# Arizona Leafy Green Marketing Committee Testimony of Casey Cullings National Leafy Greens Marketing Agreement Hearing Yuma, Arizona

My name is Casey Cullings. I am an Assistant Attorney General with the Arizona Attorney General's Office located at 1275 West Washington Street, Phoenix, Arizona 85007. I provide legal counsel to the Arizona Leafy Green Marketing Committee and am here today to testify on behalf of that Committee. The Arizona Leafy Green Marketing Committee administers the Arizona Leafy Green Products Shipper Marketing Agreement established around September 2007 and is located at 1688 West Adams, Phoenix, Arizona 85007. For convenience, I'll refer to the Arizona Leafy Green Marketing Committee as the Arizona Marketing Committee.

The Arizona Marketing Committee supports the establishment of a national leafy green marketing agreement and joined the proponent group on September 29, 2009. If a national leafy green marketing agreement is established, the Arizona Marketing Committee believes that it is in the best interest of leafy green vegetable handlers, the future national Marketing Committee and USDA to start with an agreement that is clear, concise and understandable and that accurately expresses the proponents' intent. For this reason, the purpose of my testimony is to address language in the proposed national agreement that the Arizona Marketing Committee recommends changes to. These proposed changes were previously submitted to Hank Giclas of Western Growers, who then circulated them to representatives of the proponent group. Mr. Giclas has informed me that the proponent group supports these proposed changes.

The written version of my testimony illustrates the recommended changes to the language by striking through text to be deleted and by capitalizing and underlining text to be added. It also contains a clean version of how those sections of the proposed agreement would read if the Arizona Marketing Committee's recommendations were adopted.

The Arizona Marketing Committee recommends substantive changes to the proposed national agreement as follows.

Section 970.9 offers a single definition for good agricultural practices or GAP and good handling practices or GHP. While GAP and GHP are similar, they are not identical. The proposed national agreement itself illustrates this since growers are subject to GAP audits and handlers are subject to GHP audits. Since GAP and GHP do not have identical definitions, the Arizona Marketing Committee recommends that they be defined separately in the agreement. The Arizona Marketing Committee also believes that the definitions of GAP and GHP should replicate USDA's common understanding of those terms and should not include a reference to the Association of Food and Drug Officials model codes. The Association of Food and Drug Officials model codes are a useful source for developing the actual audit metrics and should instead be referenced in section 970.67, which deals with establishing the audit metrics, rather than in the definition of GAP and GHP. The Arizona Marketing Committee proposes the following new definitions of GAP and GHP, while acknowledging that USDA is best suited to provide accurate definitions of these terms:



Good agricultural practices (GAP) refer to basic environmental and operational conditions necessary for the production of safe, wholesome fruits and vegetables as outlined in parts 1 (Farm Review), 2 (Field Harvest & Field Packing Activities) and 5 (Traceback) of the current U.S. Food and Drug Administration (FDA) "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidance document or any other revised or modified versions thereof, or any other FDA document approved as a replacement thereof and as approved by the Secretary.

Good handling practices (GHP) refer to general practices to reduce microbial food safety hazards as outlined in parts 3 (House Packing Facility), 4 (Storage and Transportation) and 5 (Traceback) of the current FDA "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidance document, or any other revised or modified versions thereof, or any other FDA document approved as a replacement thereof and as approved by the Secretary.

# § 970.9A Good agricultural and handling practices.

Good agricultural practices (GAP) REFER TO BASIC ENVIRONMENTAL AND OPERATIONAL CONDITIONS NECESSARY FOR THE PRODUCTION OF SAFE, WHOLESOME FRUITS AND VEGETABLES AS OUTLINED IN PARTS 1 (FARM REVIEW), 2 (FIELD HARVEST & FIELD PACKING ACTIVITIES), AND 5 (TRACEBACK) OF THE CURRENT U.S. FOOD AND DRUG ADMINISTRATION (FDA) "GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES" GUIDANCE DOCUMENT OR ANY OTHER REVISED OR MODIFIED VERSIONS THEREOF, OR ANY OTHER FDA DOCUMENT APPROVED AS A REPLACEMENT THEREOF AND AS APPROVED BY THE SECRETARY.

and good GOOD handling practices (GHP) refer to general practices to reduce microbial food safety hazards as outlined in PARTS 3 (HOUSE PACKING FACILITY), 4 (STORAGE AND TRANSPORTATION), AND 5 (TRACEBACK) OF the current U.S. Food and Drug Administration (FDA) "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidance document and the current Association of Food and Drug Officials (AFDO) model codes for food safety at the farm and packinghouse, or any other revised or modified versions thereof, or any other FDA document approved as a replacement thereof and as approved by the Secretary.

## § 970.9a Good agricultural practices.

Good agricultural practices (GAP) refer to basic environmental and operational conditions necessary for the production of safe, wholesome fruits and vegetables as outlined in parts 1 (Farm Review), 2 (Field Harvest & Field Packing Activities) and 5 (Traceback) of the current U.S. Food and Drug Administration (FDA) "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidance document or any other revised or modified versions thereof, or any other FDA document approved as a replacement thereof and as approved by the Secretary.

# § 970.9b Good handling practices.

Good handling practices (GHP) refer to general practices to reduce microbial food safety hazards as outlined in parts 3 (House Packing Facility), 4 (Storage and Transportation) and 5 (Traceback) of the current FDA "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" guidance document, or any other revised or modified versions thereof, or any other FDA document approved as a replacement thereof and as approved by the Secretary.

