I. INTRODUCTION
Since the passage of the Organic Foods Protection Act into law in 1990, organic trade has grown to a nearly $50 billion market. Integral to past and future growth is consumer confidence in the integrity of the USDA organic label as the gold standard. Just as integral is trust in the certification services of USDA-accredited certifiers, a third-party system that evaluates the production and flow of products from farm to market.

Under USDA certification, most operations in the organic market are subject to certification. Operations that produce, process, or further handle organic product fall under the scrutiny of certification. Within the system of certification, integrity of the product relies on a strong record trail to transparently verify an organic product has remained intact and been handled in accordance with the regulations. However, certain operations are presently excluded under the current USDA organic regulations (7 CFR 205.101(b)):

- A handling operation that handles products that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation and remain in the same package or container and are not otherwise processed while in the control of the handling operation.
- A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as organic.

The second example above is of less concern as the organic product has essentially reached its end user. However, when a product passes through an excluded handling operation, such as a broker or distributor, a complete and transparent audit trail can become challenging to follow. The regulations require a certified operation to verify organic status by tracing back to the last organic certificate holder. Excluded operations may present gaps in this trail as they fall outside of the scrutiny of certification.

This discussion document seeks to explore a means to strengthen these audit trails by further clarifying what operations are excluded from certification. It also seeks to clarify the requirements of labeling bulk packages and containers, as well as what constitutes an enclosed package or container.

II. BACKGROUND
With consumer demand and the premium organic receives, market growth has created opportunity for U.S. farmers and businesses. This opportunity continues as U.S. demand now outstrips supply in certain commodity crops such as corn, wheat, and soybeans. With increased demand comes the increase of imported grain and other products.

Much of the imported product passes through at least one—and sometimes many more—handlers, brokers, and distributors excluded from certification. Additionally, fresh produce from both domestic and imported sources often passes through similar entities not subject to certification. Operating outside of certification, these operations may be in compliance but present a gap in maintaining strong audit trails and transparent recordkeeping.
At the Fall 2010 NOSB meeting, the NOSB passed a recommendation entitled *Clarifying the Limitations of 205.101(b)*. This recommendation asked the National Organic Program to articulate their interpretation of existing regulations with respect to specifying those handling activities that are inside and outside the scope of §205.101(b), thereby implicating handling operations undertaking those activities and their eligibility or ineligibility, respectively, for exclusion from mandatory organic certification. Specifically, the NOSB recommended the following:

This notice is provided to inform the general public and interested parties that the National Organic Program (NOP) staff has determined that the limitations to the applicability of §205.101(b) have not been adequately observed and that a number of uncertified handlers have been operating in a manner inconsistent with 7 CFR Part 205 and the National Organic Program.

Handling operations selling or otherwise representing (organic) commodities such as grains, soybeans, hay, or cattle and commonly referred to as brokers, traders, or distributors of those commodities, are not excluded from the requirements of 7 CFR Part 205, including but not limited to organic certification, unless such an operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and
(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

Hay is typically sold or transported in bales of various sizes and configurations on trailers without packaging; cattle are sold on the hoof in trailers. These activities are inconsistent with §205.101(b)(1)(i). Brokers, traders or distributors of such organic goods are therefore required to be certified organic operators, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.

Commodities such as grains and soybeans are typically not packaged and are received from one container or vessel and transported in another container or vessel; this is inconsistent with §205.101(b)(1)(ii). Brokers, traders or distributors of such organic commodities are therefore required to be certified organic operations, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.

Handlers currently engaged in brokering, trading or distribution activities in a manner inconsistent with §205.101(b) are not in compliance and may be subject to penalties and fines as per §205.100(c)(1).

In February 2012 and July 2013, the Office of Inspector General (OIG) conducted audits of the NOP. The OIG audits stated that the NOP needs to ensure that organic milk is not coming into contact with prohibited substances while being transported. In OIG’s recommendations, it stated that the NOP should ensure that transporters are either certified or included in the responsible parties’ Organic System Plan (OSP).
In response to this finding and the NOSB recommendation, the NOP, in January 2014, finalized guidance entitled Certification Requirements for Handling Unpackaged Organic Products as NOP 5031, which is a part of the Program Handbook. This document provided guidance to clarify the following:

In regards to 205.101(b)(1), An operation is excluded from certification if:
- It only handles organic products that are enclosed in a package or container;
- The products remain in the same package or container for the entire period handled; and
- It does not process organic products.

