



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. Docket No. FDA-2011-N-0922; RIN 0910-AG10**

The United Fresh Produce Association appreciates the opportunity to comment on 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.

**General Comments**

**1. Produce Culls as Animal Feed**

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. Those operations will be the focus of our comments on this proposed rule. 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.

In § 507.5(a), the rule states: "This part does not apply to establishments (including 'farms' as defined in § 1.227(b) of this chapter) that are not required to register under section 415 of the Federal Food Drug and Cosmetic Act [FFDCA]". Further, in § 507.5(c), the rule states: "Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the [FFDCA] (Standards for Produce Safety)" and in § 507.5(h): "Subpart B of this part does not apply to the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the [FFDCA]." Each of these provisions seems to exempt operations that only handle raw, intact fresh produce. We support this exemption, and strongly recommend that this exemption extend to all operations that handle and ship only culls and waste of raw, intact fresh produce, consistent with our comments to the Produce Safety and Preventive Controls for Human Food proposed rules (included in our submission to this docket), including operations of any size that handle fresh fruits and vegetables as described in § 507.5(e): "...on-farm packing or holding

of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the [FFDCA] that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership...(1) Conveying, weighing, sorting, culling, or grading (incidental to storing):...(v) Other plants or plant by-products (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables.”

We further respectfully recommend that such exemption apply to any operation that ships only fresh produce culls and waste to a farming operation that uses it as animal feed, regardless of its registration requirements, including fresh-cut operations and warehouse/distributors of fresh produce. There is no evidence in the administrative record that the culls and waste generated by these operations are in any way distinguishable from an animal feed safety perspective when compared to the low-risk packing or holding activities exempted above.

In § 507.1(a), 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 [FFDCA] 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 (those that are not used for animal feed and do not require additional regulation). Inclusion of operations that sell only culls and waste as animal feed under this rule will have the consequence of ending this practice, particularly if such operations must treat or handle culls and waste in a manner so as not to be considered adulterated under FFDCA 402(a)(4). Additional consequences include: 1) culls and waste will need to be redirected elsewhere, most likely to landfills, which will create environmental issues and higher costs for producers of culls and waste, 2) higher costs for farms and operations that currently receive culls and waste for animal feed at no or low cost, and 3) no quantifiable increase in the safety of available animal feed.

### **Additional Specific Comments**

Notwithstanding our comments above, we provide the following for FDA’s consideration:

- A. § 507.1(d): “Animal food for sale in the United States must be manufactured, processed, packed, and held in accordance with the requirements in this part, subject to the exemptions in § 507.5.” While the proposed rule is silent on this, we interpret, and support, that this subparagraph limits the scope of the rule to materials sold for animal feed, and does not include produce culls and waste when such food is given away or paid to be taken away for use as animal food. We also support an interpretation of this paragraph to limit the scope of the rule to food manufactured, processed, packed, and held as animal food, not food sold to a manufacturer to be made into animal feed, nor situations where animals are permitted to feed on harvested fields.
- B. § 507.1(d): “...If a facility is required to comply with subpart B of this part and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507...” For those operations that we agree should be covered under this rule, we support this option for facilities to build on their human food Preventive Controls rather than require a facility to create a second food safety plan.
- C. § 507.1(d): “...so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances...” In the case of produce culls and waste diverted for animal feed, there is no opportunity for the operation to consider nutrient imbalances; culls and waste are not formulated or processed in a manner that allows a fresh produce handling operation to adjust nutrient content. In such cases, we believe that

consideration of nutrient imbalances should be managed by the receiver of the culls and waste. Further, what does and does not pose a hazard to animals may be different from what companies are controlling in their human food Preventive Controls plan and, except in the case of companies that are in the business of manufacturing animal feed, will be largely unknown. Guidance of species-specific hazards that FDA expects to be controlled will be needed.

- D. § 507.3 *“Qualified end-user, with respect to an animal food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment...”* We would support an interpretation of this definition whereby animal feeding operations which receive produce culls and waste from registered produce handling operations, and otherwise meet the definition of a qualified end-user, should be considered qualified end-users. Essentially, the animal feeding operation becomes the equivalent of a restaurant, serving the culls and waste directly to animal “consumers”. Likewise, produce handling operations that divert produce culls and waste to animal feeding operations, and otherwise meet the definition of a qualified facility, should be considered a qualified facility.
- E. § 507.3 *“Very small business means, for purposes of this part, a business that has less than [\$500,000/\$1,000,000/\$2,500,000] in total annual sales of animal food.”* We support that the definition only applies to sales of food intended for animals, and does not include the value of such animal food when such food is given away or paid to be taken away.
- F. Appendix: *“Although the proposed rule that is the subject of this document does not include provisions for environmental monitoring or finished product testing, the Agency believes that these regimes can play a critical role in a modern food safety system.”* When the “animal feed” is produce culls and waste, such provisions are a pointless waste of resources. Indeed, the microbiological quality of produce culls and waste is reasonably likely to meet the definition of “adulterated”. While United Fresh supports voluntary environmental monitoring of vulnerable operations for relevant human pathogens or indicators, and voluntary microbiological testing where such testing is deemed necessary by the operation, the bacteria, parasites, and viruses of concern to human food safety that may be present in culls and waste do not pose an identified animal health risk. Requiring operations that generate produce culls and waste for animal feed to implement environmental monitoring or finished product testing for animal health risks would certainly bring an end to this source of animal feed without any quantifiable increase in the safety of available animal feed.

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