The Arizona Marketing Committee believes section 970.65, as written, is problematic and contrary to the desire of the proponents. It currently says no signatory shall handle leafy green vegetables unless verified by an official audit from the Inspection Service. Literally taken, this means a handler who signs up for the agreement must not handle, that is must cease operations, until it has been verified by an official audit, and the agreement provides no mechanism for a handler to be verified by an official audit before sign up. In fact, when the first handlers sign up, the national Committee will not have been formed yet and there will be no approved audit metrics yet, and thus no way to verify the signatories. Under the California and Arizona marketing agreements, after audit metrics were adopted, original signatories were subjected to informational audits and then subsequently subject to official audits. Signatories were permitted to handle during that entire period. The Arizona Marketing Committee believes the proponents' intention for the national agreement is similar, but the current language does not accomplish that. Additionally, the current language would also force a signatory that has committed a flagrant violation of the audit metrics, as that term is understood under the California and Arizona agreements, to cease handling, that is cease operations, until the signatory corrects the problem to the satisfaction of the national Committee and the Inspection Service. Again, the Arizona Marketing Committee does not believe that is the intent of the proponents. The proponents' intent is to subject a signatory in violation to a loss of certification, not a loss of the right to conduct business. Accordingly, the Arizona Marketing Committee recommends the following replacement language to bind signatories to the requirements of the agreement and leave to other sections and future rules established by the national Committee the issue of penalties for noncompliance: "Signatories shall comply with the requirements of this agreement, including any adopted rules and regulations."

# § 970.65 Signatory parties.

No signatory to this agreement shall handle leafy green vegetables for human consumption unless such are verified as meeting the provisions of this part. This verification shall take the form of an official audit conducted by the inspection service. SIGNATORIES SHALL COMPLY WITH THE REQUIREMENTS OF THIS AGREEMENT, INCLUDING ANY ADOPTED RULES AND REGULATIONS.

#### § 970.65 Signatory parties.

Signatories shall comply with the requirements of this agreement, including any adopted rules and regulations.

The Arizona Marketing Committee recommends additions to section 970.67 to clarify that the audit metrics do not simply equal GAP, GHP and GMP, but instead consist of a combination of GAP, GHP, GMP, the AFDO model code, and other resources as selected by the Committee. In other words, as the proponents have stated during the hearing, GAP, GHP and GMP will serve as

a template from which the audit metrics will be established. The Arizona Marketing Committee also recommends the omission of some unnecessary language from this section.

It is recommended that the opening sentence read, "The Committee shall adopt, with the approval of the Secretary after notice and comment, audit metrics after consultation with the Technical Review Board" to match section 970.49(c). At the beginning of paragraph (a), the following sentence should be inserted: "GAP audit metrics shall be based on GAP, the Association of Food and Drug Officials (AFDO) current 'Model Code of Practice for Fresh Produce at the Farm and Packing House,' commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources." Also, the phrase "of process controls" should be inserted after "GAP audit metrics shall include verification." The citation to section 970.9 should be changed to say the word "GAP." It is also recommended to delete three instances of the word "and" and to replace the commas with semicolons for better clarity and readability.

It is also recommended to insert two new paragraphs between paragraphs (a) and (b), which read:

GHP audit metrics. GHP audit metrics shall be based on GHP, the Association of Food and Drug Officials (AFDO) current "Model Code of Practice for Fresh Produce at the Farm and Packing House," commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources.

GMP audit metrics. GMP audit metrics shall be based on GMP, commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources.

Current paragraph (b) would then be relabeled as paragraph (d) and begin as follows: "GHP and GMP audit metrics shall include verification of process controls related but not limited to ...." In subparagraph (iv), the citations to sections 970.9 and 970.10 should be replaced with the words "GHP and GMP."

The Arizona Marketing Committee recommends relabeling the remaining paragraphs and shortening them as follows:

- (e) Critical limits for process controls for each of the quality factors identified in the audit metrics shall be prescribed by USDA in consultation with FDA. Critical limits shall be based on sound scientific practices and shall incorporate the Committee's recommendations with regard to industry production, harvest and handling technologies.
- (f) The audit metrics may accommodate differences in production and handling environments of different regions and different leafy green vegetable products.
- (g) The Committee may revise the audit metrics at any time, with the approval of the Secretary after notice and comment, after consultation with the Technical Review Board.

(h) The Committee shall review the audit metrics a minimum of once every three years to ensure that they continually reflect the best industry practices, scientific information and industry knowledge.

## § 970.67 Audit metrics.

Audit metrics shall be recommended by the Committee to USDA for approval THE COMMITTEE SHALL ADOPT, WITH THE APPROVAL OF THE SECRETARY AFTER NOTICE AND COMMENT, AUDIT METRICS after consultation with the Technical Review Board.

- (a) GAP audit metrics. GAP AUDIT METRICS SHALL BE BASED ON GAP, THE ASSOCIATION OF FOOD AND DRUG OFFICIALS (AFDO) CURRENT "MODEL CODE OF PRACTICE FOR FRESH PRODUCE AT THE FARM AND PACKING HOUSE," COMMODITY SPECIFIC GUIDELINES DEVELOPED BY USDA IN CONJUNCTION WITH FDA, AND SPECIFIC RECOMMENDATIONS FROM SCIENTIFIC AND ACADEMIC SOURCES. GAP audit metrics shall 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, and encroachment by animals of significant risk and urban settings; or any other factors defined under §970.9, GAP or as recommended by the Committee and approved by the Secretary.
- (b) GHP AUDIT METRICS. GHP AUDIT METRICS SHALL BE BASED ON GHP, THE ASSOCIATION OF FOOD AND DRUG OFFICIALS (AFDO) CURRENT "MODEL CODE OF PRACTICE FOR FRESH PRODUCE AT THE FARM AND PACKING HOUSE," COMMODITY SPECIFIC GUIDELINES DEVELOPED BY USDA IN CONJUNCTION WITH FDA, AND SPECIFIC RECOMMENDATIONS FROM SCIENTIFIC AND ACADEMIC SOURCES.
- (C) GMP AUDIT METRICS. GMP AUDIT METRICS SHALL BE BASED ON GMP, COMMODITY SPECIFIC GUIDELINES DEVELOPED BY USDA IN CONJUNCTION WITH FDA, AND SPECIFIC RECOMMENDATIONS FROM SCIENTIFIC AND ACADEMIC SOURCES.
- (D) GHP or GMP audit metrics. Such GHP AND GMP audit metrics shall include verification of process controls related but not limited to:
- i. *Post-harvest handling process*: cooling, water, reuse of field containers, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, and employee hygiene-;
- ii. Handling and manufacturing process: wash water, wash system capacity, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, and employee hygiene, labeling of Raw Agricultural Commodity (RAC) versus ready—to-eat (RTE) products, and finished product packaging—;
- iii. *Distribution handling process*: condition and sanitation of transportation vehicles, condition and sanitation of distribution/cooler facilities, and temperature measurement of product-; AND
- iv. Any other factors defined under § 970.9 and § 970.10, GHP OR GMP or as recommended by the Committee and approved by the Secretary.

