COMMENT ON:

STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

Proposed Rule Document issued by the FOOD AND DRUG ADMINISTRATION (FDA)

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COMMENT BY: The California Leafy Green Products Handler Marketing Agreement (CA LGMA)

INTRODUCTION

The California Leafy Greens Marketing Agreement has previously submitted comments on several issues related to the proposed produce rule. This document includes suggestions and recommendations in several other areas related to the rule.

The California Leafy Green Products Handler Marketing Agreement (LGMA) is supportive of the proposed produce rule issued by the US Food and Drug Administration (FDA). As an entity that verifies, through government audit, that its members are following an accepted set of food safety practices on the farm, the LGMA recognizes the critical importance of good agricultural practices, and believes that the proposed standards will help protect public health and create a safer food supply.

There are, however, elements of the proposed rules that we believe can be improved or that should be changed. Much of our input is based on our experience of the last six years, as the LGMA has overseen the implementation of a similar set of food safety standards in the leafy greens industry. We hope and trust that our experiences and learnings can shed additional light on the standards included in the produce rule, and we offer these comments with the objective of helping FDA to improve and strengthen the proposal.

FOOD SAFETY PLAN

As proposed, the Produce Rule does not require farmers to have a written food safety plan. In section IV of the *Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, FDA states that "we are not proposing to require farms to conduct operational assessments or to develop food safety plans akin to similar requirements for facilities subject to section 418 of FSMA or our juice HACCP or seafood HACCP regulations."

LGMA Comment
The LGMA recommends that growers regulated under the Produce Rule be encouraged to maintain a food safety plan that stipulates how the on-farm food safety practices required under the rule will be carried out and verified.

Background/Rationale
The LGMA concurs with the statement in Section IV of the proposed rule: "The purpose of a food safety plan is to establish measures designed to prevent the introduction of known or reasonably foreseeable food safety hazards into or onto produce in light of the crops, practices, and conditions at the physical location of the farm and would include, for example, measures applicable to an individual farm for agricultural water, animal grazing, and any specific hazards identified in the recommended operational assessment."

The plan can and should be commensurate with the size and scope of the operation, and does not have to represent a significant burden to the grower to develop and maintain. There are, in fact, several very good resources available to growers, including the website onfarmfoodsafety.org, that exist to help growers of all sizes develop a food safety plan for their operation. We believe, however, that the successful management of all required food safety practices under the Food Safety Modernization Act will necessitate a written food safety plan - in fact, based on our experience, we believe it would be very difficult for a farmer or shipper to complete a verification audit without one. We therefore suggest that FDA encourage farmers covered by the rules to maintain a written food safety plan.

PRODUCT TESTING

In Section IV.I of the produce rule, the FDA states that it has tentatively concluded "that product testing would be impracticable as a component of science-based minimum standards proposed in this rule except as set forth in proposed subpart M under certain circumstances for sprouts."

LGMA Comment
The FDA has appropriately focused its proposed rules on practices that are designed to prevent contamination of produce from pathogens. Product testing, while it can be a useful tool in a company's food safety toolbox, is not a preventive practice, can give an unwarranted sense of security about the food supply, and should not be a mandated requirement under FSMA.

Background/Rationale
Many food safety experts in industry and academia have indicated that finished product testing is a less important element in a farm or company's food safety program than are the implementation of

preventive practices on the farm or in facilities. In a 2011 White Paper on Microbiological testing in the produce industry, the United Fresh Produce Association states that:

> *… it is important to realize that microbiological testing can never determine whether a food is pathogen-free, unless 100% of the food is tested (and then there is nothing left to sell or eat). The most one can achieve with microbiological testing is "pathogen not detected" and understand the levels of sensitivity and confidence provided by the sampling plans and testing methodologies used. International organizations recommend testing only when there is good evidence that there is a microbiological problem and that testing will help to control the problem (Codex and ICMSF). Any misunderstanding in what is achievable by microbiological testing, and the limitations of such testing, will tend to waste resources, product and potentially create a worse food safety situation than if no testing was performed.*

The report concluded that "if not properly designed and implemented, microbiological testing can provide unreliable information that can easily be taken out of context and create unwarranted concerns or false assurances about the safety of the product.

The LGMA concurs with this point of view and recommends that the FDA not require microbiological testing as part of the produce and preventive practices rules. Guidance, similar to the United Fresh document quoted above, should be provided to industry so that growers, processors and handlers can best make decisions about the degree to which testing is an effective food safety tool for their particular farms or facilities.

