the leafy green vegetable industry. Any change would require that the Board approve such a recommendation at a public meeting and then submit the recommendation to the Secretary for review. If appropriate, USDA would initiate rulemaking.

In summary, the definition of “leafy green vegetables” that appeared in the Notice of Hearing as § 970.15, is revised as discussed above and redesignated as § 970.18.

Fresh

Proponents and other witnesses stated that “fresh” means any leafy green vegetable in the raw or natural form. Proponents described the many different ways that leafy green vegetables are harvested fresh in the field. One witness described how cilantro could be harvested using any of three different methods: (1) Cut the foliage 1–2 inches above the crown (the most common method); (2) cut the whole plant just below the soil; and (3) bulk harvest into bins using a mower and conveyor. Another witness provided the example that a head of lettuce that is field-cored and wrapped in the field is considered a raw agricultural commodity in a package. Both of these examples demonstrate that while harvesting involves cutting the foliage growth from the stem or crown of the plant, such cutting does not

constitute the creation of a fresh-cut leafy green vegetable.

The term “fresh” was used often as witnesses discussed GAPs and GHPs, since both pertain only to the fresh commodity. Thus, based on record evidence, a new definition § 970.9, “fresh” is added to the proposed agreement. This is necessary to identify and describe how fresh leafy green vegetables are different from fresh-cut leafy green vegetables.

Fresh-Cut

Proponents proposed a definition of “fresh cut” to mean fresh leafy green vegetables that have been altered from their natural form by cutting, dicing, peeling, slicing, chopping, shredding, coring, or trimming, with or without washing prior to being packaged for use by the consumer, foodservice industry, or a retail establishment. Proponents provided examples of fresh-cut leafy green vegetables by citing lettuce that is shipped in bulk to the processing facility where it is washed, cored, shredded or cut, and packaged as ready-to-eat bagged salads. It was noted that this process would also apply to cabbage.

Section 970.7 is revised for clarification and redesignated as § 970.10.

In addition, proponents proposed a definition in the Notice of Hearing as § 970.8, “fresh-cut, packaged leafy green product”. However, witnesses testified that this term means the same as the definition of “fresh-cut”. This definition is being removed from the proposed agreement as unnecessary. Likewise, the definition of “Packaged” that appeared in the Notice of Hearing as § 970.18 is deleted as unnecessary.

Production Area

The term “production area” should be included in order to identify the area in which the proposed program would be applicable. According to the hearing record, the production area should include the fifty of the United States and the District of Columbia.

Proponents testified that the intent of the proposed program is to put into effect a national, standardized system to increase quality by minimizing microbial contamination of leafy green vegetables intended for raw or uncooked human consumption in the United States. Furthermore, the proposed program would assist in stabilizing market conditions if a contamination event were to occur, and would increase consumer confidence in the quality of leafy green vegetables.

According to record evidence and as discussed in Material Issue 1, leafy

green vegetables are produced and handled year-round in all 50 States and the District of Columbia. Handlers in the United States may acquire leafy green vegetables that are produced in one State, manufactured in another State, and shipped nationally for consumption by consumers. Additionally, witnesses stated that some handlers have production or manufacturing operations, or both, in multiple locations throughout the United States. Thus, the national scope of the leafy green vegetable industry supports defining the production area as all 50 States and the District of Columbia.

Lastly, the production area and the zones into which it would be divided would determine the eligibility of persons to serve on the Board. The proposed program would require that all handlers, producers, and at-large members are located within the production area. The topic of the division of the production area into zones and Board membership are further discussed in Material Issue 5(b).

Based on the hearing record, the term “production area” should be defined to mean all 50 States and the District of Columbia of the United States of America. The definition of “production area” that appeared in the Notice of Hearing as § 970.23 is redesignated as § 970.28.

Material Issue Number 4—Persons and Activities To Be Regulated

Certain terms should be defined to identify the persons and the activities that would be regulated under the proposed agreement. The proposed agreement would regulate the act of handling leafy green vegetables in the production area by those handlers would voluntarily agree to adhere to the agreement requirements. As such, the following terms should be defined: “handle”, “handler”, “importer”, “manufacture”, “manufacturer”, “signatory first handler”, and “signatory handler.”

According to record testimony, within the leafy green vegetable industry, businesses in the farm to fork continuum include growers/producers, handlers (commonly known as processors, shippers, packers), wholesalers/distributors, agents/brokers, exporters/importers, retail outlets such as grocery stores, and foodservice providers. Small farms as defined by SBA commonly sell their leafy green vegetables directly to consumers at farmer markets, through Community Supported Agriculture (CSA) programs, or to retailers. Record testimony indicates that large farm operations usually sell their leafy green vegetable

crops to handlers or directly to retailers at wholesale produce auctions.

Record testimony indicates that there basically are two types of handlers “first handlers” and “secondary handlers” or handlers other than first handlers. “First handlers” take possession of leafy green vegetables and may process and package leafy green vegetables before selling to other handlers or retailers. “Secondary handlers” such as manufacturers—the record indicates—commonly buy from first handlers. However, such handlers also could buy directly from producers.

According to record testimony, handling generally begins when the harvested leafy green vegetable crop leaves the field and is in the possession of the handler. Record testimony also indicates that fresh leafy green vegetable crops may change hands as many as three times through handling activities before reaching its final destination.

According to record evidence, the term “handle” should be defined to mean “receive, acquire, sell, process, ship, distribute, or import leafy green vegetables. The record indicates that “handle” should not include retail sales, foodservice sales, or brokering of such leafy green vegetables. According to record evidence, the act of handling places leafy green vegetables or products into the current of commerce both within the production area, and between the production area and any point outside that area. As such, “handle” which appeared in the Notice of Hearing as § 970.11 should be redesignated as § 970.14, and revised slightly for clarity.

“Handler” should be defined to mean any person who handles leafy green vegetables. The record indicates that a handler could be an individual, joint venture, partnership, corporation, or other business entity. According to record testimony, a handler represents the segment of the industry that processes, ships, sells, consigns, or imports leafy green vegetables, or any combination thereof. As proposed by under this agreement, distributors, packers, processors, shippers, and wholesalers would be handlers. The record also indicates that producers who engage in the act of handling leafy green vegetables would be considered handlers. As handlers, such producers would directly place their product into the stream of commerce, through direct sales to consumers, retailers, or other handlers such as a manufacturer or foodservice operator.

For the purposes of the proposed agreement, the term “handler” should specify that brokers, retailers, and foodservice operators would not be considered handlers unless such

persons are otherwise engaged in handling. The record indicates that generally brokers serve as intermediaries and, negotiate with producers or handlers on behalf of their customers without ever taking possession or ownership of the actual leafy green vegetables.

The term "handler" appeared in the Notice of Hearing as § 970.12, and should be re-designated § 970.15, and revised slightly for clarity.

Record evidence indicates that the term "signatory" should be modified to "signatory handler" and the definition should be revised to mean a handler located in the production area who is party to the proposed agreement. The revisions clarify that only handlers could become signatories to the proposed agreement, and that such persons would have to be located within the production area.

According to the record, a signatory handler would be responsible for meeting the requirements of the proposed agreement, complying with audit requirements, and submitting reports and other information required for the administration of the proposed agreement. In cases where a signatory handler contracts for services, the signatory handler would be responsible for verifying and retaining documentation that the contracting service provider or agent meets any requirements in effect under the proposed agreement.

Signatory handlers would be eligible to nominate persons to the Board and to serve as handler members or their alternates on the Board. Signatory handlers also would be eligible to nominate persons to serve on Committees of the Board and be eligible to serve as members of the Technical Review Committee. Additionally, record evidence indicates that signatory handlers would need to be located in the production area because they are responsible for handling leafy green vegetables in the United States.

The term "signatory", which appeared in the Notice of Hearing as § 970.26, is revised to "signatory handler", and redesignated as § 970.33.

Record testimony indicates that, signatory handlers would be identified as "first" or "secondary" handlers under the proposed agreement. Record evidence supports adding a new § 970.32. This section would establish the definition of "signatory first handler" to mean the person located in the production area who signs the proposed agreement and who is the first to handle leafy green vegetables. This definition is intended to identify signatory handlers who first receive

leafy green vegetables for the purposes of assessment collection. As proposed under the agreement and supported by the record, signatory first handlers would be financially responsible for the payment of assessments under the proposed agreement. It is important to identify the responsible party, since leafy green vegetables may be handled by several different signatory handlers and the assessment should only be applied once.

According to proponents of the proposed agreement, "signatory first handlers" would be identified as the handler who first takes possession of leafy green vegetables in their natural form from a producer with the intent to sell them to retailers or other handlers. As an example, a signatory first handler may contract with an independent harvesting company to harvest a producer's crop and deliver that crop to the signatory first handler's facility. In such a case, the signatory first handler would take ownership of the crop, yet would not be the first business entity to physically engage in the act of handling. According to record evidence, given that the harvesting company is contracted by the signatory first handler, and the handler assumes ownership, the said handler, and not the harvester, would be identified as the signatory first handler. Therefore, the signatory first handler would be responsible for ensuring that the contracting harvester is in compliance with any provisions in effect under the proposed agreement. Additionally, the signatory first handler would be responsible for the payment of assessments on such leafy green vegetables.

As another example, if a producer were to harvest a leafy green vegetable crop and then engage in the act of handling the crop that producer would be considered a "signatory first handler" and responsible for ensuring crop is in program compliance with the proposed agreement, assuming the producer in its capacity as a handler had signed the agreement.

Witnesses explained that while some leafy green vegetables are minimally handled after they are harvested, some product is sold or transferred to a secondary handler or a handler other than a first handler for further processing. These secondary handlers are commonly known as "manufacturers" or "processors". Record testimony indicates that secondary handlers or handlers other than first handlers generally buy from first handlers, and could receive product from other handlers, processors, or manufacturers. Additionally, such secondary handlers also may purchase

leafy green vegetables directly from producers.

According to the hearing record, the term "process", which is included in the definition of "handle", is synonymous with "manufacture" and means "to change fresh leafy green vegetables from their natural or raw form into packaged fresh-cut products." During the manufacturing process, leafy green vegetables are typically washed, and then shredded, cut, cored, trimmed, or blended with other types of fresh-cut leafy green vegetables, or any combination thereof. Ultimately, the processed product is packaged for distribution. Processed fresh leafy green vegetable products are then typically transported in refrigerated trucks or coolers to the secondary handler's customer. These customers may include consumers, retailers, foodservice companies, or wholesale produce operations supplying a range of products to retail and foodservice companies.

Witnesses were careful to clarify that activities of a manufacturer do not include the packing of leafy green vegetables in the field. Additionally, record testimony indicates that, in some cases, coring and trimming activities can be part of a producer or handler harvesting activity. Therefore, the definition of manufacture should not include leafy green vegetables packed in the field. Additionally, the terms "manufacture" and "process" appeared in the Notice of Hearing as § 970.16 and § 970.21, respectively, and should be combined and revised slightly for purposes of clarification and redesignated as § 970.19.

The term "manufacturer" as indicated above should be defined to mean any person who manufactures. As slightly revised, the definition should not include a retailer, a foodservice operator, or broker, except to the extent that such a person is otherwise engaged in handling. The term "manufacturer" appeared in the Notice of Hearing as § 970.17, and should be redesignated as § 970.20.

Hearing record evidence supports the inclusion of the term "import" under the definition of "handle". As such, the term "importer" should be defined to mean "a handler located in the production area who imports leafy green vegetables that are produced or handled outside of the production area." The term "importer" appeared in the Notice of Hearing as § 970.13, and should be re-designated as § 970.16.

Material Issue Number 5(a)—Definition of Terms

In addition to the definitions addressed in Material Issues 3 and 4, certain terms should be defined for the purpose of specifically designating their applicability and limitations whenever they are used in the proposed agreement.

“Act” should be defined in § 970.1 of the proposed agreement as the Agricultural Marketing Agreement Act of 1937, as amended (48 Stat. 31, as amended; 7 U.S.C. 601–674). This is the statute under which the proposed regulatory agreement would be operative.

Record evidence supports adding a new definition § 970.2, “Audit metric”, to the proposed agreement. According to the record, “audit metric” should be defined to mean an auditable standard or requirement within a process control prescribed pursuant to § 970.67.

“Audit verification” should be revised to “audit” and should mean an official review conducted by the Inspection Service to verify and document that good agricultural, handling, and manufacturing practices are adhered to throughout the growing, harvesting, packing, manufacturing, and transportation of leafy green vegetables. Additionally, according to the record, an audit would include a physical visit to the farm or facility subject to audit while it is in operation. This audit would represent a “snapshot in time” based on documentation reviewed, persons interviewed, and operations observed. The intention of the audit is to provide the auditor with a picture of the handler’s activities with the ultimate goal of ensuring that such activities comply with program requirements.

The definition for “audit verification” that appeared in the Notice of Hearing as § 970.2, should be redesignated as § 970.3, “audit”.

The term “broker” should mean a person who coordinates the sale and transportation of leafy green vegetables for retail or foodservice operators, without taking ownership of such vegetables. This definition appeared in the Notice of Hearing as § 970.3, and should be redesignated as § 970.4 and reworded for clarity.

As witnesses explained, and as recommended in this decision, the term “critical limit” should refer to a maximum or minimum value that is assigned to a process control when a biological, chemical, or a physical parameter must be controlled. This prevents or minimizes the occurrence of a food safety hazard. “Critical limit” appeared in the Notice of Hearing as

§ 970.4, and should be redesignated as § 970.6 and revised slightly for clarity.

The term “crop year” should be defined to mean the 12-month period beginning on April 1 of any year and ending on March 31 of the following year. The record indicates that leafy green vegetables are produced year round in the production area. The proposed April through March period mirrors the existing crop year in the predominant production areas for leafy green vegetables. This period represents a fixed timeline that would prescribe a period of conduct essential for the Board’s administrative activities, such as preparing an annual budget of expenses and accounting for receipts and expenditures of funds. Thus, the term “crop year” would be synonymous with “fiscal year.”

The definition of “crop year” should be revised to include authority for the Board, subject to approval of the Secretary, to recommend any other annual period if a different annual period is found to be more appropriate. The definition of “crop year” that appeared in the Notice of Hearing as § 970.5 should be revised as indicated above and redesignated as § 970.7.

The definition of “foodservice distributor” that appeared in the Notice of Hearing should be replaced by a definition of “foodservice operator”. The term should be defined to mean a person that provides leafy green vegetables to the public as a restaurant, cafeteria, industrial caterer, hospital, or nursing homes. These businesses directly deliver leafy green vegetables to consumers, either by sale or by offering for direct consumption. Foodservice operators are excluded from the definition of “handler” in their role as a foodservice operator, much the same as retailers are excluded from the term handlers in their roles as retailers.

Record evidence also supports clarifying that the list of businesses identified in the proponents’ definition of foodservice operators is not all inclusive. This clarification is being added to the definition of foodservice operator, which appeared as § 970.6 and is being revised and redesignated as § 970.8.

“Good agricultural and handling practices” refer to general practices established by FDA to reduce microbial food safety hazards in leafy green vegetables. According to the hearing record, good agricultural and handling practices are described in two FDA guideline documents, the “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” and the “Guide to Minimize Microbial

Food Safety Hazards for Fresh-cut Fruits and Vegetables”.

FDA is the agency at the U.S. Department of Health and Human Services charged with primary regulatory responsibility for food safety. The FDA guidelines referenced above, broadly referred to as “GAPs” and “GHPs”, are intended to assist the produce industry in minimizing the risk of food-borne contamination throughout the industry’s production and handling activities. According to the hearing record, GAPs and GHPs, would provide the scientific baseline or reference for all audit metrics relating to production and handling activities developed under the proposed agreement.

As witnesses explained, and as included in the proposed agreement, the Board should have authority to recommend, for approval by the Secretary, the adoption of any other documents or regulations, established for the purposes of minimizing microbial food safety hazards in the production and handling of leafy green vegetables. These documents and regulations would be used as the basis for audits conducted by the Inspection Service under the program.

Section 970.9 that appeared in the Notice of Hearing is being modified for clarification and redesignated as § 970.11.

According to the hearing record, “good manufacturing practices”, or “GMPs”, mean any FDA regulations which describe the methods, equipment, facilities, and controls required for producing fresh-cut food, including processed, packaged leafy green vegetables. Current FDA regulations appear in 21 CFR Part 110. According to the hearing record, GMPs would provide the scientific baseline or reference for all audit metrics relating to manufacturing activities developed under the proposed agreement.

As recommended in this proposed agreement, the Board should have authority to recommend, for approval by the Secretary, the adoption of FDA guidance documents, regulations, or any other documents, for use in audits conducted by the Inspection Service under this part. This definition appeared in the Notice of Hearing as § 970.10, “good manufacturing practices” and should be revised and redesignated as § 970.13, “good manufacturing practices or GMPs”.

“Inspection Service” should be defined to mean Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, its designees, or any other entity approved or recognized by USDA to conduct audits on leafy green vegetables. USDA recommends revising

this definition to more clearly define the Inspection Service's role in the audit process. This definition appeared in the Notice of Hearing as § 970.14 and should be revised and redesignated as § 970.17.

The term "National Leafy Green Vegetable Board" or "Board" be added to the list of defined terms as § 970.22 of the proposed agreement. "Board" should mean the administrative board established pursuant to § 970.40 and § 970.41.

The term "part" should be added to the proposed agreement as § 970.24 and should be defined to mean the marketing agreement regulating the handling of leafy green vegetables and all rules, and regulations issued thereunder.

As presented in the Notice of Hearing, proponents proposed that "Person" should be defined to mean an individual, partnership, corporation, association, or any other business unit or legal entity. This definition should be revised to make it consistent with the definition of the same term in the Act and redesignated as § 970.25.

The definition of "process control" should be revised so that it more clearly reflects the usage of this term as it was presented by witnesses during the hearing. "Process control" should mean a step or point within a production, harvesting, handling, manufacturing, or transportation process at which the potential for microbiological contamination can be reduced. This definition appeared in the Notice of Hearing as § 970.22, and should be revised and redesignated as § 970.26.

"Producer" is synonymous with "grower" and should be defined to mean any person engaged in a proprietary capacity in the production of leafy green vegetables for sale or delivery to a signatory handler.

Section § 970.20 of the Notice of Hearing should be modified for clarity and redesignated as § 970.27.

Witnesses proposed the addition of the term "region" to the list of definitions to clarify that "region" is distinctly different from the term "zone". As discussed later in Material Issue 5(b), zones are related to Board membership. According to record evidence, "region" should mean a production or growing area distinguished by common environmental or growing conditions including, but not limited to, geography, climate, production practices, water sources and distribution systems, and wildlife. This definition should be added to the list of definitions as § 970.29 of the proposed agreement.

"Retailer" should be defined to mean any person that sells leafy green vegetables directly to the consumer. Retailers' sales typically involve the sale of leafy green vegetables for further preparation or home consumption by the consumer. An example of a retailer would be a grocery store.

This definition appeared in the Notice of Hearing as § 970.24, and should be revised for clarity and redesignated as § 970.30.

"Secretary" means the Secretary of Agriculture of the United States or any officer or employee of the USDA who is acting on their behalf. This definition appeared in the Notice of Hearing as § 970.25 and should be redesignated as § 970.31.

"United States Department of Agriculture or USDA" should be defined to mean any officer, employee, service, program, or branch of the Department of Agriculture, or any other person acting as the Secretary's agent or representative in connection with any provisions of this part. This definition appeared in the Notice of Hearing as § 970.27 and should be revised with minor modifications for clarity and redesignated as § 970.35.

A definition of the term "United States Food and Drug Administration or FDA" should be added to the list of defined terms as § 970.36 of the proposed agreement and should mean the agency within the United States Department of Health and Human Services. This definition allows the FDA acronym to be used throughout the proposed agreement.

The definition of "Zone" that appeared in the Notice of Hearing as § 970.28 should be revised and redesignated as § 970.37. "Zone" should be defined to mean one of the subdivisions of the production area or such other subdivisions as may be established pursuant to § 970.41. Defining the zones would be important for the purpose of Board and the Technical Review Committee representation, and is related to §§ 970.40, 970.41, 970.42, 970.44, 970.46, 970.49 and 970.66.

Record evidence supports modifying the zones proposed by the proponents, as well as adding additional zones. Zones should be comprised of States that are geographically contiguous and reflect similarities in climate and crop production. Zones should also reflect the distribution of leafy green vegetable acreage, and distribution of leafy green vegetable farms. "Zone" is further discussed under Material Issue 5(b).

USDA recommends replacing the proponents' proposed five zones with eight zones, as stated below:

(1) *Zone 1* shall include the States of California and Hawaii.

(2) *Zone 2* shall include the States of Alaska, Idaho, Montana, Oregon, Washington, and Wyoming;

(3) *Zone 3* shall include the States of Arizona, Colorado, Nevada, New Mexico, and Utah;

(4) *Zone 4* shall include the States of Illinois, Iowa, Minnesota, Nebraska, North Dakota, South Dakota, and Wisconsin;

(5) *Zone 5* shall include the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas;

(6) *Zone 6* shall include the States of Delaware, District of Columbia, Indiana, Kentucky, Maryland, Michigan, Ohio, Virginia, and West Virginia;

(7) *Zone 7* shall include the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Tennessee; and,

(8) *Zone 8* shall include the States of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Material Issue 5(b)—Administrative Board

The proposed agreement should provide for the establishment of an administrative body (Board) to administer the program and to provide for its effective and efficient operation. Membership on the Board should be reflective of leafy green vegetable industry stakeholders, namely signatory handlers, producers supplying such signatory handlers, importers, retailers, foodservice operators, and the public (consumers). Further, the proposed agreement should delineate the procedures, powers, and duties of the Board.

