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April 3, 2020

Ms. Michelle Arsenault, Advisory Committee Specialist
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. S.W.
Room 2642-S, Mail Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-19-0095

Handling Subcommittee Discussion Document: Ion Exchange Filtration

Dear Ms. Arsenault,

Thank you for the opportunity to comment on the National Organic Standards Board (NOSB) Handling Subcommittee Discussion Document on ion exchange filtration. As Oregon Tilth shared in comments to the National Organic Program (NOP) last year, ion exchange technology is a unique and essential technology for the production of many organic products that is also NOP compliant and widely accepted by organic certification agencies as a filtration method. We are specifically concerned about the question outlined in the discussion document of whether ion exchange filtration causes a chemical change in the final product, and urge the Board to carefully consider the impacts of this perspective on other technologies and materials commonly used in organic production.

Chemical vs. Mechanical Filtration

The Handling Subcommittee is seeking to clarify whether or not ion exchange filtration causes a chemical change in a product. We feel it is critical to note that whether or not the product undergoes a chemical change has never previously been a compliance point when evaluating a product's ability to meet NOP Regulations. That said, our understanding is that the technology does not impart a chemical change on the product filtered using ion exchange technology.

Ion exchange technology selectively purifies materials by mechanically filtering out target ions and exchanging them with an inert ion, but does not change the standard identity of the product itself. The source of these inert ions used to recharge the exchange resins are required to be allowed National List materials (e.g., sodium, chloride, calcium). The ions to be exchanged are attached, by electrostatic force, to the resin that is immobilized within the exchange column — an effect similar to sticking a balloon to a wall via static electricity. When the product is run through the column the target ions in

the product (e.g. arsenic, sulfate, chloride) are more strongly attracted to the resin media and displace the inert ion that was placed in the column prior to filtration. At the end of this process, the target ion is removed and the inert ion used to "charge" the exchange column ends up in the final product in its place.

Given the above understanding, many certifiers (OTCO included) have allowed ion exchange technology to be used in the production of organic products given the following justifications:

- The immobilized resin (which contacts organic product but does not itself end up in organic product) does not serve an active function in the organic product and does not change the final food product as consumed, per the FDA (FDA Guidance for Industry, II(2)(C)(1)) and, therefore, would not require material review or addition to the National List. **Requiring food contact substances that do not functionally change the final product to be petitioned and added to the National List would be a major and fundamental change to how the organic regulations have been interpreted and implemented.** These resins are designed to have a long use lifetime and be repeatedly cleaned and reused.
- The materials used to recharge the ion exchange columns must be allowed for organic production, such as National List materials (e.g. sodium chloride, calcium chloride, sodium hydroxide). As outlined in the description above, these are the materials that have a functional effect in the ion exchange system and these are the ions that remain in the final product. This system is comparable to a filtration system using diatomaceous earth or perlite (both National List materials allowed for filtration, similar to the recharge materials mentioned above) and the filter frames and filter pads that hold them in place (not required to be on the National List, functionally similar to the column and resins in question for ion exchange).
- The cleaning and maintenance of the ion exchange column and media must be accurately reflected in the operator's organic system plan and must be consistent with the practices outlined in the organic regulations.
- The NOP has stated how to review ion exchange filtration and the compliance points involved in training and guidance given to certifiers in an NOP Questions and Answers page and the 2010 online training (see attached references). These points are outlined in the above bullet points and were adopted by OTCO and other certifiers as outlined in historical training and guidance provided by the NOP.
- Several nonsynthetic materials listed at 205.605(a), including citric acid, glucono delta-lactone, lactic acid, and glycerin, include ion exchange as part of the production process outlined in the Technical Evaluation Reports were classified as non-synthetic by the NOSB and NOP. The Technical Evaluation Reports for these materials specify that the ion exchange is used for purification or filtration of these products to the necessary standards and that it does not functionally change the end product (i.e. no chemical change of the material).

Uses in Organic Food Production
Ion exchange filtration is an essential technology for several types of ingredients and common food products historically certified organic (e.g., milk, juice). While some products may be able to use alternative technologies to perform similar filtrations, there are several products which require ion exchange filtration in order to make a safe or functional product. For example, in rice syrup products, ion exchange is used to remove heavy metals which occur naturally in rice (e.g. arsenic) and are concentrated by the syrup manufacturing process. Ion exchange is essential for concentrated juice production in removing certain bittering components that would prevent a saleable product. Furthermore, if it is determined that ion exchange technology causes a chemical change then the classification of several materials, as mentioned above, already voted on and listed as nonsynthetic on 205.605(a) would no longer be accurate.

Summary
In future discussions and assessments of ion exchange, Oregon Tilth asks the Handling Subcommittee to please take into consideration the history, function, uses, and essential nature of ion exchange filtration outlined above. This technology is used widely in food production and the prohibition or further restriction of its use outside of the requirements imposed above per the National Organic Program training would likely have a drastic impact on organic food production.

Thank you for your time and diligence in addressing this issue in a way that is practical and within the requirements of the regulation.

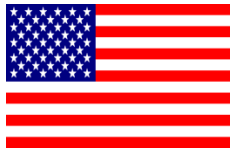
Respectfully submitted,
Oregon Tilth

Oregon Tilth is a leading certifier, educator and advocate for organic agriculture and products since 1974. Our mission to make our food system and agriculture biologically sound and socially equitable requires us to find practical ways to tackle big challenges. We advance this mission to balance the needs of people and planet through focus on core areas of certification, conservation, policy and the marketplace.

Attachments:
- NOP Online Training
- Questions & Answers page
- 2019 Comments to the National Organic Program

Certification Issues
Mark Bradley

Accreditation and International Activities Division

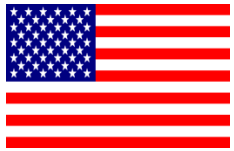


Background

New Canadian Organic Regime (COR) became effective June 30, 2009.

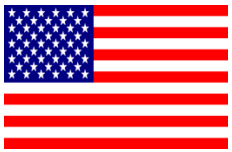
US and Canadian organic producers and handlers asked USDA and CFIA to negotiate a trade agreement to:

- Avoid disruptions in trade between the U.S. and Canada.
- Avoid the need for meeting two standards.
- Avoid the need for dual certification to both the U.S. and Canadian standards.



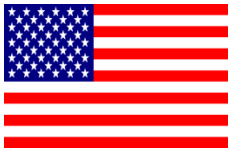
Agreement

1. Provide a list of certifying agents approved to certify products under the agreement.
2. Notify each other of changes to regulations.
3. Respond to complaints regarding products certified to our standards.
4. Ensure compliance with “critical variances.”



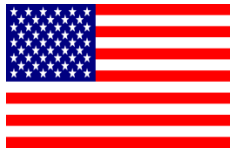
Critical Variances

- Canadian Organic Products sold in U.S.
  - Livestock products may not be produced with the use of antibiotics.



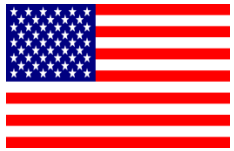
Critical Variances

- NOP Products Sold in Canada
  - No Chilean Nitrate
    - Excludes processed products
  - No hydroponics or aeroponics
  - Livestock stocking rates
    - U.S. and Canadian letters state different requirements.
    - NOP will provide clarifications



Other Issues

- Wine
  - Must be labeled in compliance with requirements in country where it is sold.
- Maple Syrup
  - Still under discussion.
  - Not listed as a critical variance.



Product ID

- Products shipped under the agreement are to be identified by a statement verified by the ACA on shipping manifests, bills of lading, contracts, transaction certificates, etc.

"Product complies with U.S. – Canadian Organic Equivalence Agreement"

Organic Systems Plans

Situation: Reviews of certifying agents have shown that some ACAs are not ensuring that the OSP is complete and demonstrates compliance with the NOP regulations prior to scheduling and conducting onsite inspections.

- OSP is not reviewed during the inspection.
- Organic producer does not have current copy of OSP.
- OSP does not provide complete list of materials used by producer as per 205.201(a)(2).

Organic Systems Plans

NOP Guidance:

- Organic system plans must be complete and demonstrate compliance to the NOP regulations prior to conducting onsite inspection.
  - Complete list of materials that the producer/handler plans to use.
- Inspectors are not allowed to complete OSPs for clients or otherwise consult.
- OSP must be available onsite and reviewed by the ACA inspector.
- Certifiers must ensure level of information in OSP is adequate.
  - The OSPs on the ATTRA website are an excellent resource.
  - Be sure attachments provide adequate detail.

Fee Estimates

Situation: Certified operations are complaining that ACA's are not providing either accurate or complete fee estimates.

- Not providing estimates at all.
- Not including cost of inspection in fee estimates.
- Fees go up for some reason.
  - Different inspector is used and additional travel makes cost go up.

Fee Estimates

205.642 – fees must be reasonable, may only charge fees filed with the Administrator, ACA must provide fee estimate, fee schedule must be available to the public.

NOP Guidance

- ACAs must provide complete and accurate fee estimates.
- Cost of inspection must be included in initial and renewal estimates.
- ACAs must ensure inspection resources are available and ensure that inspections can be conducted for the quoted price.

Updated Certificates

Situation: Operators complain that certifiers do not issue certificates in time for sale of early season crops.

- Problem occurs when dates on certificates indicate that they have expired or addendums list crops by year:
  - 2008 alfalfa hay

Updated Certificates

NOP Guidance:

- When certifiers issue dated addendums to certificates, documents must be provided in time for crops to be marketed.
- If delay is due to failure of applicant to submit necessary documents on time, ability to sell new crops or product lines will be delayed.

Accepting Other ACA Decisions

Situation: Review of labels and complaints revealed that some certifiers are approving formulations and labels that they know or should know to be noncompliant. Certifiers are contending that 205.501 (a) (13) which requires certifiers to "accept the certification decisions made by another [accredited] certifying agent."

- Examples
  - Defective labels / ingredient statements
  - Formulations
  - Ag/non-ag determinations
  - Pesticide / inert ingredient compliance

Accepting Other ACA Decisions

NOP Guidance:

- 205.501(a)(13) was designed to eliminate the need for document reviews for products produced by another ACA.
- It does not allow ACA's to ignore the use of ingredients or inputs they know to be in error.
- ACA's should contact the NOP if they find discrepancies with other certifiers.

Changing Certifiers

Situation: There is confusion as to how to move from one certifier to another. Some certified operations simply are allowing their certification to lapse with their current ACA and then they apply to a new ACA. This results in proposed adverse actions being filed by the old ACA, appeals, and sometimes revocation or suspension. Some certifiers are accepting new clients and issuing a new certificate without conducting even a review and approval of their OSP.

Changing Certifiers

NOP Guidance: To voluntarily change certifiers:

- Operations must complete a new application with the new ACA and submit a complete OSP.
- New certifier must review and approve OSP.
- An onsite inspection must be conducted prior to issuing a certificate.
- There is no use-up of labels for this situation.
  - Name of new ACA must appear on product labels.
- Certified operation must surrender old certificate.
- Adverse actions started by original ACA must be continued, surrendering the certificate does not stop the proposed adverse action.

