Response to Comments
Certification Requirements for Handling Unpackaged Organic Products

This document summarizes comments submitted to the National Organic Program (NOP) in response to the draft guidance, “Handling Bulk, Unpackaged Organic Products” (NOP 5031). The public was notified in a Federal Register notice (77 FR 5415) on February 3, 2012 of the availability of this draft guidance on the NOP website and solicited comments for sixty days.

- **CHANGES MADE IN RESPONSE TO COMMENTS**

1) **Clarify certification requirements for transporters of bulk grain, hay, milk and livestock.** Many commenters expressed concern that the draft guidance would require all transporters of bulk grain, soybeans, hay, milk and livestock to be certified. This was not the intent of the draft guidance. In the final guidance, we have clarified that operations such as those transporting grain in railcars that only transport unpackaged products, but do not sell, process or package them do not need to be certified. These operations do not meet the definition of the term “handler” under the USDA organic regulations (7 CFR 205.2).

2) **Provide more details about appropriate recordkeeping.** Many commenters provided examples of the type of documentation that can be used to verify integrity of the transport process, especially when the transporter is not required to be certified. We have incorporated reference to types of records that may be used to meet requirements, including records that demonstrate the prevention of commingling and contact with prohibited substances as set forth in section 205.272.

3) **Do not require specific reference in the Organic System Plan (OSP) to contracted transporters or haulers.** Two certifying agents, a grain distributor, a milk processor, and a trade association opposed requiring inclusion of the specific identification of all haulers and transporters in the OSP of the producer or buyer. They felt this was unnecessarily burdensome because it is difficult to predict who the transporter will be given fluctuations in the availability of transportation when organic product may be ready to sell. The comments stated that it would be more practical to include the standard operating procedures that are followed for all haulers and transporters, rather than specifying the specific haulers and transporters. In response, we removed the language requiring a direct reference in the OSP. Certified operations must keep sufficient records to identify the contracted companies they used as part of their annual certification assessment. Furthermore, in accordance with section 205.272, certified operations should include procedures used to verify prevention of contact with prohibited substances and commingling with nonorganic products in their OSP.

4) **Phase-in period requested.** Certifying agents requested an eighteen month phase in period, in order to provide enough time for operations who handle organic hay or straw to become certified. This guidance is effective on January 22, 2014. However, we find that an eighteen
month transition period is reasonable to ensure that those affected by the clarified policy can make the necessary adjustments.

- **Changes Requested But Not Made**

1) **Define “enclosed in a container” to mean impermeable with a tamper proof seal.** A number of certifying agents requested that we clarify that the exclusion from certification described at section 205.101(b) applies only to products that are enclosed in tamper-proof, impermeable containers. While we recognize that these types of containers and sealing systems are an important tool for prevention of contamination and loss of integrity for some distribution systems (e.g. rail cars hauling grain and milk tankers), we have not further defined “enclosed in a container” or “packaged”. For example, produce brokers who do not open boxes, repack, trim, re-label or otherwise handle the product are excluded from certification because they handle “packaged” products. Such products do not necessarily use impermeable boxes or seals, but these products are still considered “packaged”. Any change to specify that produce boxes are not considered “packaged” or “enclosed in a container” would require review of the impacts on the produce industry.

2) **Handlers who take ownership should be certified.** A number of commenters, including processors, a trade organization, and certifying agents stressed that brokers, traders, distributors or other handlers that take ownership or are directly paid for unpackaged (i.e., unsealed) organic product should be certified. The comments stated that without such a requirement, there is a gap in the audit trail and the integrity of the product becomes difficult to verify. In the final guidance, we have not specified that ownership determines whether a handler (e.g., broker, trader, distributor) should be certified. The exclusion from certification provided for at section 205.101(b) of the regulations is not dependent on ownership, but is based on whether the product remains enclosed in a container and is not further processed. Therefore, the final guidance specifies that if you handle (i.e., sell, package, or process) unpackaged organic product, and you are not exempt or excluded (per section 205.101), then you must be certified. We have clarified that producers and owners of certified organic products must be able to provide adequate records and audit trail for products shipped via non-certified transporters.

3) **Include a reference to section 205.307 of the USDA organic regulations.** A commenter suggested providing a reference to section 205.307: “Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups).” While this is a related topic, and applies to labeling of all non-retail packaging, it is beyond the scope of this guidance. This guidance focuses on the requirements for certification of packaged and unpackaged products, and does not address labeling.