USDA recommends that, based on record evidence, the provisions of the proposed agreement pertaining to zones, Board membership allocation among zones, eligibility requirements, and nomination procedures, be revised from those provisions that appeared in the Notice of Hearing. Specifically, USDA recommends increasing the number of zones and redefining them so that regional similarities are recognized as well as leafy green vegetable acreage and the number of farms harvesting leafy green vegetables. USDA also proposes that the Board's membership be expanded and revised to reflect the proposed changes in zones, and to increase opportunity for participation of industry representatives on the Board. Lastly, USDA proposes that eligibility requirements and nomination procedures be revised to address witness concerns regarding diverse

stakeholder (small businesses, organic businesses, diversified businesses) representation among the Board membership. This would provide for an open, transparent, and inclusive nomination, selection, and appointment process.

This Material Issue addresses §§ 970.37, 970.40, 970.41, 970.42, 970.43, 970.44, 970.45, 970.48, 970.49, 970.50, and 970.51 of the proposed agreement. These sections address the subject areas of: establishment of zones, establishment and membership of the Board, rezoning and reallocation, eligibility, term of office, nominations, alternate members, compensation and expenses, administrative procedures, and powers and duties of the Board. These sections were originally proposed in the Notice of Hearing as §§ 970.28, 970.40, 970.41, 970.42, 970.43, 970.44, 970.47, 970.48, 970.49, and 970.50, respectively.

Definition of Zones

The proponents testified that the production area should be subdivided into five zones for the purpose of industry representation on the Board and administration of the proposed agreement. The five zones were proposed as follows:

- (1) *Zone 1:* California, Washington, Oregon, Hawaii, and Alaska.
- (2) *Zone 2:* Arizona, Montana, North Dakota, Wyoming, South Dakota, Idaho, Nevada, and Utah.
- (3) *Zone 3:* New Mexico, Colorado, Nebraska, Minnesota, Iowa, Kansas, Oklahoma, Texas, Missouri, Arkansas, and Louisiana.
- (4) *Zone 4:* Wisconsin, Michigan, Ohio, Illinois, Indiana, Kentucky, Tennessee, Mississippi, Alabama, and Georgia.
- (5) *Zone 5:* Maine, New Hampshire, Vermont, New York, Connecticut, Massachusetts, Pennsylvania, New Jersey, West Virginia, Virginia, Maryland, Delaware, Rhode Island, North Carolina, South Carolina, Florida, and the District of Columbia.

For this zone structure, the proponents utilized 2007 United States Census production volume data for leafy green vegetables. Proponents explained that they attempted to anchor each zone with a key leafy green vegetable-producing State, as detailed in Material Issue 1. For this reason, the States of California and Arizona were purposefully separated so that their production volume would not be attributed to one zone, thereby not skewing the balance of Board member representation in favor of those two States and thus, a specific zone. Other anchor States that produce the majority

of leafy green vegetables in the United States are Texas, Colorado, Georgia, Florida, and New York.

Proponents explained that their intent was to create zones strictly for the purpose of industry representation on the Board. Proponents contended that the proposed zones and corresponding Board representation would provide for the development of audit metrics that recognized regional differences. Proponents further explained that they intended to develop a process that would be inclusive and transparent to allow for the participation of various stakeholder groups and the recognition of regional, geographic differences. The topic of audit metrics development is discussed in Material Issue 5(c).

A considerable number of witnesses, both those who were opposed to the establishment of the proposed agreement, as well as those who supported the concept of a national agreement but suggested improvements to the proponents' proposal, raised concerns over the proponents' proposed zones. Witnesses testified that the proposed zones were geographically too large, and did not recognize regional differences in geography, types of crops grown, production practices, environmental factors, climate, and diverse stakeholder concerns that exist in the United States leafy green vegetable industry. Witnesses also testified that the proposed zones did not accurately reflect the distribution of leafy green vegetable acreage or the distribution of farms.

Witnesses contended that the proponents' proposed zones were not established based on agricultural or climatic conditions to reflect common growing seasons or agronomic zone characteristics. Witnesses further claimed that it was unreasonable to expect representatives of zones inclusive of States that greatly differ in leafy green vegetable crop type, production methods, geography, and climate, to adequately understand the growing conditions across such a wide geography. Witnesses cited several examples to illustrate the proponents' proposed zones were geographically too large and included States in the same zone that do not share geographic and climate characteristics, but would be represented by the same membership and Board member allocation.

As an example, witnesses testified that proponents' proposed Zone 4 included 10 States that stretched from Wisconsin to Alabama. These witnesses pointed out that, as proposed, the States of Georgia and Ohio, and the States of Wisconsin and Alabama, would be in the same zone even though they have

distinct differences in geography and climate. Witnesses also noted that proponents' proposed Zone 5, which included 16 States and the District of Columbia, combined southern States such as Florida with northern States such as Vermont, Maine, and New York which vary widely in geography, climate, and production practices. Witnesses further asserted that the States in proposed Zone 5 have different soil types, water sources, growing seasons, and marketing channels.

Witnesses testified that production practices, which vary across the United States, were reflective of climates. Witnesses suggested that the proposed zones should include similar climate areas such as the Upper Midwest as one zone. An example cited by witnesses identified Upper Midwest States as having climate requiring different production practices than those found in Georgia or California. Witnesses explained that Upper Midwest States tend to have periods of hard freezes, thereby limiting their production season to the months of May through October. In contrast, witnesses noted that the State of Georgia has a high humidity climate, Northeast States have cooler climates, and Southern California has more of a desert climate.

Witnesses asserted that States having similar climate and geography should be grouped together in order to represent a contiguous area as further support of proper representation of like concerns among States. One witness offered the example of combining the States of Florida, Georgia, and Alabama as an appropriate representation of like geography, climate, and production practices. Another witness suggested subdividing the State of Maryland to place the northern half of Maryland with States west to Michigan in one zone, and southern part of Maryland with States west of the Mississippi River in another zone. Additionally, another witness suggested combining the Northeast States into one single zone because of similarities in climate.

Some witnesses suggested that the division of zones and Board membership allocation among those zones should be based on the number of leafy green vegetables acres harvested for the fresh and fresh-cut market. Witnesses explained that some production areas benefit from production environments that allow for multiple harvests of high-yielding crops, while other areas only harvest one crop per year.

According to witnesses, an example of this difference would be a producer in California that may harvest a field of immature or baby leaf varieties of leafy

green vegetables several times within one growing season, while producers of cabbage in New York may only harvest one time per growing season. In this example, if production volume were used instead of acreage, the producer in California would be given more weight in the allocation of producer seats under the proponents' proposal. However, witnesses indicated that if the number of acres were used as a basis of member allocation, the example farm in California would be equally weighted to the farm in New York. As such, witnesses suggested that the usage of acres would therefore result in a more equitable representation of producers on the Board.

Other witnesses, including those opposed to the proposed agreement, suggested using the number of farms per State to capture the distribution of producers nationwide as opposed to relying solely on production volume to determine producer representation. These witnesses explained that while some States have a concentration of large producer entities producing high-yielding crops, other States have a high number of smaller producer entities that produce leafy green vegetables as a portion of their overall farm production. Witnesses argued that under a zone and membership allocation structure that focuses on production volume, such as that proposed by the proponents, States having a high number of small, low-volume farms risk being under-represented compared to States with fewer high-volume farms. Witnesses contended that under-representation of these small farm operations would result from the proponents' proposed zones. Witnesses with this concern stated that the proposed zones and corresponding member representation on the Board should be revised to better recognize diversified, small-scale operations.

Witnesses argued that an increase in the number of zones together with a more accurate zone definition would likely result in greater opportunities for stakeholders, such as small diversified farms, farms using non-conventional production methods, and handler entities interacting with local, small-scale markets and producer associations, to gain representation. Witnesses stated that increased opportunity for stakeholders would result in the inclusion of those groups' concerns in Board decisions, including the audit metric development process.

Witnesses argued that, contrary to the proponents' position, the definition of zones and the recommendation of audit metrics by Board members are intrinsically linked. Witnesses disagreed

with the proponents' position that the division of zones would not have an impact on the process of developing audit metrics under the proposed agreement. They explained that if the proposed zones did not adequately represent regional differences in geography, climate, and production practices, the composition of Board membership would not adequately represent the complex spectrum of producer and signatory handler interests that exist in the United States leafy green vegetable industry. Furthermore, because the Board would ultimately be responsible for recommending audit metrics to USDA for approval, witnesses feared that minority and diverse stakeholder concerns would be overlooked in this process because they may not be represented on the Board.

Lastly, witnesses, including proponent witnesses, stated that the Board should have the ability to modify the number and definition of zones, in order to reflect the diverse and changing leafy green vegetable industry.

Proponent witnesses testified that their intent in defining the proposed zones was to allow for adequate participation by stakeholders to ensure consideration of diverse interests in Board decision-making, including the development of the audit metrics. However, there was record testimony that the proposed zones were geographically too large to ensure adequate representation of diverse stakeholder interests. The record further establishes that acreage of leafy green vegetables and the number of farms harvesting leafy green vegetables rather than production volume also should be considered in subdividing the production area into zones.

Throughout the hearing, proponents stated they were open to revisions in the proposed agreement to address concerns brought to light by the hearing process. Proponents asserted that they were willing to collaborate with concerned witnesses and USDA to improve the proposed agreement's effectiveness. Several proponents stated that, while their proposal attempted to present an equitable, balanced division of geographic zones and diverse perspectives of the supply chain, USDA should have the discretion, based on hearing record evidence, to modify the proposal so that it better reflects the needs of the industry. In addition, both witnesses who were opposed to the proponents' proposal and those who advocated improvements to the proposal, stated that USDA should revise the proposed zones and Board membership eligibility requirements to ensure that leafy green stakeholder

groups are adequately represented. These stakeholder groups would include, but are not limited to: Small producer and signatory handler entities, organic producers and signatory handlers, and diversified farming operations.

USDA has analyzed witness testimony in conjunction with record data and has developed recommended changes to the proposed zones. Evidence reviewed by USDA includes both Census and NASS leafy green vegetable data, and information specific to the distribution of leafy green vegetable acreage and the number of farm reporting such acreage by State. In addition, USDA considered information supplied by witnesses with regard to geography, climate, and seasonal growth patterns of different leafy green vegetable crops to more appropriately group States into zones.

USDA's analysis of the distribution of leafy green acreage throughout the production area as compared to the volume of production demonstrated that significant variances exist between areas producing high-yielding crops and those producing low-yielding crops. An acreage-based analysis places leafy green vegetable acreage having smaller annual per acre production yields on more equal footing with leafy green vegetable acreage having higher annual per acre production yields. This should result in greater and more equitable opportunity for participation in States having lower yields per acre. As such, USDA recommends that acreage rather than production volume, as proposed by proponents, should be utilized in defining zones.

Furthermore, USDA's analysis of the number of farms reporting harvest of leafy green vegetables (specifically for the fresh and fresh-cut market) allowed USDA to assess the distribution of industry stakeholders across the production area. Using the number of farms harvesting leafy green vegetables in defining zones would address concerns that States having a high number of small producer entities would be under-represented under the zone structure proposed by proponents. Lastly, defining zones on a combined analysis of leafy green vegetable acreage and the number of leafy green farms provides better representation on the Board of diverse stakeholder interests.

USDA also took into consideration witness testimony that zones should reflect grouping of States that are contiguous and share geographic and climate similarities. According to hearing record evidence, incorporating guidelines that would require, to the extent practicable, grouping of States

into zones that are contiguous and share climate and similarities in agricultural practices would result in zones comprised of States that share similar production and handling concerns.

Regarding the above, USDA recommends grouping, to the extent practicable, geographically contiguous States into zones to reflect similarities in climate and agricultural practices. For example, southeastern States such as Mississippi, Alabama, Florida, Georgia, and North and South Carolina were grouped together because of the similarity in warm, coastal climates, type of crops grown, and growing seasons. Tennessee was added to this group as record evidence indicated that the similarity between leafy green vegetable production in this State was more similar to the coastal States than its northern neighbors.

Similarly, the northeastern States stretching from Pennsylvania and New Jersey up through Maine were grouped because of similarities in crop types and growing seasons. According to the hearing record, the northeastern States produce a majority of the nation's cabbage, which is typically a colder weather crop that is harvested according to a crop cycle that is distinctly different from warm weather crops. Another example is the grouping of Arizona, New Mexico, Nevada and Utah. These States all represent warmer, drier climates with spring and summer growing and harvest seasons. These States also typically rely heavily on irrigation watering systems as rainfall is limited. Similar to the case of Tennessee, Colorado was included in the southwestern State grouping even though that State tends to have an overall cooler and wetter climate. However, according to the record, Colorado leafy green vegetable crops, growing and harvest seasons were more similar to those in Arizona and New Mexico than those in the other neighboring States of Nebraska, Wyoming, or Kansas.

States ranking among the top leafy green vegetable bearing acreage were identified so that each zone was anchored with a key leafy green vegetable producing State. This is consistent with the method applied by proponents.

In summary, the record supports increasing the number of proposed zones from 5 to 8. The zones would delineate smaller geographic areas that both reflect similarities in climate, geography, and crop production, and increase opportunity for participation of industry representative on the Board.

The zone structure would be as follows:

(1) *Zone 1* should include the States of California and Hawaii;

(2) *Zone 2* should include the States of Alaska, Idaho, Montana, Oregon, Washington, and Wyoming;

(3) *Zone 3* should include the States of Arizona, Colorado, Nevada, New Mexico, and Utah;

(4) *Zone 4* should include the States of Illinois, Iowa, Minnesota, Nebraska, North Dakota, South Dakota, and Wisconsin;

(5) *Zone 5* should include the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas;

(6) *Zone 6* should include the States of Delaware, the District of Columbia, Indiana, Kentucky, Maryland, Michigan, Ohio, Virginia, and West Virginia;

(7) *Zone 7* should include the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Tennessee;

(8) *Zone 8* should include the States of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

These zones, which were previously defined in § 970.28 of the Notice of Hearing, now appear in § 970.37.

The Board should have authority to recommend future modifications of the defined zones and to ensure proper geographic division of the production area over time. In making such a recommendation, the Board would be expected to consider factors similar to those used in deriving the zones proposed in this recommended decision.

Board Membership and Allocation of Member Seats Among Zones

Proponent witnesses advocated a Board membership of 23 members allocated among five zones, with the representation of each zone based on that zone's relative volume of leafy green vegetable production. Of the 23-member Board proposed by the proponents, 13 seats would be assigned to signatory handlers and 6 seats would be assigned to producers delivering to signatory handlers. The signatory handler and producer member seats would be allocated among the proposed five zones as follows: Four handlers and two producers from Zone 1; three handlers and one producer from Zone 2; two handlers and one producer from Zone 3; two handlers and one producer from Zone 4; and two handlers and one producer from Zone 5. In addition, the proponents' proposal would assign one seat to each of the following interest groups: Retailers, foodservice, importers (signatory handlers), and the public. As proposed by proponents, representation

of signatory handlers, producers, and the other at-large members (retailer, foodservice, importer, and public) among the 23 seats would be as follows: 13 handler seats (57 percent), 6 producer seats (26 percent), and 4 at-large seats (17 percent).

Proponents testified that even though the proposed agreement would regulate signatory handlers, the inclusion of producers delivering product to those handlers as Board members was important given that they would also be impacted by any regulations in effect under the proposed agreement. The proponents testified that the importer, retailer, foodservice, and public members are needed to represent the diverse perspectives of the farm-to-consumer leafy green vegetable supply chain. They further stated that each of these stakeholders can address unique factors associated with their sector. Proponents stated that the public member seat was intended to provide consumer representation on the Board.

Proponents explained further that specific producer and signatory handler stakeholder groups should be assured representation on the Board and, therefore, proposed representation requirements for these groups. Specifically, the proposed requirements state the majority of producer members could not be engaged in the act of handling leafy green vegetables or manufacturing fresh-cut, packaged leafy green products. In addition, the Board would include at least two small producer business entities, and four signatory handler members would be manufacturers of fresh-cut leafy green vegetables.

Proponents explained that the proposal to include producers not engaged in handling or manufacturing leafy green vegetables or products would allow for representation of "pure" producer interests on the Board. Regarding Board seats allocated to small producer entities, proponents explained that the United States leafy green vegetable production industry is comprised of many different sizes of producer operations following varying production methods, and that each type of producer is faced with unique challenges when producing for the United States leafy green vegetable industry. For this reason, proponents stated that small producer entities should be assured representation on the administrative Board. Lastly, proponents explained that manufacturers of fresh-cut leafy green vegetables face unique challenges that are different from those faced by other sectors of the leafy green vegetable industry. For this reason, proponents

stated that their representation on the Board was important to understanding issues that are particular to that part of the United States leafy green vegetable industry.

Both witnesses who were opposed to the proponents' proposal and those who advocated improvements to the proposal stated that USDA should revise, as necessary, Board membership to ensure that diverse leafy green vegetable industry stakeholder groups are represented. Witnesses testified that the proponents' proposed Board membership, which resulted from their proposed zones, appeared to be based more on ensuring the strategic voting power for certain States. These witnesses asserted that the proposed zones and corresponding Board membership would provide inequitable representation of leafy green vegetable industry stakeholders, particularly small, diversified farm operations.

The record supports the establishment of an administrative Board to administer the proposed agreement and provide for its effective and efficient operation. The record also indicates that the membership of the administrative Board should represent signatory handlers, producers supplying such handlers, importers, retailers, foodservice, and the public.

Upon consideration of the record evidence, a 3-member increase in the total size of the Board would allow for greater industry representation yet would maintain a membership that is manageable and efficient. For these reasons, the Board membership should be increased from 23 to 26 members. Of that total, USDA recommends that 22 Board member seats be designated as producer and signatory handler seats, and the remaining 4 seats be designated as importer, retailer, foodservice, and public member seats. Each member should also have an alternate who would have the same qualifications as the member for whom he or she is an alternate.

In allocating handler and grower seats, each zone's combined share of national leafy green acreage and the national number of leafy green vegetable producing farms were considered. In instances where a zone represents a greater portion of leafy green vegetable acreage or a larger number of leafy green vegetable farms, additional producer or signatory handler members would be allocated. Additionally, record evidence supports assigning a minimum of one producer member and one signatory handler representative to each zone.

Based on the foregoing discussion, the following is the allocation of producer and signatory handler members:

(1) Zone 1 should have four signatory handlers and three producers;

(2) Zone 2 should have one signatory handler and one producer;

(3) Zone 3 should have one signatory handler and one producer;

(4) Zone 4 should have one signatory handler and one producer;

(5) Zone 5 should have one signatory handler and one producer;

(6) Zone 6 should have one signatory handler and one producer;

(7) Zone 7 should have two signatory handlers and one producer; and,

(8) Zone 8 should have one signatory handler and one producer.

In addition to the producer and signatory handler seats, four seats should represent the following four groups: Importers, retailers, foodservice, and the public. Representation of these stakeholders is needed to represent the diverse perspectives of the leafy green vegetable supply chain. The representation of the proposed 26-member Board for signatory handlers, producers, and the other members (importer, foodservice, retailer, and public) would be 12 seats (46 percent), 10 seats (39 percent), and 4 seats (15 percent), respectively.

This revised allocation represents an increase in producer representation on the Board from the proponents' proposed 26 percent to 39 percent, as well as a decrease in at-large representation from the proponents' proposed 17 percent to 15 percent. The revised signatory handler representation would result in 46 percent versus the proponents' 57 percent.

The proponents' recommendations that the majority of grower members not be engaged in handling, that at least two of the grower members represent small businesses and that at least four of the handler members be manufacturers of fresh-cut products should remain in § 970.40. Additionally, to the extent practicable, Board membership should include diversified farm producers and organic producers and handlers.

Section 970.40 of the proposed agreement is being revised as discussed above.

Proponents proposed including authority to reapportion Board member seats among zones, change the number of Board members, and revise composition (the relative number of signatory handler, producer and other seats). This authority appeared in the hearing notice under § 970.40 and is being moved to a new § 970.41.

In making any recommendation to revise membership, the Board would have to consider the geographic distribution of acreage and the number of leafy green vegetable farms among the

zones. This differs somewhat from what the proponent group proposed—that the Board would need to consider shifts in production. Other criteria to consider would be the importance of new acreage, the equitable relationship between membership and zones, economies to result in promoting efficient administration of the program, and other relevant factors. The agreement should require that each zone be represented by at least one producer one signatory handler seat.

Eligibility

The proponents proposed eligibility requirements for the purpose of identifying persons who would be qualified to serve as members on the Board. Proponents proposed that in order for a signatory handler (including importers) or producer to be eligible to serve on the Board, each should be an owner, officer, or employee of a signatory handler or producer at the time of their selection and throughout their term of office in the zone for which selected.

Proponents proposed that the retail, foodservice, and public members and their respective alternate members not be engaged in the production or handling of leafy green vegetables. Additionally, the retail and foodservice members and their respective alternate members should be, at the time of their selection and throughout their term of office, an owner, officer, or employee of the firm represented by the seat selected. This would enable these members to represent all stakeholders involved in the supply chain for that sector.

Regarding the producer and signatory handler member seats, there was testimony presented at the hearing advocating that such members should be required to be a legal resident in the zone for which selected. However, record evidence supports that where a producer or handler conducts business is a more important criteria than the producer or handler's place of residence.

Multiple witnesses expressed concern that the proposed eligibility provisions could allow large leafy green vegetable producers and handlers—who often operate in multiple States—to have member seats in several zones. These witnesses testified that the agreement should limit the number of seats any one company could fill to maximize industry representation on the Board.

According to record evidence, limiting Board member representation to provide that no one company or its affiliates could be represented on the Board by more than one signatory

handler (including importer) or producer and their alternate member should provide more opportunities for diverse representation on the Board. As such, a provision is added to the proposed agreement to specify that company representation for such entities would be limited to one member seat and one alternate member seat.

Finally, the remaining members of the Board may be from any zone because they represent the production area at large. The eligibility requirements proposed in § 970.41 of the Notice of Hearing are revised as discussed above and redesignated as § 970.42.