- (e) (E) Critical limits for process controls for each of the quality factors identified in the audit metrics shall be prescribed by USDA in consultation with FDA. and any other federal or state regulatory body administering regulations impacted by the provisions of this agreement; CRITICAL LIMITS SHALL BE BASED ON SOUND SCIENTIFIC PRACTICES AND shall incorporate THE Committee COMMITTEE'S recommendations with regard to industry production, harvest and handling technologies; shall be based on sound scientific practices; and shall be approved by the Secretary.
- (d) (F) THE Audit AUDIT metrics may be developed and recommended to accommodate differences in production and handling environments of different regions and different leafy green vegetable products.
- (e) (G) The committee COMMITTEE may, at any time, recommend changes to REVISE the audit metrics AT ANY TIME, WITH THE APPROVAL OF THE SECRETARY AFTER NOTICE AND COMMENT, after consultation with the Technical Review Board for approval by the Secretary.
- (e) (H) The Committee shall recommend, to the Secretary, for approval, a schedule for review of THE audit metrics such that audit metrics are reviewed a minimum of once every three years to ensure that they continually reflect the best industry practices, scientific information and industry knowledge.

# § 970.67 Audit metrics.

The Committee shall adopt, with the approval of the Secretary after notice and comment, audit metrics after consultation with the Technical Review Board.

- (a) *GAP audit metrics*. GAP audit metrics shall be based on GAP, the Association of Food and Drug Officials (AFDO) current "Model Code of Practice for Fresh Produce at the Farm and Packing House," commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources. GAP audit metrics shall 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; production location concerns, including climatic conditions, environment, encroachment by animals of significant risk and urban settings; or any other factors defined under GAP or as recommended by the Committee and approved by the Secretary.
- (b) *GHP audit metrics*. GHP audit metrics shall be based on GHP, the Association of Food and Drug Officials (AFDO) current "Model Code of Practice for Fresh Produce at the Farm and Packing House," commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources.
- (c) GMP audit metrics. GMP audit metrics shall be based on GMP, commodity specific guidelines developed by USDA in conjunction with FDA, and specific recommendations from scientific and academic sources.
- (d) GHP and GMP audit metrics shall include verification of process controls related but not limited to:
- i. *Post-harvest handling process*: cooling, water, reuse of field containers, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, and employee hygiene;

- ii. Handling and manufacturing process: wash water, wash system capacity, bulk-bin modified atmosphere process, condition and sanitation of transportation vehicles, and employee hygiene, labeling of Raw Agricultural Commodity (RAC) versus ready—to-eat (RTE) products, and finished product packaging;
- iii. *Distribution handling process*: condition and sanitation of transportation vehicles, condition and sanitation of distribution/cooler facilities, and temperature measurement of product; and
- iv. Any other factors defined under GHP or GMP or as recommended by the Committee and approved by the Secretary.
- (e) Critical limits for process controls for each of the quality factors identified in the audit metrics shall be prescribed by USDA in consultation with FDA. Critical limits shall be based on sound scientific practices and shall incorporate the Committee's recommendations with regard to industry production, harvest and handling technologies.
- (f) The audit metrics may accommodate differences in production and handling environments of different regions and different leafy green vegetable products.
- (g) The Committee may revise the audit metrics at any time, with the approval of the Secretary after notice and comment, after consultation with the Technical Review Board.
- (h) The Committee shall review the audit metrics a minimum of once every three years to ensure that they continually reflect the best industry practices, scientific information and industry knowledge.

In section 970.69 paragraph (a), the word "will" should be changed to "shall" in two instances, the word "who" should be changed to "that" and the phrase "shall use the mark" should be omitted.

The Arizona Marketing Committee recommends simplifying paragraph (b) to: "The Committee may license signatories to affix the official certification mark to bills of lading or manifests or to use the mark in other ways recommended by the Committee and approved by the Secretary to carry out the purposes of this agreement." It also recommends adding a paragraph (c) reading: "A signatory's compliance with this agreement is a condition precedent and subsequent to the signatory's entitlement to use the mark. A signatory shall not use the mark until it has demonstrated compliance with the audit metrics through a verification audit. The Committee may suspend or revoke a signatory's license to use the mark for non-compliance with the agreement, including adopted rules and regulations."

Notably, these recommended changes clarify that a new signatory cannot use the mark until it has had its first verification audit. This relates to the proposed change to section 970.65 regarding signatories.

#### § 970.69 Official certification mark.

(a) USDA will-SHALL obtain and grant to the Committee the use of a U.S. registered certification mark that will be the agreement's official mark (mark). This mark will-SHALL be licensed to signatories who THAT comply with the terms of this agreement. Signatories shall use the mark in accordance with this section and shall use the mark consistent with the mark registration.