Business Changes

NOP Guidance:

- Accreditation and certification are not transferrable.
- When there is a sale, merger, or transfer of ownership of an ACA, new owner(s) must submit a new application for accreditation, complete a document review, and pass an onsite audit prior to accreditation.
- When there is a sale, merger, or transfer of ownership of a certified operation, new owner(s) must prepare a new OSP, apply for certification, and pass an onsite inspection prior to certification.
- Examples:
  - Change from a sole proprietorship to a LLC.
  - Merger with another certifying agency or other business entity.

Label Approvals

Situation: NOP complaint investigations reveal that ACA's are not reviewing and approving all labels prior to use in commerce.

- Some deficiencies are due to faulty processes.
- Some handlers are not presenting labels to ACA's prior to printing.

Label Approvals

NOP Guidance:

- ACA's must approve all labels before allowing their use in markets.
- ACA's must notify certified operations of this requirement.
- ACA's are responsible for labels they have not reviewed.
  - Must issue notice of noncompliance.
  - Must not allow continued use of labels with serious noncompliance.

Use-up of Labels with Errors

Situation: Compliance reviews revealed that some certifiers are allowing handlers to continue to use up existing supplies of labels with serious errors.

- Serious errors (major noncompliance):
  - Labels which display wrong product category based on formulation.
  - Display of the seal on products that are not eligible.
  - Missing name of certifying agent or other required information.

Use-up of Labels with Errors

NOP Guidance:

- ACA's must not allow use-up of labels with serious noncompliance. No exceptions.
- Certifiers must notify operations of noncompliance as soon as it is identified.

Subcontracting

Situation: Unaccredited certifiers are performing services under another certifier's accreditation.

- Inspectors have been found to be unqualified and some have misapplied the NOP regulations.
- Some subcontracted organization have been denied accreditation.

Subcontracting

NOP Guidance:

- All ACA's must provide a full disclosure of
  - Subcontracting relationships.
  - Inspectors who will be used.
  - Countries where services are provided.

Ion Exchange

Situation: Certifiers are asking if ion exchange is allowed in organic handling. Specific questions are what materials may be used to charge the ion exchange columns.

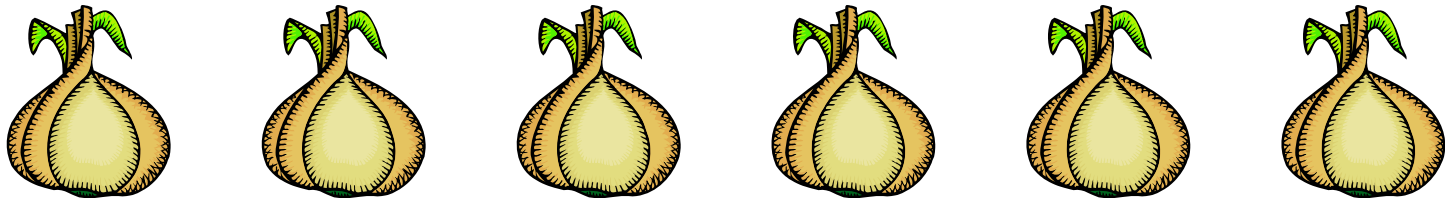
Ion Exchange

NOP Guidance:

- NOP has posted policy that ion exchange technology is allowed, as long as materials used are on the National List.
- For example-
  - Listed items:
    - Sodium hydroxide
    - Sodium chloride
  - Not listed:
    - Hydrochloric acid

Crop Rotation

Situation: We have received multiple complaints about operations changing certifiers because their former certifier would not approve their crop rotation. Some certifiers are allowing double cropping and calling it a crop rotation, with the same crop planted in the same ground at the same time, year after year.



Crop Rotation

NOP Guidance:

- All items in 205.205 Crop rotation practice standard and crop rotation definition must be met.
- "…alternating annual crops on a specific field…in successive crop years so that the same species or family are not grown repeatedly without interruption on the same field."
- Double cropping where the same crop is planted in the same field at the same time in successive crop years does not meet this standard, nor would it likely address the pest management aspect of the standard.
- Many recommendations are for a 3-7 year rotation.

Micronutrient Fertilizers

Situation: NOP onsite audits have shown that certifiers are not requiring testing to be conducted to show that micronutrient fertilizers are needed before approving use.

- Certifiers have asked if regular testing is required.

Micronutrient Fertilizers

NOP Guidance:

- Regulations at 205.601(j)(6) allow micronutrients, but "soil deficiency must be documented by testing."
- Regularity of testing is not prescribed. May be provided on a broad basis by local Extension Specialists.
- Must be included in OSP along with basis for determination of need.
- ACA must ensure that cultural methods have been tried before using synthetic applications.
- No chloride or nitrate forms.

Handling by Exempt Operations

Situation: Some certifiers are applying the $5,000 exemption to handlers that process products for subsequent use in certified operations.

- Specific examples:
  - Grain cleaners
  - Slaughter facilities
  - Small hay producers

Handling by Exempt Operations

NOP Guidance:

- Operations that process products for sale or use as ingredients identified as organic are not included in the $5,000 exemption for small producers.
- Small hay producers may sell hay as organic (not “certified” organic), but livestock that consume the feed may not be sold as organic.

Questions?

questions and answers

The questions and answers below are categorized by subject matter and will be updated on a monthly basis.

General Topics
Definitions
Applicability
Organic Production and Handling Requirements
Labels, Labeling, and Market Information
Certification
Accreditation of Certifying Agents
National List of Allowed and Prohibited Substances
State Organic Programs
Exporting Organic Products

General Topics

Q: Where can I get a copy of the National Organic Program regulations?

A: You can obtain a copy of the NOP regulations by contacting the NOP through this website.

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Definitions

There are no Questions and Answers for Definitions at this time

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Applicability

Posted 6/26/03
Q: Can salt and water be certified organic under the National Organic Program?

A: No. Salt, in all of its forms, and water can not be certified as organic under the National Organic Program. Only agricultural products produced and handled in accordance with the National Organic Program may be certified as organically produced. Salts are minerals not agricultural products. Water is a chemical substance used in the production of agricultural products but is not itself an agricultural product. Section 2106(c) (7 U.S.C. 6505 (c)) of the Organic Foods Production Act of 1990, as amended, and section 205.302 of the National Organic Program require the exclusion of salt and water when calculating the percentage of organic ingredients in a multi-ingredient product. Further, National Organic Program sections 205.303(b)(1) and 205.304(b)(1) provide that ï¿½Water or salt included as ingredients cannot be identified as organic.ï¿½

Q: When must organic producers and handlers be certified to continue to market their product as organic?

A: Beginning on October 21, 2002, producers and handlers must be certified by a USDA-accredited certifying agent to sell, label, or represent their products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)." Please see section 205.101 for exemptions from certification.

Q: I am a small farmer. Will I have to be certified?

A: It depends. If your gross agricultural income from organic sales total $5,000 or less annually, you are exempt from certification (see section 205.101(a)(1) of the NOP regulations). Exempt operations must comply with the applicable requirements of subpart C and the labeling requirements at section 205.310 of the NOP regulations.

Q: I am a small processor. Do I have to be certified?

A: It depends. If your gross agricultural income from organic sales total $5,000 or less annually, you are exempt from certification (see section 205.101(a)(1) of the NOP regulations). Exempt operations must comply with the applicable requirements of subpart C and the labeling requirements at section 205.310 of the NOP regulations. For other possible handler exemptions see section 205.101 of the NOP regulations.

Q: I sell less than $5,000 worth of organic product. Can I be certified?

A: Yes. Any qualified agricultural production or handling operation may be certified as an organic production and handling operation. This includes all qualified production and handling operations eligible for exemption or exclusion under section 205.101 of the NOP regulations.

Q: Can non-certified companies use the word "organic?"

A: Producers and handlers that qualify for exemption or exclusion from certification may use the term "organic" in compliance with the labeling requirements specific to their exemption or exclusion (see section 205.101 of NOP regulations).

Q: What type of records would be acceptable to National Organic Program as proof of exempt organic operations showing compliance with the labeling requirements, production requirements, handling requirements, record keeping, audit trail, and non use of prohibited substances.

A: Examples of records to be kept by exempt operations are listed in the preamble of Subpart B, Applicability. Exempt operations must comply with the applicable organic production and handling requirements of subpart C of the national standards and meet the labeling requirements of section 205.310. Therefore, each exempt operation should maintain records which demonstrate compliance with the Organic Foods Production Act (OFPA) of 1990 and the national standards. It is the decision of the exempt operation as to which records it needs to demonstrate compliance.

Q: Are exempt operations subject to National Organic Program (NOP) audit? If so, what fee would be charged to those operations?

A: Yes. Exempt operations that produce or handle agricultural products to be sold, labeled, or represented as "100 percent organic" or "organic" are subject to NOP compliance audits. Costs associated with compliance audits would be borne by the NOP.

Q: How was the gross receipt threshold of $5,000 established? What steps would be necessary to raise the limit?

A: The $5,000 producer or handler exemption in ï¿½205.101(a) of the national standards was mandated by OFPA (7 U.S.C. 6505(d)). Actions necessary to raise the limit of the $5,000 producer/handler exemption would include congressional amendment of OFPA ï¿½6505(d).

Q: Please explain who may use the term organic and how the term is to be used.

A: Any production or handling operation certified according to the provisions of subpart E, Certification, may use the term "organic" (ï¿½205.100). Production or handling operations that are exempted or excluded under ï¿½205.101 may use the term "organic" according to the regulations specified in ï¿½205.310, Labeling; provided, they comply with the production and handling requirements of subpart C of the national standards.

Q: What are the penalties for misuse of the term "organic"?

A: Any operation that knowingly sells or labels a product as "organic", except in accordance with the Act (OFPA) and the national standards, may be subject to a civil penalty of not more than $10,000 per violation and the provisions of 18 U.S.C 1001.

Q: Who will be responsible for the enforcement of the National Organic Program and how will a typical prosecution proceed?

A: USDA, accredited certifying agents, and where applicable, approved State Organic Programs will be responsible for enforcement of the national regulations. Compliance procedures for certified organic operations, accredited certifying agents, and State Organic Programs are specified in sections 205.660 through 205.668 of the national standards.

Q: When a retail establishment markets products supplied from a certified producer, in the event the producer is found non-compliant, will the retailer be subject to any legal recourse from the NOP? Do the same rules apply (to the retailer) for products produced by exempt and non-exempt producers?

A: If a provider of product to a retail food establishment is found to be in violation of the national organic standards and the retail food establishment is not a party to that violation, there will be no action by the National Organic Program (NOP) against the retail food establishment. This holds true for certified producers and handlers as well as those claiming exemption under section 205.101.

Any person, including a retail food establishment, who knowingly sells or labels a product as organic, except in accordance with the OFPA and the national organic standards, shall be subject to a civil penalty of not more than $10,000 per violation.

Products that have entered the channels of commerce before the certified operation's suspension or revocation will not result in a product recall, unless the non-compliance involves a food safety issue. For further information see page 80627 of the national organic standards.

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Organic Production and Handling Requirements

Posted 11/29/05

Q: With Avian Influenza becoming an increasingly serious issue in the poultry industry, what can organic poultry producers and their certifying agents do to help recognize and prevent the spread of this disease?

A: USDAï¿½s Animal and Plant Health Inspection Service has provided guidance to poultry producers, including free range and organic producers, regarding biosecurity considerations for their operations ï¿½ this guidance is found at http://www.aphis.usda.gov/vs/birdbiosecurity/

Integral to the National Organic Program is a management plan for each organic production facility ï¿½ among other things, this plan must address preventative livestock health care practices, including sanitation practices that will be followed to minimize the occurrence and spread of diseases and parasites.

