Before the United States Department of Agriculture
Agriculture Marketing Service

Docket No. AO-FV-09-0138; AMS-FV-09-0029; FV09-970-1

Brief on Behalf of Chiquita Brands International, Inc. and its wholly owned subsidiary Fresh Express Incorporated

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I. PRELIMINARY STATEMENT

This is a proceeding to adopt the National Leafy Greens Marketing Agreement by Public Act No. 10, 73d Congress (May 12, 1933), as amended and as reenacted and amended by the Agriculture Marketing Agreement Act of 1937, as amended (48 Stat. 31, as amended 7 U.S.C. 601 et seq.). We are appreciative of the fair hearing of the facts by the AMS throughout the course of the hearings and the consideration of our brief.

Following the submission of a revised draft of a Proposed Federal Marketing Agreement for Leafy Greens by a coalition of proponents on July 31, 2009 ("Proposed NLGMA"), the United States Department of Agriculture's Agricultural Marketing Service ("AMS") announced the dates and locations of seven hearings on the Proposed NLGMA and published the announcement in the Federal Register at 74 Fed. Reg. 45565 September 3, 2009. The hearings were to provide an opportunity for the public to convey their evidence and views before any marketing agreement takes effect. The public hearings were conducted in seven states during the period between September 22, 2009 and October 22, 2009.

The hearings were conducted by the presiding Administrative Law Judge, Marc R. Hillson. The record consists of 4,924 pages of testimony. References to the transcript are designated by the letter "R" followed by the page number. The time for filing briefs was January 27, 2010. This brief is filed on behalf of Chiquita Brands International, Inc. and its wholly owned subsidiary Fresh Express Incorporated. This brief is in support of a national food safety system harmonized with current global standards and provides comments and proposed amendments to this proposal to accomplish this objective.

II. PROPOSED AMENDMENTS AND EXCEPTIONS

The notice of hearing listed one single Proposal submitted by the proponent Group. The comments and proposed amendments apply to the Proposed NLGMA.

A. The Scope of the Proposed NLGMA is too Broad.

1. The Identified Purpose in § 970.35 of the Proposed NLGMA is Not Consistent with the Original Mandate of a National Leafy Greens Agreement.

The Proposed NLGMA identifies the Purpose of the Agreement in § 970.35. The purpose identified in § 970.35 in relevant part is ". . . to enhance the quality of fresh leafy green vegetable products available in the marketplace through the application of good agricultural production and handling practices. . ." The true purpose of both submitted proposed agreements was to increase consumer confidence in leafy greens by minimizing the potential for microbial contamination. This purpose is further outlined in the Justification of Proposed Federal Marketing Agreement for Leafy Greens available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5077207. This justification makes clear that the proposal was designed to correct and minimize microbial contamination in the production and handling of leafy green vegetables placed in the market for human consumption (R. 579). Food safety was the articulated goal and remains the goal today; quality can be addressed by each party individually and will be dictated ultimately by customer and consumer preference. Food safety is quite different from quality and the only reason it is used in this context is to get the Proposed NLGMA adopted through the Agriculture Marketing Service (R. 829). Accordingly, the Purpose section should be redrafted to eliminate the language quoted above and reflect the true purpose of the Proposed Agreement (R.49, 4331).

2. Verification Audits of Processing Facilities Cannot only Be Limited to Fresh Cut Packaged Leafy Green Product.

The Definition of Fresh Cut in Packaged Leafy Green Product Set Forth in § 970.8 includes any leafy green vegetable defined under § 970.15 that is fresh cut-cut and packaged for human consumption (R. 370). This definition excludes from regulation all whole or cut non-leafy green vegetables or non-produce ingredients co-mingled with fresh-cut leafy green vegetables in packaged products, however, any auditing of a processing plant in accordance with the requirements of § 970.66 Verification Audits and § 970.67 Audit Metrics will not be able to distinguish leafy green production from production of other cut vegetables processed with leafy greens in a processing plant (R. 111, 173).

A majority of processing facilities that are currently inspected and under jurisdiction by the Food and Drug Administration ("FDA") also process multiple non-leafy green vegetables and non-produce ingredients. Accordingly, not only are processing facilities already subject to comprehensive auditing and enforcement activities by the FDA but including them in the Proposed NLGMA verification audit is outside of the Proposed NLGMA scope (R. 606). Any audit of handling and manufacturing systems would include an audit of items not included in the Proposed NLGMA and an assessment of the audit metrics would not be reflective of leafy greens compliance. For instance, in Audit Metrics § 970.67 (ii) wash water, wash system capacity, bulk-bin modified atmosphere process, condition of sanitation of transportation vehicles, employee hygiene and labeling of Raw Agricultural Commodity versus ready to eat products and finished

product packaging are all items which would include both leafy greens and non-leafy green items in a processing plant.