(b) The Committee may license signatories to affix the official certification mark to bills of lading or manifests, subject to the verification, suspension, revocation requirements, or any other such uses OR TO USE THE MARK IN OTHER WAYS recommended by the Committee and approved by the Secretary to carry out the purposes of this Agreement AGREEMENT. (C) A signatory's compliance with the regulations under this Agreement AGREEMENT is a condition precedent and subsequent to the signatory's entitlement to use the mark. A SIGNATORY SHALL NOT USE THE MARK UNTIL IT HAS DEMONSTRATED COMPLIANCE WITH THE AUDIT METRICS THROUGH A VERIFICATION AUDIT. THE COMMITTEE MAY SUSPEND OR REVOKE A SIGNATORY'S LICENSE TO USE THE MARK FOR NON-COMPLIANCE WITH THE AGREEMENT, INCLUDING ADOPTED RULES AND REGULATIONS.

#### § 970.69 Official certification mark.

- (a) USDA shall obtain and grant to the Committee the use of a U.S. registered certification mark that will be the agreement's official mark (mark). This mark shall be licensed to signatories that comply with the terms of this agreement. Signatories shall use the mark in accordance with this section and consistent with the mark registration.
- (b) The Committee may license signatories to affix the official certification mark to bills of lading or manifests or to use the mark in other ways recommended by the Committee and approved by the Secretary to carry out the purposes of this agreement.
- (c) A signatory's compliance with this agreement is a condition precedent and subsequent to the signatory's entitlement to use the mark. A signatory shall not use the mark until it has demonstrated compliance with the audit metrics through a verification audit. The Committee may suspend or revoke a signatory's license to use the mark for non-compliance with the agreement, including adopted rules and regulations.

The Arizona Marketing Committee recommends renumbering section 970.83 Compliance to section 970.73 so that it falls under the heading "Duties and Responsibilities of Signatories" rather than "Reports and Records." It also recommends omitting current paragraphs (a)(1)-(6) because they are mostly redundant of each other and are already covered by sections 970.65, 970.66 & 970.80. The opening sentence of the section should also be substantially revised to make it more clear and be labeled as the new paragraph (a) as follows: "The Committee and its authorized representatives shall oversee signatories' compliance with this agreement. In conjunction with USDA, the Committee shall establish rules setting out penalties and required remedial action for signatories that are out of compliance with the requirements of this agreement. Penalties may include withdrawal of audit services and the privilege to use the official certification mark."

Paragraph (b) should have a period at the end. Finally, the Arizona Marketing Committee recommends adding a new paragraph (d) to make it clear that a signatory can appeal decertification decisions or other penalties. It recommends the paragraph to read: "A signatory may appeal a penalty assessed pursuant to subsection (a) according to rules and procedures established by the Committee."

§ 970.83 970.73 Compliance.

Compliance with the provisions of this agreement will be overseen by the Committee and any staff hired or appointed to undertake this responsibility. (A) THE COMMITTEE AND ITS AUTHORIZED REPRESENTATIVES SHALL OVERSEE SIGNATORIES' COMPLIANCE WITH THIS AGREEMENT. In conjunction with USDA, the Committee shall establish a policy for signatory handlers for non-conformities identified through verification audits: RULES SETTING OUT PENALTIES AND REQUIRED REMEDIAL ACTION FOR SIGNATORIES OUT OF COMPLIANCE WITH THE REQUIREMENTS OF THIS AGREEMENT. PENALTIES MAY INCLUDE WITHDRAWAL OF AUDIT SERVICES AND THE PRIVILEGE TO USE THE OFFICIAL CERTIFICATION MARK.

- (a) A signatory shall be subject to withdrawal of audit services, shall lose the privilege of the use of the official certification mark, and may be subject to misbranding or trademark violations, if the signatory:
- (1) Produces or acquires leafy green vegetables or products without an inspection service verification audit, pursuant to § 970.9 and § 970.10.
- (2) Fails to obtain audit verification on the production, handling or manufacturing of leafy green vegetable or products, pursuant to § 970.66, and ships such vegetables or products for human consumption;
- (3) Ships or places into the current of commerce leafy green vegetables or products that fail to meet requirements under this agreement, pursuant to § 970.66 and § 970.67, for human consumption;
- (4) Commingles leafy green vegetables that fail to meet the requirements of this agreement with leafy green vegetables verified to meet the requirements of the agreement and ships the commingled lot for human consumption;
  - (5) Fails to maintain and provide access to records, pursuant to § 970.80; or
  - (6) Otherwise violates any provision of this part.
- (b) Any lot or portion thereof leafy green vegetables which is deemed an immediate threat to public health by Inspection Service staff during the course of a verification audit shall be reported by USDA to FDA.
- (c) Failure to comply with the provisions of this agreement may also result in additional remedies or penalties, such as injunctive relief, as authorized under the Act.
- (D) A SIGNATORY MAY APPEAL A PENALTY ASSESSED PURSUANT TO SUBSECTION (A) ACCORDING TO RULES AND PROCEDURES ESTABLISHED BY THE COMMITTEE.

## § 970.73 Compliance.

- (a) The Committee and its authorized representatives shall oversee signatories' compliance with this agreement. In conjunction with USDA, the Committee shall establish rules setting out penalties and required remedial action for signatories out of compliance with the requirements of this agreement. Penalties may include withdrawal of audit services and the privilege to use the official certification mark.
- (b) Any lot or portion thereof leafy green vegetables which is deemed an immediate threat to public health by Inspection Service staff during the course of a verification audit shall be reported by USDA to FDA
- (c) Failure to comply with the provisions of this agreement may also result in additional remedies or penalties, such as injunctive relief, as authorized under the Act.

(d) A signatory may appeal a penalty assessed pursuant to subsection (a) according to rules and procedures established by the Committee.