In other words, the excluded operation must receive certified organic products in wholesale or retail containers and distribute them in the same wholesale or retail containers without opening, reconstituting, altering, repackaging, processing, or relabeling the products.

The guidance goes on to describe several types of operations that don’t require certification, operations that are excluded (don’t need to be certified), and operations that are not excluded (need to be certified):

Examples of operations that are not required to be certified:
- Transportation companies that move certified organic hay or straw (wrapped or unwrapped) or milk from a certified organic farm to a certified organic buyer or processing facility;
- Transportation companies that transport certified organic grain from certified operations to a certified handling facility; and
- Transportation companies that move certified organic livestock from a certified organic farm to a certified organic slaughter facility.

And:

Excluded examples (those that do not need to be certified):
- Wholesale distributors, brokers, and traders that sell boxed or otherwise sealed containers of certified organic products (e.g., sealed tote bags, 55 gallon juice drums, boxed cereal, milk in cartons);
- Trucking or other transportation companies that transport boxed or otherwise sealed containers of certified organic products; and
- Produce handlers who do not open, repack, trim, or re-label certified organic products (e.g., bagged salad greens, boxed produce).

As well as examples of non-excluded operations (those that must be certified):

- Operations that handle certified organic hay or straw (wrapped or unwrapped) by combining or splitting loads or lots;
- Operations that handle unpackaged grain (including combining or splitting loads or lots), package, or otherwise handle the product other than for transport; and
- Fruit and vegetable wholesalers that package or label containers of certified organic produce for sale as organic.

The program also published NOP 5031-1 *Response to Comments Certification Requirements for Handling Unpackaged Organic Products*. In this document, there is a discussion of changes requested but not made to Guidance NOP 5031. Some of these changes requested but not made are as follows:
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 tamperproof, 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.

Recent press revealed conventional product fraudulently sold as organic. Investigations conducted by the NOP have since shown at least one instance of fraudulent trade took place within the scope of certification. This news has made national headlines and has been raised in Senate Agricultural Committee hearings. It is important that consumers are confident in the integrity of the NOP control system, and it is prudent to re-review rules and guidance about excluded operations. Clarification of what operations are truly exempt from certification, the requirements of labeling bulk packages and containers, and what constitutes an enclosed package or container can aid in overall integrity and greater transparency in the supply chain.

III. RELEVANT AREAS OF THE RULE
§205.2 Terms defined.

**Bulk.** The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.
Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

§205.101 Exemptions and exclusions from certification.

(b) Exclusions. (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in §205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in §205.272; and

(ii) The labeling provisions of §205.310.

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

§205.201 Organic production and handling system plan.

(a)(6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§205.303 Packaged products labeled “100 percent organic” or “organic.”

(b) Agricultural products in packages described in §205.301(a) and (b) must:

(1) For products labeled “organic,” identify each organic ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient
statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§205.306 Labeling of livestock feed.
(b) Livestock feed products described in §205.301(e)(1) and (e)(2) must:
(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

§205.401 Application for certification.
A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:
(d) Other information necessary to determine compliance with the Act and the regulations in this part

§205.406 Continuation of certification.
(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:
(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

NOP Guidance 5031 Certification Requirements for Handling Unpackaged Organic Products

NOP 5031-1 Response to Comments Certification Requirements for Handling Unpackaged Organic Products.

IV. DISCUSSION
This discussion will seek to build upon the scope and applicability of NOP 5031. Readers should refer to this document to understand why transport operations that do not sell, label, or repack organic product do not require certification. Additionally, if not specifically clarified in this proposal, current guidance in NOP 5031 should remain. For example, NOP 5031 makes clear that operations involved in the sale of unenclosed product need to be certified. We agree with this interpretation, and such guidance should remain in place.

Upon further review of standards and guidance, the NOSB suggests the following clarifications to NOP Guidance 5031 to further strengthen organic integrity in the supply chain.