Accordingly, processing facilities should be removed from the Proposed NLGMA as they are (i) currently under the clear jurisdiction of the FDA and potentially the USDA if meat products are also handled within them and therefore subject to current regulations, inspection, and enforcement activities of the FDA and USDA respectively, and (ii) any verification audits will be outside of the scope of the Proposed NLGMA as they will include non-leafy greens produce items. (R.761-762, R. 615)

B. USDA Does not Have Appropriate Jurisdiction to Perform Functions under the Proposed NLGMA.

1. Food Safety is Outside of the Jurisdiction of the AMS Therefore the Broad Powers Under the Proposed NLGMA Provided to the Secretary are Outside of Secretaries Jurisdiction.

Marketing Agreements are designed to stabilize the market conditions for certain agricultural commodities by regulating the handling of those commodities in interstate and foreign commerce. Marketing Agreements are administered by the Agriculture Marketing Service ("AMS"), an agency within the USDA, and are authorized under Agricultural Marketing Agreement Act of 1937 as amended, 7 U.S.C. §§ 601-14; 671-74 ("AMAA"). Marketing Agreements are permitted provided there is reason to believe that issuance of the Agreement will tend to effectuate the declared policy of the AMAA. § 7 U.S.C. 602 outlines the policy of the AMAA, it does not include the furtherance of food safety or the reduction of microbial contamination of any products, rather it includes items related to pricing, consumer protection with respect to pricing, conducting research, establishing and maintaining such orderly marketing conditions for any agricultural commodities, to establish and maintain production research, marketing research, and development projects, container and pack requirements establish minimum standards of quality and maturity and such grading and inspection requirements for agricultural commodities (R. 364, 365, 366).

Accordingly, if the AMS does not have the authority to administer the Proposed NLGMA then the Secretary of the USDA does not have the authority to perform the functions and enforce the terms of the NLGMA, especially to the extent identified in the Proposed NLGMA (R.16, 3892, 4340).

2. The Secretary Has Broad Powers to Perform Several Functions Under the Agreement Outside of Its Jurisdiction.

Not only does the Secretary not have the ability to conduct a majority of its authorized acts under the Proposed NLGMA Agreement as a result of the lack of jurisdiction of the AMS, but the USDA itself does not have the jurisdiction over leafy

greens as it purports to exert through the implementation of the Proposed NLGMA (R. 20).

The FDA is responsible for ensuring that all domestic and imported food products – except for certain meat and poultry – are safe, nutritious, wholesome, and accurately labeled. The primary statutes governing FDA's activities are the Food Drug and Cosmetic Act (FDCA 21 U.S.C 301 et seq.), Public Health Service Act, as amended (42 U.S.C 201 et seq.); and the Egg Products Inspection Act as amended (21 U.S.C. 1031 et seq.) (R. 575, 661, 662). The USDA's FSIS regulates the safety, wholesomeness, proper labeling of most domestic and imported meat and poultry and their products sold for human consumption.

The only touch-point between produce and the USDA is via the AMS and the Perishable Agricultural Commodities Act ("PACA"). The AMS' purpose as stated on its website is to administer "programs that facilitate the efficient, fair marketing of U.S. agricultural products, including food, fiber, and specialty crops." Voluntary tools that industry can use to help promote and communicate quality and wholesomeness to consumers via quality inspections and the market news reports quality grade standards, grading, certification, auditing, inspection, and laboratory analysis.

Clearly, the intent of the Proposed NLGMA as discussed elsewhere and reflected in the GAP Audit requirements and other food safety measures contained in the Proposed NLGMA, is to promote food safety. This mandate is far outside the jurisdiction and expertise of the USDA and the AMS. The AMS was used as a tool to enter into a marketing agreement, however, any marketing agreement such as the Proposed NLGMA is outside of the jurisdiction of the AMS and therefore also the USDA and the Secretary. (R. 17, 387)

3. The USDA does not have the Authority to Mandate GAP Audits Under the Proposed Agreement for Foreign Suppliers of Product.

Section 970.66 (a) (2) provides that 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 validations and verification audits by USDA licensed inspectors. Accordingly, USDA inspectors would have to be present in the foreign jurisdiction to perform the audit on the foreign supplier prior to the import of the leafy green vegetables (R. 1326).

Since the AMS does not have the authority to administer the Proposed NLGMA then the USDA inspectors certainly do not have jurisdiction over non-signatory foreign growers and handlers to perform audits and enforce these auditing requirements. (R. 71)

C. Proposed NLGMA is not Harmonized with Global Food Standards and Does Not Recognize Adherence With other Recognized Global Food Standards.