USDA has brought the APHIS biosecurity guidance materials to the attention of its accredited organic certifying agents for their use in working with organic poultry producers.

If it is determined by a producer and certifier that for the health, safety, and welfare of poultry there is need for temporary confinement of birds, provision exists within the National Organic Program for such confinement without a loss of organic certification.

If Federal or State animal health authorities determine that more prescriptive actions are required, organic producers could be required to adhere to those actions.

Posted 1/14/05

Q: If a producer adheres to all aspects of the National Organic Program (NOP), including never utilizing biotech-derived seeds, but a certifying agent tests and detects the presence of biotech-derived material in the crop, is that cropï¿½s status determined to be no longer ï¿½certified organic?ï¿½ And, if so, what in the NOP supports this conclusion?

A: It is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production

standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations (ï¿½205.2ï¿½Terms defined, and ï¿½205.105ï¿½Allowed and prohibited substances, methods, and ingredients in organic production and handling). The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods will not affect the status of the organic operation. As to the status of the commodity, USDAï¿½s position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship. (See page 80556 of the preamble, ï¿½Applicabilityï¿½Clarifications; (1) ï¿½Genetic driftï¿½).

Posted 1/14/05

Q: Do insufficient buffers or barriers that result in unintended contact with a product of genetic modification threaten the farmï¿½s certification or use of the field for the production of organic crops? If an organic producer or handler is found to have not implemented measures necessary to prevent commingling of organic and non-organic products, would that threaten the certification of the producer or handler?

A: In order to become a certified organic operation, a producer must submit an Organic System Plan (plan) to a USDA-accredited certifying agent for approval. That plan must include, among other things, evidence that sufficient buffer zones have been incorporated into the operation to ensure the integrity of the organic crop operation. The certifying agent must not approve a plan that does not provide evidence of sound measures taken to ensure the integrity of the organic crop operation, including buffer zones and other steps to prevent commingling with unapproved non-organic materials or conventional crops. If a producer does not adhere to such preventive measures, the certifying agent is expected to denote such failure as a noncompliance and take appropriate measures toward correction by the producer. Inadequate buffer zones should not be approved in the first place and failure to comply with approved buffer zones constitutes a noncompliance with the approved organic system plan. (See the preamble, page 80558, on Subpart Cï¿½General Requirements, which describe what must be contained in an organic system plan, and ï¿½205.2 under terms defined ï¿½ Buffer zone.)

However, even when all precautions have been taken, and an approved buffer zone fails to provide the protection that both the operator and the certifying agent reasonably expected, certifying agents must not ï¿½retroactivelyï¿½ punish the producer by an enforcement action or ï¿½de-certifyï¿½ the organic crop. The appropriate action to take in this case is to re-evaluate the buffer zone and other preventive measures in the plan to ensure improved integrity and performance in the future. As to the status of the commodity, USDAï¿½s position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship. (See page 80556 of the preamble, ï¿½Applicabilityï¿½Clarifications; (1) ï¿½Genetic driftï¿½).

Posted 1/14/05

Q: Has any certified organic operation that refrains from intentional use of biotech seeds ever lost certification for the inadvertent presence of biotech material in its crop?

A: No accredited certifying agent has reported to us that certification has been lost due to adventitious presence of biotech material. In one instance, a producer admitted to deliberately planting GM seed and representing the crop as organic, for which we took enforcement action and he is no longer certified.

Posted 1/14/05

Q: Are food labels stating ï¿½GM, GE, or GMO-freeï¿½ part of the National Organic Standards?

A: They are not. Truthful labeling is embodied in the National Organic Standards, as supported by USDAï¿½s Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC) ï¿½ the agencies with respective jurisdiction over truthful labeling laws. In the preamble of the National Organic Program final regulations, we stated that organic is not synonymous with ï¿½GM-free,ï¿½ when we said: ï¿½These phrases mayï¿½be used as additional, eco-labels, provided they are truthful statementsï¿½[but] they are not permitted as replacements for the term

ï¿½organic.ï¿½ï¿½ (See page 80586 of the preamble, under ï¿½Labelingï¿½Changes Requested But Not Made: (7) Use of Other Terms as Synonymous for ï¿½organicï¿½).

Posted 1/14/05

Q: Is there a working definition of the word ï¿½contaminationï¿½ within the NOP? Are all products of genetic modification considered ï¿½prohibited substancesï¿½ as defined in the final regulations? And, what actions are authorized or required when organic crops or products are found to contain unintended or inadvertent genetically modified hybrids or other genetically modified substances?

A: There is no definition in the final regulations of the National Organic Standards for the word ï¿½contamination.ï¿½ By our count, ï¿½contaminationï¿½ is mentioned nearly 50 times in the regulations.

All genetically modified practices or products are indeed considered prohibited, as cited in 205.105, the paragraph that describes ï¿½excluded methods.ï¿½ Please refer back to the above issue when considering the adventitious presence of a genetically modified or genetically-engineered substance. Such adventitious presence does not affect the status of the certified operation and does not necessarily result in loss of organic status for the organic product, provided it was produced in adherence with all of the organic requirements under 7 CFR 205.

Again, the action regarding the final productï¿½s status in this case is left to the determination by the buyer and seller of the product. Contamination by a prohibited substance, when mandated by a government body, however, would result in loss of organic status for the product, even when all other regulations had been followed. In the case of an emergency spray program, for example, if the spray is a prohibited substance but is mandated by a State or Federal program, the cropï¿½s organic status is lost and that crop must be diverted for sale in the conventional market. Neither the operation nor the landï¿½s organic status is altered by an emergency spray program, however. (See ï¿½205.672 Emergency pest or disease treatment.)

Posted 3/6/03

Q: Do I have to subtract the use of steam condensate when calculating the percentage of organically produced ingredients? For example; blanching fruits or vegetables, cooking organic ingredients with steam, or other uses for processing with steam.

A: No.

Posted 1/6/03

Q: One of my clients extracts the oil from organic mint leaves. Although he suspected that a recent crop of mint leaves may have come in contact with a prohibited pesticide, residue testing showed that the unprocessed mint leaves had a residue level which does not exceed 5 percent of the EPA tolerance for that particular pesticide.

Is it possible that although the pesticide residue level was okay in the raw mint leaves, the mint oil could contain a residue level above 5 percent of the EPA tolerance level, meaning the mint oil couldnï¿½t be sold as organic?

A: It is possible. The Environmental Protection Agency has established pesticide residue tolerance levels for many processed products (mint oil is a processed product), and these tolerance levels are different from the levels established for the raw product from which the processed product is made.

In this case, there is a separate tolerance level established for mint oil, and the mint oil cannot contain pesticide residue greater than 5 percent of the EPA tolerance established for mint oil for that particular pesticide and still be sold as organic.

When there is no EPA tolerance level established for a processed product, the tolerance level established for the raw product from which the processed product is made will be used to determine if the pesticide residue level is acceptable for that processed product.

EPA pesticide residue tolerance levels can be found at www.access.gpo.gov/nara/cfr/waisidx_01/40cfr180_01.html.

Posted 12/9/02

Q: I operate a certified organic farm, and I wish to purchase compost from a commercial compost operation. Does this compost have to be certified organic?

A: No. Although a commercial compost operation may become USDA certified, there is no requirement for it to do so, and there is no requirement for you to use certified organic compost.

However, any compost you use must meet all the requirements of the NOP regulations, section 205.203. The burden of proving that a compost used on a certified organic operation meets all the requirements of section 205.203 rests with the certified organic operation that uses the compost. That operation must show in its organic systems plan, and be able to prove to its certifying agent, that the compost it uses meets the NOP requirements.

Posted 10/18/02

Q: Must seeds for cover crops be organic?

A: Yes, unless conditions meet those outlined in Section 205.204, provided below:

ï¿½ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: Except, That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available, Except, That, organically produced seed must be used for the production of edible sprouts;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with ï¿½ 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

Posted 10/16/02

Q: Can wood treated with fungicides or other prohibited substances be used for fence posts, trellis systems, etc., in organic production?

A: As provided in Section 205.206(f), the producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock. The Preamble (Crop Production--Changes Based on Comments (7)) elaborates on 205.206(f) as follows:

> ï¿½This provision prohibits the use of lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with an organic production site. We included this modification to clarify that the prohibition applies to lumber used in direct contact with organically produced and handled crops and livestock and **does not include uses, such as lumber for fence posts or building materials, that are isolated from production.** The prohibition applies to lumber used in crop production, such as the frames of a planting bed, and for raising livestock, such as the boards used to build a farrowing house.ï¿½

Q: Do fields have to meet any size requirements in order to produce crops certified as

organic?

A: No. There are no field-size requirements relative to whether or not an operation can be certified organic.

Q: Is the feed that is fed to organic livestock and poultry "vegetarian" feed?

A: Not necessarily. Although as stated in the National Organic Standards subpart C, section 205.237(b)(5), "The producer of an organic operation must not feed mammalian or poultry slaughter by-products to mammals or poultry." there is no restriction against organic livestock feed containing appropriate fish products.

Q: I know organic agriculture prohibits the use of GMOs, but do the guidelines allow for a small amount of contamination?

A: As GMO contamination of organic crops relates to genetic drift, the Preamble to the National Organic Program regulations, Applicability, Clarifications (1) Genetic Drift, states:

"This regulation prohibits the use of excluded methods [which include GMOs] in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation."

However, if a certifying agent has reason to suspect that an organic product has come into contact with prohibited substances or been produced using excluded methods, the certifying agent can call for testing, which under certain conditions could result in that product no longer being considered "organic."

For a complete discussion of this issue, you must read the National Organic Standards, subpart G, Administrative, sections 205.670 ï¿½ 205.671.

Q: Can reclaimed water be used for irrigation on organic farms?

A: Generally, the National Organic Standards place no further restrictions on reclaimed water used for irrigation beyond those imposed by State Departments of Natural Resources. However, to fully answer this question, we would need to know how and from what source the water is being reclaimed.

Q: We are a meat processing plant interested in processing all natural pork and beef. What kind of general information can you give us?

A: There are now specific USDA standards that must be met by all producers and processors who wish to label their agricultural products as organic. (Please note that "natural" is not synonymous with "organic.") These producers and handlers must be certified by USDA-accredited certifying agents by October 21, 2002. The organic standards for producing and processing livestock can be found in the National Organic Standards, subpart C, Sections 205.236 ï¿½ 205.272.

A list of USDA accredited certifying agents can be found on the NOP website at www.ams.usda.gov/nop.

Q: Must manure used to fertilize organic crops come from an organic source, that is from an animal that has been raised in accordance with the organic standards?

A: No. There are no restrictions as to the source of manure. For greater detail on soil fertility and crop nutrient management, please read the National Organic Program regulations, subpart C, section 205.203. This topic is further discussed in the Preamble to the National Organic Program regulations, under the section headed Crop Production, Changes Requested but Not Made, (2) No Prohibition on Manure from Nonorganic Operations.

Q: Are there any known health hazards associated with using animal waste as fertilizer

for organic crops?