INCLUDE SPECIFIC STANDARDS IN GUIDANCE DOCUMENTS, RATHER THAN REGULATION

As proposed, the specific standards included in the Produce Rule are spelled out in the proposed legislation itself, in subparts A through O.

LGMA Comment

The LGMA recommends that the FDA utilize guidance rather than regulation to establish specific standards for food safety, thus allowing those standards to be updated and improved as new research and information becomes available.

Background/Rationale

When the LGMA was being developed in 2006/07, it became apparent that there were significant gaps in available science. While regulatory agencies, food safety experts and researchers were in agreement on the key risk areas that needed to be addressed (water, wildlife, soil amendments, etc.), much was not clear about just what measurable standards would be appropriate.

Since that time, a great deal of new research has been completed. Because the LGMA's good agricultural practices are not part of legislation but rather maintained by a group of outside industry and food safety experts, changes can be made quickly. For example, following a 2006 outbreak of E. coli, FDA issued a final report that pinpointed a form of irrigation water that saw a mixing of irrigation water with dairy runoff as the likely source of contamination. This report brought an area to light that was not specifically addressed in the LGMA metrics. But the structure of the LGMA allowed a new provision - a new metric, so to speak – to be added in a matter of weeks. Had those standards been part of either state or federal legislation, it would no doubt have been far more difficult and taken far more time to make that necessary change.

Based on our experience, and the fact that extensive research continues to address gaps in knowledge about the most effective food safety practices, we believe it would be appropriate for FDA to create or accept guidance documents to define specific standards and food safety practices, and to incorporate those guidance documents into the rule by reference.

FARM DEFINITION

Section 1.227 of Subpart A defines a farm as a "facility" in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. According to the proposed Produce Rule, farms are defined as:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and
(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.

<u>LGMA Comment</u>
The LGMA recommends that the definition for "farm" be amended by removing the terms facility and facilities and stating that a farm is the general physical location where covered products as proposed for definition in this Subpart A are produced and harvested.

<u>Background/Rationale</u>
Calling a farm a facility will promote confusion as a facility in and of itself cannot produce covered produce as defined in § 111.3. It should be described for what it is; the physical location where the covered produce is produced, harvested, packed (as applicable) and transported from that physical location to a facility where it may be subject to further handling, washing, processing, packing and storage prior to entering commerce.

NON-FECAL ANIMAL BY-PRODUCT

The Proposed Produce Rule defines non-fecal animal by-product as "solid waste (other than excreta) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations."

LGMA Comment
The LGMA recommends that the use of "non-fecal animal by-product" be subject to a requirement that the commercial, institutional or agricultural operations that are generating the product provide a guarantee that the product is free from any animal products.

Background/Rationale
Several items included in FDA's definition of non-fecal animal by-product are also covered under the LGMA's "Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens" (hereafter referred to as metrics) as common forms of non-synthetic soil amendments. The list includes blood meal, fish meal and fish emulsions, and since these products are derived from animal sources, it is not clear how one can be assured that these products do not contain animal excreta with any degree of certainty. Therefore, the LGMA considers products blood meal, fish meal and fish emulsions to be soil amendments which may contain animal excreta.

The LGMA metrics provide two options for ensuring such products do not contain animal excreta. The first requires each lot to be sampled with a defined sampling plan and tested with an approved method by an accredited laboratory to determine if the lot complies with the metrics' specific acceptance criteria for *Salmonella spp.* and *E. coli* 0157:H7. Or in lieu of mandatory sampling and testing, the manufacturer of the products may provide a letter of guaranty to the grower stating that the product(s) do not contain any animal excreta.

We recommend that similar requirements be included in the Produce Rule. As the farmer may not have the time or resources to provide such testing or documentation, it is appropriate to look to the supplier to provide it as a condition of purchase.

PRE-CONSUMER VEGETATIVE WASTE

Pre-consumer vegetative waste is defined in the proposed Produce Rule as:

> *Solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their*

packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

LGMA Comment

The LGMA recommends that the use of "pre-consumer vegetative waste" be subject to a requirement that the commercial, institutional or agricultural operations who are generating the product test the product for compliance with proposed § 112.55 or provide a guarantee that the product is free from animal excreta.

Background/Rationale

According to commercial composters, it is currently difficult to ensure that "pre-consumer vegetative waste" or commercial green waste (as it's commonly referred to) does not potentially contain animal products. Therefore, the LGMA considers green waste to be a soil amendment which may contain animal excreta. Like non-fecal animal by-product, the metrics require such products to be sampled and tested to ensure they comply with the metrics acceptance criteria for *Salmonella spp a*nd *E. coli* 0157:H7. Similarly, in lieu of testing, the manufacturer of these products may provide the grower with a letter of guaranty stating that the product does not contain any animal excreta.