The Arizona Marketing Committee is concerned with the requirements for withdrawal under section 970.98. Currently, the proposed agreement says a signatory that is still a handler can only withdraw if it is not in violation of the agreement. This means that if a signatory has not paid its assessments, it must continue as a signatory and accrue additional assessments for at least another year. It also means if a signatory is not in compliance with the audit metrics, it must also remain a signatory even if it doesn't want to. On the unpaid assessment issue, the agreement should provide that unpaid assessments are still required to be paid even if a handler ceases to be a signatory, but it is not necessary to force that handler to continue as a signatory. On noncompliance with audit metrics, whether the out of compliance handler continues as a signatory or not, it cannot use the certification mark, so there is questionable justification for forcing that handler to remain a signatory.

The Arizona Marketing Committee agrees that an orderly withdrawal from agreement by signatories is necessary for planning and budgeting purposes, and accordingly recommends strengthening this section by requiring notice of withdrawal at least 30 days prior to the start of a new fiscal year so that the national Committee can account for those withdrawals in budgeting for the subsequent year.

The Arizona Marketing Committee recommends the following replacement language for this section:

- (a) A signatory may withdraw from this agreement by either:
- (i) Filing a written request for withdrawal for the subsequent crop year with the Committee at least 30 days prior to the start of the subsequent crop year or
- (ii) Filing a written notice with the Committee stating that the signatory ceases to be a handler of leafy green vegetables or products.
- (b) A signatory's withdrawal does not relieve the signatory of the obligation to pay assessments or charges due.
- (c) A signatory that withdraws shall not use the official certification mark.

## § 970.98 Withdrawal.

Release from this agreement may be obtained, provided that a signatory handler is not in violation of the provisions of this agreement and has fulfilled all of his or her obligations, including payment of any assessments or charges levied pursuant to this agreement, under any of the following conditions:

- (a) A SIGNATORY MAY WITHDRAW FROM THIS AGREEMENT BY EITHER:
- (I) FILING A signatory handler may file with the Committee a written request for withdrawal at the close of a crop year, effective for the succeeding crop year. FOR THE SUBSEQUENT CROP YEAR WITH THE COMMITTEE AT LEAST 30 DAYS PRIOR TO THE START OF THE SUBSEQUENT CROP YEAR OR
- (II) FILING A WRITTEN NOTICE WITH THE COMMITTEE STATING THAT THE SIGNATORY (b) Immediate withdrawal may be effectuated when a signatory handler ceases to

be a handler of leafy green vegetables or products and gives notice thereof to the Committee in writing.

- (B) A SIGNATORY'S WITHDRAWAL DOES NOT RELIEVE THE SIGNATORY OF THE OBLIGATION TO PAY ASSESSMENTS OR CHARGES DUE.
- (C) A SIGNATORY THAT WITHDRAWS SHALL NOT USE THE OFFICIAL CERTIFICATION MARK.

# § 970.98 Withdrawal.

- (a) A signatory may withdraw from this agreement by either:
- (i) Filing a written request for withdrawal for the subsequent crop year with the Committee at least 30 days prior to the start of the subsequent crop year or
- (ii) Filing a written notice with the Committee stating that the signatory ceases to be a handler of leafy green vegetables or products.
- (b) A signatory's withdrawal does not relieve the signatory of the obligation to pay assessments or charges due.
- (c) A signatory that withdraws shall not use the official certification mark.

I will now describe small grammatical and other very minor changes that the Arizona Marketing Committee recommends.

In section 970.2, where it says "throughout the growing, harvesting, packing, operation and transportation," the Committee recommends "throughout the growing, harvesting, packing and transportation operations." The Committee also recommends removing the citations to sections 970.9, 970.10, and 970.14 as unnecessary. Additionally, the Committee believes the reference to sections 970.9 and 970.10 are inaccurate since those sections define GAP, GHP and GMP, and while GAP, GHP, and GMP are intended to form the template for the audit metrics, they are not necessarily identical to the audit metrics, and the audit verification described in section 970.2 is intended to verify compliance with the actual audit metrics.

#### § 970.2 Audit verification.

Audit verification means the physical visit to the farm and/or facility when it is in operation by an Inspection Service audit team to verify and document that good agricultural, handling, and manufacturing practices are adhered to throughout the growing, harvesting, packing, operation and transportation OPERATIONS as defined in § 970.9, and § 970.10. This verification shall take the form of an official audit conducted by the Inspection Service, § 970.14. An audit verification is a snapshot in time based on documentation reviewed, persons interviewed and operations observed, and is intended to represent the past and ongoing activities of the auditee.

#### § 970.2 Audit verification.

Audit verification means the physical visit to the farm and/or facility when it is in operation by an Inspection Service audit team to verify and document that good agricultural, handling, and manufacturing practices are adhered to throughout the growing, harvesting, packing, and transportation operations. This verification shall take the form of an official audit conducted by the Inspection Service. An audit verification is a snapshot in time based on

documentation reviewed, persons interviewed and operations observed, and is intended to represent the past and ongoing activities of the auditee.

Section 970.19 defines "person" as including an individual or entity. Therefore, the Arizona Marketing Committee recommends using the word "person" in sections 970.3 and 970.6. So section 970.3 should begin "Broker means a person who coordinates" and section 970.6 should begin "Foodservice distributor means a person who provides." Also, in section 970.3, the phrase "leafy green vegetable retail" should be "leafy green vegetables for retail."

#### § 970.3 Broker.

Broker means an individual or entity that A PERSON WHO coordinates the sale and transport of fresh leafy green vegetable VEGETABLES FOR retail or foodservice buyers without taking ownership of the product.

## § 970.6 Foodservice distributor.

Foodservice distributor means an individual or entity that A PERSON WHO provides leafy green vegetables to restaurants, cafeterias, industrial caterers, hospitals and nursing homes.

## § 970.3 Broker.

*Broker* means a person who coordinates the sale and transport of fresh leafy green vegetables for retail or foodservice buyers without taking ownership of the product.

## § 970.6 Foodservice distributor.

Foodservice distributor means a person who provides leafy green vegetables to restaurants, cafeterias, industrial caterers, hospitals and nursing homes.