An operation is excluded from certification if:
- It only handles organic products that are enclosed in a package or container;
- The products remain in the same package or container for the entire period handled; and
- The package or container is labeled as “organic”. When labeled as “organic”, products must also contain the “certified organic by” certifier statement and name the handler and ingredient list (if applicable).
- It does not process organic products
The NOSB finds these additional recommendations are compliant with the standards as currently written and help to maintain organic integrity by limiting loopholes in supply chain documentation and labeling. This would clarify the following:

To be exempt, product must not only be enclosed in a package or container, but that package, container, or product must be labeled as “organic” and include the “certified organic by” certifier statement next to the name of the handler, as well as an organic ingredient list (as applicable). We find the labeling of product or containers to be required based on the text of §205.101 (b)(1). This section states the exemption only applies to operations or the portion of the operation that sells “organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” …” The requirement that products be labeled makes fraud, commingling, and contamination more difficult given the clear statement to all who come into contact with the product. Furthermore, §205.303 Packaged products labeled “100 percent organic” or “organic”, requires that packaged production labeled as organic also “identify each organic ingredient in the ingredient statement with the word “organic”; “below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *;” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product” [emphasis added]. For livestock feed, similar requirements are outlined in §205.306. These additional labeling requirements are referred to as “accompanying requirements” for the remainder of this document.

The term label is defined by the NOP in section 205.2:

**Label:** A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed or graphic material which contains only information about the weight of the product.

The definition makes the elements of a label clear. To be a label it must be “written, printed or graphically displayed” and must meet one of the following elements:

- Be on the immediate a container, or
- Affixed to the agricultural product, or
- Affixed to a bulk container containing an agricultural product [applies to retail only, see bulk below]

Bulk is also defined and is clearly limited to retail sale situations. Section 205.2 defines bulk as “the presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased.” Since bulk labeling only applies in the retail environment, handlers of unpacked and unlabeled products in a non-retail environment must meet one of the other elements (a label on the immediate container or affixed to the agricultural product) to be considered labeled and thus eligible for exemption.

Operations involved in the sale and distribution of retail-labeled organic products would be exempt if such products were already packed, remained in the same packaging, and were not further processed or packaged. This remains true regardless of how the non-retail containers containing retail-labeled products are packed. However, such non-retail containers must comply with the requirements of §205.307, and retail-labeled product must comply with §205.303. Similarly, operations involved in the sale of labeled and packaged organic livestock feed products would be exempted if such products were already packed, remained in the same packaging, and were not further processed or packaged; however, such packaging would need to comply with §205.306.
This interpretation does not require transport operations that do not sell, package, or process (such as rail cars of grain or tankers with liquid products) to be certified. Both operations that load and unload organic products into the rail car/tanker would need to maintain proper audit trail documentation of the organic products they receive and package (loading/unloading), including documenting that organic integrity was maintained throughout transit. In the example of a rail car/tanker, the rail car or tanker itself would be considered the container, so transit and physical handling of the rail car/tanker itself would not need to be certified. However, operations involved in the loading and unloading of product into the rail car/tanker would need to be certified since the §205.101(b)(1)(i) and (ii) exemption only applies when the products “are packaged or otherwise enclosed in a container prior to being received or acquired by the operation, and remain in the same package or container and are not otherwise processed while in the control of the handling operation.” Additionally, the rail car or tanker would also need to be physically labeled as organic with the accompanying requirements for any operation in the supply chain that is selling the product in order to be exempted from certification. If the rail car or tanker is not labeled, then any operation involved in selling, packaging, or processing would need to be certified since they did not meet the definition for exemption; this would include brokers/traders who sell these products regardless of their ownership of the product. We find it prudent for the NOP, under the authority of §205.401 and §205.406, to require that the same labeling information be included on packing slips as necessary to determine compliance with the regulations during audits. This would be an additional requirement and cannot be completed in lieu of physically labeling the product/container.

If products were packed and remained packed in discrete containers like sacks, boxes, pails, drums, totes, etc. and labeled as organic with the accompanying requirements, then operations involved in the product’s sale, but not processing or packaging, are exempt operations per §205.101(b)(1). However, in this case, operations purchasing or receiving these products for further processing or packing would need to maintain audit trial documents that verify the organic compliance and integrity of the product as labeled. If the same containers were not labeled as organic with the accompanying requirements, then operations involved in the sale of the same product packed in the same containers would need to be certified since they do not meet the “labeled” requirement of §205.101(b)(1). In this case, the selling party would be the same as the party providing evidence of organic certification. Operations purchasing or receiving these products for further processing, packing, or sale would need to maintain audit trial documents that clearly demonstrated that the selling party is certified organic.