Since the grower or farmer utilizing these products may not have the time, expertise or resources to provide such testing or treatment, it is appropriate for the supplier to provide the required documentation.

ALTERNATIVES

The LGMA supports the provision specified in proposed section 112.12 that provides a process to establish alternatives to specific requirements pertaining to water and soil amendments. However, we would encourage FDA to accept alternatives for other areas of the proposed regulations as well (not just for water and soil amendments).

LGMA Comment

The ability to amend and/or adopt new procedures, standards, tolerances, etc. in a timely manner that is based upon current data, research, and other new information is very important to a food safety system on the farm. FDA's proposed Produce Rule addresses the changing realities of research by making it possible for farmers to implement alternative approaches to the proposed water and soil amendment requirements. The LGMA supports this section of the proposed rule.

However, we recognize that other areas of the proposed regulations – including practices related to animal encroachment, environmental assessment and worker practices – are also subject to new and improved information. And we would encourage FDA to make the implementation of alternatives possible for all of these areas as well, not just for water and soil amendment requirements.

Background/Rationale

The LGMA provides a mechanism for amending its metrics which is similar to what FDA has proposed in section 112.12. An independent group of food safety experts has the responsibility for managing this process, ensuring that established procedures and requirements are followed.

As noted, the basic principles that are proposed in this regulation for establishing alternatives are similar to LGMA's and include that any the proposed action is; 1) supported by applicable science and research, 2) going to enhance food safety and 3) sufficiently vetted to provide ample opportunity for interested to parties provide input and comments. Like FDA, we understand the importance of requiring a process and safeguards are necessary to ensure provisions addressing agricultural water and soil amendments quality provide for equivalency to the proposed regulations.

SUBPART D-STANDARDS DIRECTED TO HEALTH AND HYGIENE.

Overall, the LGMA supports FDA's proposed regulations addressing health and hygiene, and specifically, the provisions in proposed § 112.31 and § 112.33.

LGMA Comment

The LGMA recommends that FDA maintain existing language as proposed in sections 112.31 and 112.33. The requirements in those proposed sections are similar to those established in the LGMA's metrics and address: 1) taking measures to prevent contamination from persons with health conditions; 2) excluding such effected persons from handling fresh produce; 3) worker training on these requirements; 4) requiring specific practices for handwashing and 5) health and hygiene requirements for visitors.

Background/Rationale

The provisions of these proposed sections are recognized as the basic requirements for personal sanitation and hygiene. They reflect the accepted industry practices that should be in place and required for all personnel involved with harvesting, packing and transporting fresh produce. In addition, the requirements for basic employee health and hygiene are already codified in state and federal laws and regulations (in California and many other states).

USE OF NON-SPECIFIC TERMINOLOGY

Throughout the proposed Produce Rule, the FDA has included regulatory language that is non-specific. Examples include:

- Section 112.32(1) Maintaining *adequate* personal cleanliness to protect against contamination of covered produce and food-contact surfaces;
- Section 112.32(2) Avoiding contact with animals other than working animals, and taking appropriate steps to *minimize* the likelihood of contamination of covered produce when in direct contact with working animals;
- Section 112.83(a): If under the circumstances there is a *reasonable probability* that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion.
- Section 112.83(2)(b): If animal intrusion, as made evident by observation of *significant quantities* of animals, animal excreta or crop destruction via grazing, occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112
- Section 112.112: You must take all measures *reasonably necessary* to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.
- Section 112.113: You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or *reasonably foreseeable* hazards, for example, by avoiding contact of cut surfaces of harvested produce with soil.
- Section 112.127(a): You must take *reasonable precautions* to prevent contamination of covered produce, food-contact surfaces, and food-packing materials in fully-enclosed buildings with known or *reasonably foreseeable* hazards from domesticated animals by:

<u>LGMA Comment</u>
The LGMA recommends that terms like "adequate," "minimize the likelihood of," "reasonable probability," and "significant quantities" be replaced with more specific guidelines or standards.

<u>Background/Rationale</u>
Our recommendation is based upon experiences from conducting thousands of LGMA audits. Subjective terms like "adequate" and "likelihood" often lead to wide and inconsistent interpretation and lack of uniformity in enforcing provisions. We have also found that having non-subjective language makes it easier to develop effective worker training programs and establish guidelines that are practical and understandable to the workers and responsible supervisors. The resulting outcomes are improved compliance with sanitation and hygiene practices for workers.