Alternate Members

Proponents proposed that each Board member should be assigned an alternate member for the purpose of assuring continuity and stability of Board operations. Alternate members would act in the place and stead of the Board members they are alternates for when the Board members cannot fulfill their Board obligations. Alternate members would succeed their member in the event of that member's death, removal, resignation or disqualification. The alternate would then serve until a successor was selected and qualified.

According to proponents, alternate members would be subject to the same eligibility requirements as Board members and would be nominated in the same manner as Board members. Proponents explained that providing alternate Board members would ensure full representation of the industry, as well as full representation of their particular zone and group (producers, signatory handlers, or other stakeholder members).

The record supports the proponents' proposal regarding alternate members. This proposal appeared as § 970.44 of the Notice of Hearing and is redesignated as § 970.45. The last sentence of that section is removed as it is duplicative of language that appears in § 970.49.

Nominations

A nomination mechanism should be established through which members and alternate members of the Board would be nominated, selected, and appointed by the Secretary. Record evidence supports revising § 970.43 of the Notice of Hearing to improve transparency in the selection and appointment of Board members.

In their proposal, proponents described a nomination process to identify Board member nominees and to provide for their selection and appointment by USDA. Proponents explained that names of nominees

would be collected by USDA (initially) and by the Board (for subsequent nominations) at producer and signatory handler meetings, by mail, or through any form of electronically verifiable communication. Names received as nominees for producer and signatory handler member seats would then be placed on a ballot and would be voted on by their peers, respectively. A list of nominees receiving the highest number of votes would be forwarded to USDA for selection and appointment by the Secretary. Proponents explained that once the producer and signatory handler members had been appointed, those members would nominate the retailer, foodservice, importer, and public members and their alternate members. Final selection and appointment of the retailer, foodservice operator, importer, and public member would be made by the Secretary.

Proponents further explained that, as part of the nomination process, nominees would be required to indicate in advance of selection their interest to serve as a member, alternate, or both, and that they are willing to accept the seat for which selected. According to the record, agreeing in advance to serve as a Board member or alternate member would avoid possible delays in the appointment of the Board.

According to proponents, the proposed agreement would provide, in times when nominations are not made in a timely manner and as specified, the Secretary authority to appoint members and alternates who meet the proposed eligibility requirements. Furthermore, proponents explained that in the event that any vacancy were to arise on the Board due to an individual's disqualification, removal, resignation, or death, a successor member or alternate member would be nominated and selected in accordance with the proposed nomination and acceptance procedures, or at the discretion of the Secretary.

A considerable number of witnesses, both those who were opposed to the establishment of the agreement, as well as those who supported the concept of a national program but suggested improvements to the proponents' proposal, raised concerns over the proposed nomination and selection process outlined by the proponents.

The primary concern among these witnesses focused on what was perceived as a closed nomination process. These witnesses stated that a peer nomination and ballot system, in combination with the proponents' proposed zones and limited number of Board member seats, would result in the inability of diverse stakeholders to

successfully compete and receive nomination and appointment to the Board. Substantial concern was raised over the potential for large producer and signatory handler entities to control the nomination process and the resulting list of nominees forwarded to the Secretary for approval.

Additional concern was voiced over the process outlined by proponents for the nomination of the retailer, foodservice, importer, and public member seats. Witnesses argued that because the proponents' proposal allowed nominations for these positions to be made exclusively by appointed producer and signatory handler members to USDA, the proposed process lacked transparency or the opportunity for input from industry representatives not appointed to the Board.

Many witnesses testified that in the absence of proposed zones that better reflected regional differences and an increase in Board membership to allow for greater industry participation, all Board member selections should be made by the Secretary.

These witnesses advocated the establishment of a system under which a peer nomination voting process would be replaced by an industry-wide nomination process, with selection and appointment by the Secretary. Others suggested that nominations should be made by the general public, with selection and appointment by the Secretary. According to witnesses making these suggestions, their recommendations would lead to a transparent process for the identification and selection of Board members, and would improve the potential for diverse stakeholders to participate on the Board.

Record evidence supports that a process for Board member nominations is necessary. Further, record evidence supports that nominations for producer and signatory handler (including importer) member seats and their alternate member seats of the Board, should be made by their respective peers. As such, nominations for signatory handler member seats and their alternates only would be made by signatory handlers. Likewise, only producers supplying signatory handlers would be allowed to nominate eligible producers for producer member seats and their alternate seats.

Record evidence supports that the nomination process for the retailer, foodservice, and public member, and their alternates, should be revised to allow for nominations to be received at meetings, by mail, or by any form of electronically verifiable communication

from any person in the production area. This revision would allow for greater industry and public participation in the nomination of persons representing the retail, foodservice, and public communities and would allow for greater transparency in that process.

As part of the nomination process, nominees would be required to indicate in advance of selection their interest to serve as a member, alternate, or both, and that they are willing to accept the seat for which selected. This would avoid possible delays in the appointment of the Board.

The record evidence supports revising the proponents' nomination process by removing the industry vote on nominees received. Instead, all names received during the nomination period should be forwarded to the Secretary, together with necessary information concerning their eligibility.

The Secretary would appoint from those nominees the members and alternate members of the Board on the basis of the representation provided for in §§ 970.40 through 970.42 of this proposed agreement.

Finally, the record supports nomination provisions with regard to acceptance, failure to nominate, and vacancies. Sections 970.43(c), (d) and (e) as published in the Notice of Hearing are redesignated as § 970.44(c), (e) and (f).

Term of Office

The proponents proposed that the term of office for Board members and alternates should begin on April 1 and continue for two years. The record indicates that leafy green vegetables are produced year round and that a term of office beginning on April 1 corresponds to the beginning of the time period designated in the definition of crop year. This language was published in the Notice of Hearing as § 970.42 and is redesignated as § 970.43.

This decision recommends the two-year term of office as proposed by proponents for Board members and their alternates to increase industry participation in administering the proposed agreement. The two-year term of office would apply to all Board members, including those representing the public. The maximum number of terms that an individual would be allowed to serve as a member on the Board would be three consecutive two-year terms of office, or a maximum of six consecutive years. Thus, once a person has served as a Board member for six consecutive years, that person would not be eligible for re-nomination to the Board until after 12 consecutive months out of office. Such 6-year term

limits would not apply to alternate members to ensure continuity in Board operations.

Compensation and Expenses

According to record evidence, Board members and alternate members, committee and subcommittee members, including those members serving on the Technical Review Committee and the Research and Development Committee, would necessarily incur some expenses while attending meetings, or performing other duties under the proposed agreement. Proponents propose that reasonable expenses, which could include expenses associated with travel, meals, and lodging, should be reimbursed. However, proponents explained these same members and alternate members would not receive any compensation for their time. No specific testimony was received in opposition to this proposal. A provision for compensation and expenses was proposed in the Notice of Hearing as § 970.47 and is redesignated as § 970.48.

Quorum and Voting Provisions

The proponents proposed that provisions establishing quorum and voting procedures would be necessary for the effective functioning of the proposed Board. In their proposal, proponents stated that having a quorum requirement would ensure a majority of Board members be present prior to the Board voting on any action. According to proponents, a quorum would be met when a majority of all Board members were present at a meeting, including at least one member from each zone. If a quorum were met, proponents stated that voting requirements for any action taken by the Board would require the concurrence of a majority of all the members present at the meeting.

The proponents identified three Board actions that would require more than a simple majority vote. Proponents proposed that a minimum concurrence of two-thirds of the Board members at a meeting be required for Board actions related to the acceptance of GAPs, GHPs, and GMPs, as well as changes in the assessment rate and termination of the agreement. Proponents explained that for these specific actions a 2/3 vote requirement would be needed due to the importance of changes to audit metrics, assessments, or termination.

One witness testifying in favor of the super-majority provision clarified that the original language proposed by the proponents and published in the Notice of Hearing erroneously referred to "acceptance of Good Agricultural, Handling, and Manufacturing Practices" instead of audit metrics. The witness

explained that Good Agricultural, Handling, and Manufacturing Practices are guidelines that are independent of the proposed agreement and, therefore, would not be subject to recommended revisions proposed by the Board. The witness offered that approval of audit metrics would better capture the intent of the proponent group. Hearing record evidence supports replacing "acceptance of Good Agricultural, Handling, and Manufacturing Practices" with "approval of the audit metrics as provided in § 970.67" in § 970.49 of the proposed agreement.

In the event that a Board member were absent from a meeting, witnesses explained that that member's alternate could serve in the absent member's place and stead for the purpose of constituting a quorum and voting. Proponents further explained that if both the member and their alternate were unable to attend a meeting, the absent member or Board could designate any other alternate from the same zone and group who is present at the meeting to serve in the absent member's place and stead.

For example, Zone 7 is proposed to be allocated two signatory handler members. If one of the two Zone 7 signatory handler members were present at a meeting and both the other member and their alternate were both absent, the alternate for the first member could serve in the place and stead of the absent member because they would represent both the same zone and group as the absentee. In this scenario, the alternate member would be selected to serve in the place and stead of the absentee by either the absent Board member or the Board. In this same example, if an available alternate member was a signatory handler from a different zone or was an alternate producer for Zone 7, that alternate could not be designated to serve.

Proponent witnesses testified that meetings of the Board should be open to the public, and notice of meetings should be given to the Secretary in the same manner as is given to members of the Board. The record indicates that at Board meetings, members could cast their vote by voice, hand, or in writing.

Additionally, a member participating by telephone would need to confirm his or her vote in writing. According to the record, a videoconference would be considered an assembled meeting and all votes would be considered as cast in person without need for subsequent written confirmation.

The record supports the need to establish quorum requirements and voting procedures so that meetings are conducted in an orderly manner and

that adequate representation in Board decisions. However, the proposed language should be modified to state that a majority of all appointed members of the Board shall constitute a quorum. This would address situations in which a zone may not have any appointed members.

No specific testimony was received in opposition to this proposal. Accordingly, the provisions regarding quorum and voting procedures in § 970.48 would be revised as previously discussed above and redesignated as § 970.49.

Powers

Proponent witnesses testified that certain powers should be assigned to the Board in order for it to carry out its functions under the proposed agreement. Proponents indicated that these powers would enable the Board to make recommendations to the USDA that reflect the conditions in the industry based on their knowledge and experience. To this end, the proponents included six powers in their proposal:

(1) To administer the proposed agreement in accordance with its terms and provisions;

(2) To make such rules and regulations, with the approval of the Secretary, as may be necessary to effectuate the terms and provisions of the proposed agreement;

(3) To adopt, with the approval of the Secretary after notice and comment, audit metrics to administer the terms and provisions of the proposed agreement;

(4) To cooperate with existing State boards, commissions and agreements through memorandum of understanding to affect the purposes of the proposed agreement;

(5) To receive, investigate, and report to the Secretary complaints of violation of the provisions of the proposed agreement; and,

(6) To recommend to the Secretary amendments to the proposed agreement.

No specific testimony was received in opposition to this proposal.

Certain powers should be granted to the Board to enable it to properly administer the proposed program. Upon review, power 3 above is included in power 2 and is therefore duplicative, while power 4 is more appropriately included under Board duties. The section "Powers" originally was included in the Notice of Hearing as § 970.49 and is revised and redesignated as § 970.50.

Duties

Proponents stated that specific duties are necessary for the Board to fully

execute its responsibilities under the proposed agreement. They pertain to specific activities authorized under the proposed agreement, such as investigating and compiling information regarding leafy green vegetables, and to the general administration of the proposed agreement including hiring employees, appointing officers, and keeping records of all Board transactions.

The specific duties of the Board proposed by the proponents are as follows:

(a) To act as intermediary between the Secretary and any signatory with respect to the operations of the agreement;

(b) To select from among its members a chairperson and such other officers as may be necessary, and to define the duties of such officers;

(c) To establish subcommittees and advisory boards to aid the Committee in the performance of its duties under the agreement;

(d) To adopt such bylaws for the conduct of its business as it may deem advisable;

(e) To keep minutes, books, and records which clearly reflect all the acts and transactions of the Committee and subcommittees, and these shall be subject to examination by the Secretary at any time;

(f) To appoint such employees or agents as it may deem necessary, and to determine the compensation and define the duties of each;

(g) To cause its financial statements to be audited by a certified public accountant at least once each crop year and at such other times as the Committee may deem necessary or as the Secretary may request. Such audit shall include an examination of the receipt of assessments and the disbursement of all funds. The Committee shall provide the Secretary with a copy of all audits and shall make copies of such audits, after the removal of any confidential information that may be contained in them, available for examination at the offices of the Committee;

(h) To investigate the production, handling and marketing of leafy green vegetables and to assemble data in connection therewith; and,

(i) To furnish such available information as may be deemed pertinent or as requested by the Secretary.

Record evidence indicates that, in addition to the duties proposed by the proponents, the duty to develop an annual budget for review and approval by the Secretary should be included. Witnesses testifying in favor of this addition stated that development of a budget is necessary to ensure proper

financial planning of Board expected expenditures and anticipated receipts. In addition, the development of an annual budget would be instrumental in determining, along with production estimates, the annual assessment rate. The witness stated that the budget should be reviewed and approved by USDA to ensure the fiscal responsibility in the proposed agreement's administration.

At the hearing, some witnesses raised questions regarding the protection of confidential information, especially within the context of financial reports developed by the Board, and audit of Board annual financials, including receipt of assessments and the disbursement of all funds. Witnesses expressed concern over the need to maintain confidentiality of proprietary information when such reports are written or audits conducted.

The duties proposed by the proponents and listed above are reasonable and necessary. No specific testimony was received in opposition to this proposal. This proposal was included in the Notice of Hearing as § 970.50 and is revised as previously discussed and redesignated as § 970.51.

Material Issue Number 5(c)—Audit Metrics and Verification Audits

According to record evidence, the proposed agreement should provide that verification audits be conducted to verify that signatory handlers are complying with the provisions of the proposed program. This would include audits of signatory handler operations to ensure that GHP audit metrics are being adhered to, as well as producer operations delivering to those handlers to ensure that GAP audit metrics are being adhered to. Verification audits should also be conducted of manufacturer operations (for those manufacturers who are signatories to the proposed agreement) to ensure that GMP audit metrics are being adhered to. Proposed provisions for verification audits are provided for in § 970.66.

Record evidence supports providing the Board with the authority to recommend audit metrics. Audit metrics established under the proposed program would represent a set of auditable standards or process control that would allow an auditor to determine if a producer or handler is in compliance with the program. Provisions for the development of audit metrics are provided for in § 907.67.

In addition, a Technical Review Committee (TRC) should be established to assist the Board in the development of audit metrics. Members of the TRC would represent signatory handlers and

producers throughout the production area, as well as stakeholder interest groups including but not limited to organic and non-conventional agriculture, small business operations, members of the scientific community, and interested government agencies. Authority for the TRC would be provided for in § 970.46 (formerly § 970.45).

Provisions requiring traceability should be established under the proposed program. The ability to trace produce during all stages of production, handling, and distribution would be a key factor in ensuring compliance. Witnesses stated that traceability would also provide for increased information about the source and movement of produce within the leafy green vegetable industry in the event that a contamination incident was to occur. Provisions relating to traceability are provided for under § 970.68.

According to the hearing record, an official mark should be developed for the purposes of identifying compliant participants in the proposed program. The proposed mark would be used on bills of lading, manifests or other like documentation that is standard in pre-retail market transactions. In addition, the Board should have the authority to recommend other uses of the official mark. Any other such uses would require the approval of the Secretary. Provisions for the development and usage of the official mark are provided for under § 970.69.

The record also supports the establishment of provisions allowing for any financially interested person to request an administrative review if it is believed that the results of an audit are in error. These proposed provisions are included in § 970.70.

Provision for the Secretary to modify, suspend, or terminate regulations in effect under the proposed program should also be included in the proposed agreement. This is provided for in § 970.71.

Verification Audits

As explained in Material Issue 5(a), the term “verification audit” should be defined to mean an official audit conducted by the Inspection Service to verify and document that good agricultural, handling, and manufacturing practices are adhered to throughout the growing, harvesting, packing and transportation of leafy green vegetables. According to the record, a verification audit would include a physical visit to the farm or facility subject to audit while it is in operation, to the extent practicable, and would represent a snapshot in time

based on documentation reviewed, persons interviewed and operations observed. Information gathered during the audit would reflect past and ongoing activities of the signatory handler or their supplying producer(s) to the Inspection Service.

Section 970.66 of the proponents’ proposed language describes verification audit provisions for GAPs, GHPs and GMPs audits. Proponents stated that signatory handlers would be required to ensure that any leafy green vegetables handled by their operation have been subject to GAPs verification audits. Proponents further stated that the GAPs audits should reflect FDA production and harvest guidelines, referred to in proposed § 970.11, and should meet audit metrics provided for under proposed § 970.67.

Proponents also stated that all signatory handlers to the proposed program should be subject to GHPs or GMPs verification audits, whichever is applicable. Such audits would verify that signatory handlers operate under auditable conditions that meet general FDA guidelines referred to in § 970.11 or FDA manufacturing regulations referred to in § 970.13, and should meet audit metrics provided for under proposed § 970.67.

Proponents explained that audits were necessary to ensure the integrity of all leafy green vegetables handled under the program. Proponents stated that quality assurance of leafy green vegetables begins in the field where the produce is grown, but that the integrity of that quality should be maintained through all stages post-production through delivery to market. By ensuring that leafy green vegetables are consistently subject to GAPs, GHPs and GMPs, proponents asserted that the potential for microbial contamination of those vegetables would be minimized. These practices would support the delivery of quality products to the marketplace.

According to the hearing record, proponents further stated that signatory handlers of the proposed program should not be allowed to import leafy green vegetables produced or handled in foreign countries that have not been subject to GAPs, GHPs or GMPs verification audits by the Inspection Service or agencies approved to audit on its behalf. Proponents stated that any foreign leafy green vegetables that are imported should be subject to comparable requirements that would be in effect in the United States if this proposed program were implemented.

According to the hearing record, all audits should be conducted by the Inspection Service or any other such

agency that is authorized to audit on its behalf. Proponents explained that audits should be conducted on a regular schedule that would ensure every handler is audited during their corresponding production season. In addition, unannounced audits of handlers and associated producers should be performed during the production season in each zone.

Finally, § 970.66 is revised for clarity.

Administrative Review

Under proposed § 970.70, any signatory handler denied the use of the official certification mark as a result of failing an audit should be allowed to petition for reconsideration of the results. Proponents proposed that such person could request an administrative review if it is believed that a material fact of the original verification audit was misinterpreted. Administrative reviews would be conducted in accordance with the USDA audit verification procedures for any audit program in effect.

The record evidence also supports that a financially interested person should have recourse if an auditing error is made. Witnesses also stated that the person requesting the review should pay the cost of the review, and would be subsequently provided a copy of the review results.

This section is revised for clarity.

Audit Metrics

According to the hearing record and as defined in Material Issue 5(a), “audit metric” refers to an auditable standard or requirement used to verify that a production, handling or manufacturing system intended to prevent, reduce or eliminate a microbiological hazard is being effectively and accurately followed. A collection of such standards is referred to as “audit metrics” and together establish the framework within which the process controls intended to ensure good agricultural, handling or manufacturing practices can be verified as being met.

One example of this is an audit metric that provides that water used in a production field to be verified as meeting a quality standard. However, the way that an individual producer may meet that standard would differ depending on whether the water was sourced from municipal or private wells, delivered via canal irrigation, applied to the crop in a foliar or non-foliar application, or was rain water. The applicable process control also would differ.

Each audit metric is a specific measure of GAPs, GHPs, or GMPs compliance. To the extent that production, handling and

manufacturing environments present different factors that need to be controlled during those processes, metrics may differ by zone or region. Moreover, according to the hearing record, the auditable actions taken by a producer, handler, or manufacturer to meet metric standards may also vary due to differences in business size, or cultural growing and handling practices. According to the record, audit metrics should incorporate current industry production, harvest and handling technologies, and should be based on scientific practices.

Section 970.67 of the proponents' proposed language describes the development and implementation of audit metrics under the proposed program. This language states that audit metrics may be recommended by the Board to USDA for approval after consultation with the Technical Review Committee. The Technical Review Committee, and any subcommittees established thereunder, would provide the Board with production and handling perspectives of the various regions, particular challenges of individual regions, as well as scientific review and food safety expertise.

The proponents' proposal contained a list of areas that may be addressed in establishing audit metrics for GAPs, GHPs, and GMPs. They are included in paragraphs (a) and (b), and those paragraphs are revised for clarity.

Hearing record evidence indicates concern over the method by which critical limits for process controls and quality factors would be identified and established under the proposed program. Witnesses stated that any proposed critical limits should be science-based, should reflect the broad spectrum of industry practices across the country, and should reflect or coordinate with FDA and other existing Federal or State regulation.

Portions of § 970.67(c) of the Notice of Hearing should be divided for clarity and redesignated as § 970.67(c), (d), and (e). Paragraph (c) should state that critical limits for process controls for each quality factor identified in GAPs, GHPs or GMPs audit metrics may be recommended by the Board, after consultation with the Technical Review Committee, for approval of the Secretary, or may be developed by USDA.

Paragraph (d) should state that USDA may consult with appropriate government entities and consider recommendations made by the Board after Board consultation with the Technical Review Committee.

Paragraph (e) should state that Board recommendations, including critical

limits, shall incorporate current industry production, harvest and handling technologies, should be based on scientific practices.

Paragraph § 970.67(d) of the Notice of Hearing should be redesignated as a new § 970.67(f). This paragraph states that audit metrics may be developed and recommended to accommodate differences in production, harvest, and handling environments of different regions.

A new § 970.67(h) should be added to state that audit metrics may be developed and recommended to accommodate differences in production, harvest and handling environments of imported leafy green vegetables and their products.