In section 970.10, for more clarity and precision, it should begin, "Good manufacturing practices (GMP) means FDA regulations located at 21 CFR § 110, which describe ...."

## § 970.10 Good manufacturing practices.

Good manufacturing practices (GMP) means any FDA regulations LOCATED AT (21 CFR § 110) that, WHICH describe the methods, equipment, facilities, and controls required for producing processed food, including fresh-leafy green vegetable products, or any other FDA regulation approved as a replacement or supplement thereof as approved by the Secretary.

## § 970.10 Good manufacturing practices.

Good manufacturing practices (GMP) means FDA regulations located at 21 CFR § 110, which describe the methods, equipment, facilities, and controls required for producing processed food, including fresh-leafy green vegetable products, or any other FDA regulation approved as a replacement or supplement thereof as approved by the Secretary.

In section 970.21, the phrase "process does not apply to retailer" should be "process does not apply to a retailer."

#### § 970.21 Process.

*Process* is synonymous with manufacture and means to change fresh leafy green vegetables from their natural form into fresh-cut, packaged products: *Provided*, that process does not apply to  $\underline{A}$  retailer or foodservice distributor except to the extent that such a person is otherwise engaged in processing for non-retail purposes.

## § 970.21 Process.

*Process* is synonymous with manufacture and means to change fresh leafy green vegetables from their natural form into fresh-cut, packaged products: *Provided*, that process does not apply to a retailer or foodservice distributor except to the extent that such a person is otherwise engaged in processing for non-retail purposes.

In section 970.45, it says there will be a 13 member board, but then enumerates 14 members. So the number 13 should be replaced with the number 14.

#### § 970.45 Technical Review Board.

A Technical Review Board is hereby established for the purpose of assisting the Committee in developing audit metrics in § 970.67 and any other function that the Committee may recommend and the Secretary approve. The Technical Review Board shall consist of 13 14 members as follows: 1 representative from each zone who is elected by the Committee producer and handler members from the corresponding zone; 1 produce food safety expert from a land grant university within each zone elected by the producer and handler members from the corresponding zone; 1 representative from USDA Natural Resources Conservation Service (NRCS) appointed by the Secretary; 1 representative of the US Environmental Protection Agency (EPA) designated by the Administrator, and 2 representatives from FDA designated by the Commissioner. The Technical Review Board may appoint subcommittees as necessary to facilitate input and review from regions throughout the production area. Subcommittees may consist of producers, handlers, and other interested parties as deemed appropriate by the Technical Review Board.

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In section 970.48 paragraph (a), the use of the word "full" in the first sentence, as in "full Committee", is confusing and should be omitted. If the full Committee were present, then there would automatically be several members present from each zone. The apparent intent is to make sure that if, for example, only 12 of the 23 members of the Committee attend a meeting, that a quorum cannot be established unless among the 12 there is at least one member from each zone. Again, dropping the word "full" in this instance makes the sentence clearer.

In the second sentence of paragraph (a), however, the Arizona Marketing Committee recommends inserting the word "full" before "Committee." It is the proponents' intent that two-thirds of the entire 23 member Committee approve certain actions as opposed to two-thirds of a quorum, and adding the word "full" makes that intent clear. It is also recommended to switch the conjunction "and" to "or" as well as to add a semicolon after "assessment rates."

In paragraph (d), it is presently unclear how a Committee member participating in a meeting by telephone must vote if all the other members are present at the meeting in person. The Arizona Marketing Committee recommends altering the language so that it says "Provided, that if an assembled meeting is held, all members present shall cast votes in person." This would clarify that a member participating by phone would always promptly confirm his vote in writing regardless of whether the other members were present in person or also participating by phone.

#### § 970.48 Procedure.

- (a) A majority of all the members of the Committee shall constitute a quorum: *Provided*, that each zone shall be represented by at least one member or his or her alternate at any meeting of the full-Committee. Committee action shall require the concurrence of a majority of the members except that acceptance of Good Agricultural, Handling and Manufacturing Practices; assessment rates; <u>OR</u> and termination of the agreement must be approved by a 2/3 majority of the <u>FULL</u> Committee.
- (b) In the event that a member of the Committee and alternate are unable to attend the meeting, the member or the Committee may designate any other alternate from the same zone or group (handler, producer) who is present at the meeting to serve in the member's place.
- (c)The Committee shall give to the Secretary the same notice of each meeting that is given to the members of the Committee.
- (d) The Committee 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 <u>MEMBERS PRESENT</u> votes shall be cast <u>VOTES</u> in person. A videoconference shall be considered an assembled meeting and all votes shall be considered as cast in person.

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In section 970.49 paragraph (c), it is recommended to end the sentence after "audit metrics," which would drop the cross-references. The Arizona Marketing Committee does not believe it makes sense to say the national Committee shall adopt audit metrics to administer GAP, GHP or GMP, which are sections 970.9 and 970.10, nor does it make sense to say the Committee shall adopt audit metrics to administer the audit metrics, which is section 970.67. While the reference to section 970.66 is correct, it is unnecessary to state.

# § 970.49 Powers.

The Committee shall have the following powers:

- (a) To administer the agreement 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 the agreement;
- (c) To adopt, with the approval of the Secretary after notice and comment, audit metrics to administer the terms and provisions in §§ 970.9, 970.10, 970.66, and 970.67;
- (d) To collaborate with existing state boards, commissions and agreements through memorandum of understanding to affect the purposes of the agreement;
- (e) To receive, investigate, and report to the Secretary complaints of violation of the provisions of the agreement; and,
  - (f) To recommend to the Secretary amendments to the agreement.

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  - (c) To adopt, with the approval of the Secretary after notice and comment, audit metrics;
- (d) To collaborate with existing state boards, commissions and agreements through memorandum of understanding to affect the purposes of the agreement;
- (e) To receive, investigate, and report to the Secretary complaints of violation of the provisions of the agreement; and,
  - (f) To recommend to the Secretary amendments to the agreement.

