



## **AMERICERT INTERNATIONAL**

(Formerly known as OIA North America)

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### **GUIDANCE ON THE USE OF INTERNAL ASSIGNED NOT LIKELY TO REPEAT LOT NUMBERS FOR INGREDIENTS AND PRODUCTS RECEIVED**

**v.071622**

#### **1. The Importance of unique internal assigned lot numbers**

For certified organic handlers, Americert has a policy that products or ingredients received by an organic operation must be assigned, by the handler, at receiving of the shipment, a unique not likely to repeat lot number which is different from the supplier assigned lot number and which is recorded and subsequently used in records relevant to the handling and processing of those ingredients and products. It's worth emphasizing that this internally assigned lot number is distinct and different from any supplier assigned lot number and both are recorded in the receiving records (which creates the linkage between these two numbers).

For operations encountering this requirement for the first time, questions (and comments) abound. For instance operations frequently want to know why this is required, where in the regulation this requirement can be found, and what is the best and easiest way to address this requirement.

#### **2. What is the scenario which is being addressed by requiring a unique not likely to repeat internally assigned lot number required?**

The factual reason why this requirement exists is that it happens (and more often than you may think) that an organic operation receives more than one shipment of an ingredient or product from an organic supplier which carries the same lot supplier assigned lot number on more than one shipment. Of course, that this would occasionally occur is predictable because it would be a rare fluke that the organic handler receiving organic products or ingredients would have purchased the entire specific lot of an organic product or ingredient and in fact it is common that the lot number assigned by the supplier covers a range of shipping events and is unique to the production event, not the shipping event. In such cases, it is possible that an organic handler will receive more than one shipment that carries the same supplier assigned lot number. This is an example of multiple shipments with the same lot number. There is also the converse situation as well--situations where a single shipment from a supplier includes more than one supplier assigned lot number. Both of these scenarios are a problem under the USDA NOP organic standards as described in the next section.

#### **3. What is the regulatory basis for the requirement of assigning a unique non-repeating internally assigned lot number?**

Operations sometimes ask to see the specific mention in the regulation of the requirement to use a unique non-repeating internally assigned lot number. A quick search of the regulation will show that there is no specific reference in the regulation to a unique non-repeating internally assigned lot number. This is because in most cases the regulation, rather than impose detailed specific requirements for each situation which may occur in the actual operations of certified organic handlers or growers, instead lays out broad principles of risks which must be avoided and certain functionality of the organic system plan which must be achieved. '

Note for instance that the regulation does not mention the use of quaternary ammonium sanitizers on food contact surfaces either, yet it is almost universally recognized that quat based sanitizers may not be used on food contact surfaces unless there is a specific and documented process of adequate removal of quat residues after use (usually involving the use of quat test strips capable of registering a zero ppm residue). In the case of the quat products and the restrictions on use, there is no mention of quat products in the regulation and the requirements for the use of quat products arise not from a specific mention in the regulation but from broader concerns with protecting organic integrity which is addressed broadly in section 205.272 of the organic standards (Commingling and Contact with Prohibited Substances Prevention Practice Standard).

The requirement to use unique non-repeating internally assigned lot number in reference to individual shipments of organic ingredients or products upon receipt similarly is not specifically mentioned in the regulation because it



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arises from other specific principles which organic operations must abide by and specific functionality that organic control systems must demonstrate, both of which are described in the regulations. In the instant case, these requirements are most broadly contained in section 205.2 of the organic standards and section 205.103 of the organic standards.

Section 205.103 (Recordkeeping by certified operations) describes the recordkeeping requirements of certified organic operations and requires that operations maintain records of all transactions and activities of the operation which demonstrate compliance with organic requirements and which are sufficiently detailed as to be readily understood and audited. It is worth noting the term “audited” as this becomes quickly relevant in determining the required organization of records including the level of detail and the specific functionality required. Records must have the level of detail and proper organization to allow records to be “audited” and not only that but to be “readily” understood and audited. So what does the term “audited” mean in the context of organic certification? The answer to this question could be as short as a paragraph or as long as a book (depending on the level of detail one wished to pursue). In the current treatment we will stick to the broadest description on the level of principles and functionality.