1. The Proposed NLGMA should be harmonized with Global Food Safety Standards.

The Proposed NLGMA needs to be integrated into current efforts surrounding the harmonization of global food safety standards. This would include, but is not limited to, current work and activities being considered by the FDA to establish a voluntary import certification program. If this integration is not completed, the result could be an additional set of standards for lettuce and leafy greens that may directly conflict with current globally accepted standards and/or those for other non leafy green domestic products being manufactured (R. 3545). These global standards are already in existence and are being harmonized with industry participants, regulators, customers and consumers (R. 3187).

The handlers and growers of lettuce and leafy greens increasingly must satisfy the food safety demands of their customers in a global market place and are increasingly being required to obtain a food safety certification to global food safety programs or schemes (many recognized by the Global Food Safety Initiative - GFSI). GFSI's primary objectives are to promote convergence between food safety standards through maintaining a benchmarking process for food safety management schemes and to improve cost efficiency throughout the food supply chain through the common acceptance of GFSI recognized standards by retailers and customers around the world. Under this GFSI approach, food-safety related schemes are submitted to GFSI and undergo a benchmarking process against the GFSI Guidance Document to obtain recognition by GFSI. Global companies obtaining certification to any one of the GFSI recognized food safety schemes (e.g., Safe Quality Foods (SQF), British Retail Consortium (BRC), Food Safety System Certification 22000 (FSSC 22000), IFS, and GlobalGAP) could then be recognized by retailers and customers worldwide under the vision "Once Certified, Accepted Everywhere." For such companies already certified to a GFSI recognized standard, the Proposed NLGMA audits of fields and manufacturing facilities will be redundant and will not provide any additional level of food safety assurance. To avoid this duplication of time and cost, the Proposed NLGMA must integrate with the GFSI model and provide a method of recognizing and allowing valid GFSI certifications to satisfy its audit requirements. (R. 1144-1145, 1427, 2448-2449, 3422-3423)

Additionally, to harmonize with the GFSI model, the auditors of the Proposed NLGMA need to be certified and compliant with an internationally recognized accreditation scheme, (e.g., ISO 65). Doing so will ensure the continuing competency and calibration of its auditors. (R. 3647-3652)

Furthermore, by defining and adopting its own GAP standards for lettuce and leafy greens, the Proposed NLGMA encourages the development of an independent set of GAP standards rather than a set of GAPs harmonized with other high food safety management commodities such as tomatoes, melons, and peppers. To avoid a proliferation and redundancy of GAPS, the Proposed NLGMA must align itself with current industry efforts by such organizations as the United Fresh Produce Association

GAP Harmonization Initiative, Produce Marketing Association, Grocery Manufacturers, and Center of Science in the Public Interest to harmonize produce standards (R. 3424,).

2. Traceability Should be Consistent with Industry Initiatives and Current Regulations.

Currently the Food Drug and Cosmetic Act 21 U.S.C 414 (b), requires persons who manufacture, process, transport, pack, distribute, receive, hold or import food maintain records of the immediately preceding source and the immediate subsequent recipients (R. 576). Additionally, both proposed Food Safety Bills H.R. 2749 and S.510 address increased record keeping requirements. However, most importantly, there is a comprehensive industry led Traceability Initiative. The Produce Traceability Initiative ("PTI") is an industry-led effort to enhance traceability throughout the entire produce supply chain. The Initiative's sponsor associations include United Fresh Produce Association (United Fresh), Canadian Produce Marketing Association (CPMA) and Produce Marketing Association (PMA).

Section § 970.68 of the Proposed NLGMA mandates traceability at all stages of production, processing and distribution. Members will have to track their product from their suppliers to their customers. Accordingly, there is no consistency with this requirement, the law or industry initiatives, which are already addressing traceability and in a more detailed and comprehensive manner. (R. 57-58, 3827, 3828)

3. Compliance Authority and Standards Should Correspond with the Food Drug and Cosmetic Act.

The Food Drug and Cosmetic Act (FDCA 21 U.S.C 301 et seq.) has been the nation's primary structure and authority concerning FDA regulated foods. The FDCA mandates criteria for determining where a product is violative and places jurisdiction for the enforcement as it relates to plant and vegetables with the FDA (R. 3638, 3639).

Under the Proposed NLGMA compliance with the provisions of the Proposed NLGMA is overseen by the Committee and any staff hired or appointed to undertake the responsibility (§ 970.83). Clearly, this is at odds with existing legislation which places enforcement with the FDA (R. 3494).