In section 970.50, the Arizona Marketing Committee recommends adding a paragraph (j) reading "to submit a budget to the Secretary for each fiscal year" to make clear that the national Committee has a responsibility to adopt a budget.

## § 970.50 Duties.

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

- (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-; and,
  - (J) TO SUBMIT A BUDGET TO THE SECRETARY FOR EACH FISCAL YEAR.

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- (h) To investigate the production, handling and marketing of leafy green vegetables and to assemble data in connection therewith;
- (i) To furnish such available information as may be deemed pertinent or as requested by the Secretary; and,
  - (j) To submit a budget to the Secretary for each fiscal year.

In section 970.55, the phrase "the Committee is authorized to incur such expenses ... likely to be incurred by it" is not helpful. A better choice of words would be ""the Committee is authorized to incur such expenses as ... are necessary and proper."

# § 970.55 Expenses.

The Committee is authorized to incur such expenses as the Secretary finds are reasonable, NECESSARY AND PROPER and likely to be incurred by it during each crop year for the maintenance and functioning of the Committee, including the payment of audit and inspection fees, 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 Committee.

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In section 970.57 paragraph (a), "fiscal periods" should be replaced with "fiscal year's" since fiscal year is defined in the agreement and fiscal period is not. In paragraph (b), the word "refunds" should be just "funds."

#### § 970.57 Accounting.

(a) If, at the end of a crop year, the assessments collected are in excess of expenses incurred, the Committee, with the approval of the Secretary, may carry over such excess into subsequent crop years as an operating monetary reserve, except that funds already in such reserve shall not exceed approximately two (2) fiscal periods' YEAR'S budgeted expenses, or

such lower limits as the Committee, with the approval of the Secretary, may establish. Funds in such reserve shall be available for use by the Committee for expenses authorized pursuant to § 970.55 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 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.

(b) Upon termination of this part, any refunds <u>FUNDS</u> not required to defray the necessary expenses of liquidation shall be used, to the extent practicable, to fulfill any obligations under § 970.75, Research and promotion.

# § 970.57 Accounting.

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- (b) Upon termination of this part, any funds not required to defray the necessary expenses of liquidation shall be used, to the extent practicable, to fulfill any obligations under § 970.75, Research and promotion.

In section 970.58, the word "Committee" should be capitalized the two times it appears.

# 970.58 Contributions.

The <u>committee COMMITTEE</u> may accept voluntary contributions but these shall only be used to pay expenses incurred pursuant to § 970.75, Research and promotion. Furthermore, such contributions shall be free from any encumbrances by the donor and the <u>committee COMMITTEE</u> shall retain complete control of their use.

#### 970.58 Contributions.

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Section 970.66 is wordy, redundant, and a little confusing. The Arizona Marketing Committee recommends the following replacement language to make the section more clear, concise, and understandable:

(a) *GAP audits*. Signatories shall ensure that any leafy green vegetables handled by their operation were grown by producers, foreign or domestic, that have been subject to GAP verification audits. Such audits shall verify

that the producers' leafy green vegetables are produced under auditable conditions that meet the GAP audit metrics.

- (b) GHP and GMP audits.
- (1) Signatories shall be subject to GHP and GMP verification audits, as applicable. Such audits shall verify that the signatories operate under auditable conditions that meet the GHP and GMP audit metrics.
- (2) Signatories shall not handle leafy green vegetables from handlers, foreign or domestic, that have not been subject to GHP and GMP verification audits, as applicable.
- (c) The Inspection Service, or an authorized designee, shall conduct all GAP and GHP audits under this agreement and shall certify handlers and producers as meeting the GAP and GHP audit metrics. The Inspection Service, the FDA, or an authorized designee shall conduct all GMP audits under this agreement and shall certify handlers as meeting the GMP audit metrics.
- (d) Audits shall be conducted on a regular schedule that ensures every handler is audited during their corresponding production season. In addition, random unannounced audits of handlers and associated producers shall be performed during the production season in each zone.

This proposed language also clarifies that audits are based on the audit metrics adopted by the national Committee and not simply on GAP, GHP or GMP.

# § 970.66 Verification audits.

- (a) GAP audits.
- (1) Signatory handlers SIGNATORIES shall ensure that any leafy green vegetables handled by their operation ARE GROWN BY PRODUCERS, FOREIGN OR DOMESTIC, THAT have been subject to GAP validation and verification audits. Such audits shall verify that such product was THE PRODUCERS' LEAFY GREEN VEGETABLES ARE produced under auditable conditions that meet production and harvest requirements as outlined in the GAPs (§ 970.9) and as further defined in any applicable audit metrics provided for under § 970.67 THE GAP AUDIT METRICS.
- (2) No signatory handlers subject to the provisions of this agreement shall receive leafy green vegetables produced in foreign countries that have not been subject to GAP validation and verification audits by USDA licensed inspectors. Such audits shall verify that such product was produced under auditable conditions that meet production and harvest requirements as outlined in the GAPs (§ 970.9) and as further defined in any applicable audit metrics provided for under § 970.67.
  - (b) GHP or GMP audits.
- (1) All signatory handlers <u>SIGNATORIES</u> shall be subject to <u>audit verificationsGHP</u> <u>AND GMP VERIFICATION AUDITS</u>, <u>AS APPLICABLE</u>. Such audits shall verify that <u>such THE</u> signatories operate under auditable conditions that meet <del>requirements outlined in the GHPs or GMPs</del>, (§ 970.9 and § 970.10) and as further defined in any applicable audit metrics provided for under § 970.67THE GHP AND GMP AUDIT METRICS.
- (2) No signatory handlers subject to the provisions of this agreement shall receive SIGNATORIES SHALL NOT HANDLE leafy green vegetables from handlers, in foreign OR

<u>DOMESTIC</u>, eountries that have not been subject to GHP, <u>AND</u> GMP validation and verification audits, <u>AS APPLICABLE</u> by Inspection Service or the FDA. Such audits shall verify that such product was produced under auditable conditions that meet production and harvest requirements as outlined in the GAPs (§ 970.9) and as further defined in any applicable audit metrics provided for under § 970.67.