A: Properly managed animal waste should not cause any known health hazards. Animal waste used to fertilize organic crops must be managed in accordance with the National Organic Program regulationsï¿½ soil fertility and crop nutrient management practice standard, as stated in the National Organic Program regulations, subpart C, section 205.203(c), which states, "The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances." See this section for a description of plant and animal materials, including manure and compost.

Q: Is it safe to say that using organic fertilizers and other organic farming practices is better for the soil and less of a threat to ground and surface water than commercial methods?

A: USDAï¿½s National Organic Program is a marketing program and makes no claims that organic farming is "better" in any respect than conventional farming.

Q: Has the National Organic Program issued any guidance or sample plans regarding the development of production and handling system plans?

A: The National Organic Program has issued no specific guidance or samples relating to the development of organic production and handling system plans. However the NOP is helping to fund the development of crop and livestock checksheets designed for organic farmers to use in assessing their compliance with the National Organic Standards. The checksheets are being developed by the National Center for Appropriate Technology (NCAT). For more information, visit NCATï¿½s website at www.ncat.org.

Q: Is the use of ionizing radiation allowed at any stage of production or handling of agricultural products labeled organic?

A: No. Irradiation in the production and handling of organic food is prohibited by the National Organic Standards, subpart B, Applicability, section 205.105, Allowed and prohibited substances, methods, and ingredients in organic production and handling, which states, "To be sold or labeled as '100 percent organic,' 'organic,' or 'made with organic (specified ingredients or food group(s)),' the product must be produced and handled without the use of: (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26 ...

Q: Under the National Organic Standards, can the certifying agent approve ion exchange for the processing of organic foods?

A: The National Organic Standards do not prohibit the use of ion exchange in organic food processing as a technology. However, the National Organic Standards do prohibit the use of synthetic substances used in or on processed products unless included in National List section 205.605 as an allowed substance. Accordingly, ion exchange may not be used in the processing of organic foods unless the synthetic substances used in the ion exchange process are listed as approved substances in National List section 205.605.

Q: Can I use homeopathic treatments to treat my livestock?

A: The National Organic Standards do not prohibit use of homeopathic treatments in the production of organic livestock. The producer must make certain that such treatment(s) does not contain a prohibited substance. (Section 205.105(a))

Q: Can I remove organic calves from my farm, raise them conventionally for a year, bring them back to the farm, and then manage them organically for one year prior to the production of organic milk and milk products?

A: No. Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may not be sold, labeled, or represented as organically produced. (Section 205.236(b)(1))

Q: Can I sell an organic dairy animal as slaughter stock?

A: Dairy animals that have been under continuous organic management since the last third of gestation may be sold, labeled, or represented as organic slaughter stock. Conversely, dairy animals that have **not** been under continuous organic management since the last third of gestation may **not** be sold, labeled, or represented as organic slaughter stock. (Section 205.236(b)(2))

Q: Do all dairy animals have to be organic from the last third of gestation to produce organic milk or milk products?

A: No. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic. Except that, in the case of the conversion of an entire distinct herd, the animals must receive a minimum of 80 percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements during the first 9 months of the 1-year conversion period. (Section 205.236(a)(2))

Q: Does Breeder Seed need to be raised organically in order for its progeny; i.e., Foundation, Registered, and/or Certified[1] Seed, to be sold, labeled, or represented as organic seed?

A: No. The seed of any generation planted with conventional, untreated seed and produced under organic conditions can be certified as organic. In other words, untreated seed of Foundation, Registered, or Certified generations may be sown in an organic seed field/cage/greenhouse, and the progeny will qualify as organic seed. Many varieties are only legal for sale as a class of certified seed according to the Plant Variety Protection Act (PVP), Title V. Check with your official state seed certification agency for the specific varieties protected by PVP, Title V. Additionally, it is not necessary to use only genetically[1] certified [2] untreated seed to produce organic seed. Any generation of ï¿½common,ï¿½ untreated seed may also be used.

[1] The use of the term ï¿½geneticallyï¿½ in this sentence in no way implies or authorizes the use of genetically modified organisms.
[2] Certified ï¿½ As defined by the Federal Seed Act Regulations (7 C.F.R. 201(2) (ee)).

Q: Does organic seed always need to be used to produce an organic crop?

A: For edible sprouts, yes; for all other organic crops, no. The National Organic Standards (7 C.F.R. 205.204 (a) (1)) provides that nonorganically produced, untreated seeds may be used to produce an organic crop when an equivalent organically produced variety is not commercially available. The National Organic Standards (7 C.F.R. 205.204 (a) (2)) also provides that nonorganically produced, treated seeds may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available. The seed treatment, however, must be with a substance included on the National List of synthetic substances allowed for use in organic crop production. The only time that a seed treated with a prohibited substance may be used to produce an organic crop is when use of the prohibited substance is a requirement of Federal or State phytosanitary regulations.

Q: How does the National Organic Program (NOP) interpret ï¿½equivalent varietyï¿½ in 7 C.F.R. 205.504(a) (1-2)?

A: An equivalent variety means a variety exhibiting the same ï¿½typeï¿½ (such as head lettuce types, leaf lettuce types, etc.) and similar agronomic characteristics such as insect and disease resistance when compared to the original varietal choice.

ï¿½Typeï¿½ is defined by the Federal Seed Act of 1939 (7 U.S.C. 1551-1661.) as either (A) a group of varieties so nearly similar that the individual varieties cannot be clearly differentiated except under special conditions, or (B) when used with a variety name means seed of the variety named which may be mixed with seed of other varieties of the same kind and similar character, the manner of and the circumstances connected with the use of the designation to be governed by the rules and regulations prescribed under section 1592 of the Federal Seed Act.

Variety is defined by the Federal Seed Act as a subdivision of a kind which is characterized

by growth, plant, fruit, seed, or other characters by which it can be differentiated from other sorts of the same kind, for example, Marquis wheat, Flat Dutch cabbage, Manchu soybeans, Oxheart carrot, and so forth. Kind means one or more related species or subspecies which singly or collectively is known by one common name, for example, soybean, flax, carrot, radish, cabbage, cauliflower, and so forth.

Q: How many generations removed from the present must a grower research the breeding techniques for a given variety to ensure compliance with the NOP? In many cases it is impossible to research breeding techniques of older varieties as breeding methods are usually highly confidential and in some cases lost to history.

A: Effective October 21, 2002, plant breeders developing new varieties for use in certified organic production must comply with the requirements of the NOP.

All varieties (open pollinated and hybrid) in existence prior to October 21, 2002 may be used by organic producers provided that these varieties have not been produced using Genetically Modified Organisms (GMO).

What constitutes GMO is defined by NOP through the term ï¿½excluded methods,ï¿½ (7 C.F.R. 205.2).

Q: How detailed does my Organic Systems Plan (OSP) have to be?

A: The OSP must be sufficient in detail for the certifying agent to determine that your production or handling operation is in compliance with the applicable NOP regulations. The extent of this detail will be determined in collaboration with your certifying agent.

Q: Do I have to follow the Organic System Plan (OSP) I have filed with my certifying agent?

A: Yes. Your OSP is a detailed description of how your operation will achieve, document, and sustain compliance with all applicable provisions of the NOP regulations. Before granting certification to your operation, your certifying agent must concur that your OSP fulfills the requirements of NOP regulations. Your OSP must be annually updated and approved by your certifying agent (see section 205.406 of the NOP regulations). In addition, your OSP may be modified at any time upon request to and written approval from your certifying agent. If you deviate from your previously approved OSP without written approval from your certifying agent, you are no longer in compliance with NOP regulations and could be subject to suspension or revocation of your certification.

Q: Do NOP regulations require the use of organic seed?

A: NOP regulations require the use of organic seed when commercially available. For your options when organic seed is not commercially available see section 205.204 of the NOP regulations or consult your certifying agent.

Q: During the implementation period can a processor (handler) continue to use product ingredients sourced from production operations that have not been certified by a USDA accredited certifier, but have been certified by other certifiers?

A: Yes. During the implementation period, a handler would be allowed to source organic agricultural product ingredients from operations that have not been certified by a USDA accredited certifier. All organic handling operations must discontinue such practices and comply with NOP regulations by October 21, 2002.

Q: How will I find out about changes regarding laws, regulations, policies, and procedures?

A: The NOP will notify accredited certifying agents of changes and pending changes to laws, regulations, policies, and procedures and post such changes and pending changes to its website. Certifying agents should, in turn, notify their clients of such changes and pending changes. Amendments to the NOP regulations will require rulemaking with an opportunity for public comment. This rulemaking is published in the Federal Register. The NOP will issue news releases on Federal Register publications and post such news releases and Federal

Register documents to its website.

Q: How will a National Organic Program audit of a producer be conducted?

A: Producer audits/evaluations will be conducted by accredited certifying agents according to the provisions specified in subpart E, Certification, of the national standards.

Q: When are the greenhouse production and apicultural standards expected to be published?

A: Proposed greenhouse and mushroom standards were announced by the National Organic Standards Boardï¿½s (NOSB) Crops Committee at the June 2001 NOSB meeting. The proposals were posted at the NOSB link on the National Organic Program (NOP) website for public comment through July 31, 2001. The NOSB created an apiculture task force at its June 2001 meeting. Final recommendations for greenhouse, mushroom and apiculture standards will be submitted to the full NOSB for review and approval at its October 15 - 17, 2001, meeting in Washington, D.C. Pending the NOSB decision on the proposed recommendations, the NOP will begin rulemaking for greenhouse, mushroom and apiculture standards in October 2001. NOPï¿½s goal will be implementation of these standards by October 21, 2002.

Q: Please provide discussion, examples, and guidance. on buffer zones. Section 205.202 requires distinct boundaries and "adequate" buffer zones, but minimums are not specified, nor is the term adequate defined.

A: Section 202.202(c) requires distinct, defined boundaries and buffer zones to prevent the unintended application of a prohibited substance to land under organic management.

In examining this issue, USDA concluded that imposing a specific size for buffer zones could impose unnecessary burdens on some organic producers without offering greater protection of organic fields and crops from unintended contact with prohibited substances. For example, buffer zones might not be needed for an organic farm if it were completely surrounded by wilderness or areas not in agricultural production. Accordingly, the national standards do not specify specific dimensions for buffer zones, but leaves the determination of their size to the organic producer and the certifying agent on a case-by-case basis.

It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use in organic production systems. The organic system plan must outline steps that an organic operation will take to avoid drift from neighboring operations, particularly drift of synthetic chemical pesticides.

When considering drift issues, both certifying agents and producers must remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Organic Foods Production Act and the national standards. The national standards prohibit the use of genetically modified organisms (defined in the standards as excluded methods) in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the regulations. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Therefore, while the national organic standards provide significant discretion in establishing buffer zone dimensions, buffer zones should not be sized at distances which attempt to achieve a zero tolerance for prohibited substances. The intent of the regulations are to foster a collaborative effort between the certifying agents and their grower clients to determine an appropriate buffer zone with each party being fully cognizant of the process-based nature of the organic label claim.

Q: Does the National Organic Program plan to provide any training or workshops at the producer/grower level?

A: USDA does not envision conducting any training or workshops at the producer or handler level. USDA has entered into a cooperative agreement with the National Center for Appropriate Technology to provide compliance tools for organic agricultural producers and certifying

agents.

Q: How does the National Organic Program (NOP) envision that producers/growers can become familiar with the intricacies of this new regulation?