Paragraph § 970.67(e) of the Notice of Hearing should be redesignated as a new § 970.67(g). This paragraph states that after consultation with the Technical Review Committee, the Board may, at any time, recommend changes to the audit metrics for approval by the Secretary.

According to the hearing record, the Board should be required to review audit metrics periodically. Witnesses explained that systematic reviews needed to occur to ensure that audit metrics continually reflect the best industry practices, scientific information, and industry knowledge. This review should occur at least every 3 years. This language was originally included in the Notice of Hearing as § 970.67(f) and should be redesignated as § 970.67(h).

Technical Review Committee

According to the proponent proposal, the audit metrics development process would require consultative sessions with a subcommittee, the Technical Review Committee. TRC membership would include industry representation, food safety professionals, members of the scientific community, and representatives from selected government agencies. Proponents stated that the proposed TRC and its members would ensure that current industry practices as well as current scientific research and technology were integrated into any proposed metrics. This subcommittee was originally identified as the Technical Review Board in the Notice of Hearing, and is being renamed the Technical Review Committee.

According to the proponents' proposal, the Technical Review Committee would have 14 members appointed by the Board. The 14 members would include: One representative from each of the five originally proposed zones; one food safety representative from a land grant

university from within each zone; one representative of the USDA Natural Resources Conservation Service appointed by the Secretary; one representative of the U.S. Environmental Protection Agency designated by that agency's Administrator; and, two representatives of FDA appointed by that administration's Commissioner.

Proponents stated that it was their intent to provide an administrative structure and Technical Review Committee that would allow fresh leafy green vegetable industry stakeholders to proactively engage in the process of recommending audit metrics for approval and implementation by USDA.

Proponents explained that their proposal provided authority for additional subcommittees under both the Board and the Technical Review Committee to be established. Through these subcommittees, industry stakeholders could work cooperatively to develop and recommend uniform, auditable, science-based production and handling audit metrics that also incorporated any necessary specific measures to accommodate differences in size of operation, geographic location, or other environmental challenges for a given region. Also, recommendations would be addressed by the full Board, would require Secretary approval, and would be subject to a public rulemaking process.

During the hearing, several witnesses raised concerns over the proposed structure of the Technical Review Committee. In particular, witnesses stated that producer interests, especially those of small producers, diversified farm operations, and organic farms, were not given adequate representation. Moreover, witnesses stated that the Technical Review Committee, as proposed by the proponents, did not provide adequate involvement of local, State, and other Federal government interests in the development of metrics. These witnesses explained that any metrics established under the proposed program could impact existing regulation or areas of shared jurisdiction by those entities.

Areas of particular stakeholder concern noted during the hearing include: Water quality and usage, conservation practices, wildlife and habitat management, and natural resource management. Regulatory jurisdiction over some of these topics is shared by multiple Federal, State, and local government bodies. Witnesses concerned over the audit metric development process argued the need to include input and information from representatives of these regulatory

bodies to mitigate the potential for conflicting requirements being placed on producers or handlers.

Lastly, witnesses who voiced concerns over the initial proposal's five geographic zones also voiced concerns over the Board's ability to appoint members of the Technical Review Committee. Opponents stated that without more appropriate stakeholder representation on the Board, the placement of members on the Technical Review Committee would not be reflective of the industry's diversity.

On the last day of the hearing, proponents submitted a modified Technical Review Committee structure. Proponents presenting modified language explained that the revised language attempted to address opposing witness' concerns. The revised language outlined a new Technical Review Committee that would consist of 21 members to include: One handler and one producer representative from each of the initial zones elected by the Board members of that zone; one producer representative considered a small business entity under the SBA guidelines and one organic producer elected by all Board members; one produce safety expert from a land grant university within each of the initial zones elected by the producer and handler members from the corresponding zone; one representative of the USDA Natural Resources Conservation Service appointed by the Secretary; one representative of the United States Environmental Protection Agency designated by that agency's Administrator; and, two representatives of FDA appointed by that administration's Commissioner. Proponents explained that their proposed modifications would improve producer representation on the TRC. Moreover, the addition of seats designated for small businesses and organic operations would ensure that these stakeholder interests were represented in the audit metric development process.

The alternative Technical Review Committee structure would improve the representation of stakeholder interests, but needs to be revised to reflect the modified zone definitions.

Each of the eight zones, as recommended in § 970.37, would have one signatory handler, one producer, and one food safety expert. One of the eight producer seats would have to be filled by a producer meeting the SBA definition of small agricultural producer, and one must be filled by a certified organic producer. In addition, the Secretary would appoint one representative from the USDA Natural

Resources Conservation Service. The Technical Review Committee would therefore consist of 25 members. This proposed language is presented in § 970.46.

Additionally, the Secretary would have authority to appoint such USDA representation on the Committee as deemed appropriate. Record evidence indicates that this may include representatives of the National Organic Program, Agricultural Research Service, and National Institute of Food and Agriculture.

Further, USDA may consult with other Federal agencies, as appropriate, whose interests may be affected by audit metrics identified in §§ 970.66 and 970.67, and may allow for representatives of those agencies to participate in the work of the Technical Review Committee. Agencies identified as potentially having a collaborative interest include, but are not limited to: United States Environmental Protection Agency, FDA Center for Food Safety and Applied Nutrition, and Department of Interior Fish and Wildlife Service.

The proponent proposal did not include specific nomination procedures for TRC members. However, record evidence supports a process that would allow for broad industry participation in Committee nominations. Accordingly, TRC nomination procedures are being added that are similar to those for Board members.

For the purposes of establishing the initial TRC, nominations would be conducted by the Secretary by means of meetings of producer and signatory handler representatives, by mail, or by any other form of electronically verifiable communication (such as fax, videoconference, conference call). The Secretary would then select and appoint the members from such nominations.

Subsequent to the nomination of the initial members, all successor members would be nominated by producers and signatory handlers. In addition, the Board could recommend nominees to USDA. The Board would forward the entire list of nominees received to USDA for final selection and appointment by the Secretary.

Authority should be added for the Board to recommend modifications to the membership of the TRC. Any such recommendations by the Board would require approval of the Secretary. This authority would provide flexibility to recommend adjustments or changes to the structure of the TRC over time.

Finally, the TRC should have the authority to appoint subcommittees as necessary to facilitate the development of audit metrics specific to regions, or production, handling, or manufacturing

environments that produce, handle, or manufacture leafy green vegetables. Subcommittees may consist of producers, handlers, and other interested parties as deemed appropriate by the TRC.

USDA recommends that § 970.45 of the Notice of Hearing be revised as previously discussed and redesignated as § 970.46.

Traceability

According to proponents of the proposed program, the ability to trace a product during production, processing, and distribution would be a key factor in increasing information and communication within the market, as well as ensuring compliance.

In the case of a contamination event, timely communication about the scope of the contamination is essential to addressing consumer concerns and reducing the economic impact of the event on the industry and removing contaminated product from the market. For this reason, proponents recommended including authority to implement traceability requirements under the proposed program. These requirements would allow for a more efficient recall of contaminated product if a contamination event were to occur.

Proponents explained that information required under a traceability system would allow for a more rapid and accurate identification of both the source location of the contamination, and the distribution of product coming from that source. Signatory handlers would need to have in place systems and procedures that will allow them to track their products.

Official Certification Mark

According to the hearing record, an official mark or trademark should be developed for the purposes of identifying compliant participants in the proposed program. Evidence presented during the hearing also supports that any such mark should be developed through the use of funds collected under proposed § 970.56 and according to the provisions of proposed § 970.55. The mark would be the property of the United States Government as represented by the Board and would be used for the benefit of the Board, its signatories and their affiliated producers.

Proponents explained that the proposed mark would be used on bills of lading, manifests and other like documentation that is standard in pre-retail market transactions. Proponents indicated that use of the mark would lead to buyer confidence in producer, handler, and manufacturer transactions

because it would indicate that the product being sold met program standards. Proponents also stated that use of the mark would facilitate traceability.

Proponents stated that their intention was to not use the official certification mark on retail or consumer packaging. While some proponents suggested that the mark could be used in literature or informational campaigns designed to inform participants of the fresh produce industry about the scope and mission of the proposed program, proponent testimony did not anticipate the use of the mark at the consumer level for marketing purposes.

Many witnesses who were opposed to the proposed program were also opposed to the development of the mark and stated that the proponents' proposed language did not clearly prohibit the use of such mark on consumer packaging. These witnesses stated that if the mark were used on consumer packaging, its use would lead to an unfair marketing advantage for participants of the program over those opting not to participate.

The proposed agreement should provide authority for the Board to recommend, subject to approval of the Secretary, alternative uses of the official certification mark is important to ensuring flexibility of the proposed provisions and their application under the proposed program. However, based on record evidence, the use of the mark on consumer packages would be prohibited. The authority to recommend alternative uses would allow the Board to address unanticipated circumstances that may present themselves in the future.

Lastly, hearing record evidence demonstrates that a signatory handler's compliance with the proposed program would be a condition precedent and subsequent to the signatory handler's use of the mark. As discussed under Material Issue 5(f), use of the mark would also be subject to verification, suspension and revocation provisions of the proposed program.

In summary, the record supports authority for the development of a registered certification mark. The proposed regulatory text published in the Notice of Hearing under § 970.69 is revised to reflect the change discussed above and for clarification.

Modification, Suspension and Termination

The Secretary may modify, suspend, or terminate regulations in effect under the proposed program based on Board recommendations or otherwise. This would allow changes in any regulations

established under the program. This provision appears in § 970.71.

Material Issue Number 5(d) Expenses, Assessments, Accounting and Contributions

The Board should be authorized to incur reasonable and necessary expenses and to collect assessments to fund such expenses. Further, the proposed agreement should provide for handling of excess assessments collected and should authorize the Board to accept voluntary contributions.

Expenses

The record evidence supports that the Board should be authorized, under § 970.55 of the proposed agreement, to incur such expense as the Secretary finds are reasonable and likely to be incurred during each crop year. Necessary expenses for the maintenance and functioning of the Board would generally include, but would not be limited to, administrative expenses such as employee salaries and benefits; establishment of an office and equipping that office; telephone and mail services; and business and travel-related expenses for the Board staff. As discussed previously, expenses incurred by Board members and alternate members, committee members, and subcommittee members in attending meetings or performing other official duties should also be reimbursable expenses. According to the hearing record, the proposed agreement should also authorize the Board to incur expenses related to research, development, and education activities pursuant to § 970.75. The types of activities that could be funded under this authority are discussed under Material Issue 5(h).

According to the hearing record, the Board should also pay for GAP audit fees for verification audits conducted on producers delivering to signatory handlers as well as GHP audit fees for those signatory handlers. Having uniform assessments pay for such audit costs should alleviate concerns raised about the relative costs of audits for operations of varying size and in different locations. Having the Board pay audit fees could also result in more efficiencies for the program.

The record evidence is that the Board would pay for direct audit costs. Any additional costs related to inspection service travel would be borne by the signatory first handler. Specifics as to which costs would be paid out of assessment funds could be included in any memorandum of understanding between the Board and the Inspection Service.

The record evidence is that GHP and GMP audits conducted on second signatory handlers should not be paid for by the Board. This is because those handlers would not be required to pay assessments on the leafy green vegetables that they handle or manufacture.

Minor clarifying changes have been made to § 970.55.

Assessments

The proponents testified that funds to cover the Board's administrative expenses should be obtained through the collection of assessments from signatory first handlers who handle leafy green vegetables in the production area. These assessments would reflect each signatory first handler's proportional share of the volume of leafy green vegetables subject to regulation under the proposed agreement. As such, assessments would be based on the total amount of leafy green vegetables handled by each signatory first handler.

According to the hearing record, prior to the beginning of each crop year and as necessary thereafter, the Board should prepare and recommend to USDA an estimated budget of expenses including a rate of assessment calculated to adequately cover the cost of such projected expenditures. Proponents stated that any such assessment rate could include a supplemental assessment rate if it was determined beneficial to the administration of the program. A supplemental assessment rate could be used to address a specific problem. An example would be the need to fund a research project that only affects cabbage. In this example, the Board could assess a supplemental assessment rate on cabbage, which would be in addition to the regular administrative assessment rate. Funds derived from these supplemental assessment rates would then be specifically earmarked to pay for the cabbage research project in this example.

Testimony indicates that the preparation of a budget prior to the beginning of each crop year would provide a basis for the Board's assessment rate formulation. Once approved at the Board level, the annual budget and assessment rate recommendations would be submitted to USDA for review and approval.

As supported by the record, the proposed agreement contains a maximum assessment rate limit of \$0.05 per 24-pound carton of leafy green vegetables or equivalent (including any supplemental assessment rate). According to the hearing record, lettuce

has traditionally been shipped in 24-pound cartons and is widely considered a standard of measurement for the leafy green vegetable industry. For leafy green vegetables not typically shipped in 24-pound cartons, the Board would recommend appropriate formulas to calculate equivalent units of measurement for assessment purposes.

The intent of the maximum limit on the assessment rate is to assure signatory handlers that program expenses would be kept within specified limits. Proponents stated that the maximum limit is based on experience with the State marketing agreement programs in California and Arizona. They testified that the initial California assessment level was two cents per 24-count carton equivalent, and it was lowered to a penny and a half per carton equivalent after the second year. Given this experience, the proponents anticipate that the actual cost of the proposed agreement, if implemented, would be covered by an assessment rate below the proposed maximum limit.

Should a signatory first handler fail to timely pay assessments, record evidence indicates that such handler should be required to pay the Board, in addition to the overdue assessments, an interest or late payment charge, or both, on any outstanding balance. The time period in which assessments should be paid to the Board, the rate of interest, and any late payment charge would be recommended by the Board and approved by the Secretary through the public rulemaking process.

According to hearing record evidence, late payment charges and interest on unpaid balances are reasonable to encourage timely payment of assessments and to compensate the Board for expenses incurred in collecting unpaid assessments. Witnesses stated that timely collection of assessments would be important in order to efficiently and effectively administer the provisions of this proposed agreement.

The proponents testified that the Board may accept, but not require, advance payments of assessments, which would be credited toward assessments levied against that signatory first handler for the crop year. In addition, the Board would be authorized to borrow money to cover operating expenses when assessment and reserve funds are not sufficient.

Revisions have been made to § 970.56 and paragraph (c) of that section has been deleted as unnecessary.

Excess Funds

The proponents proposed procedures for accounting of excess funds in § 970.57 of the proposed agreement. They indicated that such procedures would be necessary to assure signatory handlers and the industry that there would be proper disposition of excess funds, and that a detailed accounting would be made of such disposition. This section would allow the Board, with the approval of the Secretary, to establish an operating monetary reserve. This would permit the Board to carry over to subsequent crop years any excess funds in a reserve, if funds already in the reserve do not exceed approximately two years' expenses. If reserve funds exceed that amount, the assessment rate should be reduced to bring the reserve to a more reasonable level. These reserve funds could be used to defray expenses during any crop year before assessment income is sufficient to cover such expenses; to cover deficits incurred during any crop year when assessment income is less than expenses; to fulfill any obligations under § 970.75; and, to cover necessary expenses of liquidation in the event of termination of the program.

In lieu of depositing excess funds in a monetary reserve, the proponents proposed that § 970.57 would also provide the Board with the necessary authority to credit each handler's account, or to refund each handler directly, with a proportionate share of any excess assessment funds at the end of each crop year.

Clarifying changes have been made to § 970.57.

Voluntary Contributions

The proponents testified that in addition to assessment and other income, such as interest, the Board should be able to receive voluntary contributions for the conduct of research, development, and education activities authorized under § 970.75 of the proposed agreement. Testimony supported having such contributions free from any encumbrances by the donor, and that the Board should retain complete control of the use of such funds. This authority appears in § 970.58.

Material Issue Number 5(e)—Reporting and Recordkeeping

The proposed agreement should provide that signatory handlers periodically submit reports and other information to the Board and to maintain records regarding the handling of leafy green vegetables. Further, to ensure compliance with the Act, the

proposed agreement should provide that all reports and other information submitted by signatory handlers remain in the custody of employees or authorized agents of the Board at all times. Finally, the proposed agreement should authorize agents or employees of USDA and the Board to access the premises of signatory handlers during reasonable business hours to verify compliance with the proposed agreement.

Reports and Recordkeeping

The record indicates that the Board should have the authority, with the approval of the Secretary, to require under § 970.80(a) that signatory handlers submit to the Board such reports and information as the Board may need to perform its functions and fulfill its responsibilities under the proposed agreement. The Board would require reports and information for such purposes as collecting assessments; analyzing leafy green vegetable markets and marketing trends with the objective of preparing and evaluating research and development projects; developing and recommending rules and regulations; and determining whether signatory handlers are complying with the requirements of the proposed agreement.

Hearing testimony includes witness statements that reports potentially required under the proposed agreement could include production, inventory, and sales data; customer and supplier lists; and testing and audit reports. This should not be construed as a complete list of information the Board might require, nor all of the information necessary for the proper conduct of Board operations under the proposed agreement. Therefore, the Board should have the authority, with the approval of the Secretary, to require each signatory handler to furnish such information as it finds necessary to perform its duties under the proposed agreement.

Under § 970.80(b), proponents testified that signatory handlers should be required to maintain records of all receipts and acquisitions of leafy green vegetables as may be necessary to verify the reports that are submitted to the Board. This would also include all documentation relating to audit reports. All records would be maintained for at least two years after the end of the crop year of their applicability. The records maintained should be sufficient to document and substantiate each signatory handler's compliance with the proposed agreement. Witnesses testified that these records may be needed to assist in compliance investigations.

Paragraphs (a) and (b) of § 970.80 are revised for clarification, and paragraph (c) is deleted as it is not necessary.

Confidential Information

As required by the Act and supported through testimony provided by witnesses at the hearing, § 970.81 would require that all reports and information submitted by signatory handlers be received by, and at all times be in the custody of, employees or authorized agents of the Board. Information submitted by signatory handlers affecting the trade position, financial condition, or business operation of such handlers could not be disclosed by the employees of the Board, or by any agents authorized by the Board, to any person or entity other than the Secretary. Witnesses testified that reports and information that contain proprietary market and business information could affect the trade position, financial condition, or business operation of the affected signatory handler, and that confidentiality would be necessary to protect the businesses submitting the information. The Board would also confidentially hold any data or information obtained or extracted from reports or information submitted by signatory handlers. The proponents also stated that, although information from reports and information may be combined and made available in the form of general reports, the identities of the individuals furnishing the information should not be disclosed. Combined information in general reports could be helpful to the Board and to the leafy green vegetable industry.

Minor revisions have been made to § 970.81 for clarification.

Verification of Reports

In § 970.82, the proponents proposed procedures for verifying that reports filed by signatory handlers are in compliance with the requirements of the proposed agreement. For this purpose, the hearing record indicates that authorized agents or employees of the Board, and the Secretary, should have access to the premises of all signatory handlers during reasonable business hours. In addition to having access to a signatory handler's premises to verify that all reports have been submitted accurately, the proponents indicated that authorized agents or employees of the Board, and the Secretary, should also have access to check GAPs audit verification records for compliance with the proposed agreement.

Record evidence indicates that authorized agents or employees of the

Board, as well as the Secretary, should have reasonable access to any signatory handler's premises during regular business hours (those hours when the signatory is actually engaged in growing, harvesting, packing, or transporting leafy green vegetables). The record verification should be conducted through a visit to the signatory handler's facility, where documentation would be reviewed and personnel interviewed to ascertain compliance with this part.

In regards to the general issue of reporting and recordkeeping, evidence indicates that handlers of leafy green vegetables and products already collect and maintain much of the information proposed for submission to the Board under the proposed agreement provisions. Furthermore, hearing testimony suggests that the proposed agreement would be beneficial to the industry by helping to standardize how information is collected, maintained, and disseminated. An additional benefit to the reporting and recordkeeping requirements of the proposed agreement would be enhanced traceability and identification of product due to the more consistent and generally available nature of the digitized information likely required by handlers.

Although some small and organic producers and handlers currently not associated with any food quality verification program expressed concerns about the additional personnel and cost possibly required for adherence to the proposed reporting and recordkeeping requirements, others currently associated with a food quality verification program of some kind testified that good recordkeeping has helped adhere to the food quality verification program and been beneficial to overall farm operation. These witnesses also expressed the belief that the reporting requirements herein proposed would not constitute an undue burden on leafy green vegetable businesses.

Section 970.82 is modified slightly for clarification.

Material Issue Number 5(f)— Compliance

The proposed agreement should provide the Board and USDA with the authority to withdraw audit services, withdraw the use of the official certification mark, or seek remedies or penalties should signatory handlers be in non-compliance with the proposed agreement. In addition, the proposed agreement should provide that any immediate threat to public health be reported to appropriate health officials. This is necessary for the program to be

effective and to help ensure that it is administered fairly to all participants.

Under § 970.83, proponents testified that compliance of the proposed agreement would be overseen by the Board and USDA. The Board would establish a policy in the form of a compliance program under which non-compliance actions would be identified either by the Inspection Service or by Board compliance staff. Non-compliance actions may be identified during scheduled or unscheduled audits, visits to a farm or facility, or from anonymous complaints. Proponents and other witnesses supported the proposal that any signatory handler not in compliance with the proposed agreement could be subject to withdrawal of audit services, could lose the privilege of the use of the official certification mark, or be subject to misbranding or trademark violations, depending on the level of non-compliance. It was further proposed by proponents under § 970.83(c) that failure to comply with the provisions of this proposed agreement may also result in additional remedies or penalties.

According to the hearing record, signatory handlers would be obligated to adhere to program requirements. Such requirements would include such things as acquiring only leafy green vegetables that have been grown in accordance with GAPs; receiving successful audits verifying that GHPs and GMPs (if applicable) are being adhered to; filing reports and maintaining records; and paying assessments. Failure to comply with these requirements could result in action against the signatory handlers.