- (c) All audits shall be conducted by the Inspection Service, and certified as to meeting the regulations of this part. THE INSPECTION SERVICE, OR AN AUTHORIZED DESIGNEE, SHALL CONDUCT ALL GAP AND GHP AUDITS UNDER THIS AGREEMENT AND SHALL CERTIFY HANDLERS AND PRODUCERS AS MEETING THE GAP AND GHP AUDIT METRICS. THE INSPECTION SERVICE, THE FDA, OR AN AUTHORIZED DESIGNEE SHALL CONDUCT ALL GMP AUDITS UNDER THIS AGREEMENT AND SHALL CERTIFY HANDLERS AS MEETING THE GMP AUDIT METRICS.
- (d) Audits shall be conducted on a regular schedule that ensures every handler is audited during their corresponding production season. In addition, random unannounced audits of handlers and associated producers will also SHALL be performed during the production season in each zone.

## § 970.66 Verification audits.

- (a) *GAP audits*. Signatories shall ensure that any leafy green vegetables handled by their operation are grown by producers, foreign or domestic, that have been subject to GAP verification audits. Such audits shall verify that the producers' leafy green vegetables are produced under auditable conditions that meet the GAP audit metrics.
  - (b) GHP and GMP audits.
- (1) Signatories shall be subject to GHP and GMP verification audits, as applicable. Such audits shall verify that the signatories operate under auditable conditions that meet the GHP and GMP audit metrics.
- (2) Signatories shall not handle leafy green vegetables from handlers, foreign or domestic, that have not been subject to GHP and GMP verification audits, as applicable.
- (c) The Inspection Service, or an authorized designee, shall conduct all GAP and GHP audits under this agreement and shall certify handlers and producers as meeting the GAP and GHP audit metrics. The Inspection Service, the FDA, or an authorized designee shall conduct all GMP audits under this agreement and shall certify handlers as meeting the GMP audit metrics.
- (d) Audits shall be conducted on a regular schedule that ensures every handler is audited during their corresponding production season. In addition, random unannounced audits of handlers and associated producers shall be performed during the production season in each zone.

In section 970.70, the Arizona Marketing Committee recommends two changes. First, the title should be changed to Administrative Review of Audits since this section strictly applies to what could be called administrative appeals of findings by the Inspection Service during an audit and does not encompass any administrative appeal of findings by the national Committee or the Secretary. Second, the section should be rewritten for clarity and conciseness and to use more proper regulatory language as follows: "A signatory or any financially interested person may request an administrative review of a verification audit if it believes a material error was made by the Inspection Service. Administrative reviews shall be conducted in accordance with USDA audit verification procedures. The person requesting the review shall pay the cost of the review. The review results shall be issued to the person making the request."

## § 970.70 Administrative review OF AUDITS.

Any A signatory OR ANY FINANCIALLY INTERESTED PERSON denied the use of the official certification mark may request an administrative review if it is believed that a material fact of the original OF A verification audit was misinterpreted IF IT BELIEVES A MATERIAL ERROR WAS MADE BY THE INSPECTION SERVICE. Administrative reviews would SHALL be conducted in accordance with the USDA audit verification procedures for any audit program in effect under this agreement. Any financially interested person may request an administrative review if it is believed that the original audit verification is in error. The person requesting the review would SHALL pay the cost of the review. The review results shall be issued to the person making the request.

## § 970.70 Administrative review of audits.

A signatory or any financially interested person may request an administrative review of a verification audit if it believes a material error was made by the Inspection Service. Administrative reviews shall be conducted in accordance with USDA audit verification procedures. The person requesting the review shall pay the cost of the review. The review results shall be issued to the person making the request.

In section 970.75, the word "and" appearing before "development projects" should be removed. Also, the section should refer to funds collected pursuant to section 970.56 and section 970.58. Section 970.58 allows the Committee to receive voluntary contributions for research and promotion.

#### § 970.75 Research and promotion.

The Committee, with the approval of the Secretary, may establish or provide for the establishment of marketing research, and development projects, and/or promotional activities, including paid advertising, designed to assist, improve, or promote the efficient adoption, implementation, and marketplace acceptance of the agreement and of leafy green vegetables or products handled by signatory members. The expenses of such projects shall be budgeted and paid from funds collected pursuant to § 970.56 AND § 970.58.

## § 970.75 Research and promotion.

The Committee, with the approval of the Secretary, may establish or provide for the establishment of marketing research, development projects, and/or promotional activities, including paid advertising, designed to assist, improve, or promote the efficient adoption, implementation, and marketplace acceptance of the agreement and of leafy green vegetables or products handled by signatory members. The expenses of such projects shall be budgeted and paid from funds collected pursuant to § 970.56 and § 970.58.

In section 970.85, the phrase "subsequent crop year leafy green vegetables" should be simply "subsequent crop years."

#### § 970.85 Effective time.

The provisions of this part, as well as any amendments, shall apply to 2010-2011 and subsequent crop year leafy green vegetables <u>YEARS</u> and shall continue in force and effect until modified, suspended, or terminated.

# § 970.85 Effective time.

The provisions of this part, as well as any amendments, shall apply to 2010-2011 and subsequent crop years and shall continue in force and effect until modified, suspended, or terminated.

In conclusion, the Arizona Marketing Committee offers these recommended revisions to the proposed national marketing agreement in order to clarify the terms of the agreement and to better fulfill the intent of the proponents. The Arizona Marketing Committee expresses hope that these recommendations will be incorporated into the agreement.