A: Under the NOP, USDA provides oversight to accredited certifying agents. Certifying agents provide oversight to producers and handlers. Section 205.501(a)(8) requires that certifying agents provide sufficient information to persons seeking certification to enable them to comply with OFPA and national organic standards. USDA has entered into a cooperative agreement with the National Center for Appropriate Technology to provide compliance tools for organic agricultural producers and certifying agents.

Q: Do nonagricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents? My certifying agent says yes because of the prohibition on the use of volatile synthetic solvents found in section 205.270(c)(2).

A: No. Section 205.270(c)(2) prohibits the use of a volatile synthetic solvent unless included on the National List as an allowed substance. However, synthetic solvents do not have to be on the National List to be allowed in the production of an allowed nonagricultural substance found on the National List. The use of volatile synthetic solvents in the production of allowed nonagricultural substances included on the National List is considered approved through the materials review process, unless otherwise stated through an annotation to the approved substance. (Example: ï¿½ 205.605(a)(9), Flavors -- nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.)

Top

Labels, Labeling, and Market Information

national orgainc program seal

Posted 12/9/02

Q: We are a company that makes bread using certified organic flour and other ingredients. The yeast we use is grown and cultured using certified organic substrates, and the yeast producers follow the NOP regulations for production and processing. Using this yeast, can we label our bread 100 percent organic?

A: You do not say whether or not the yeast has been certified organic by a USDA-accredited certifying agent. If the yeast is certified organic, and all the rest of the ingredients in your bread have been certified organic, you may label your bread as 100 percent organic. If the yeast has not been certified, then your bread does not contain 100 percent organic ingredients. Therefore, you may not label your bread as 100 percent organic.

Posted 11/12/02

Q: I use flavorings in the manufacture of my organic agricultural products. I have proof that these flavorings are from nonsynthetic sources, and are produced without the use of synthetic solvents, carriers, or artificial preservatives as required in section 205.605 (a) 9. However, these flavorings do not come from a certified organic operation. In which categories of organic agricultural products am I allowed to use these flavorings (100 percent organic; organic; made with (at least 70 percent) organic ingredients)?

A: 100 percent organicï¿½No. Products labeled 100 percent organic must contain 100 percent certified organic ingredients.

Organicï¿½Yes. As long as the flavorings constitute 5 percent or less of the total ingredients, and meet the requirements of section 205.605(a)(9).

Made with (at least 70 percent) organic ingredientsï¿½Yes. As long as the flavorings meet the requirements of section 205.605(a)(9).

Posted 11/12/02

Q: How are producers whose company names include the term ï¿½organicï¿½ affected by the NOP regulations? For example, could a company selling organically produced

vegetables call itself Blue Sky Organic?

A: The short answer is yes, as long as that company is not trying to mislead by using that name. For a more thorough explanation, I refer you to a pertinent section of the Preamble to the NOP regulations below:

Labeling - Changes Requested But Not Made

(1) "Organic" in Company Names. Many commenters stated that the term, "organic," must not be used as part of a company name if the company does not market organically produced foods. They are concerned that the term in a company name would incorrectly imply that the product, itself, is organically produced.

While we understand commenter concerns, we do not know the extent of the problem. We do not believe those concerns require such a prohibition in the regulations at this time. These regulations may not be the best mechanism to address the issue. Section 6519(b) of the Act provides the Secretary with the authority to take action against misuse of the term, "organic." USDA will monitor use of the term, "organic," in company names and will work with the FTC to take action against such misuse of the term. These determinations must be made on a case-by-case basis.

Q: On what agricultural products can the USDA Organic Seal be displayed?

A: The USDA Organic Seal may appear on organic agricultural products that are certified 100 percent organic or products that are certified as containing at least 95 percent organic ingredients.

Q: Is this seal in use now?

A: The seal may not be used until October 21, 2002.

Q: Are there any size, font, or color requirements placed on the use of the USDA Organic Seal? How can I get a copy?

A: Yes. The required specifications for the USDA Organic Seal can be found in the National Organic Program regulations, subpart D, Label, Labeling, and Market Information, section 205.311, which can be accessed at the NOP website: http://www.ams.usda.gov/nop/NOP/standards.html. A camera-ready copy of the seal is also available at http://www.ams.usda.gov/nop/Consumers/Seal.html.

Q: I know the USDA Organic Seal cannot appear on any products before October 21, 2002. Does this prohibition also apply to advertising materials?

A: The USDA organic seal cannot appear on products or on any advertising materials, including, but not limited to signage or catalogs before October 21, 2002.

Q: We want to label our poultry "natural." Where in the National Organic Standards do we look for the labeling requirements for using this term?

A: Please note that "organic" is not synonymous with "natural." There is nothing in USDAï¿½s National Organic Standards defining or regulating the use of the term "natural." USDAï¿½s Food Safety and Inspection Service (FSIS) regulates the term "natural" on meat and poultry labels.

Basically, FSIS defines "natural" in the following way: "A product containing no artificial ingredient or added color and is only minimally processed (a process which does not fundamentally alter the raw product) may be labeled natural. The label must explain the use of the term natural (such as--no added colorings or artificial ingredients; minimally processed). You will find this definition and many other labeling terms, including "free range" at the FSIS web site: www.fsis.usda.gov/oa/pubs/lablterm.htm. The FSIS labeling policy book, which goes into much greater technical detail can be accessed at: www.fsis.usda.gov.

Q: As the manager of a retail store, I purchase bulk, certified organic product, then put it in bins where consumers scoop out the amount they want. What signs can I post

regarding the organic status of the product?

A: You may provide the same information as provided on the original container or shipping documents, as described in the National Organic Standards, section 205.308. For example, "If the product is prepared in a certified facility, the retail display, labeling, and display containers may use: the USDA seal; and the seal, logo, or other identifying mark of the certifying agent ï¿½"

Q: In the produce area of my retail store, I display bulk product. I donï¿½t want to confuse consumers by displaying several different certifier names, seals and logos. What signage options do I have?

A: For non-packaged organic agricultural products, a retail store may make the same claims as those on the shipping documents or container. The USDA Organic Seal, or the certifierï¿½s logo, or both may be used for certified products. The only restriction is that the certifierï¿½s logo may not be more prominently displayed than the USDA seal (see National Organic Standards, section 205.308). As an alternative, retail stores may simply refer to a product as "organic" and not use any seals or names of certifiers.

Q: I have a deli in my retail store that makes various multi-ingredient products, where 70-95 percent of the ingredients are certified organic. These products are packaged at the customerï¿½s request, and the only thing we put on the package is price information. What organic claims can we make on the signs describing the products?

A: Your signs may indicate that the products you package are "made with (specified ingredients or food group(s))," as explained in the National Organic Standards, section 205.309. You may not list more than three ingredients/food groups. For example, you may sell chicken salad, with a sign that reads, "chicken salad made with organic chicken, celery, and grapes."

You may not represent the chicken salad as "certified organic," use the USDA Organic Seal, or the seal or name of any certifying agent (see section 205.310.)

Q: As a manager of a retail store, if I buy organic products from a small-scale organic producer who is exempt from certification, how can I label these products?

A: As explained in the National Organic Standards section 205.310, if you buy an organic product from an exempt operation, and you do not process this product any further, you may identify this product as "organic." For example, you could buy apples from an exempt producer and identify these apples to your customers as "organic." Butï¿½you may not identify these apples as being "certified organic," you may not display the USDA Organic Seal in conjunction with these apples, nor in any way represent these apples as certified organic.

If you further process these same apples, to make applesauce, for example, you may not identify the applesauce as being made with organic apples, or call it organic applesauce.

Q: Are there any restrictions on putting "place of origin" information on the label of an agricultural product that is certified organic; for example, "Organically Grown in Montana?"

A: No. The National Organic Standards do not prohibit the placement of truthful information on the labels of certified organic agricultural products.

Q. Section 205.303(b)(2) states that I must identify the certifying agent, preceded by "Certified organic by * * *" or similar phrase, on the information panel below the name of the handler or distributor. Can I meet this requirement by placing the name, acronym, logo, or seal of the certifying agent anywhere on the information panel?

A. To meet the requirements of section 205.303(b)(2), the full name or registered trade name of the certifying agent (which may include acronyms, if the acronym is a registered trade name) must be placed on the information panel below or otherwise near the information identifying the handler or distributorï¿½s name. No other printed material or information may be placed between the certifying agentï¿½s name and the name of the manufacturer or distributor. Certifying agentsï¿½ logos or seals and non-registered acronyms may not be used

to meet the requirements of section 205.303(b)(2).

Q. Is there a rule for rounding when calculating the percentage of organically produced ingredients?

A. As provided in section 205.302(b) of the National Organic Standards, the percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number. For example, 69.99 percent would be rounded to 69 percent.

Q. To meet the requirements of section 205.303(b)(2) and 205.304(b)(2), can a handler identify the name of the certifying agent of the finished product using the following statement: "Certified organic by (insert certifying agent's name here) in accordance with the organic standards of the U.S. Department of Agriculture?"

A. Yes.

Q. With respect to application of the USDA seal on packaging material, does the term ï¿½transparentï¿½ in section 205.311(b)(2) refer to the backgrounds of the upper half of the circle and the word ï¿½organicï¿½ prior to application on packaging material, or does it refer to the transparency of the packaging material on which the USDA seal has been applied?

A. The term ï¿½transparentï¿½ in section 205.311(b)(2) refers to the backgrounds of the upper half of the circle and the word ï¿½organicï¿½ prior to application on packaging material. For example, if a certified organic handler of pasta chooses to apply the black and transparent version of the USDA seal on a brown shipping container, the brown color of the container may show through the transparent portions of the USDA seal.

Q. ï¿½As a certified handler can I make specific certification or production claims on the PDP such as Certified Organic,ï¿½ ï¿½Grower Certified,ï¿½ ï¿½Facility Certified,ï¿½ ï¿½Product Certified,ï¿½ ï¿½Organically Raised,ï¿½ or ï¿½Organically Grownï¿½ in addition to or in place of ï¿½100 percent organic,ï¿½ ï¿½organic,ï¿½ or ï¿½made with organic (specified ingredients or food group(s))ï¿½?ï¿½

A. Certified operations are not prohibited from making truthful PDP label claims. However, alternative labeling claims must not be used to misrepresent a product. For example, alternative PDP label claims must not be constructed so as to mislead a consumer into thinking that a ï¿½made withï¿½ product was actually an ï¿½organicï¿½ product.

Further, the NOP may, in the future, engage in rulemaking to limit the use of alternative PDP claims when it has determined that these alternative claims are being used to misrepresent the product.

Finally, exempt or excluded producers and handlers may not represent their operations as certified or use the term ï¿½certifiedï¿½ when labeling their product.

Q: How do I label my products until the NOP regulations are fully implemented on October 21, 2002?

A: Until October 21, 2002, producers and handlers of organically produced agricultural products may continue their current labeling practices. All certified organic operations must discontinue the use of their current labeling practices and adhere to the labeling standards provided in subpart D, Labeling, of the Final Rule (October 20, 2002ï¿½old labeling practices allowed; October 21, 2002ï¿½old labeling practices not allowed).

Organic products that enter the chain of commerce before October 21, 2002 will not be in violation of NOP regulations. However, beginning October 21, 2002, all organic agricultural products that enter the chain of commerce must be labeled according to NOP regulations.

Q: Who should approve my label before I go to print?