Furthermore, the FDCA provides clear guidance as to Prohibited Acts and enforcement for prohibited acts including the possibility for injunctive relief, fines, penalties and criteria for conducting a recall (FDCA 21 U.S.C 301 et seq.). Under 21 C.F.R. 7.3 (n) recalls are separated into different classes I-III based on the probability that exposure to a violative product will cause adverse health consequences. Most notably all enforcement and the structure of any recall is that the product is violative of the act or is found to present, through credible evidence, a threat of serious or adverse health consequences or death to humans or animals.

Conversely, under the Proposed NLGMA § 970.83 6 (c), failure to comply with the provisions of the Agreement may result in additional remedies or penalties, such as injunctive relief, as authorized under the Act. It appears as though there does not need to be any finding that the leafy greens are a threat to human health or violate a standard. These remedies can be employed for a failure to receive an inspection or co-mingling with non-NLGMA leafy greens, despite the fact that leafy greens covered by the agreement will be routinely co-mingled with items that are not covered by the Proposed NLGMA.

Accordingly, the USDA's Secretary authority is not consistent with current regulations governing food products and the broad powers vested in the USDA to obtain injunctive relief for a violation of the Proposed NLGMA are outside of the law and any appropriate jurisdiction of the USDA (R. 17).

D. The Proposed NLGMA Subjects Entities to Large Costs.

1. Costs of Participation.

As a Company that consistently exceeds the standards contained in the Proposed NLGMA, the proposed assessments capping out at $0.05 per case seems excessive. In addition, companies may be subject to multiple assessments due to (i) the assessment applying to small growers and as small growers they may not be able to pay and as a result will pass through the costs of the assessments to processors and handlers, and (ii) as a member of other industry organizations that also charge assessments for membership and auditing we will be subject to assessments to those organizations for the similar auditing function and participation (R. 543).

Any food safety program has to be consistent to be effective which is why no grower should be exempt. However, there is ample testimony as to the inability of small growers to be able to manage the assessments. In effect, small growers will end up passing the assessment through to handlers and processors (R. 2163-2165).

Further, today, growers, processors and handlers are subject to multiple internal, third party and organizational audits. Processors are additionally frequently inspected by the FDA. The goal should be to have one auditing standard and use that same audit for all organizations and produce commodities. Accordingly, we propose that there is harmonization between the Proposed NLGMA and existing industry organizations that have an auditing function. As a result, the costs of auditing would be less expensive and we would not incur the cost of multiple auditing fees (R. 114).

E. Committees and Technical Review Boards Should Appropriately Reflect Both the Purpose of the Agreement and Lead to Proportional Representation.

1. Membership on the Proposed LGMA Administrative Committees should be proportional to production volume or number of Handlers in Each Zone.

Section 970.28 of the Proposed NLGMA describes the Zones from where the particular representatives make up the Committee in accordance with Section § 970.40. Zone 1 encompasses California, Washington, Oregon, Hawaii and Alaska. Zone 2 includes Arizona, Montana, North Dakota, Wyoming, South Dakota, Idaho, Nevada and Utah. Clearly, Zone 1 and 2 contain the bulk of leafy green production and manufacturing areas. However, Zone 1 and 2 combined only have 10 members of the 23 member Committee. Clearly this is disproportionate to the amount of production in the correlating production areas.

Accordingly, we suggest that the representation from Zone 1 and 2 accurately reflect the total volume of production and processing in those areas by volume which would result in an increased representation for those two zones (R. 385, 624).

2. Technical Review Board Should Reflect the Purpose of the Proposed NLGMA.

Section 970.45 Technical Review Board describes the establishment of a technical review board to assist the Committee in developing audit metrics. The section goes on to describe the technical review board composition and identify mandatory members that include "1 representative from the USDA Natural Resources Conservation Service (NRCS) appointed by Secretary; 1 representative of the US Environmental Protection Agency (EPA) designated by the Administrator . . ." In order to be consistent with the stated purpose and the amendment proposed above, these members should not be included in a review board as their perspective, background and scientific expertise would not contribute to food safety and consumer confidence (R. 384, 69, 400).

F. Budget Should be Approved in Advance by Committee Members on an Annual Basis.

The Proposed NLGMA is supported by the Members which are required to pay assessments. However, rather than the budget being controlled by and then set by the Committee, as representative for the Members, the Secretary of the USDA is granted broad spending powers with no checks on the powers. Section 970.66 provides in relevant part "The Committee is authorized to incur such expenses as the Secretary finds are reasonable 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 provisions of this part, determine to be appropriate." There is no requirement that a budget or forecast is created and approved by the Committee n are there limitations on spending activities.

The Members clearly have no control over the spending or use of their assessments yet have to keep paying their assessments throughout their membership. Committee members are representatives for the members and therefore should have some power over spending and budgeting. Each year there should be a budget approved in