The record shows that the intent of the program would be to improve vegetable quality by reducing the risk of contamination. As such, the focus would be to establish and maintain best practices. If a signatory handler were found to be out of compliance with the audit metrics established under the program, the first step would be to require that handler to take appropriate corrective action to address and correct any non-conformities.

According to record evidence, non-compliance by signatory handlers would be identified and classified at various levels from minor to flagrant violations of the proposed agreement. Other than in cases of immediate threat to public health, any signatory handler found in violation of the proposed agreement would be allowed to address and correct any actions that led to non-compliance of the proposed agreement. If a signatory handler were to fail to take appropriate verifiable corrective, the signatory handler could be subject to

withdrawal of audit services or lose the use of the official certification mark.

According to the hearing record, the status of a signatory handler's compliance would be public information and may be posted on a Web site.

The Notice of Hearing also contained a provision in § 970.83(b) that any detection of an S threat to public health should be reported to FDA. Record evidence supports notification of any appropriate health officials, not just FDA.

Section 970.83 of the proposed agreement is revised for clarification and to remove unnecessary language.

Material Issue Number 5(g)—Exemptions

USDA recommends that the Board should have the authority to exempt small quantities of leafy green vegetables from any or all program requirements.

Section § 970.72, "Exemptions," of the Notice of Hearing stated in part: "The [Board], with the approval of the Secretary, may establish such rules, regulations, and safeguards that exempt from any and all requirements pursuant to this part, such quantities of leafy green vegetables or products as do not interfere with the objective of this part."

While the proponents' proposal would have permitted the Board to exempt a given quantity of leafy green vegetables from the requirements of the agreement, during the hearing sessions, both proponents and the opponents of this agreement opposed that any quantity of leafy green vegetables should become exempt from the agreement. Witnesses' rationale for this opposition was that any quantity of exempt leafy green vegetables, be it from a small, organic, or large farm, may jeopardize the ultimate goal of this program which is to make the production and handling of leafy green vegetables safer.

While the objectives of the program should not be compromised, the agreement should authorize an exemption if an unforeseen circumstance arises which would make such an exemption reasonable. Furthermore, the Board should have authority to recommend rules and regulations to ensure that such leafy green vegetables are handled and used only as authorized under the agreement.

Clarifying changes are made to § 970.72.

Material Issue Number 5(h)—Research, Development, and Education

The proposed agreement should authorize the Board to conduct research,

including market research, development projects, and to develop and implement educational and outreach programs intended to facilitate the adoption, implementation, and administration of the agreement. In addition, the proposed agreement should establish a Research and Development Committee to assist the Board in carrying out the aforementioned programs.

Research, Development, Education and Outreach

Proponent witnesses testified that the proposed agreement should provide the Board authority to establish marketing research and development projects, and or promotional activities, including paid advertising, to assist or promote the efficient adoption, implementation, and marketplace acceptance of the agreement and leafy green vegetables. As proposed by proponents, such projects and activities would require approval by the Secretary, and would be funded by collected assessments and voluntary contributions as specified in proposed §§ 970.56 and 970.58, respectively.

Proponent witnesses testified that the authority for market research was necessary to better understand and communicate with key leafy green vegetable industry audiences—such as buyers. The authority for the conduct of market research and development projects generally was supported by witnesses. However, some witnesses suggested the types of research specified under the proposed agreement should be expanded beyond market research. Specifically, these witnesses stated the proposed agreement should authorize food safety research such as best practices in production, handling, and manufacturing of leafy green vegetables, contamination risk management including reducing the risk of cross-contamination in the food supply chain, and identification of measures to reduce microbial contamination. While proponents supported research associated with quality in areas such as production, handling, and manufacturing practices for leafy green vegetables, they did not support the use of collected funds for generic research on risks associated with leafy green vegetables.

Several witnesses who expressed concern about the potential impact audit metrics could have on small business entities suggested the proposed agreement should provide authority to the Board to develop and implement educational and outreach programs. This recommendation was supported by the proponents of the proposed agreement.

Witnesses supporting the authority for educational and outreach programs stated the programs should be designed to assist small businesses comply with the proposed agreement. They asserted these programs could be effective tools for providing training to entities, particularly small entities, about the proposed agreement, its audit metrics and other requirements. Such programs, the witnesses asserted, also could be used to increase awareness of the proposed agreement within the leafy green vegetable industry supply chain.

Witnesses supporting inclusion of a training component explained that training should be made available to producers, handlers, and persons conducting verification audits under the proposed agreement. According to these witnesses, training for producers and handlers would assist in program compliance and ensure a clear understanding of the proposed agreement and its requirements. Witnesses advocating training for auditors stated that such would provide consistency and accuracy in audit verifications.

Additionally, in implementing educational and outreach programs under the proposed agreement, witnesses advocated cooperation with existing state, local, and Federal agencies, universities, or other organizations already successfully operating such programs within their regions or communities.

Based on the record evidence, the proposed agreement should authorize the Board to conduct research (including market research), development projects, and education and outreach programs. The proposed programs would help to expand knowledge about the leafy green vegetable industry, the proposed agreement, its audit metrics, and requirements. The programs also would assist in increasing awareness on the proposed agreement among leafy green vegetable stakeholders. Lastly, the programs should allow the proposed agreement to become more accessible to small entities, organic, diversified, and unconventional operations within the leafy green vegetable industry.

Record evidence establishes that the proposed agreement should authorize the Board to provide for the conduct of market research and development projects as proposed by proponents. These projects would allow the Board to compile information related to the leafy green vegetable industry to better understand the industry, facilitate communications with industry stakeholders, and evaluate the proposed agreement. This authority also would

help ensure the proposed agreement is functioning properly and meeting its intended purpose.

The record evidence further establishes that authority to conduct research under the proposed agreement should be expanded beyond market research. The record evidence supports authority for the conduct of research projects designed to assist or improve the development of audit metrics related to the production, handling, and manufacturing of leafy green vegetables. The broader research authority would allow for the conduct of research that is applicable to various production environments and practices, spanning from conventional, to organic, to others. The proposed authority also would allow research concerning contamination risk management as well as other relevant areas. Record evidence supports providing broad research authority to ensure relevant areas related to leafy green vegetables could be researched, if deemed necessary and appropriate.

Record evidence supports the inclusion of authority for the development and implementation of educational and outreach programs under the proposed agreement. Record evidence indicates that these programs would be critical to facilitate awareness and education of the proposed agreement.

As supported by record evidence, the proposed educational and outreach authority would allow the Board to develop tools that aid growers and handlers, particularly small entities, comply with program requirements. According to record evidence, these tools could include templates to aid producers and handlers with recordkeeping requirements, and how-to guides to assist with complying with audit metrics and implementing best practices. Additionally, record evidence indicates that the proposed authority for educational and outreach programs would allow for the development and implementation of training programs for persons responsible for conducting audit verifications to ensure consistency and accuracy. As supported by the record, the proposed authority would allow the Board to coordinate with local, State, and Federal agencies, and other organizations in designing and implementing educational and outreach programs.

Record evidence supports that the educational and outreach programs should be funded by authorized receipts of the Board, including assessment income, voluntary contributions, and miscellaneous income such as interest. As provided in the proposed agreement,

the expenses for the activities described above would be budgeted and paid from funds collected pursuant to §§ 970.56 and 970.58, both assessments and contributions.

Based on the record evidence, all research, development projects, and education and outreach programs to be conducted under the proposed agreement in a given fiscal period should be required to be submitted by the Board to the Secretary for approval prior to being undertaken. The amount of funds to be spent on research, development projects, and education and outreach programs would be included in the annual budget required to be submitted to the Secretary for review and approval. Additionally, the Board would be required to report to the Secretary at least annually on the progress of each project and at the conclusion of each project. These are common USDA program requirements to ensure the effective conduct of authorized projects and the proper use of collected funds.

Promotion and Advertising

Regarding the proponents' proposed authority for the conduct of promotion and advertising activities, proponent witnesses testified that the intended target audience for outreach and promotion of the proposed agreement was buyers and others within the leafy green vegetable industry. Proponent witnesses stated that they fundamentally believed funds collected under the proposed agreement should not be used for consumer advertising or other marketing campaigns designed to promote food safety and or leafy green vegetables.

Several witnesses—those in support of the proposed agreement and those opposed to it—expressed concern regarding the authority to engage in promotion and advertising activities. These witnesses opposed any marketing efforts targeted to consumers. The witnesses further contended that such marketing of the proposed agreement would imply that leafy green vegetables covered under the proposed agreement were safer than those that were not covered under the agreement, thus creating a competitive advantage for entities associated with the proposed agreement.

The testimony of a witness supported the conduct of generic promotional activities under the proposed agreement. However, testimony of the proponents indicated the proposed agreement was not designed to use collected assessments to fund the generic promotion of leafy green vegetables to consumers.

Based on record evidence, the proposed agreement should not provide for the conduct of promotion and advertising activities. The record clearly demonstrates a lack of support for the inclusion of such authority.

As detailed above, § 970.75 “Research and Promotion”, as proposed by proponents, should be revised and included in the proposed agreement as “Research, Development, and Education.”

Research and Development Committee

The proponents proposed that a “Market Review Board” as specified in § 970.46 of their proposal be established to advise the administrative body on retail, foodservice, and consumer issues to maximize consumer confidence through market acceptance and recognition of the proposed agreement. Proponent witnesses explained that the Market Review Board would assist with promotion and acceptance of the proposed agreement throughout the leafy green vegetable supply chain.

As proposed by proponents, the Market Review Board would be appointed by the administrative body and would consist of a minimum of nine members as follows: Two representatives of retail grocers, two representatives of foodservice operations, three consumers, and two representatives from land grant universities with expertise in fresh vegetable marketing, economics, or consumer acceptance. Under the proponents' proposal, the administrative body also would have the authority to appoint additional representatives from consumer, retail, and foodservice organizations.

Several witnesses expressed concerns over the potential role of the proposed Market Review Board relating to the promotion of the proposed agreement to maximize consumer acceptance through market acceptance of the proposed agreement. These witnesses believed that marketplace acceptance of the proposed agreement related to promotion of the program to consumers. These witnesses were opposed to the proposed marketing and promotion authorities, including paid advertising, that were outlined in § 970.75 “Research and Promotion” of the proponents' proposal.

Based on the record evidence, the proponents' proposed Market Review Board should be removed from the proposed agreement and, in its place, a Research and Development Committee should be established. The name of the committee reflects the role and responsibilities of the committee as described below.

As supported by record evidence, the Research and Development Committee should be established for the purpose of assisting the Board in the oversight and management of research, development projects, and education and outreach activities under the proposed agreement, as authorized under proposed § 970.75. The record evidence also indicates that the membership structure proposed by proponents for the Market Review Board should be adopted for the proposed Research and Development Committee and modified slightly for clarity. However, based on record evidence, the nomination and selection process for this committee should be expanded to ensure broader participation by interested parties as detailed below.

Record evidence indicates that persons appointed to this committee should have expertise in certain areas to aid them in performing the committee's roles and responsibilities. As such, the proposed agreement should specify that persons should have expertise in one of, but not limited to, the following areas: The production, handling, and marketing of leafy green vegetables; small, diversified, or organic production practices; agricultural economics; or educational outreach in the specified or related areas.

The expanded nomination and selection process would address concerns raised by witnesses regarding the selection of members to this Committee. Witnesses expressed concerns that the proponents' proposal limited the persons that could be identified and, thus, selected to be members of this Committee. The broader process offered in this recommended decision would allow for more participation from interested persons in the nomination process, and would provide that selections be made by the Secretary.

Record evidence supports that nominations for the Research and Development Committee should be received from producers and signatory handlers at meetings, by mail, or by any form of electronically verifiable communication. In addition, the Board also would be allowed to recommend nominees to the Secretary. The Secretary would select and appoint the members from such nominations or from other qualified persons. Record evidence also supports providing authority for the appointment of additional members to this Committee by the Secretary. This provision is consistent with the proponents' proposal, which would have allowed for the appointment of additional

representatives of retailers, consumers, and foodservice companies.

As supported by record evidence, the membership of the Research and Development Committee could be modified based on recommendations by the Board and approval of the Secretary, or as otherwise deemed appropriate by USDA. Additionally, the Research and Development Committee should be allowed to appoint subcommittees as necessary to assist it in carrying out its roles. Subcommittees could be comprised of producers, signatory handlers, and other interested parties such as representatives of consumers, retailers, and foodservice organizations as deemed appropriate by the Research and Development Committee. The above described proposed language should be included in the proposed agreement as § 970.47 "Research and Development Committee", and should take the place and stead of the proponents' proposed Market Review Board.

Material Issue Number 5(i)—Common Terms

The provisions of proposed §§ 970.85 through 970.96 are common to marketing agreements and orders now operating. All such provisions are necessary to effectuate the other provisions of the marketing agreement and to effectuate the declared policy of the Act. The record evidence supports inclusion of each provision. These provisions are identified by the section number and heading as follows: § 970.85 Effective time; § 970.86 Rights of Secretary; § 970.87 Personal liability; § 970.88 Separability; § 970.89 Derogation; § 970.90 Duration of immunities; § 970.91 Agents; § 970.92 Suspension or termination; § 970.93 Proceedings upon termination; § 970.94 Effect of termination or amendment; § 970.95 Amendments and § 970.96 Counterparts. Minor changes to these sections are made for clarification.

Material Issue Number 6—Handler Sign-up and Withdrawal

Based on a review of the hearing record, the proposed agreement should provide for two handler sign-up phases to facilitate initial implementation of the program, including the nomination and selection of the initial Board. Also, the agreement should provide for handler withdrawal from the agreement.

Handler Sign-Up

A two-phase approach to the handler sign-up process would be used. An initial phase of at least 60 days would be established. This would allow for the nomination of producer and signatory handler members and alternate

members of the Board, and the selection of an initial Board by the Secretary. The specific time frame would be established at the time the agreement becomes effective.

Handlers who sign up during this initial sign-up period would be eligible to serve as initial members of the Board. Proponent witnesses explained that the initial sign-up period should be for a specified period of time so that handlers know in what time frame they may sign-up for this agreement to be eligible to serve on the initial Board. After this initial sign-up period, a handler may become a signatory to this agreement at any time.

Section 970.97 has been changed to add an initial sign-up phase and change the title of the section from "Additional parties" to "Handler Sign-up".

Handler Withdrawal From the Agreement

The agreement should also provide that signatory handlers may withdraw from the program. Record evidence supported a process wherein a signatory handler could file a written notice of withdrawal with the Board during any crop year. The withdrawal would become effective at the beginning of the subsequent crop year. The signatory handler would remain responsible for any obligations (including payment of assessments) incurred during the period that handler was a signatory handler.

In addition, a signatory handler could receive immediately withdrawal from the program if they cease to be a handler of leafy green vegetables and give notice to the Board in writing. Again the signatory handler would be responsible for any obligations incurred during the period of participation in the program.

Section 970.98 has been revised for clarity, including the addition of language to state that upon withdrawing from the agreement, the withdrawing party would no longer be permitted to use any official certification mark developed under the agreement.

Small Business Consideration

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions so that small businesses will not be unduly or disproportionately burdened. Small agricultural service firms, which include handlers that would be eligible to be signatories under the proposed

agreement, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000.

According to data published in the Blue Book, there are over 2,200 handlers, which include approximately 300 importers and over 100 fresh cut processors, of leafy green vegetables in the U.S. As noted earlier, there may be additional small handler businesses, specifically producers who are engaged in handling, not included in this total.

While the hearing record does not contain data to estimate average annual sales for handlers, the majority of handlers who testified at the hearing indicated they had annual sales of leafy green vegetables in excess of the SBA definition for a small agricultural service firm.

The hearing record indicates that, according to the latest Census of Agriculture, 8,216 farms harvested leafy green vegetables from 433,023 acres for the fresh market in 2007. Statistics for the leafy green industry presented at the hearing show that the total value for leafy green vegetable crops was approximately \$2.5 billion in 2008.

Small agricultural producers have been defined by the SBA as those with annual receipts of less than \$750,000. Based on the information presented at the hearing, 89 percent of farms producing leafy green vegetables in the United States would be considered small businesses as defined by the SBA.

In addition to handlers and producers, other persons including retailers, food service representatives, food safety experts, and other members of the public could nominate or serve on the boards or committees as appropriate. The reporting burden on such persons is discussed in the Paperwork Reduction Act section that follows.

In 2007, 69 percent of leafy green vegetable farms had annual gross sales under \$100,000, 12 percent had annual gross sales between \$100,000 and \$299,000, 8 percent had annual gross sales between \$300,000 and \$749,000, with the remaining 11 percent of farms producing leafy green vegetables in the United States having annual gross sales over \$750,000.

Since the spinach outbreak in 2006, large and small leafy green vegetable producers and handlers in all parts of the country have had to become more knowledgeable about produce contamination. This has led many of them to initiate or increase good agricultural, handling and manufacturing practices and programs. Other initiatives include the implementation of the California and Arizona State marketing agreement

programs which are designed to minimize the potential of contamination from leafy green vegetables produced within the respective States.

An economist with a science-based consulting firm (Intertox) testified as a proponent witness. This witness presented evidence that a majority of the volume of leafy green vegetables production is currently being produced under the California or Arizona State marketing agreements. In California, which accounts for 75 percent of U.S. leafy green vegetables production, 99 percent of this production is covered under the LGMA. Arizona represents 15 percent of U.S. production; 90 percent of that volume is covered by the Arizona agreement. For those producers and handlers, implementation of a national marketing agreement would not likely cause significant additional costs.

If adopted, the proposed agreement would authorize the development and implementation of audit metrics that are consistent with FDA GAPs and GMPs, and current USDA GHPs. While the proposed program would be voluntary, handlers who choose to become signatories would be required to comply. Many of the farms that produce leafy green vegetables would be subject to certain requirements under the proposed marketing agreement if they opt to sell to signatory handlers.

Evidence provided at the hearing indicates that large farms almost always sell to handlers under seasonal contracts and that these relationships are usually long-term. These large farms produce most of the volume of leafy green vegetables in the U.S., and are quite likely to supply handlers who would be signatories under the proposed agreement.

A key economic issue to examine in considering the proposed agreement is the benefits and costs to signatory handlers, and to producers supplying such handlers.

Benefits of the Proposed Program

The record evidence from handlers and producers who handle and produce a vast majority of the volume of leafy green vegetables in the U.S. is that although the proposed program would impose some additional costs on signatory handlers and the growers who sell to them, those costs would be outweighed by the benefits expected to accrue to the U.S. leafy green vegetable industry.

A primary benefit of the proposed agreement is the reduced likelihood of food contamination outbreaks in leafy green vegetables and products handled in the United States. Two witnesses presented estimates of the impacts of

food contamination outbreaks in terms of lost sales. A measure of the benefit of the proposed program is the avoidance of lost sales.

An economist on the faculty at Arizona State University testifying as a proponent witness stated that, based on his research, the cost of a food contamination outbreak is high and borne by all producers in that industry. He estimated that a food contamination outbreak event could lead to a 10 percent long-term reduction in demand for leafy green vegetables. In addition, the witness stated that without intervention, such as a national agreement, the leafy green vegetable industry could face a major food contamination incident, on average, every 10 years, leading to significant financial losses.

Record testimony indicates that producers and handlers can derive some benefit from their investments to minimize food contamination but the value of that investment is diminished if others do not similarly invest. The record further indicates that a collective action program with government oversight, such as a marketing agreement, can be used to intervene in a market system if the market is not producing enough of a public good; in this case investment to minimize food contamination outbreaks.

In the absence of collective action, individual producers may not have sufficient incentive to invest in food quality verification programs since it is not a tangible food characteristic for their buyers or final consumers. The witness noted that producers who do not invest, or who under-invest, in such quality or best practices programs create a "free rider" problem, since they do not pay their fair share of the production cost for what consumers expect to buy—a fresh leafy green product that is not contaminated.

Additional evidence about sales and price impacts to producers and handlers from the 2006 spinach outbreak was presented by a witness from California State University-Fresno. The witness stated that although the contaminated spinach was grown in California, producer sales throughout the nation were affected. Even after the source was isolated and consumers were assured that eating fresh spinach was again safe, sales lagged for a significant period of time and the commodity may have experienced long term loss of goodwill. Due to reduced shipments and lower prices from August through December 2006, the farm level loss in U.S. spinach sales was estimated at \$12 million; the estimated loss at the retail level was \$63 million.

The record testimony indicates that the benefits to a producer of implementing a best practices or food safety plan can include higher prices received by producers, maintaining and growing sales, reducing liability costs and improving operational efficiency. The witness also noted that the benefits tend to accrue over time and are uncertain.

The proposed program has the potential to increase the number of producers, including small producers, following standard GAPs. This could result in handlers buying leafy green vegetables from more small producers.

The proposed agreement also has the potential to reduce the redundancy of multiple audit verifications to which many handlers are currently subjected due to specific buyer requirements. Reducing multiple audit verifications will reduce costs and improve efficiency for both signatory handlers and their supplying producers.

Evidence was presented at the hearing that, due to food contamination outbreaks in recent years, producers of the vast majority of leafy green vegetable production currently have contracts that stipulate production standards that need to be met to deliver their leafy green vegetables to handlers. These standards are generally mandated to handlers by retail and food service buyers, but consequently have an impact on producers who must also conform to the standards in order to sell to handlers.

A USDA Economic Research Service and University of Arizona research report was submitted at the hearing regarding the fresh-cut vegetable industry. Fifteen lettuce and bagged salad shippers were interviewed in 1999–2000. This research indicated that most leafy greens shippers were diversified mixed-vegetable shippers and many engaged in some degree of processing. In 1999, 80 percent of these shippers had requests from retailers for, and were providing, third-party food safety certification.

Evidence was presented at the hearings that the lack of one set of production and handling standards in the leafy green vegetable industry often results in producers having to comply with different sets of standards for different customers.