A: Your certifying agent will review your label for compliance with NOP labeling requirements. Labels normally approved by a Federal agency such as FDA, FSIS, or BATF must be approved by those regulatory agencies.

Q: Can I make label claims in addition to "organic" on my product?

A: NOP regulations do not prohibit a producer or handler from making additional claims regarding their product as long as they are truthful and not misleading to the consumer. Such label claims may have to be approved by Federal agencies such as FDA, FSIS, or BATF.

Q: Do I have to include the certifier's address on the information panel of my product's package?

A: No. You must identify the certifier's name on the information panel. All other information related to your certifying agent is optional.

Q: When does organic product have to be labeled "For Export Only"?

A: A product must be labeled "For Export Only" when that product has been produced in the United States to an organic standard other than the National Organic Standards (NOS).

Q: Can domestically produced organic product that meets the NOS and an international organic standard make a claim regarding the international standard on the PDP without violating the NOS?

A: Yes. Truthful label claims are allowed under the NOS.

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Certification

Posted 11/29/05

Q: With Avian Influenza becoming an increasingly serious issue in the poultry industry, what can organic poultry producers and their certifying agents do to help recognize and prevent the spread of this disease?

A: USDAï¿½s Animal and Plant Health Inspection Service has provided guidance to poultry producers, including free range and organic producers, regarding biosecurity considerations for their operations ï¿½ this guidance is found at http://www.aphis.usda.gov/vs/birdbiosecurity/

Integral to the National Organic Program is a management plan for each organic production facility ï¿½ among other things, this plan must address preventative livestock health care practices, including sanitation practices that will be followed to minimize the occurrence and spread of diseases and parasites.

USDA has brought the APHIS biosecurity guidance materials to the attention of its accredited organic certifying agents for their use in working with organic poultry producers.

If it is determined by a producer and certifier that for the health, safety, and welfare of poultry there is need for temporary confinement of birds, provision exists within the National Organic Program for such confinement without a loss of organic certification.

If Federal or State animal health authorities determine that more prescriptive actions are required, organic producers could be required to adhere to those actions.

Posted 3/25/03

Certification Status during the Appeals Process described in 7 C.F.R. ï¿½205.680-681

USDAï¿½s National Organic Program has received questions from producers, processors, handlers, distributors, and retailers regarding the status of a certified operation during the appeals process described in 7 C.F.R. ï¿½205.680-681.

7 C.F.R. ï¿½205.680-681 provides that persons subject to the Organic Foods Production Act of 1990 who believe they are adversely affected by a noncompliance decision of the National Organic Programï¿½s program manager, State Organic Program, or accredited certifying agent may appeal the decision to the Administrator of the Department of Agricultureï¿½s (USDA)

Agricultural Marketing Service or a State Programï¿½s Governing State Official.

Certification status, including the ability to market products as organic, is not diminished during the appeals process. Certification continues in full force and effect throughout the entire process including any formal administrative proceeding conducted pursuant to USDAï¿½s Uniform Rules of Practice, 7 C.F.R. Part 1, Subpart H, or a State Organic Programï¿½s Rules of Procedure.

Posted 11/8/02
Q: I am a certifying agent who has an application from a wool producer and processor. How is wool production and processing addressed in the NOP regulations?

A: Wool is considered an inedible fiber, along with cotton, flax, etc. Inedible fibers are addressed in the Preamble to Final Rule as follows:

(6) Nonedible Fibers Products in the NOP. Some commenters asked the NOP to clarify the certification status of fibers such as cotton and flax. The final rule allows for certification of organically produced fibers such as cotton and flax. However, the processing of these fibers is not covered by the final rule. Therefore, goods that utilize organic fibers in their manufacture may only be labeled as a "made with..." product; e.g., a cotton shirt labeled "made with organic cotton."

In other words, the sheep must be certified organic in accordance with the NOP livestock standards, or the cotton, flax, etc., must be certified organic in accordance with the NOP crop standards to be identified as organic in a finished product. Also, since processing is not covered in the final rule, there are no synthetic processing aids used in fiber processing on the National List.

Posted 10/18/02
Q: I am an organic certifying agent in New England. An organic maple syrup producer has applied to me for certification. Should I require that the producer implement best management practices as recommended by the Vermont Cooperative Extension maple specialists; for example, requiring that the tree trunk reach a certain diameter before tapping, prohibiting the use of a vacuum system, or requiring that all health spouts be removed each year for proper healing of the tap-hole?

A: The National Organic Program encourages all producers to employ best management practices as outlined by the authorities in that specific field of agriculture, as long as they are not prohibited by the National Organic Program regulations. There is nothing in the NOP regulations that would prohibit any practice that youï¿½ve listed in your question.

Posted 10/16/02
Q: A processing facility contracts with two farms for their production. Is it possible to certify those two farms under the name of the processing facility if they are contracted to produce only for that facility?

A: Yes. Production operations that are contracted to supply only a specific processing/handling facility can be certified as part of that unit. They must be included in the certified operationï¿½s organic systems handling plan and be inspected by the certifying agent.

Posted 10/16/02
Q: If a certified operation uses a warehouse or storage facility to store organic product must the warehouse be certified, too?

A: No. However, the warehouse/storage facility must be included in the certified operationï¿½s organic systems plan so that the certifying agent is aware of where the product is being stored and can verify that the facility is compliant with any applicable standards; for example, prevention of commingling and contact with prohibited substances, as outlined in Section 205.101 (b)(1).

Posted 10/16/02
Q: I am applying for organic certification of my farm. However, I used a substance during the 2002 growing season that had been on the OMRI list of approved substances,

but is not allowed by the National Organic Program. Can I still be certified, assuming I meet all the requirements of the National Organic Program?

A: Yes. Since the substance had previously been accepted as part of good organic farming practices and you used it in good faith, the status of your land and your eligibility for certification is not affected.

Posted 10/16/02

Q: Does a feed mill producing a feed supplement that will be mixed with feed to be fed to cows at an organic dairy need to be certified?

A: No. As discussed in the Preamble, ï¿½Livestock Productionï¿½Changes Based on Comments (4)ï¿½ a natural feed additive [supplement] can be from any source, provided it is not classified as a prohibited substance on the National List, and must be in compliance with the Federal Food, Drug and Cosmetic Act.

However, if the feed mill is also producing feed to be used in organic livestock production, the mill must be certified.

Q. Can an accredited certifying agent include an expiration date or renewal date on a certificate of organic operation?

A. No. Section 205.404(c) provides that once certified, a production or handling operationï¿½s organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic programï¿½s governing State official, or the Administrator. Accordingly, the NOP prohibits any language on the certificate of organic operation that indicates an expiration or renewal date.

In order to minimize confusion, NOP encourages all accredited certifying agents to prominently display the phrase, ï¿½Certification good until surrendered, suspended, or revoked.ï¿½ on the certificate of organic operation.

Q: Will organic producers and handlers apply to the USDA to be certified?

A: No. Producers and handlers will apply directly to the USDA-accredited certifying agent of their choice for certification (see section 205.401 of the NOP regulations).

Q: How long is my Organic Certificate good for?

A: Your organic certificate remains good until you voluntarily surrender your certification or your certification is suspended or revoked by the certifying agent, the State Organic Program's governing State official, or the Administrator for violation of the Act or NOP regulations. The certifying agent will issue an updated certificate of organic operation as needed.

Q: How, and in what ways, do the national organic standards differ from the organic certification requirements for international trade, such as the European Union standards?

A: The USDA national organic standards should be considered in two segments: (1) the verification system that includes certification of organic agricultural products and accreditation of certifying agents and (2) the production, handling and labeling standards under which organic agricultural products are produced and sold. NOP is consistent with the internationally accepted guidelines for certification and accreditation, International Standardization Organization Guides 65 and 61, respectively. However, NOP requirements for production, handling, labeling and allowed and prohibited materials differ significantly from those of other countries, such as the European Union (EU), particularly in livestock production standards.

Q: If U.S. national organic standards differ from foreign organic standards, such as the EU, are there plans to standardize the regulations?

A: No. The NOP, in conjunction with the USDA Foreign Agriculture Service and the U.S. Trade Representative, has begun to establish a process through which equivalency or other trade agreements can be negotiated with governments of foreign countries to which U.S. organic products are exported.

Q: Is it possible for producers/growers to meet the U.S. national organic standards and foreign organic standards?

A: Section 205.300(b) allows for production and export of products produced in the U.S. and certified to foreign national organic standards or foreign contractor buyer requirements. Such products may be labeled in accordance with the organic labeling of the receiving country or contract buyer. Such products must be exported. The shipping containers and shipping documents must meet the labeling requirements of section 205.307(c), including the requirement that such containers and documents be clearly marked "For Export Only." For further information see section 205.307(c).

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Accreditation of Certifying Agents

Posted 1/2/03
The National Organic Program (NOP) has been asked a number of questions regarding how to fulfill the requirement of section 205.501(a)(15)(ii) of the National Organic Standards (NOS) that states certifying agents must submit to the Administrator a copy of a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year. Based on the questions asked by certifying agents, the NOP provides the following responses to clarify section 205.501(a)(15)(ii):

Q: Does the NOP favor a method of transmission for the lists (i.e. fax, e-mail, US mail, FedEx, or a combination of these)?

A: NOP prefers to receive the lists via e-mail at Arthur.Neal@usda.gov

Q: Is there a particular format preferred by the NOP for the lists? (Word document, Excel spreadsheet, data base listing, etc.)?

A: When submitting lists via email, NOP prefers to receive them in Excel Spreadsheet format.

Q: Does the NOP want the mailing address for the operators, or the physical location of the operation?

A: NOP requires both addresses, if applicable.

Q: The NOS requires that the lists should show the operations "granted certification during the preceding year". Should the lists only contain new operations granted certification, or all operations, including certification renewals?

A: Because this is the initial year for full implementation of the NOS, the NOP requires a complete list of all organic operations certified by the certifying agent as of midnight, December 31, 2002. This would include all operations going through an annual update.

Q: The NOS only asks for the name, address, and telephone number of the operations. Does the NOP also want the categories for which the operations are certified?

A: The NOS does not require identification of the categories for which the operations are certified. However, NOP encourages the submission of this information. Such information will be valuable in identifying the size, scope, and characteristics of the organic production and handling industry.

Q: The NOS requires that the lists be submitted "on" January 2. Can the lists be submitted "on or before" January 2?

A: Yes, the lists may be submitted ï¿½on or beforeï¿½ January 2; provided they are complete through the end of the calendar year.

Q: How will a National Organic Program audit of a certifying agent be conducted?

A: The National Organic Program only conducts site evaluations and on-site review audits of certifying agents. Auditors conducting the reviews will follow the procedures specified in the International Organization for Standardization (ISO) 10011 guidelines, "Guidelines for Auditing Quality Systems." Accredited certifying agents will be reviewed based on their ability to comply with the national standards.

December 31, 2002

Q: Please discuss fees associated with audits.

A: Through October 21, 2002, applicants seeking initial accreditation under the National Organic Program (NOP) will only be assessed travel expenses. The NOP will absorb all labor charges for accreditation services through October 21, 2002. After October 21, 2002, applicants for initial accreditation and renewal of accreditation will be assessed fees in accordance to sections 205.640 and 205.641 of subpart G, Fees. Fees for certification are assessed by the certifying agent. Such fees must be in compliance with section 205.642 of the national standards.