V. RECOMMENDATIONS

The NOSB recommends the NOP make the following change to Guidance document NOP 5031:

1. Revise to make clear that exemption only applies to packaged and labeled product:
   An operation is excluded from certification if:
   • It only handles organic products that are enclosed in a package or container;
   • The products remain in the same package or container for the entire period handled; and
   • The package or container is labeled as “organic”. When labeled as “organic”, products must also contain the “certified organic by” certifier statement and name the handler and ingredient list (if applicable).
   • It does not process organic products

2. Revise to make clear that unlabeled, unenclosed produce handlers in a non-retail environment must be certified.

3. Provide additional examples of operations that need to be certified and those excluded. An example of a template that can be expanded upon is provided in Attachment A.

4. Provide additional training to certifiers and certified handlers on proper ways to verify that organic certification documents of purchased products matches product as labeled when
5. Provide additional guidance to certified handlers and certifiers on proper audit trail documentation for purchases of unpackaged, unlabeled product from certified operations. Such documentation must be sufficient to connect sale, receipt, and integrity of unlabeled product. Certifiers should be trained on how to audit to this requirement.

6. Include in the accreditation audit of certifiers a verification that this policy is properly interpreted by the certifier.

VI. REQUEST FOR PUBLIC COMMENT
While it is uncommon for the subcommittee to seek questions in a proposal, the NOSB believes action is needed urgently to further ensure the integrity of organic products in the marketplace and maintain continued consumer confidence. The NOSB believes the NOP will be able to make any needed modifications to this NOSB recommendation based on a summary of the comments received when the NOP publishes draft guidance.

The NOSB is requesting public comment from the community on these clarifications, implementation by certifiers, and impacts on existing trade. Please respond to the following questions, as well as provide any other information that would be helpful in moving this issue forward:

1. What negative impact might there be on the trade and movement of organic product with these clarifications?
2. What economic impact might there be based on these clarifications?
3. What impact will these clarifications have on maintaining organic integrity?

Subcommittee vote
Motion to approve this proposal on excluded operations in the supply chain
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 4 No: 0  Abstain: 0  Recuse: 0  Absent: 1

Approved by Scott Rice, CACS Chair, to transmit to NOP August 29, 2017
### Attachment A – Template for clarification

<table>
<thead>
<tr>
<th>#</th>
<th>Handling Action of operation</th>
<th>Product already enclosed in a container?</th>
<th>Product already labeled organic?</th>
<th>Does Operation need to be certified?</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Process a product</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td>Bakery making bread</td>
</tr>
<tr>
<td>2</td>
<td>Package a product</td>
<td>n/a</td>
<td>n/a</td>
<td>Yes</td>
<td>Labeling blank cans of already packed soup</td>
</tr>
<tr>
<td>3</td>
<td>Sell a product</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Brokering Grains (whether or not taking physical possession) or Fruit distributor where fruit is in open trays and fruit itself is not stickered</td>
</tr>
<tr>
<td>4</td>
<td>Sell a product</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Distributor of enclosed product that is not specifically labeled as organic.</td>
</tr>
<tr>
<td>5</td>
<td>Sell a product</td>
<td>No</td>
<td>Yes</td>
<td>No – but still comply with 272</td>
<td>Fruit distributor where fruit is in open trays and fruit itself is stickered</td>
</tr>
<tr>
<td>6</td>
<td>Sell a product</td>
<td>Yes</td>
<td>Yes</td>
<td>No – but still comply with 272</td>
<td>Distributor of packed and organically labeled product in discreet enclosed containers.</td>
</tr>
<tr>
<td>7</td>
<td>Transit a product</td>
<td>n/a</td>
<td>n/a</td>
<td>No – but still comply with 272</td>
<td>Operations that load and unload unlabeled products would need to be certified as required under #4. However, the operation transporting would not require certification.</td>
</tr>
</tbody>
</table>

### Attachment B

**NOP 5031: Guidance - Certification Requirements for Handling Unpackaged Organic Products**

### Attachment C

**NOP 5031-1: Response to Comments - Certification Requirements for Handling Unpackaged Organic Products**