Based on record testimony by those who favor the proposed agreement, support was expressed for a government program that would become an industry standard. If this proposal is implemented, supporters of the proposed agreement believe that the multiplicity of private standards would be replaced or minimized with a science-based, consistent, and scalable

program that standardizes GAPs, GHPs, and GMPs throughout the industry. The leafy green vegetable industry also may benefit from the proposed agreement's ability to make timely adjustments to GAP and GHP audit metrics, as appropriate, through the mechanisms of the agreement.

The record evidence shows that the proposed agreement would likely result in some cost increases for producers and handlers, especially in the short run (both start-up costs and ongoing annual costs), but in the long run there could be some cost decreases from streamlining of differing buyer standards and being subject to fewer audits.

Compliance Cost Estimates

Based on record evidence, the proposed agreement would result in total one-time modification costs at the farm level for all leafy green acreage outside of California and Arizona estimated to range between \$1.2 and \$3.0 million, and an estimated average range of \$14–\$34 per acre for modification costs. The record evidence indicates that this modification costs estimate is in addition to an estimated \$6.1–\$14.7 million already expended at the farm level for producers under State marketing agreement programs.

Under the proposed agreement, total seasonal (annual) cost increases at the farm level for all leafy green acreage outside of California and Arizona are estimated to range from \$2.7 to \$4.4 million, which is an estimated average range of \$30–\$50 per acre annual compliance costs. These annual cost estimates would be in addition to the estimated \$13.0–\$21.7 million being expended at the farm level for producers under State marketing agreement programs. We are relying primarily on cost estimates published in a University of California report submitted at the hearing. However, a wider range of cost estimates was submitted by a proponent witness and is included subsequently in Table 2.

Based on record data, annual handler assessments that would be collected under the proposed agreement are estimated to range between \$5.7 and \$28.6 million. Annual per acre compliance costs, not including assessments, for handlers who also are producers are estimated to range between \$48 and \$105 per acre.

Producer Cost Impact Estimates

Under the proposed agreement, signatory handlers would be required to ensure that producers that supply them with leafy green vegetables are producing in accordance with a set of

“best” practices. The most immediate and significant changes for producers, especially small ones, would be the increased expenses of supplying signatory handlers. While some producers may currently be applying and implementing GAPs, many producers would have to make physical modifications in their operations, add to their current recordkeeping requirements, and increase their administrative oversight over certain aspects of their farming enterprise.

Record evidence supports a program where the costs resulting from participation are proportional to the size of businesses involved and do not unduly or disproportionately impact small entities.

Witnesses at the hearing provided evidence of the cost of compliance with food quality verification requirements that were used in this document to compute producer cost estimates of implementation of the proposed program. Cost per acre data was combined with estimates of the number of acres to provide overall national cost estimates.

Data derived from the 2007 Census of Agriculture (2007 Census), which was presented at the hearing, showed that the total number of U.S. acres of leafy greens outside of California and Arizona was 88,572, representing 20 percent of total U.S. acres. Combined acres for California and Arizona total 344,451.

	Acres	Percentage of U.S. acres
United States	433,023
California	271,040	63
Arizona	73,411	17
All other States ...	88,572	20

Source: NASS, USDA

Two reports submitted as evidence at the hearing (the “UC report” and the “Intertox report”) included estimates of compliance cost per acre.¹ The cost impact estimates are summarized in three tables, two of which focus on producer costs, and a third one covers first handler assessment costs.

Table 1 presents computations of producer costs using cost data from the UC report and acreage data from the 2007 Census. The \$14 per acre figure appearing in the 2nd column of Table 4 was rounded off from a \$13.60 cost estimate in the UC Report.² The standard deviation was rounded off to

¹ Exhibit 43 “Producers’ Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs”, by S. Hardesty and Y. Kusumose, UC Davis; and Exhibit 34A “Marketing Data and Cost Overview” by Diane Wetherington, Intertox.

² “Cost per acre of leafy greens” on the bottom row of Table 4 of the UC Report.

\$20² and added to the mean cost to give an upper range estimate of \$34 per acre. Multiplying the cost figures of \$14 and \$34 per acre by 88,572 acres yields a range of estimated farm modification costs of \$1.2 to \$3.0 million for all leafy green acreage outside of California and Arizona.

To provide an estimate of the total cost for modifications for the industry as a whole, the fourth column adds the costs in column three to an estimated cost expended by producers in California and Arizona. However, additional California and Arizona farm modification costs for compliance

would likely be minimal, since most acreage is already participating in the leafy green marketing agreements in those two States and/or have already completed modifications in response to contractual GAPs and audit verification cost obligations from buyers.

TABLE 1—RANGE OF FARM MODIFICATION COST ESTIMATES FOR PRODUCER COMPLIANCE WITH THE PROPOSED PROGRAM
[one time expenditures, not seasonal]

	Per acre cost in California*	Total modification cost for farms outside of CA, AZ***	Total modification cost for farms in the U.S.***
		----- \$ million -----	
Mean cost of producers in survey	\$14	\$1.2	\$6.1
Mean cost plus \$20 per acre*	34	3.0	14.7

*Farm modification cost based on 2009 UC report of impact of California LGMA by S. Hardesty, presented at the hearing in Monterey.

**Approximately one standard deviation from the mean cost of producers surveyed in the 2009 UC report.

***To get Total Modification Cost, per acre cost is multiplied by acreage data from 2007 Census (88,572 acres of leafy greens outside of CA and AZ; total U.S. leafy green acres of 433,023 is the sum of 344,451 acres in California and Arizona plus 88,572 outside of those two States).

The most common changes in leafy green farming operations made by respondents (to the survey that was the basis of the UC report) were installing or improving fencing and bathroom/hand-washing facilities. The total cost of the investments/modifications for LGMA compliance averaged \$21,490, or \$13.60 per acre, with a range from \$0 to \$150,500. The cost for modifications reported by small farms was \$14.82 per acre. The figures for medium and large farms were \$18.05 and \$8.29 per acre, respectively. In the UC report, a small farm was defined as a farm with annual gross revenue from leafy green

vegetables of under \$1 million. Revenue of \$1 million to \$10 million was defined as medium, and a large farm had leafy green revenues over \$10 million annually.

The survey results indicated that one-third of respondents reduced production area under cultivation, averaging a 1.5 percent reduction, to meet buffer zone requirements. Evidence presented at the hearing indicates small producers tend to have numerous small plots of land. Buffer zone land loss, if required under the proposed agreement, could be a much

larger percent for those producers with small, scattered plots.

Another key impact to examine is the increased seasonal cost that would be incurred every year by producers for compliance with the proposed program. A range of compliance cost increases is presented in Table 2, based on cost data drawn from the UC and Intertox reports.³ Table 2 presents a range of per acre of cost increases for producer compliance—four cost levels at \$20 increments: \$10, \$30, \$50, and \$70.⁴ Individual producer costs could vary substantially from these estimates of mean costs per acre.

TABLE 2—RANGE OF SEASONAL COST INCREASE ESTIMATES FOR PRODUCER COMPLIANCE WITH THE PROPOSED PROGRAM

Increased cost per acre		Seasonal cost increases for farms outside of CA, AZ*	Seasonal cost increases for farms in the U.S.*
		\$ million	
\$10	* * *	\$0.9	\$4.3
30	* *	2.7	13.0
50	* *	4.4	21.7

³In table 5 in the UC report, the bottom rows show that the mean food safety costs per acre were \$24.04 and \$54.63. The difference between those figures (\$30.59, rounded to \$30) represents one estimate of increased California producer expenditure on food safety after the California LGMA went into effect in 2007, compared to seasonal food safety expenses already incurred prior to the LGMA. In table 6 of the UC report, mean per acre costs of \$36.46 and \$84.36 appear in the bottom rows. The difference between them is \$47.90, which is rounded to \$50. The \$30 and \$50 costs represent a range of estimates of the cost impact of the additional requirements to comply with the California LGMA. Since cost data from

other regions of the U.S. were not submitted at the hearing, it is assumed that a similar range of additional expenditures would be likely in other states under the proposed program.

⁴Table 13 on page 13 of the Intertox report indicates costs of \$35 and \$45 for a producer growing 200 acres of leafy greens. Table 14 on page 14 presents per acre cost estimates of \$20, \$30 and \$50 for a 10,000-acre producer. Tables 15 and 16 (on page 16 of the Intertox report) present costs for producer-handlers. For a producer-handler shipping 200,000 cartons annually, the per acre cost estimates were \$67 and \$95. For an operation shipping 9.5 million cartons, the food safety costs were \$48 and \$105. The cost elements in the tables

included personnel, water testing, third party audits, recordkeeping, training, equipment, and a category called "ranch care, pest control, chlorine." Given this range of total costs from the Intertox report, it is assumed that a range of cost increases (averaged over all producers) could range from \$10 to \$70 per acre.

TABLE 2—RANGE OF SEASONAL COST INCREASE ESTIMATES FOR PRODUCER COMPLIANCE WITH THE PROPOSED PROGRAM—Continued

Increased cost per acre		Seasonal cost increases for farms outside of CA, AZ*	Seasonal cost increases for farms in the U.S.*
70	* * *	6.2	30.3

* Acreage data from 2007 Census, 88,572 acres of leafy greens outside of CA and AZ plus 271,040 acres of leafy greens in CA and AZ equals U.S. leafy green acres of 433,023.

** In the UC report, a producer survey yielded a mean estimated increase of about \$30. A separate estimate of “Seasonal Food Safety Losses and Activities” showed increased per acre expenditure of about \$48, which is rounded to \$50 in the table above.

*** The Intertox report included producer food safety costs from ranging from \$20 to \$50 per acre, and for producer/handlers, from \$48 to \$105 per acre, for all food safety expenses, not just those incurred for compliance. Given this range of total costs, it is assumed that a range of net increased costs (averaged over all producers) could range from \$10 to \$70 per acre. Individual producer costs could vary substantially from these estimates of mean costs per acre.

Multiplying the cost figures of \$30 to \$50 per acre by 88,572 acres yields a range of seasonal cost increase estimates for program compliance of \$2.7 to \$4.4 million for all leafy green acreage outside of California and Arizona. Adding Intertox submitted estimates increases the range to \$900,000 to \$6.2 million. Just as with modification costs discussed above, it is assumed that California and Arizona farm seasonal cost increases for program compliance would be minimal, since most acreage is already participating in the leafy green marketing agreements in those two States and/or have already undertaken seasonal GAPs or audit verification expenditures in response to contractual obligations from buyers. However, to provide an estimate of the total seasonal costs for the industry as a whole, the fourth column adds the costs in column three to an estimated cost expended by producers in California and Arizona, most of who are covered by State marketing agreements.

Results of the UC report included per acre seasonal (annual) food safety cost estimates of \$0 to \$200 in 2007. This estimate includes requirements of private standards audits in addition to LGMA compliance. The average increase in seasonal compliance cost for producers of all sizes was \$30.59 per acre. Total seasonal compliance costs reported by small farms were \$38.57 per acre. The figures for medium and large farms were \$85.89 and \$33.22 per acre, respectively. Taking all costs into consideration, average compliance costs totaled 1.0–1.3 percent of producers’ leafy green vegetable revenues.

A researcher on the faculty at California State University at Fresno testified as a proponent witness. The witness reported results of a survey taken on the costs of complying with the LGMA. Three significant cost increases as a result of the LGMA were \$400–500 per audit per farm for compliance audits, one additional employee for food

quality and best practices procedures, and increased water testing averaging a total of \$3,657 per month.

Record evidence indicates that a large proportion of commercial leafy green vegetable production is already complying with the California and or Arizona marketing agreements, therefore, the proposed agreement would not cause these producers to incur significant cost increases since they have already invested in food quality verification and related compliance.

Record evidence indicates that, based on a 2008 survey of LGMA participants, the types of costs associated with the agreement included additional personnel costs, additional water and soil amendment tests, traceability processes and increased recordkeeping. According to the record evidence, small producers reported costs associated with the LGMA of \$35 to \$45 per acre; for large producers, costs were \$20 to \$50 per acre. Small producers in the survey had made little investment prior to the LGMA. In the absence of specific buyer or program requirements, such as the National Organic Program, costs were small and/or not broken out from other operating expenses in the survey.

The costs cited in the Intertox testimony represent 1–2 percent of total operating costs and include all food quality and best practices procedure costs, not just those associated with the LGMA. Numerous proponent witnesses testified that these costs were representative of their costs as a producer or handler.

Evidence provided at the hearing indicates that most, if not all, large producers have initiated some food quality and best practices procedures even if they were not regulated under either of the two State marketing agreements currently in effect.

Some small producers testified that they had initiated good agricultural practices in recent years, including

some which increased cash costs, such as new or added testing of the growing environment. Many stated that they were spending more of their time on food safety issues, including attending training. Most small producers testifying were concerned with potential recordkeeping requirements that they believed would be burdensome under the proposed agreement. Evidence presented at the hearing suggested that most producers are spending time and/or money trying to reduce the potential for food contamination, but the efforts are not consistent and vary from producer to producer. It is anticipated that the proposed agreement would have minimal impact on small producers that market directly through local farmers’ markets or similar community outlets, because these handling entities would likely not be signatories to the proposed agreement.

Producer/Handler Cost Impact Estimates

According to record evidence, a large producer who also is a large handler would have food quality and best practices procedure costs ranging from \$48 to \$105 per acre. The evidence indicates the largest cost increase for large producers was hiring or assigning food safety personnel to manage food quality and best practices procedure compliance. Further evidence indicates that a small handler who is also a small producer would have audit verification or compliance related costs ranging from \$67 to \$95 per acre. This is based on a representative farm growing and shipping 200,000 cartons of leafy green vegetables per year (approximately 950 acres).

Assessment Cost Impacts on Handlers

Under the proposed agreement, signatory first handlers would be assessed based on their volume of leafy green vegetables handled for the fresh market. These assessments would cover

the administrative costs of the proposed program as well as audit verification fees for signatory first handlers and their producers. Additionally, signatory handlers other than first handlers would pay costs associated with the conduct of audit verifications. The record evidence indicates that USDA's current rate is \$92 per hour per auditor.

Table 3 shows alternative assessment rates and a computation illustrating the total cost to all U.S. leafy green vegetable signatory handlers of the California and Arizona marketing agreements, and signatory first handlers under the proposed agreement. An assessment rate of one cent per carton is equivalent to \$13.04 per acre. This

computation is based on a carton weight of 24 pounds and an average yield. The three-year average U.S. yield (2007–2009) for the 5 major leafy greens is 313 hundredweight (cwt.) per acre.

Multiplying \$13.04 per acre times California and Arizona acreage of 344,451 yields an estimate of \$4.5 million in total assessments for those two States. The \$4.5 million assessment figure represents an approximation of the average of annual payments by handlers since the State LGMAs were implemented in 2007; those States would therefore likely not see a significant change in assessment payments if the rate was approximately one cent per carton. At one cent per

carton, the total assessment cost to handlers in all other States is estimated at \$1.2 million, based on 88,172 acres, if all producers in those States sold their entire leafy green production to signatory handlers.

In 2009, 167.7 million pounds of fresh lettuce, spinach and cabbage were imported in the U.S. Record evidence indicates that some of the leafy green vegetables imported into the United States are produced and/or shipped by large U.S. companies. Assessments on the quantity of imports are estimated to add \$70,000 to potential total assessments at the assessment rate of one cent per carton.

TABLE 3—ESTIMATE OF POTENTIAL HANDLER ASSESSMENTS UNDER ALTERNATIVE PAYMENT RATES

Assessment rates		Total assessments**				
Per carton	Per acre equivalent*	California and Arizona	All other states	Assessments on domestic production	Imports***	Total assessments
\$	\$ per acre	----- \$ million -----				
0.01	13.04	4.49	1.16	5.65	0.07	5.72
0.03	39.13	13.48	3.47	16.94	0.21	17.15
0.05	65.21	22.46	5.78	28.24	0.35	28.59

* Computation of per acre equivalent: \$0.05 per carton/24 lbs. per carton = \$0.002083 per pound, or \$0.2083 per cwt; Average yield for 5 major leafy greens (2007–2009) = 313 cwt. per acre; \$0.2083 per cwt. × 313 cwt. per acre = \$65.21 per acre.

** Computed by multiplying Per Acre Equivalent Assessment Rate by Acres (California and Arizona = 344,451; all other States = 88,172).

*** Imports are assumed to be 167.7 million pounds.

If the rate were five cents per carton, the per-acre equivalent rate would be \$65.21. California and Arizona handlers would pay \$22.5 million, an increase of \$18 million from the estimated \$4.5 million that they have been paying in recent years to their respective State LGMAs. Handlers in all other States would pay \$5.8 million. If all U.S. producers sold their entire leafy green production to signatory first handlers under the proposed agreement, if imports were equal to 2009 levels and if the assessment rate were five cents per carton, the estimate of total assessment payments would be \$28.6 million. The three cent per carton rate shown in the table represents an intermediate level of assessment.

Concerns of Small Handlers and Producers

Hearing evidence indicates that participants representing small businesses and organic operations were concerned about the potential costs associated with any proposed best practices resulting from the implementation of this proposed agreement. A number of those who testified at the hearing expressed concern that, if implemented, the proposed agreement might have a

disproportionate impact on small producers relative to larger producers. The cost to producers of implementing GAPs requirements is likely to be highly variable, based on individual farm situations, and may or may not be disproportionately different for small producers in relation to their larger counterparts.

In AMS's analysis of the proposed agreement, consideration was given to its potential impact on small producers. In particular, this proposed rule broadens Board representation and membership of the proposed Technical Review Committee, provides for coordination with programs and other independent entities, and would include the addition of education and outreach authority to support the transition of small businesses into compliance with the proposed agreement.

In response to comments received during the hearing, AMS is recommending changes to the proposal to make the Board and Committee more fully representative of the varied business sizes and diverse production cultures which comprise the domestic leafy green vegetables industry. The changes to representation on the Board and Technical Review Committee

would ensure that the interests of small entities would be considered in the establishment of the audit metrics under the agreement.

The proposed modifications are intended to ensure representation in the process so that the audit metrics developed would be scale-appropriate and would not disproportionately burden small entities. As recommended in this proposed rule, the Secretary would have final approval of audit metrics.

The establishment of audit metrics would include considering the recommendations in a public forum. A super majority vote by the Board is required for recommendations to be forwarded to the Secretary for approval through the informal rulemaking process. That process would include public notice, the opportunity for public comment, and final approval by USDA.

Since audits paid for by the Board with assessment funds are based on volume handled, small handlers should not be at a disadvantage in participating in the proposed program in relation to large handlers. In addition, since producers within the production area (U.S. grown) would not be required to pay either assessments or auditing costs, small producers should not be at a

disadvantage in relation to larger producers for these costs.

The hearing record indicates support for moving forward with the proposed agreement as revised to ensure that concerns of small, organic and diversified operations are addressed.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), AMS announces its intention to request an approval of a new information collection for the proposed National Marketing Agreement Regulating Leafy Green Vegetables.

Title: National Marketing Agreement Regulating Leafy Green Vegetables.
OMB Number: 0581-NEW.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the proposed National Marketing Agreement Regulating Leafy Green Vegetables.

The proposed agreement for leafy green vegetables would authorize the development and implementation of production and handling regulations (audit metrics). Such audit metrics would reflect GAPs, GHPs, and GMPs. AMS is the agency that would provide oversight of the proposed agreement, and any administrative rules and regulations issued under the proposed program.

Upon implementation of the proposed agreement or during amendatory proceedings, handlers would be offered the opportunity to sign an agreement to indicate their willingness to comply with the provisions of the new or amended agreement. The proposed agreement would be voluntary in that only handlers who sign the proposed agreement would become signatory handlers who are subject to its requirements. AMS also would provide a certificate of resolution for each signatory handler organization to sign, documenting the handler's approval of the proposed agreement.

If the proposed agreement is established, nomination forms for signatory handlers and producers and background information forms would be used to nominate and appoint Board members and alternates. Producer, signatory handler, and importer members would be nominated to serve as representatives on the Board by their peers who also are subject to the

National Marketing Agreement Regulating Leafy Green Vegetables. The general public would nominate three additional members and their alternates to represent one from each of the following: Retailers, foodservice operators, and the public. Each producer, signatory handler, importer, retailer, foodservice operator, and person of the general public would be allowed to nominate oneself to the Board as a member or alternate. Each person nominated would be required to complete a background information form. All nominations would be submitted to the Secretary for selection and appointment as Board members and alternate members.

Following the selection of the Board, committee nomination forms and background information forms would be used to nominate and appoint members to the Technical Review Committee and the Research and Development Committee. Each producer and signatory handler would have the opportunity to submit a nomination form with the names of persons to be considered for nomination to these committees. Persons who are nominated would be required to complete a background information form. All nominations would be submitted to the Secretary for selection and appointment as committee members.

The forms covered under this information collection request would be for the submission of minimum information necessary to ascertain handler support for the proposed agreement, to appoint Board members and their alternates, and appoint members to specific committees of the Board. Additional reporting and recordkeeping requirements may subsequently be recommended by the Board for its use in administering the proposed agreement. The burden imposed by any additional requirements would be submitted for approval by the OMB.

The information collected would be used only by authorized representatives of USDA, including AMS, Fruit and Vegetable Programs' regional and headquarters staff, and authorized employees of the Board, if established. Section 608(d)(2) of the Act provides for confidential treatment of information.

Total Annual Estimated Burden

The total burden for the information collection request under the proposed agreement is as follows:

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response.

Estimated Number of Respondents: 2,370 (2,200 handlers, 140 producers, 30 public).

Estimated Number of Annual Responses: 4,790.

Estimated Number of Responses per Respondent: 2.02.

Estimated Total Annual Burden on Respondents: 522 hours.

Estimated Annual Burden for Each Form

For each new form, the proposed request for approval of new information collections under the proposed agreement are as follows:

FV-307 National Marketing Agreement Regulating Leafy Green Vegetables. Handlers would use this form to indicate their willingness to comply with the provisions of the proposed agreement. The proposed National Marketing Agreement Regulating Leafy Green Vegetables form would be completed if the proposed agreement is implemented and in any future amendment of the agreement.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per response.