Q: Does the National Organic Program (NOP) have plans to produce a national list of accredited certifying agents?

A: Yes. The first announcement of accredited certifying agents will not occur until on or about April 21, 2002. At this time, the NOP will provide a list of accredited certifying agents which will be accessible on the NOP website at http://www.ams.usda.gov/nop/CertifyingAgents/Accredited.html or by request through the NOP office at 1400 Independence Avenue, SW; Room 2510 South Building; Washington, D.C.; 20250.

Q: As a result of the conflict of interest provisions in the national standards, what mechanisms, if any, are there for certifying agents to provide compliance information?

A: Section 205.501(a)(8) requires that certifying agents provide applicants with sufficient information to enable them to comply with the OFPA and regulations. Section 205.501(a)(11)(iv) prohibits certifying agents from giving advice or providing consultancy services to certification applicants or certified operations for the purpose of overcoming barriers to certification. In other words, certifying agents must explain the regulations, but they cannot tell producers or handlers how to correct a noncompliance. Additional discussion of this issue may be found on page 80601 of the national standards.

Q: Based on the conflict of interest provisions in the national standards, how does National Organic Program envision the producer obtaining the correct information to achieve compliance?

A: To address barriers to certification and other organic issues particular to the geographical area, certifying agents may sponsor in-house publications, conferences, workshops, informational meetings, field days, or other educational activities for which participation is voluntary and open to the general public. To overcome barriers to certification, producers and handlers may seek out consultancy services from sources such as educational institutions, State cooperative extension, private consultants, and other producers and handlers.

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National List of Allowed and Prohibited Substances

Q: Do nonagricultural substances included on the National List of Allowed and Prohibited Substances have to be produced without the use of volatile synthetic solvents? My certifying agent says yes because of the prohibition on the use of volatile synthetic solvents found in section 205.270(c)(2).

A: No. Section 205.270(c)(2) prohibits the use of a volatile synthetic solvent unless included on the National List as an allowed substance. However, synthetic solvents do not have to be on the National List to be allowed in the production of an allowed nonagricultural substance found on the National List. The use of volatile synthetic solvents in the production of allowed

nonagricultural substances included on the National List is considered approved through the materials review process, unless otherwise stated through an annotation to the approved substance. (Example: ï¿½ 205.605(a)(9), Flavors -- nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.)

Use of Chlorine in Organic Handling Operations - 7 C.F.R 205.601(a)(2), 205.603(a)(3), and 205.605(b)(9) provides for the use of chlorine materials as algicides, disinfectants and sanitizers in organic crop, livestock and handling operations. The annotation on the use of chlorine materials restricts the residual chlorine levels in the water to the maximum residual disinfectant limit under the Safe Drinking Water Act. This limit is currently established by the Environmental Protection Agency (EPA) at 4 mg/L for chlorine. The National Organic Program has received a number of questions regarding the use of chlorine in certified operations and the sampling protocol to be used by accredited certifying agents (ACA) in monitoring the maximum residual disinfectant limit for chlorine materials. The following Q and Aï¿½s are designed to clarify these issues.

Q. As an ACA, at what point in crop, livestock or handling operations should I monitor for the maximum residual disinfectant limit?

A. ACAï¿½s must monitor the discharge or effluent point to ensure that certified operators are meeting the 4 mg/L limit as set forth by the Safe Drinking Water Act.

Q. As a crop, livestock or handling operation, am I restricted to use chlorine at the maximum residual disinfectant limit specified under the Safe Drinking Water Act, currently 4 mg/L, at the beginning of the wash/rinse water cycle?

A. No. Levels of chlorine used to prepare water to be used to disinfect/sanitize tools, equipment, product or food contact surfaces may be higher than 4 mg/L and should be at levels sufficient to control microbial contaminants. Therefore, chlorine use at the beginning of the applicable water cycle in an organic operation is not limited to 4 mg/L.

Q: Can nonagricultural substances not appearing on the National List of Allowed and Prohibited Substances be used as ingredients in or on a product labeled as "made with organic (specified ingredients or food group(s)).?"

A: A "made with organic (specified ingredients or food group(s))" product must, in accordance with section 205.105(c) of the Final Rule, be produced and handled without the use of nonagricultural substances used in or on processed products, except when the nonagricultural substances are included in section 205.605 of the National List of Allowed and Prohibited Substances. Accordingly, the reference to nonorganic ingredients in section 205.301(c) refers to *agricultural* ingredients only and should not be construed to include nonagricultural ingredients.

To further clarify the Departmentï¿½s intent, a "made with organic (specified ingredients or food group(s))" product must contain at least 70 percent organic agricultural ingredients that have been produced without the use of:

1. Synthetic substances unless the substances and their use are allowed under section 205.601 or section 205.603 of the National List of Allowed and Prohibited Substances.

2. Nonsynthetic substances prohibited under section 205.602 or section 205.604 of the National List of Allowed and Prohibited Substances.

3. Nonagricultural substances unless the substances are allowed under section 205.605 of the National List of Allowed and Prohibited Substances.

Additionally, the remainder of the ingredients in a "made with organic (specified ingredients or food group(s))" product (up to 30 percent) may include:

1. Nonagricultural products listed in section 205.605 of the National List.

2. Nonorganically produced agricultural products, raw or processed, that have been produced using synthetic, nonsynthetic, and nonagricultural substances without regard to sections 205.601 through 205.605 of the National List of Allowed and Prohibited Substances, except that the use of excluded methods, sewage sludge, and ionizing radiation are prohibited. Nonorganically produced

agricultural products listed in section 205.606 of the National List of Allowed and Prohibited Substances must comply with the restrictions placed on that product by section 205.606.

Q: Will there be a generic list of allowed naturals?

A: No, there will not be a generic list of allowed natural materials, because all naturals are allowed unless prohibited on the National List.

Q. What is the ï¿½maximum residual disinfectant level?ï¿½

A. ï¿½Maximum residual disinfectant levelï¿½ is a term defined by the Environmental Protection Agency (EPA) as the highest level of a disinfectant allowed in drinking water. This level is currently established by EPA at 4 mg/L for chlorine. Practically applied under the National Organic Standards, the term ï¿½maximum residual disinfectant levelï¿½ refers to the chlorine level of the waste water at the discharge or effluent point.

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State Organic Programs

Q: Can a State request review of a proposed State Organic Program (SOP) before all the statutory and regulatory rules have been changed? For instance, can a State specify its intent to adopt legislation or rules in its request for approval, rather than having those statutes or rules finalized?

A: A State has two options: (1) It can submit a final SOP to USDA for approval; or (2) It may submit to USDA, a draft SOP for review prior to finalization of statutes, regulations, or procedures. When this option is used, USDA will provide feedback to the State regarding any changes necessary to receive approval. A State can then use the feedback to finalize its SOP. The SOP would, then, be submitted to USDA for approval.

Q: Can a State require registration of all certifying agents operating within the State?

A: Yes; provided that the registration program does not discriminate against the certifying agents.

Q: Can a State with an approved State Organic Program (SOP) review the operations of certifying agents operating within the State?

A: Only States with approved SOPs may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State (See section 205.668(c)).

Q: Can a State require certifying agents operating within the State to comply with the approved State Organic Programï¿½s (SOPï¿½s) more restrictive requirements?

A: Accredited certifying agents operating within a State with an approved SOP must comply with the SOPï¿½s more restrictive requirements. A violation of the Stateï¿½s approved more restrictive requirements is a violation of the National Organic Standards (NOS). Only the USDA may take enforcement action against an accredited certifying agent for violating the NOS. States with approved SOPs may review and investigate complaints of noncompliance and report their findings to the NOP for enforcement action (See section 205.668(c)).

Q: When is a State considered to have a State Organic Program (SOP)?

A: A State is considered to have an SOP when it receives USDA approval. To receive approval, a proposed SOP must meet the National Organic Standards, receive approval for any identified more restrictive requirements, and contain noncompliance, mediation, and appeals procedures that meet the requirements of USDA. The basis for the recommendation to approve or disapprove will be based on compliance with the requirements of Sections 205.620 through 205.622, 205.661 through 205.663, 205.668, and 205.680 and 205.681 of the NOS (7 CFR 205.620-.622, 205.661-.663, 205.668, and 205.680-.681).

Q: Who is responsible for handling a U.S. District Court appeal of a Stateï¿½s final decision?

A: The appeal is on a State action, and the State is responsible for defending its action.

Q: What discretion, if any, does a State Organic Program (SOP) have in handling an appeal of an enforcement action initiated by an accredited certifying agent?

A: None. Approved SOPs are required to handle all appeals of enforcement actions initiated by certifying agents against certified operations operating within the State.

Q: Can a State Organic Program (SOP) include additional enforcement provisions, such as authority to issue cease and desist orders, obtain injunctions to stop the sale of noncompliant products, or summarily suspend certifications?

A: A State may request approval of an SOP that includes more restrictive enforcement requirements that do not deny due process.

Q: Will an approved State Organic Program (SOP) be responsible for revoking the certification of a certified operation based in foreign countries?

A: When a certified entity operates in multiple locations and one of those locations is within the jurisdiction of an SOP, the State is responsible for enforcing compliance by that portion of the certified operation.

Q: If a certified producer or handler fails to meet the continuation of certification requirements and contests a proposed revocation of certification, can a State with a State Organic Program (SOP) stop that entity from selling its product as "organic" prior to completion of the appeals process?

A: A stop sale before completion of the appeals process would be a denial of due process.

Q: Is it possible for organic growers to be in compliance with the National Organic Program if their State does not create a State Organic Program.

A: Yes. A State does not have to create a State Organic Program or become an accredited certifying agent for organic growers within the State to be in compliance with the requirements of the National Organic Program.

Q: Please explain the options available to a State considering the possibility of creating a State Organic Program (SOP) under the National Organic Program (NOP).

A: *Option 1:* A State may choose not to establish an SOP or provide certification services under the NOP. Under this option, organic growers may seek organic certification by any certifying agent accredited under the NOP. The State would not be responsibly connected to enforcement of the NOP. Enforcement would be shared jointly by the NOP and the certifying agent.

Option 2: A State may choose to only provide certification services under the NOP. Under this option, the State would have to apply for accreditation. As an accredited certifying agent, the State would be responsible for conducting certifications, enforcing the production and handling standards of the NOP, and maintaining compliance with other applicable NOP regulations. USDA will be responsible for oversight of the State certifying agent. Organic producers and handlers within that State could choose to be certified by the State or any other accredited certifying agent.

Option 3: A State may choose to establish an SOP. Under this option, all organic producers or handlers in the State would have to be certified according to the SOP, which would include the requirements of the NOP and the more restrictive provisions unique to that State and approved by the USDA. The State would assume enforcement responsibility, within its borders, for the requirements in the national standards and its SOP (ï¿½205.620(d)). However, the State may not initiate proceedings to suspend or revoke the accreditation of any certifying agent accredited by USDA. Suspension or revocation of an accredited certifying agent may only be pursued by the USDA. Organic producers and handlers may seek and obtain organic

certification from any certifying agent accredited under the NOP.

Option 4: A State may choose a combination of Options 2 and 3.

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Exporting Organic Products

Q: When does organic product have to be labeled "For Export Only"?

A: A product must be labeled "For Export Only" when that product has been produced in the United States to an organic standard other than the National Organic Standards (NOS).