Section 205.2 of the USDA NOP organic standards is titled “Terms defined” and provides the specific regulatory definitions for certain terms used in the regulation. Of interest to us is the definition of the term “audit” as it appears in the phrase “audit trail”: *Audit trail. Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as “100 percent organic,” the organic ingredients of any agricultural product labeled as “organic” or “made with organic (specified ingredients)” or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.*

The NOP has issued instruction, guidance, and training on how to conduct audits of the recordkeeping system of organic operations, such as in NOP 2601 (Instruction on The Organic Certification Process) where it describes (section 3.4) in general terms the recordkeeping functionality which must be audited during onsite inspections: “Evaluation of the recordkeeping system and verification of activities through appropriate records; . . . Reconciliation of the volume of organic products produced or received with the amount of organic products shipped, handled and/or sold, also known as trace-back audits or in out balances”.

Further, in instances where organic products or ingredients are determined to be contaminated with prohibited substances, sections 205.661, 205.670 and 205.671 of the NOP regulations and NOP Instruction 2613, requires Americert to investigate the cause of contamination and whether or not the contamination was willful.

In Americert’s determination it is the confluence of these concerns, principles and requirements which supports the specific requirement for organic handlers to use a unique non-repeating internally assigned lot number as follows:

- Section 205.2 requires that audits must be conducted by Americert and that among the items which must be reviewed is the sufficiency of the operation to clearly record the source, transfer of ownership, and transportation of organic products and ingredients.
- NOP Instruction 2601 further elaborates that records maintained by operations must be sufficient to allow Americert to reconcile the volume of organic products produced or received with the amount of organic products shipped, handled and/or sold.
- Section 205.103 requires that operations maintain records that record all transactions and activities of the operation, that demonstrate compliance with organic requirements and which are sufficiently detailed as to be readily understood and audited.



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- The term “readily” is not defined in the regulations and therefore its meaning in the regulation is the same as its common definition: without delay or difficulty, easily.
- The requirements of responding to pesticide residue contamination (sections 205.670-671 and NOP Instruction 2613) and to conduct investigations of noncompliance (generally) and in response to complaints (section 205.661) requires Americert to determine the cause of the contamination; Because that cause may originate at the supplier, occur in transit, or occur after receipt by the certified organic handler, it is necessary to be able to associate lot numbers with their specific shipping history.

When all of these requirements, concerns, principles and required functionality are seen in the context of actual audit and recordkeeping activities, Americert has determined that these support a requirement that organic handlers assign unique non-repeating internally assigned lot number to incoming shipments.

#### 4. Common Objections or Questions About this Requirement:

Operations that object or question this requirement typically raise three arguments---all of which Americert rejects:

A. The operation has never encountered a situation where the supplier assigned lot number spans multiple shipments or a situation where the shipment comprises two different supplier assigned lot numbers: Americert accepts that this may be true, but it misses the point. The situation does occur, even if this particular operation has not encountered it personally. Americert is in a better vantage point to determine whether or not such occurrences happen frequently enough across certified organic operations such as to warrant a preventative measure and we have determined that the situation is both sufficiently common as to warrant a preventative measure and has significant enough consequences (the inability to determine causes of contamination events) that such a preventative measure is required even if the occurrences were rare (which they are not).

This system wide risk analysis is the basis for many different laws, rules, and regulations in many domains, not just organic certification. A case in point is the requirement to wear a seatbelt when driving an automobile; I personally have never been in car accident where wearing my seatbelt was necessary to prevent injury. However, that does not mean that such risks do not exist on a systems wide basis for drivers generally; Likewise my prior good luck does not insulate me from the risk of injury in future accidents and so the rule requiring me to wear a seat belt addresses both a valid system wide concern and is designed to protect me individually in a situation (a car accident with injuries) that is not rare, even though it is absent from my own direct personal experience.

B. If there was a situation where there was a problem with an ingredient, I would recall the entire production associated with that lot number and not limit it to any specific shipment of ingredients or products received, so I don't need to be able to distinguish between different receiving events for the same supplier assigned lot number: Once again, this misses the point. Although Americert commends this approach, and while this approach does protect consumer expectations and their confidence in the organic brand, it fails to serve Americert's, the NOP's, and other certifying agents' general systems approach and the certifying agent's specific regulatory responsibilities. The prevention of fraud and contamination in the organic supply chain is a systems wide responsibility. The NOP expects certifiers to investigate the specific causes of contamination so the causes can be corrected (both in individual instances and in a broader systematic context) and so that certifying agents can determine if such instances of contamination are willful (either through purposeful fraud or knowing noncompliance with the organic regulations). To this end, the NOP requires certifying agents to cooperate and share information in investigations, audits, and other compliance activities and requires certifying agents to determine with specificity the cause of incidents of contamination. In order to be able to determine the cause, it is necessary to look at the individual history of a shipment, not just a lot number, because the contamination could arise in transportation or after receipt by the certified organic handler. Only when individual shipments are