Respondents: Handlers of leafy green vegetables.

Estimated Number of Respondents: 2,200.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 183.26 hours.

FV-308A Certificate of Resolution. This form would document corporate handlers' support for the proposed agreement. The certificate of resolution would be completed if the proposed agreement is implemented and in any future amendment of the agreement.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per response.

Respondents: Incorporated handlers of leafy green vegetables.

Estimated Number of Respondents: 2,100.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 174.93 hours.

FV-309 Nomination Form by Producers/Signatory Handlers. Producers and signatory handlers of leafy green vegetables would use this form to nominate themselves or other producers and signatory handlers to serve on the Board. This form also would include the nomination of the importer member and their alternate. For the purpose of this calculation, it is estimated that 70 producers and 70

signatory handlers would offer nominations.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 10 minutes per response.

Respondents: Producers and signatory handlers of leafy green vegetables.

Estimated Number of Respondents: 140.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 23.38 hours.

FV-310 Nomination Form by General Public. Any person located in the production area would use this form to nominate themselves or other persons from the public to serve as a retailer, foodservice representative, and public member or alternate member on the Board. For the purpose of this calculation, it is estimated that 30 persons would offer nominations.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 10 minutes per response.

Respondents: General Public.

Estimated Number of Respondents: 30.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 5.10 hours.

FV-311 Background Information. This proposed rule recommends the Board be comprised of 26 members and 26 alternates. This form would be used by nominated candidates to provide their qualifications to serve on the Board. For the purpose of this calculation, it is estimated that 170 persons would agree to be candidates to serve on the Board.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30 minutes per response.

Respondents: Signatory handlers, importers, producers, retailers, foodservice representatives, and general public nominees.

Estimated Number of Respondents: 170.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 85.0 hours.

FV-312 Committee Nomination Form. Producers and signatory handlers of leafy green vegetables would use this form to nominate persons to serve on the Technical Review Committee or the Research and Development Committee. For the purpose of this calculation, it is estimated that 40 producers and 35 signatory handlers would offer nominations.

Estimate of Burden: Public reporting burden for this collection of information

is estimated to average 10 minutes per response.

Respondents: Producers and signatory handlers of leafy green vegetables, and the Board.

Estimated Number of Respondents: 75.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 12.75 hours.

FV-313 Committee Background Information. This recommended decision proposes that the Technical Review Committee consist of a minimum of 10 members and the Research and Development Committee consist of a minimum of 9 members. This form would be used by candidates that have been nominated to provide their qualifications to serve on the Technical Review Committee or the Research and Development Committee. For the purpose of this calculation, it is estimated that 20 producers, 15 signatory handlers, and 40 other persons would agree to be candidates to serve on these committees.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30 minutes per response.

Respondents: Producers and signatory handlers of leafy green vegetables, retailers, foodservice representatives, food safety experts, and other persons.

Estimated Number of Respondents: 75.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 37.50 hours.

If this proposed agreement is established by USDA, the Board could recommend to the Department other forms (such as monthly assessment report, contact information form, withdrawal form, *etc.*) which would be needed to administer the proposed agreement. All such forms would be subject to USDA and OMB review and approval.

Comments: Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581-NEW and the Proposed National Marketing Agreement Regulating Leafy Green Vegetables, and be sent to USDA in care of the Docket Clerk at the previously-mentioned address. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval of the above-described forms. All comments will become a matter of public record.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Civil Justice Reform

The marketing agreement proposed herein has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of marketing agreements issued under the Act.

Rulings on Briefs of Interested Persons, Proposed Findings and Conclusions

Briefs, proposed findings and conclusions, and the evidence in the record were considered in making the findings and conclusions set forth in this recommended decision. To the extent that the suggested findings and conclusions filed by interested persons are inconsistent with the findings and conclusions of this recommended decision, the requests to make such findings or to reach such conclusions are denied.

General Findings

1. The proposed agreement and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The proposed agreement regulates the handling of leafy green vegetables grown in the production area in the same manner as, and is applicable only to, persons in the respective classes of commercial and industrial activity specified in the proposed agreement upon which a hearing has been held;

3. The proposed agreement prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the

production and marketing of leafy green vegetables in the production area; and

4. All handling of leafy green vegetables grown in the production, or handled as imported product from outside the production area, as defined in the proposed agreement, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

A 90-day comment period is provided to allow interested persons to respond to this proposal. All written exceptions timely received will be considered. After consideration of any comments received, the Secretary will issue a Secretary's Decision which, if warranted, would include a handler sign-up period.

List of Subjects in 7 CFR Part 970

Marketing agreements, Reporting and recordkeeping requirements, Vegetables.

Title 7, Chapter IX is proposed to be amended by adding Part 970 to read as follows:

PART 970—NATIONAL MARKETING AGREEMENT REGULATING LEAFY GREEN VEGETABLES

Subpart—Agreement Regulating Signatory Handlers

Definitions

Sec.

- 970.1 Act.
- 970.2 Audit metric.
- 970.3 Audit.
- 970.4 Broker.
- 970.6 Critical limit.
- 970.7 Crop year.
- 970.8 Foodservice operator.
- 970.9 Fresh.
- 970.10 Fresh-cut.
- 970.11 Good agricultural and handling practices.
- 970.13 Good manufacturing practices or GMPs.
- 970.14 Handle.
- 970.15 Handler.
- 970.16 Importer.
- 970.17 Inspection Service.
- 970.18 Leafy green vegetables.
- 970.19 Manufacture.
- 970.20 Manufacturer.
- 970.22 National Leafy Green Vegetable Board or Board.
- 970.23 Packaged.
- 970.24 Part.
- 970.25 Person.
- 970.26 Process control.
- 970.27 Producer.
- 970.28 Production area.
- 970.29 Region.
- 970.30 Retailer.
- 970.31 Secretary.
- 970.32 Signatory first handler.
- 970.33 Signatory handler.
- 970.35 United States Department of Agriculture or USDA.
- 970.36 United States Food and Drug Administration or FDA.

970.37 Zone.

Purpose

970.39 Purpose.

National Leafy Green Vegetable Board

- 970.40 Establishment and membership.
- 970.41 Reallocation of membership.
- 970.42 Eligibility.
- 970.43 Term of office.
- 970.44 Nominations.
- 970.45 Alternate members.
- 970.46 Technical Review Committee.
- 970.47 Research and Development Committee.
- 970.48 Compensation and expenses.
- 970.49 Procedure.
- 970.50 Powers.
- 970.51 Duties.

Expenses and Assessments

- 970.55 Expenses.
- 970.56 Assessments.
- 970.57 Accounting.
- 970.58 Contributions.

Duties and Responsibilities of Signatory Handlers

- 970.65 Signatory handlers.
- 970.66 Verification audits.
- 970.67 Audit metrics.
- 970.68 Traceability.
- 970.69 Official certification mark.
- 970.70 Administrative review of audits.
- 970.71 Modification, suspension, or termination of regulations.
- 970.72 Exemptions.

Research and Development

- 970.75 Research, development, and education.

Reports and Records

- 970.80 Reports and recordkeeping.
- 970.81 Confidential information.
- 970.82 Verification of reports.
- 970.83 Compliance.

Miscellaneous

- 970.85 Effective time.
- 970.86 Rights of the Secretary.
- 970.87 Personal liability.
- 970.88 Separability.
- 970.89 Derogation.
- 970.90 Duration of immunities.
- 970.91 Agents.
- 970.92 Suspension or termination.
- 970.93 Proceedings upon termination.
- 970.94 Effect of termination or amendment.
- 970.95 Amendments.
- 970.96 Counterparts.
- 970.97 Handler sign-up.
- 970.98 Withdrawal.
- 970.99 OMB control number.

Authority: U.S.C. 601–674.

Subpart—Agreement Regulating Signatory Handlers

Definitions

§ 970.1 Act.

Act means Public Act No. 10, 73rd Congress (May 12, 1933), as amended and as reenacted and amended by the Agricultural Marketing Agreement Act

of 1937, as amended (48 Stat. 31, as amended; 7 U.S.C. 601–674).

§ 970.2 Audit metric.

Audit metric means an auditable standard or requirement within a process control prescribed pursuant to § 970.67.

§ 970.3 Audit.

Audit means an official review conducted by the Inspection Service to verify and document that good agricultural, handling, and manufacturing practices are adhered to throughout the growing, harvesting, packing, manufacturing, and transportation of leafy green vegetables. The audit includes a physical visit to the farm or facility subject to audit while it is in operation, where practicable, and represents a “snapshot in time” based on documentation reviewed, persons interviewed, and operations observed, and is intended to reflect past and ongoing activities.

§ 970.4 Broker.

Broker means a person who coordinates the sale and transportation of leafy green vegetables for retail or foodservice operators, without taking ownership of such leafy green vegetables.

§ 970.6 Critical limit.

Critical limit means a maximum or minimum value that is assigned to a process control when a biological, chemical, or a physical parameter must be controlled to prevent or minimize the occurrence of a food safety hazard.

§ 970.7 Crop year.

Crop year is synonymous with *fiscal year* and means the 12-month period beginning on April 1 of any year and ending on March 31 of the following year, or any other period recommended by the Board and approved by the Secretary.

§ 970.8 Foodservice operator.

Foodservice operator means a business (including but not limited to an industrial caterer or hospital) that receives or purchases leafy green vegetables from handlers and delivers such vegetables to consumers, either by sale or by offering for direct consumption.

§ 970.9 Fresh.

Fresh means any leafy green vegetable in the raw or natural form.

§ 970.10 Fresh-cut.

Fresh-cut is synonymous with *products* and means leafy green vegetables that have been altered from

their fresh form by cutting, dicing, peeling, slicing, chopping, shredding, coring, or trimming, with or without washing prior to being packaged for use by the consumer, foodservice industry, or a retail establishment.

§ 970.11 Good agricultural and handling practices.

Good agricultural practices or GAPs and *Good handling practices or GHPs* refer to general practices to reduce microbial food safety hazards in leafy green vegetables, as described in sections of the current FDA “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” and the current FDA “Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables” that are applicable to the production and harvesting activities of leafy green vegetables, or any other revised or modified versions thereof, or any other documents or regulations, as recommended by the Board and approved by the Secretary for use in audits conducted by the Inspection Service under this part.

§ 970.13 Good manufacturing practices or GMPs.

Good manufacturing practices or GMPs means any FDA regulations that appear in 21 CFR Part 110 or as otherwise amended, which describe the methods, equipment, facilities, and controls required for producing fresh-cut processed food, including packaged leafy green vegetables, or FDA guidance documents, regulations, or any other documents recommended by the Board and approved by the Secretary for use in audits conducted by the Inspection Service under this part.

§ 970.14 Handle.

Handle means to receive, acquire, sell, process, ship, distribute, or import leafy green vegetables: Provided, that handle does not include brokering, retail sales, or foodservice sales of leafy green vegetables.

§ 970.15 Handler.

Handler means any person who handles leafy green vegetables: Provided, that, this definition does not include a retailer, foodservice operator, or a broker, except to the extent such person is otherwise engaged in handling.

§ 970.16 Importer.

Importer means a handler located in the production area who imports leafy green vegetables that are produced or handled outside of the production area.”

§ 970.17 Inspection Service.

Inspection Service means the Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, its designees, or any other entity approved or recognized by USDA to conduct audits on leafy green vegetables.

§ 970.18 Leafy green vegetables.

(a) *Leafy green vegetables* means the mature and immature leafy portions of any of the following vegetables and any varieties thereof that are for human consumption in their fresh or fresh-cut form: arugula, cabbage (red, green, and savoy), chard, cilantro, cress, dandelion, endivia, endive (escarole), kale, lettuce (head, leaf, and romaine), mâche, mizuna, parsley, radicchio, spinach, tat soi, winter purslane, or any other leafy green vegetable recommended by the Board and approved by the Secretary. The Board may recommend, subject to the approval of the Secretary, the removal of any leafy green vegetable from this definition.

(b) Combinations of the above listed leafy green vegetables are covered by the requirements established under this part. This includes spring mix.

(c) All non-leafy green vegetables or non-produce ingredients commingled with fresh-cut leafy green vegetables in packaged products (e.g., salad kits which may contain carrots, meat, cheese, and/or dressings) are not covered by this part.

§ 970.19 Manufacture.

Manufacture is synonymous with process and means to change fresh leafy green vegetables to fresh-cut leafy green vegetables: Provided, that manufacture does not include leafy green vegetables packed in the field or apply to retailing, foodservice operators, or brokering, except to the extent that a retailer, foodservice operator, or broker is otherwise engaged in manufacturing for non-retail purposes.

§ 970.20 Manufacturer.

Manufacturer means any person who manufactures: Provided, that, this definition does not include a retailer, a foodservice operator, or broker, except to the extent that such a person is otherwise engaged in handling.

§ 970.22 National Leafy Green Vegetable Board or Board.

National Leafy Green Vegetable Board or Board means the administrative board established pursuant to § 970.40, or as affected pursuant to § 970.41.

§ 970.23 Packaged.

Packaged is synonymous with containerized and means leafy green vegetables that are uniformly wrapped

or sealed, such as cellophane, clamshells, cartons or totes.

§ 970.24 Part.

Part means the marketing agreement regulating the handling of leafy green vegetables by signatory handlers and all rules, regulations and supplementary subparts issued thereunder.

§ 970.25 Person.

Person means an individual, partnership, corporation, association, or any other business unit.

§ 970.26 Process control.

Process control means a step or point within a production, harvesting, handling, manufacturing, or transportation process at which the potential for microbiological contamination can be reduced.

§ 970.27 Producer.

Producer is synonymous with grower and means any person engaged in a proprietary capacity in the production of leafy green vegetables for sale or delivery to a signatory handler.

§ 970.28 Production area.

Production area means all fifty States and the District of Columbia of the United States of America.

§ 970.29 Region.

Region means a production or growing area distinguished by common environmental or growing conditions including, but not limited to, geography, climate, production practices, water sources and distribution systems, or wildlife. Regions are not synonymous with zones.

§ 970.30 Retailer.

Retailer means any person that sells leafy green vegetables directly to the consumer.

§ 970.31 Secretary.

Secretary means the Secretary of Agriculture of the United States or any officer or employee of the United States Department of Agriculture who is, or who may hereafter be, authorized to act in his or her stead.

§ 970.32 Signatory first handler.

Signatory first handler means the person located in the production area that first handles leafy green vegetables and who is party to this part.

§ 970.33 Signatory handler.

Signatory handler means a handler located in the production area who is party to this part.

§ 970.35 United States Department of Agriculture or USDA.

United States Department of Agriculture or USDA means any officer, employee, service, program or branch of the Department of Agriculture, or any other person acting as the Secretary's agent or representative in connection with any provisions of this part.

§ 970.36 United States Food and Drug Administration or FDA.

United States Food and Drug Administration or FDA means the government agency within the United States Department of Health and Human Services.

§ 970.37 Zone.

Zone means the applicable one of the following described subdivisions of the production area or such other subdivisions as recommended by the Board and approved by the Secretary:

(a) *Zone 1* shall include the States of California and Hawaii.

(b) *Zone 2* shall include the States of Alaska, Idaho, Montana, Oregon, Washington, and Wyoming;

(c) *Zone 3* shall include the States of Arizona, Colorado, Nevada, New Mexico, and Utah;

(d) *Zone 4* shall include the States of Illinois, Iowa, Minnesota, Nebraska, North Dakota, South Dakota, and Wisconsin;

(e) *Zone 5* shall include the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas;

(f) *Zone 6* shall include the States of Delaware, District of Columbia, Indiana, Kentucky, Maryland, Michigan, Ohio, Virginia, and West Virginia;

(g) *Zone 7* shall include the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Tennessee; and,

(h) *Zone 8* shall include the States of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Purpose**§ 970.39 Purpose.**

The purpose of this agreement is to: Implement a uniform, auditable, science-based food quality verification program conducted by the USDA; enhance the quality of leafy green vegetables available in the marketplace through the application of good agricultural production, handling, and manufacturing practices; foster greater cooperation with local, State, and Federal agencies and other organizations; and, improve consumer confidence in leafy green vegetables.

National Leafy Green Vegetable Board**§ 970.40 Establishment and membership.**

(a) A National Leafy Green Vegetable Board is hereby established to administer the terms and provisions of this part. Such Board shall consist of twenty-six members, each of whom shall have an alternate who shall have the same qualifications as the member for whom he or she is an alternate. Board membership shall be allocated as follows:

(1) Four signatory handlers and three producers from Zone 1;

(2) One signatory handler and one producer from Zone 2;

(3) One signatory handler and one producer from Zone 3;

(4) One signatory handler and one producer from Zone 4;

(5) One signatory handler and one producer from Zone 5;

(6) One signatory handler and one producer from Zone 6;

(7) Two signatory handlers and one producer from Zone 7;

(8) One signatory handler and one producer from Zone 8;

(9) One importer representative from the production area;

(10) One retailer representative from the production area;

(11) One foodservice representative from the production area; and,

(12) One public member representative from the production area.

(b) A majority of the producer members of the Board shall not be engaged in the handling of leafy green vegetables or the manufacturing of fresh-cut products, and two producers must be small producers. Further, at least four handler members must be engaged in the manufacturing of fresh-cut leafy green products.

(c) To the extent practicable, Board membership shall include representation of the following stakeholder groups:

(1) Producers that meet the Small Business Administration's (SBA) definition small agricultural producers.

(2) Diversified farm producers who produce a variety of crops or animals, or both, on one farm, as distinguished from specialization of a single commodity. For the purposes of this subpart, variety of crops means any crop in addition to those included in the definition of leafy green vegetables.

(3) Producers and signatory handlers representing certified organic businesses meeting the SBA definition of small business entity.

(4) Producers and signatory handlers representing certified organic businesses that exceed the SBA definition of small business entity.

§ 970.41 Reallocation of membership.

The Board may recommend, subject to the approval of the Secretary, reallocation of Board members among zones, changes in the number of Board members, and changes in the composition of the Board by revising the number of members representing various industry sectors, *Provided*, that each zone must be represented by at least one producer and one signatory handler. In making such recommendations, the Board shall consider the following factors:

(a) Shifts in acreage and number of producers within zones;

(b) The importance of new acreage in its relation to existing zones;

(c) The equitable relationship between membership and zones;

(d) Economies to result in promoting efficient administration due to reallocation or changing the composition of membership; and,

(e) Other relevant factors.

§ 970.42 Eligibility.

(a) Each signatory handler member (including importer) and his or her alternate member at the time of his or her selection and throughout his or her term of office shall be a signatory handler (including importer), or an officer or employee of a signatory handler in the zone for which selected.

(b) Each producer member and his or her alternate member at the time of his or her selection and through his or her term of office shall be a producer, or an officer or employee of a producer in the zone for which selected.

(c) No signatory handler (including importer) or producer shall be represented on the Board by more than one member and one alternate member.

(d) The retailer, foodservice, and public members and their alternate members may not be engaged in the production or handling of leafy green vegetables. The retailer and foodservice members and their alternates shall be, at the time of their selection and throughout their term of office, an owner, officer or employee for the seat selected.

§ 970.43 Term of office.

Members and alternate members of the Board shall serve for terms of two (2) years beginning on April 1 and ending on March 31. Each member and alternate member shall continue to serve until a successor is selected and has qualified. Members shall not serve more than three (3) consecutive two-year terms of office or for a total of six (6) consecutive years.

§ 970.44 Nominations.

Nomination of Board members and alternate members shall follow the procedure set forth in this section, or such other procedure as may be recommended by the Board and approved by the Secretary.

(a) *Producer and signatory handler (including importer) nominations.* Nominations for the producer and signatory handler (including importer) members and alternate members shall be received at meetings, by mail, or by any form of electronically verifiable communication. Only persons eligible to serve on the Board as producers and signatory handlers shall be eligible to nominate producer and signatory handler (including importer) members and alternate members.

(b) *Retailer, foodservice and public member nominations.* Nominations for the retailer, foodservice, and public members and their alternate members shall be received at meetings, by mail, or by any form of electronically verifiable communication. Any person from the production area shall be eligible to nominate the retailer, foodservice, and public members and their alternate members.

(c) *Acceptance.* Each nominee shall qualify by advising the Secretary that, if selected, such person agrees to serve in the seat and position appointed.

(d) *Selection.* A report shall be provided to the Secretary detailing all nominations prior to the beginning of each two-year term of office, together with all necessary data and other information as requested by the Secretary. The Secretary shall appoint from those nominees or from other qualified persons, the members and alternate members of the Board on the basis of the representation provided for in §§ 970.40 through 970.42.

(e) *Failure to nominate.* If nominations are not made within the time and manner specified in this part, the Secretary may, without regard to nominations, select the members and alternate members of the Board on the basis of the representation provided for in §§ 970.40 through 970.42.

(f) *Vacancies.* To fill a vacancy on the Board occasioned by the failure of any person selected as member or alternate member to qualify, or in the event of the death, removal, resignation, or disqualification of any member or alternate member, a successor for the unexpired term of such member or alternate member shall be nominated and selected in the manner specified in paragraphs (a) and (b) of this section. If the names of nominees to fill any such vacancy are not made available to the Secretary within a reasonable time after

such vacancy occurs, the Secretary may appoint from other qualified persons without regard to nominations on the basis of representation provided for in §§ 970.40 through 970.42.

§ 970.45 Alternate members.

An alternate for a member shall act in the place and stead of such member during the member's absence or, in the event of the member's death, removal, resignation, or disqualification, until a successor for such member's unexpired term has been selected and has qualified.

§ 970.46 Technical Review Committee.

A Technical Review Committee is hereby established for the purpose of assisting the Board in developing audit metrics in § 970.67.

