December 15, 2014

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
http://www.regulations.gov/

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals – Supplementary Proposal.
Docket No. FDA–2011–N–0922; RIN 0910–AG10

The United Fresh Produce Association ("United Fresh") appreciates the opportunity to comment on the supplementary proposal to the proposed regulation *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals* ("Animal Feed rule").

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

Produce Culls as Animal Feed

In our March 2014 comments to the proposed rule, we said that, while some fresh produce handling operations may grow, handle or ship produce to animal feed manufacturers, the animal feed coming from the vast majority of such operations are produce culls and waste; i.e., those produce and trims that are not of appropriate quality to be sold for human food and are discarded by the operation. U.S. farms, packinghouses, repackers, fresh-cut processors, distributors, warehouses, retail and foodservice operations generate considerable tonnage of produce culls and waste, which represent an important source of nutrients to animal feeding operations. Such discards are frequently sold, given away, or the operation pays to have them taken away to serve as animal feed. This practice benefits the farm or other operations that receive the culls and waste at low or no cost, and is in lieu of an alternative practice of shipping the waste to a landfill. We further noted that requiring registered operations that generate produce culls and waste for animal feed to develop a hazard analysis and implement preventive controls and other requirements under this rule for such human food by-products would be considered unnecessarily burdensome by the produce industry and would certainly bring an end to this source of animal feed.

We commend FDA for recognizing this unintended consequence and proposing new § 507.12(a), which expressly states that "*Except as provided by paragraph (b) of this section, the*

requirements of this part do not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if: (1) The human food

processor is subject to and in compliance with subpart B of part 117 of this chapter, and in compliance with all applicable human food safety requirements of the FFDCA and implementing regulations; and (2) The human food processor does not further manufacture/process the by-products intended for animal food." We further agree and support the intent of new § 507.28 in this proposed rule and § 117.95 in the Preventive Controls for Human Food rule, which define the basic GMPs for the holding and distribution of such human food by-products for animal feed.

However, we believe that FDA has gone too far in defining those conditions. Requirements that "*(1) containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food*", "*(3) labeling identifying the product by the common and usual name must be affixed to or accompany animal food*" and "*(b) shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use*" are unnecessarily prescriptive. Fresh produce operations hold and distribute culls and waste for animal feed in numerous ways, some of which are inconsistent with the above paragraphs of this subpart. As one example, operations may use augers, pipes/shoots or conveyor belts to transport culls and waste from an inspection or processing line directly to a transport vehicle outside of the building; such would make it difficult to label in compliance with paragraph 3. Further, while it is common for produce handling facilities to use dedicated containers and vehicles to hold and transport culls and waste for animal feed, it is also common to re-use those containers and vehicles without first being "cleaned" or "inspected". We remind FDA that the culls and produce waste being directed to animal feed are not just out of specification; much may be decayed, which is unacceptable for human food but is used routinely for farm animal feed. Further, once they reach the farm, these human food by-products are typically dumped onto the ground for the animals to eat. Cleaning and inspecting containers and vehicles before filling with such waste is pointless.

In developing subpart B of proposed part 117 and revising the GMPs of part 110, FDA deleted most of the "how to comply" provisions of the rule, leaving it to operations to determine how best to meet the expectations. We recommend that FDA do the same here, and simplify § 507.28 and § 117.95 to only what is necessary, e.g., "*Human food by-products held for distribution as animal food must be held and distributed under conditions that will protect against contamination which may be harmful to animals from sources such as chemicals, trash and garbage*".

However, we remain concerned with § 507.1(a), where the rule proposes "The criteria and definitions in this part will apply in determining whether an animal food is adulterated:…(2) Within the meaning of section 402(a)(4) of the Federal Food Drug and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth…" Produce culls and waste will always be adulterated by this definition, which is why they are redirected away from uses for human food. However, the condition and quality of culls and waste are generally still suitable for animal feed and, as noted above, they will not be used under sanitary conditions at the farm. We therefore recommend that FDA clarify that this requirement does not apply to human food by-products described under § 507.12(a).

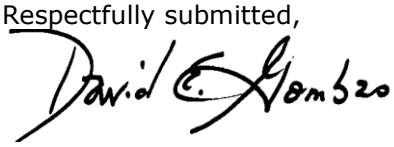
Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

We note in the preamble (79 FR 58486) that FDA intends an exemption for certain low-risk activity/animal food combinations when performed on-farm by a very small business (defined as an operation with less than $2,500,000 annual animal food sales). As we've noted in our comments to the supplementary proposals and proposed rules for Produce Safety and Preventive Controls for Human Food, the distinction is artificial and not risk-based for on-farm and off-farm

operations that perform exactly the same activities on exactly the same kinds of commodities, and create exactly the same kinds of human food by-products to be used as animal feed. We recognize FDA's desire not to relinquish expanded regulatory authorities over facilities currently required to be registered, and the statutory directive in the Food Safety Modernization Act that the Preventive Controls rules shall apply to registered facilities and exempt farms, but we see no reason to not expand the exemptions intended here to registered, off-farm facilities that perform those activities that would exempt an on-farm facility of the same size.

The members of United Fresh hope that FDA finds value in these considered comments, and we stand ready to clarify or assist FDA in these recommended interpretations and changes to the proposed rule.

Respectfully submitted,



David E. Gombas, Ph.D.
Senior Vice President
Food Safety and Technology