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associated with internally assigned unique non-repeating internally assigned lot numbers, can individual shipment histories and the history of how individual shipments were handled after receipt be analyzed with sufficient granularity to pinpoint causes of contamination when those occur in transit or after receipt by the organic handler.

C. I don't see in the regulation where this specific requirement is explicitly listed: See section 3 of this document.

D. This seems to be above and beyond the traceability and recall requirements which are based on food safety:

Yes, they are. They derive from different regulations and different regulatory concerns. See section 3 of this document for the relevant organic certification based regulatory basis and the specific regulatory concerns.

### 5. How to Comply with this Requirement:

There are many ways to comply with this requirement and Americert will accept any method which allows the granular association of supplier assigned lot numbers with the specific receiving event from a single shipment. Well know and simple methods of complying with this requirement are as follows:

A. Use the supplier assigned lot number with an additional prefix or suffix added: The addition of a simple suffix or prefix to the supplier assigned lot number is an easy and widely used method of complying with this requirement. Such prefix or suffix may be serially assigned or derive from the date:

An operation, when it notices that a supplier assigned lot number has repeated in a subsequent shipment could add a simple single digit prefix or suffix to the supplier assigned lot number to create the new unique internally assigned lot number. Example: The handler receives a shipment of an ingredient which carries the supplier assigned lot number of 123. The handler has procedure for identifying the fact that this supplier assigned lot number has reoccurred in a subsequent shipment. Because this is the 2<sup>nd</sup> time the handler has received this lot number from a supplier, it assigns the internal lot number of 123-2 to the shipment and records the internal assigned lot number and the original lot number in the receiving log in order to create a link between them. All subsequent references to a lot number in records for this shipment of ingredients or products uses the lot number 123-2. Variations on this approach use a prefix or suffix that records the Julian date of receipt of the product, or even some derivation of the date of receipt (e.g. the day of the month received (123-15, etc) or the day and month of receipt (123-0101)).

(Note that an astute observer might note that these practices do not completely eliminate the risk that shipments and lot numbers cannot be associated as there are scenarios where for example in using the day of the month system, there still exists the theoretical possibility that the same lot number will be received more than once and received on the same day in the different months. However, this is considered sufficiently unlikely that the risk has been reduced by an order of magnitude and is considered sufficiently addressed even if not perfectly prevented).

B. Use of an Entirely Different Internally Assigned Lot Number: In this approach, the internally assigned lot number does not have an intrinsic relationship to the supplier assigned lot number as no part of the internally assigned lot number derives from the supplier assigned lot number. In this system, the internally assigned lot number derives from the date received or is serially assigned. For instance, the internal assigned lot number may be the date of receipt in any format that is not likely to repeat (e.g. the day of receipt, month and day or the Julian date). Both this internal assigned lot number and the supplier assigned lot number are recorded in the receiving log, creating a link between the two. All subsequent references to a lot number in records for this shipment of ingredients or products uses the internal assigned lot number.

Note that in this system, an internally assigned lot number only has to be unique in reference to that product or ingredient, not across products or ingredients. For instance a shipment of organic sugar and organic lemon juice



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received on the same day can be assigned the same lot number and this not considered repeating because the identity of the ingredient itself distinguishes the two ingredient lot numbers; In other words, there would not be instances where organic sugar and organic lemon juice would be used interchangeably in manufacturing, packing, or shipping and accordingly, the internally assigned lot numbers are distinguishable by reference to the product or ingredient itself (e.g. a production record records the use of organic lemon juice, water, and organic sugar, and then lists the internal assigned lot number for the ingredient and in such instances there is no risk of confusing which received shipment was used because the identity of the ingredients are distinct and not fungible).

Other methods of creating a unique non-repeating internally assigned lot number are acceptable as long as they serve to reasonably link ingredients to the date of receipt. Please contact Americert is you are unsure if your method is compliant.