(a) The Technical Review Committee shall consist of one producer, one signatory handler, and one food safety expert from each zone. Of the producer members, at least one must be a small producer as defined by the Small Business Administration and one must be a certified organic producer. In addition, the Technical Review Committee shall include one representative from the USDA Natural Resources Conservation Service to be appointed by the Secretary.

(b) The Secretary may appoint additional representatives from USDA agencies including, but not limited to: National Organic Program, Agricultural Research Service, and National Institute of Food and Agriculture.

(c) USDA may consult with and invite representation from agencies outside of USDA including, but not limited to: the United States Environmental Protection Agency, FDA, and the United States Department of Interior Fish and Wildlife Service.

(d) *Nomination and selection.* Nominations for positions prescribed in paragraph (a) of this section shall be received from producers and signatory handlers at meetings, by mail, or by any form of electronically verifiable communication. In addition, the Board may recommend nominees to USDA. The Secretary may select and appoint the members from such nominations or from other qualified persons.

(e) The membership of the Technical Review Committee may be modified based on recommendations by the Board and approval of the Secretary, or as otherwise deemed appropriate by USDA.

(f) The Technical Review Committee may appoint subcommittees as necessary to facilitate the development of audit metrics. Subcommittees may consist of producers, signatory handlers,

and other interested persons as deemed appropriate by the Technical Review Committee.

§ 970.47 Research and Development Committee.

The Research and Development Committee is hereby established for the purpose of providing advice to the Board on research, development, and educational and outreach programs as authorized under § 970.75.

(a) The Research and Development Committee shall consist of 9 members as follows: Two representatives of retailers; two representatives from foodservice companies; three public representatives, and two representatives from land grant universities with expertise in one, but not limited to, the following areas: The production, handling, and marketing of leafy green vegetables; small, diversified, or organic production and handling practices; agricultural economics; or educational outreach in the specified or related areas.

(b) *Nomination and selection.* Nominations shall be received from producers and signatory handlers at meetings, by mail, or by any form of electronically verifiable communication. The Board may recommend nominees to USDA. The Secretary shall select and appoint the members from such nominations or from other qualified persons.

(c) The membership of the Research and Development Committee may be modified based on recommendations by the Board and approval of the Secretary, or as otherwise deemed appropriate by USDA.

(d) The Research and Development Committee may appoint subcommittees as necessary. Subcommittees may consist of producers, signatory handlers, and other interested persons as deemed appropriate by the Research and Development Committee.

§ 970.48 Compensation and expenses.

All Board members, alternate Board members, committee members, and subcommittee members, shall serve without compensation, but shall be reimbursed for necessary and reasonable expenses incurred in the performance of their duties under this part.

§ 970.49 Procedure.

(a) A majority of all the appointed members of the Board shall constitute a quorum: *Provided*, That each zone with an appointed member shall be represented by at least one member or his or her alternate at any meeting of the full Board. Board action shall require the concurrence of a majority of present members except that recommendations

for the Secretary's approval of audit metrics, assessment rates, and termination of the agreement must be approved by a 2/3 vote of present members.

(b) In the event that a producer or signatory handler member of the Board and their alternate are unable to attend the meeting, the absent member or the Board may designate any other alternate from the same zone and group (signatory handler, producer) who is present at the meeting to serve in the member's place.

(c) The Board shall give to the Secretary the same notice of each meeting that is given to the members of the Board.

(d) The Board may vote by telephone or other means of communication, and any votes so cast shall be confirmed promptly in writing: *Provided*, That, if an assembled meeting is held, all members present shall cast votes in person. A videoconference shall be considered an assembled meeting and all votes shall be considered as cast in person.

§ 970.50 Powers.

The Board shall have the following powers:

(a) To administer this part in accordance with its terms and provisions;

(b) To make such rules and regulations, with the approval of the Secretary, as may be necessary to effectuate the terms and provisions of this part;

(c) To receive, investigate, and report to the Secretary complaints of violations of the provisions of this part; and

(d) To recommend to the Secretary amendments to the part.

§ 970.51 Duties.

The Board shall have, among others, the following duties:

(a) To select from among its members a chairperson and such other officers as may be necessary, and to define the duties of such officers;

(b) To adopt such bylaws for the conduct of its business as it may deem advisable;

(c) To keep minutes, books, and records which clearly reflect all the acts and transactions of the Board, committees, and subcommittees, and these shall be subject to examination by the Secretary at any time;

(d) To appoint such employees or agents as it may deem necessary, and to determine the compensation and define the duties of each;

(e) To submit a budget to the Secretary for each crop year;

(f) To cause its books to be audited by a certified public accountant at least

once each crop year and at such other times as the Board may deem necessary or as the Secretary may request. Such audit shall include an examination of the receipt of income and the disbursement of all funds. The Board staff shall provide the Secretary with a copy of all audits and shall make copies of such audits available for examination at the office of the Board; *Provided*, That all confidential information is treated pursuant to § 970.81;

(g) To investigate the production, handling, and manufacturing of leafy green vegetables and to assemble data in connection therewith;

(h) To establish subcommittees to aid the Board in the performance of its duties under this part;

(i) To collaborate with existing State boards, commissions, and governing bodies of State agreements through memoranda of understanding to affect the purposes of this part;

(j) To recommend, after consultation with the Technical Review Committee, for approval of the Secretary audit metrics as provided for in § 970.67;

(k) To act as intermediary between the Secretary and any signatory handler with respect to the operations of this part; and

(l) To furnish such available information as may be deemed pertinent or as requested by the Secretary.

Expenses and Assessments

§ 970.55 Expenses.

The Board is authorized to incur such expenses as the Secretary finds are reasonable for the maintenance and functioning of the Board during each crop year, including the payment of audit fees, activities provided for under § 970.75, and for such other purposes as the Secretary may, pursuant to the provisions of this part, determine to be appropriate. Such expenses shall be paid from assessments received pursuant to § 970.56 and other funds available to the Board.

§ 970.56 Assessments.

(a) Each signatory first handler shall be responsible for paying the Board such handler's pro-rata share of the Board's expenses authorized by the Secretary for each crop year. The payment of assessments for the maintenance and functioning of the Board, as described in § 970.55, may be required under this part throughout the period it is in effect irrespective of whether particular provisions thereof are suspended or become inoperative.

(b) Based upon recommendation of the Board, or other available data, the Secretary shall fix a base rate of assessment for all leafy green vegetables

that signatory first handlers shall pay during each crop year. The Board may recommend and the Secretary may approve supplemental assessments, but no combination of assessment and supplemental assessments may exceed the cap established in paragraph (c) of this section.

(c) Based on the recommendation of the Board, or other available data, the Secretary may change or modify the base rate assessment. The assessment shall be set at the lowest rate practical to carry out the objectives of this part. The assessment rate shall not exceed \$0.05 per 24-pound carton or equivalent of leafy green vegetables.

(d) Assessments not paid by a signatory first handler within a prescribed period of time may be subject to an interest or late payment charge, or both. The period of time, rate of interest, and late payment charge may be recommended by the Board and approved by the Secretary.

(e) In order to provide funds for the administration of this part, the Board may accept, but not require, advance payments of assessments, which shall be credited toward assessments levied against such signatory first handler during the crop year. The Board may also borrow money, subject to approval by the Secretary, for such purposes when assessment and reserve funds are not sufficient to cover Board expenses.

§ 970.57 Accounting.

If, at the end of a crop year, the assessments collected are in excess of expenses incurred, the Board, with the approval of the Secretary, may carry over such excess into subsequent crop years as an operating monetary reserve, except that total funds already in such reserve shall not exceed approximately two (2) crop years' budgeted expenses. Funds in such reserve shall be available for use by the Board for expenses authorized pursuant to § 970.55 and § 970.75, and to cover necessary expenses of liquidation in the event of termination of this part. If any such excess is not retained in a reserve, each signatory handler entitled to a proportionate refund shall be credited with such refund against the operations of the following crop year, or be paid such refund.

§ 970.58 Contributions.

The Board may accept voluntary contributions but these shall only be used to pay expenses incurred pursuant to § 970.75. Such contributions shall be free from any encumbrances by the donor and the Board shall retain complete control of their use.

Duties and Responsibilities of Signatory Handlers

§ 970.65 Signatory handlers.

No signatory handler to this part shall handle leafy green vegetables for human consumption unless such are verified as meeting the verification audit provisions of this part. Such verification shall take the form of an official audit conducted by the Inspection Service pursuant to § 970.66.

§ 970.66 Verification audits.

(a) *GAPs audits.* (1) Signatory handlers shall ensure that any leafy green vegetables handled by a handler's facilities have been subject to GAPs audits conducted by the Inspection Service. Such audits shall verify that the leafy green vegetables were produced under auditable conditions that meet production and harvest guidelines referred to in § 970.11 and any applicable audit metrics under § 970.67.

(2) No signatory handler subject to the provisions of this part shall receive leafy green vegetables produced outside the production area that have not been subject to GAPs audits conducted by the Inspection Service. Such audits shall verify that such product was produced under auditable conditions that meet production and harvest requirements referred to in § 970.11 and in applicable audit metrics under § 970.67.

(b) *GHPs or GMPs audits.* (1) All signatory handlers shall be subject to audits. Such audits shall verify that such handlers operate under auditable conditions that meet guidelines provided for in the GHPs or GMPs referred to in § 970.11 and § 970.13 and in applicable audit metrics under § 970.67.

(2) No signatory handlers subject to the provisions of this part shall receive leafy green vegetables from handlers outside the production area that have not been subject to GHPs or GMPs audits conducted by the Inspection Service. Such audits shall verify that the leafy green vegetables were produced under auditable conditions that meet production and harvest guidelines referred to in § 970.11 and applicable audit metrics provided for in § 970.67.

(c) Audits shall be conducted on a regular schedule that ensures every signatory handler is audited at least once a crop year. In addition, random unannounced audits of signatory handlers and associated producers shall be performed during the production season in each zone.

§ 970.67 Audit metrics.

After consultation with the Technical Review Committee, the Board may

recommend audit metrics to the Secretary for approval.

(a) *GAPs audit metrics.* Audit metrics for GAPs may include verification of process controls related but not limited to: Water quality, soil amendments, machine harvest, hand harvest (including direct contact with soil during harvest), transfer of human pathogens by field workers, field sanitation, equipment-facilitated cross contamination, flooding, water usage to prevent dehydration, and production location concerns, including climatic conditions and environment, encroachment of animals of significant risk, and urban settings.

(b) *GHPs and GMPs audit metrics.* Audit metrics for GHPs and GMPs may include verification of process controls related but not limited to:

(1) Post-harvest handling processes: Cooling, water, reuse of field containers, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, and employee hygiene.

(2) Handling and manufacturing processes: Wash water, wash system capacity, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, employee hygiene, labeling of Raw Agricultural Commodity versus ready-to-eat products, and finished product packaging.

(3) Distribution handling processes: Condition and sanitation of transportation vehicles, condition and sanitation of distribution and cooler facilities, and temperature measurement of product.

(c) Critical limits for process controls for each step or point identified in GAPs, GHPs, or GMPs audit metrics may be recommended by the Board, after consultation with the Technical Review Committee, for approval of the Secretary, or may be developed by USDA.

(d) Technical Review Committee recommendations, including critical limits, shall incorporate current leafy green vegetable industry production, harvest and handling technologies, and be based on scientific practices.

(e) Audit metrics may be developed and recommended to accommodate differences in production, harvest, and handling environments of different regions and of different leafy green vegetables.

(f) After consultation with the Technical Review Committee, the Board may, at any time, recommend changes to audit metrics for approval by the Secretary.

(g) The Board shall review audit metrics a minimum of once every three

years to ensure that they continually reflect the best leafy green vegetable industry practices, scientific information, and industry knowledge.

§ 970.68 Traceability.

(a) The traceability of leafy green vegetables by signatory handlers shall be established at production, handling, manufacturing, and distribution.

(b) Signatory handlers shall have the ability to track their leafy green vegetables from their supplier(s) to their customer(s) and shall have in place systems and procedures that allow for this information to be made available during an audit by the Inspection Service.

(c) Documents necessary for verification shall be maintained for two years.

§ 970.69 Official certification mark.

(a) Any registered certified mark developed under this part are the property of the United States Government as represented by the Board and shall inure to the benefit of the Board. This mark shall be used in accordance with this section and consistent with the mark's registration.

(b) The Board may license signatory handlers to affix the official certification mark to bills of lading or manifests, or any other such uses recommended by the Board and approved by the Secretary to carry out the purpose of this part, *Provided*, that such mark may not be used on consumer packages. The use of the official certification mark shall be subject to the verification, suspension, or revocation requirements of this part.

(c) A signatory handler's compliance with the regulations under this part is a condition precedent and subsequent to the signatory handler's entitlement to use the official certification mark.

§ 970.70 Administrative review of audits.

(a) Any financially interested person may request an administrative review of an audit if it is believed that the original audit is in error.

(b) Any signatory handler denied the use of the official certification mark may request an administrative review of an audit if it is believed that a material fact of the original audit was misinterpreted.

(c) Administrative reviews will be conducted in accordance with the USDA audit verification procedures for any audit program in effect under this part. The person requesting the review shall pay for the cost of the review. The review results shall be issued to the person making the request.

§ 970.71 Modification, suspension, or termination of regulations.

(a) In the event that the Board, at any time, finds that any regulations issued under this part should be modified or suspended, it shall, pursuant to § 970.49, so recommend to the Secretary.

(b) Whenever the Secretary finds from the recommendations and information submitted by the Board or from other available information, that any regulations issued under this part should be modified, suspended, or terminated in order to effectuate the declared policy of the Act, the Secretary shall modify, suspend or terminate such provisions. If the Secretary finds that a regulation obstructs or does not tend to effectuate the declared policy of the Act, the Secretary shall suspend or terminate such regulation.

§ 970.72 Exemptions.

With the approval of the Secretary, the Board may recommend rules, regulations, and safeguards that exempt leafy green vegetables from any or all requirements pursuant to this part. The Board may require reports or certifications, or impose other conditions as are necessary to ensure that such exempted leafy green vegetables are handled only as authorized.

Research and Development**§ 970.75 Research, development, and education.**

The Board, with the approval of the Secretary, may establish or provide for the establishment of research, including market research, related to production, handling, and manufacturing leafy green vegetables, developments projects, and educational and outreach programs, designed to assist, improve, or promote the efficient adoption, implementation, and administration of this part. The expenses of such projects shall be budgeted and paid from funds collected pursuant to §§ 970.56 and 970.58.

Reports and Records**§ 970.80 Reports and recordkeeping.**

(a) Each signatory handler shall report all receipts and acquisitions of all leafy green vegetables and such other reports or information as recommended by the Board and approved by the Secretary that may be necessary to enable the Board to carry out the provisions of this part.

(b) Each signatory handler shall maintain records of all receipts and acquisitions of leafy green vegetables and all documentation relating to audit reports. Such records shall be

maintained for at least two years after the end of the crop year of their applicability. Such recordkeeping shall be sufficient to document and substantiate the signatory handler compliance with this part.

§ 970.81 Confidential information.

All reports and information submitted by signatory handlers pursuant to the provisions of this part shall be received by, and at all times be in the custody of, employees or authorized agents of the Board. No such employees or authorized agents shall disclose to any person, other than the Secretary upon request therefore, data, or information obtained or extracted from such reports and information which might affect the trade position, financial condition, or business operation of the particular signatory handler from whom received: *Provided*, That such data and information may be combined and made available in the form of general reports in which the identities of the individual persons furnishing the information is not disclosed.

§ 970.82 Verification of reports.

(a) For the purpose of checking and verifying reports filed by signatory handlers, the Board, through its authorized agents or employees, and the Secretary shall have access to any signatory handler's premises during regular business hours, and shall be permitted at any such time to:

(1) Examine such premises and any leafy green vegetables held by such signatory handler, and any and all records of the signatory handler with respect to such signatory handler's acquisition, sales, uses and shipments thereof; and

(2) Examine any and all records of such signatory handler with respect to activities carried out pursuant to § 970.66.

(b) Each signatory handler shall furnish all labor and equipment necessary.

§ 970.83 Compliance.

(a) A signatory handler may be subject to withdrawal of audit services or may lose the privilege of the use of the official certification mark if the signatory handler:

(1) Produces or acquires leafy green vegetables without an Inspection Service audit pursuant to §§ 970.66 and 970.67;

(2) Fails to obtain audit on the production, handling, or manufacturing of leafy green vegetables handled pursuant to § 970.66 and ships such leafy green vegetables for human consumption;

(3) Fails to successfully pass any audit conducted under this part, or fails to take appropriate verifiable corrective action to address non-conformities;

(4) Ships or places into the current of commerce leafy green vegetables for human consumption that fail to meet requirements under this part pursuant to §§ 970.66 and 970.67;

(5) Comingles leafy green vegetables that fail to meet the requirements of this part with leafy green vegetables and ships the comingled lot for human consumption;

(6) Fails to maintain and provide access to records pursuant to § 970.80; or

(7) Otherwise violates any of the provisions of this part.

(b) Any lot, or portion thereof, of leafy green vegetables that is deemed to be an immediate threat to public health by Inspection Service staff during the course of an audit shall be reported by USDA to appropriate health officials.

(c) Failure to comply with the provisions of this part may result in additional remedies or penalties.

Miscellaneous**§ 970.85 Effective time.**

The provisions of this part, as well as any amendments, shall continue in force and effect until modified, suspended, or terminated.

§ 970.86 Rights of the Secretary.

Members and alternates of the Board, committees, subcommittees, and any agents, employees, or representatives thereof, shall be subject to removal or suspension by the Secretary at any time. Each and every decision, determination, or other act of the Board shall be subject to the continuing right of the Secretary to disapprove of the same at any time. Upon such disapproval, the disapproved action of the Board shall be deemed null and void.

§ 970.87 Personal liability.

No member or alternate member of the Board or the committees, and no employee or agent of the Board or the committees, shall be held personally responsible, either individually or jointly with others, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member, alternate, employee, or agent, except for acts of dishonesty, willful misconduct, or gross negligence.

§ 970.88 Separability.

If any provision of this part is declared invalid or the applicability thereof to any person, circumstance, or thing is held invalid, the validity of the

remainder of this part or the applicability thereof to any other person, circumstance, or thing shall not be affected thereby.

§ 970.89 Derogation.

Nothing contained in this part is, or shall be construed to be, in derogation or in modification of the rights of the Secretary or of the United States to exercise any powers granted by the Act or otherwise, or, in accordance with such powers, to act in the premises whenever such action is deemed advisable.

§ 970.90 Duration of immunities.

The benefits, privileges, and immunities conferred upon any person by virtue of this part shall cease upon its termination, except with respect to acts done under and during the existence of this part.

§ 970.91 Agents.

The Secretary may, by designation in writing, name any officer or employee of the United States, or name any agency or program in the USDA, to act as the Secretary's agent or representative in connection with any of the provisions of this part.

§ 970.92 Suspension or termination.

- (a) The Secretary may at any time terminate the provisions of this part.
- (b) The Secretary shall terminate or suspend the operations of any or all of the provisions of this part whenever it is found that such provisions do not tend to effectuate the declared policy of the Act.
- (c) The provisions of this part shall, in any event, terminate whenever the provisions of the Act authorizing them cease.

§ 970.93 Proceedings upon termination.

Upon the termination of this part, the then functioning members of the Board shall continue as joint trustees, for the purpose of liquidating the affairs of the Board. Action by such trustees shall require the concurrence of a majority of said trustees. Such trustees shall continue in such capacity until

discharged by the Secretary, and shall account for all receipts and disbursements and deliver all property on hand, together with all books and records of the Board and the joint trustees, to such persons as the Secretary may direct; and shall upon the request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such person full title and right to all the funds, properties, and claims vested in the Board or the joint trustees, pursuant to this part. Any person to whom funds, property, or claims have been transferred or delivered by the Board or the joint trustees, pursuant to this section, shall be subject to the same obligations imposed upon the members of said Board and upon said joint trustees.

§ 970.94 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this part or any regulation issued pursuant thereto, or the issuance of any amendment to either thereof, shall not:

- (a) Affect or waive any right, duty, obligation, or liability which shall have arisen or which may thereafter arise, in connection with any provisions of this part or any regulation issued thereunder;
- (b) Release or extinguish any violation of this part or any regulation issued; or
- (c) Affect or impair any rights or remedies of the Secretary, or of any other persons, with respect to such violation.

§ 970.95 Amendments.

Amendments to this part may be proposed from time to time by the Board, or by any interested person affected by its provisions, including the Secretary.

§ 970.96 Counterparts.

This part may be executed in multiple counterparts and, when one counterpart is signed by the Secretary, all such counterparts shall constitute, when taken together, one and the same

instrument as if all signatures were contained in one original.

§ 970.97 Handler sign-up.

(a) After the effective date of this part, there shall be an initial sign-up period of a length to be determined by the Secretary for handlers to become signatories. Handlers who sign up during the initial sign-up period and their corresponding producers are eligible to serve as initial members of the Board pursuant to § 970.42.

(b) After the initial sign-up period ends, a handler may become a signatory at any time by executing a counterpart to this part and delivering it to the Secretary. This agreement shall take effect as to such new contracting party at the time such counterpart is delivered to the Secretary. The obligations, benefits, privileges, and immunities conferred by this agreement shall then be effective as to such new contracting party.

§ 970.98 Withdrawal.

Release from this agreement may be obtained under the following conditions:

- (a) A signatory may file with the Board a written request for withdrawal at any time, but such withdrawal will become effective at the beginning of the next crop year.
- (b) Immediate withdrawal may be effectuated when a signatory handler ceases to be a handler of leafy green vegetables and gives written notice thereof to the Board.
- (c) A signatory handler's withdrawal does not relieve the signatory handler of any obligation incurred while a signatory to this agreement.
- (d) A signatory handler that withdraws shall not use the official certification mark once no longer a signatory handler.

Dated: April 22, 2011.

Rayne Pegg,
Administrator, Agricultural Marketing Service.

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