Q: Can domestically produced organic product that meets the NOS and an international organic standard make a claim regarding the international standard on the PDP without violating the NOS?

A: Yes. Truthful label claims are allowed under the NOS.

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USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2642-South, STOP 0268
Washington, DC 20250-0268

August 27, 2019

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program

SUBJECT: Request to Review Ion Exchange Filtration

The National Organic Program (NOP) requests that the National Organic Standards Board (NOSB) provide recommendations related to ion exchange filtration for handling organic products.

The NOP has received questions about whether USDA organic regulations require that nonagricultural substances used in ion exchange filtration (*e.g.*, resins, membranes, and recharging/regenerating solutions) be included on the National List (§ 205.605). The NOP has learned that certifiers have different policies on this topic. Some certifiers require that only the solutions used to recharge ion exchange membranes/resins be on the National List. Other certifiers require all materials, including ion exchange membranes/resins, be on the National List.

We are requesting the Board's recommendation(s) to help us address inconsistencies between certifiers and to ensure that organic handling operations, certifiers, and other interested parties have an opportunity to provide input. The NOP seeks information about the various ways ion exchange filtration is used by organic operations, the substances used in these processes, potential alternatives to ion exchange technology, and recommendation(s) on whether it is appropriate to include these substances on the National List.

The NOP is providing the following supplemental information as attachments to support your review:

- Notice from NOP to Certifiers, May 7, 2019
- Notice from NOP to Certifiers, July 3, 2019
- Letter from Quality Assurance International to NOP, June 5, 2019
- Letter from Oregon Tilth to NOP, August 7, 2019
- Letter from CCOF to NOP, August 9, 2019

We thank you in advance for your work on this topic, and we look forward to your recommendations.

[sent via email by NOP on May 7, 2019]

Subject: Notice to Certifying Agents – Ion Exchange

Notice to Certifying Agents

Dear USDA-accredited Certifying Agent:

The National Organic Program (NOP) was notified of a discrepancy between certifying agents in the review of ion-exchange for processing organic products.

Decision
This notice clarifies that ion-exchange filtration is allowed in organic processing.
However, **nonagricultural** substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). This includes, but is not limited to, resins, membranes, and recharging materials. Certifiers that have previously approved use of ion-exchange filtration as part of an organic system plan need to review the ion-exchange process, including resins, membranes, and recharging solutions, to determine if the filtration practices are compliant. If the filtration practices are determined not to be compliant, the affected operations need to be notified. Previously approved filtration practices that are not in compliance must be removed from organic system plans by **May 1, 2020.**

Additional information on this decision is provided below:

Background
Ion-exchange may be used to clarify, decolor, or otherwise filter liquids using a chemical exchange process. The process uses a chemically charged material to selectively remove unwanted molecules from the liquid upon contact. For the purpose of this notice, the term 'ion-exchange resin' is defined as a membrane, resin, or solid material with charged molecules available for exchange with mobile molecules in a fluid. Because repeated use saturates ion-exchange resins with unwanted molecules, recharging (*i.e.,* flushing or regenerating) with chemical solutions is required for continued use. Filtration processes using ion-exchange technology may use a range of ion-exchange resins (*e.g.,* polymeric resin beads, zeolite minerals, activated carbon) and recharging solutions (*e.g.,* sodium chloride, potassium chloride, hydrochloric acid) that may be synthetic or natural.

Justification
USDA organic regulations prohibit use of **nonagricultural** substances "in or on processed products" that are "100 % organic," "organic," or "made with organic …" except as provided in § 205.605" (§ 205.105(c)). Section 205.605 allows several nonagricultural (nonsynthetic and synthetic) filtering aids. For example, bentonite, diatomaceous earth, and perlite are included at § 205.605(a). Activated charcoal and cellulose are listed at § 205.605(b). These substances were added to the National List following a technical review process to ensure compliance with the Organic Foods Production Act (7 U.S.C. 6501 *et seq.*) criteria *before* allowing for use in or on organic food. If not included on the National

List for use in organic processing, nonagricultural substances used in ion-exchange filtration are considered non-compliant.

Some have argued that ion-exchange resins are food-contact substances that do not chemically affect the finished product. We disagree, because the ion-exchange process is a chemical process intended to have an effect in the food. During ion-exchange filtration, chemical molecules in the liquid being processed are exchanged with chemical molecules on the ion-exchange resin. This results in a different chemical composition of the processed product. Unlike physical filtration methods that selectively remove larger unwanted particles from the liquid passing through the filter, ion-exchange filtration replaces unwanted molecules with different chemical molecules in the liquid being processed.

The U.S. Food and Drug Administration (FDA) considers ion-exchange membranes and ion-exchange resins to be secondary direct food additives (see 21 CFR 173.20 and 173.25). The FDA does not consider ion-exchange resins or ion-exchange membranes to be food contact substances. These substances are defined as "any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food" (21 CFR 170.3(e)(3)). Because ion-exchange resins do provide an effect in foods, they are not considered food-contact substances. As such, to ensure the organic integrity of foods processed using ion-exchange filtration, **any nonagricultural materials used in the ion-exchange process must be on the National List for use in organic processing**

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[sent via email by NOP on July 3, 2019]

Subject: Notice of Delayed implementation of Ion-Exchange

Dear USDA-accredited Certifying Agent:

On May 7, 2019, the National Organic Program (NOP) notified certifying agents that all nonagricultural substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). We noted that previously approved noncompliant filtration practices must be removed from organic system plans by May 1, 2020.

Following the notification to certifiers, we received requests to clarify our rationale, extend the timeframe for implementation, and/or provide opportunities for input from stakeholders and certifiers. This feedback provided additional information to be considered in resolving the current conflict related to ion-exchange technology for use in organic handling. Additional information also came from NOP discussion about the classification of ion-exchange materials with the U.S. Food and Drug Administration, to evaluate how such materials interact with the organic product. **After reviewing this new information, we are delaying the May 1, 2020 implementation date while we gather more information and seek advice from the National Organic Standards Board (NOSB) given the complexity of the issue.**

More broadly, material conflicts between certifiers are rare, but when they occur, they are often complex, and the initial information is not always the complete picture. **The NOP recognizes that we need to enhance our processes to allow for earlier information gathering and increased organic stakeholder engagement when these complex conflicts occur.**

We are drafting new procedures to address this need. These procedures will include more broadly assessing certifier decisions and practices beyond those certifiers involved in the conflict raised to NOP. This will help clarify: (1) whether the conflict is a simple one, where certifier(s) have made errors in materials decision-making that simply need to be corrected OR (2) whether the conflict is a more complex and nuanced one that would benefit from public feedback. Complex conflicts may then lead to new work agenda items for the National Organic Standards Board for subsequent NOP decision-making.

Jennifer Tucker, Ph.D.
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USDA Agricultural Marketing Service

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June 5, 2019

Ms. Jennifer Tucker, Ph.D
Deputy Administrator
USDA Agricultural Marketing Service
National Organic Program

Dear Jenny,

Please find more information below regarding QAI's justification for allowing ion exchange in organic handling. QAI is not the only certifier who has allowed ion exchange for several decades. Ion exchange has been discussed at the certifier and NOP level, with differing opinions and guidance provided at different times. However, we believe that ion exchange is compatible with organic processing principles, so long as recharge materials are on the National list or do not have any contact with organic ingredients/products. This is also consistent with the most recent NOP training provided to certifiers in 2010. Our justification is as follows:

1. **Food Contact Substances:** The recent clarification from the NOP regarding ion exchange claims that the resins and membrane materials are secondary direct food additives rather than food contact substances. Ion exchange resins/membranes are classified by FDA as food contact substances, which supersedes the CFR references sited in the clarification. Food contact substances can be used in organic handling unless expressly prohibited or restricted by the NOP Regulation. Other examples of food contact substances permitted in organic handling include packaging materials and food handling equipment.

2. **Resins and membranes do not exchange molecules with the organic product:** Resins are plastic-type polymers coated with fixed ions that are permanently bound within the polymer matrix of the resin. The fixed ions are only there to facilitate removal of the salts, color, flavor, odor compounds, acids and other impurities present in the organic product solution. They can also remove harmful heavy metals. These coatings are not removed from the resin and do not interact or change the organic product in any way. These resins are very commonly used for ion exchange in the food & beverage industries. In this capacity, the permanent nature of the resin is similar to a stainless steel surface or a rubber belt on a food contact processing line.

3. **Recharge Materials can "exchange" ions with the organic product and can also be flushed from the resin matrix prior to organic handling:** The materials used to recharge the resin matrix are materials that *could* interact with the organic product and "exchange" a molecule. For example, hydrogen could exchange with an undesirable molecule in the organic product such as salt. Certifiers have been requiring that these recharge materials are on the National List or flushed out of the resin matrix with water prior to organic handling.

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The 2010 NOP Training slides (slides 25 and 26) refer to materials used for recharging, not resins or membranes. According to the slides, "ion exchange technology is allowed, as long as materials used are on the National List." The materials listed in the example, e.g., sodium hydroxide and sodium chloride, are compounds used to recharge the exchange resins, not the exchange resins themselves. It is the exchange resins that FDA considers to be food contact substances. The compounds in the recharging solutions are Generally Recognized to be Safe (GRAS) and not subject to FDA regulation as either food contact substances or as food additives.

The recharge materials are used in order to return the resins to their factory initial state and so they can be used again to absorb impurities from the organic material. When the resin beds are saturated with ions, the resin is unable to adsorb impurities and so has to be cleaned of the ions before it can adsorb more. It is first rinsed with water to remove all traces of syrup and then the resin bed is regenerated (recharged) with hydrochloric acid (HCl - cation resin) and sodium hydroxide (NaOH - anion bed) to remove any salts or contaminates from the previous batch of syrup. The resin is then washed with low flow then a high flow of deionized water until the conductivity of the rinse water indicates all traces of HCl (or sodium hydroxide) are removed. It can also be flushed with a national list material like citric acid, as an additional intervening event, and then flushed again with water. The ion exchange bed is then placed in recirculation to ensure pH is near neutral. The resin bed is then in the same state it was in upon receipt from its manufacturer and ready for organic production. In other words, recharge materials (HCl and NaOH), one of which is on the National List (NaOH) and one that isn't (HCl), can be removed from the resin before it's reuse for organic production. This is a similar situation where non-NL materials are used for cleaning and sanitation of food contact surfaces as long as there is an intervening event with a NL material (water wash as the most common example) prior to renewed contact with organic food.

If hydrogen is needed for the cation exchange, hydrogen from the water rinse has become part of the resin during the recharge rinse process. If a hydroxide is needed for exchange during the anion process, then sodium hydroxide, which is on the national list, does not need to be removed from the resin bed prior to use. See #4 for more information.

4. **No Chemical Change occurs as a result of Ion Exchange:** See below for a simple flow chart illustrating the process. The finished product is chemically unchanged from the initial organic ingredient. The only changes are the removal of ions that are considered undesirable impurities that can have adverse effects on finished products that use the organic product as an ingredient.

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Organic product (eg, organic rice syrup)

Salt ↓ ↑ hydrogen ions

Ion exchange resin bed

The first stage is the **Cation Process** where the ion exchange filter takes salt (Na+) from syrup and replaces it with hydrogen ions (H+) from water. Other impurities like organic acids, chlorides, heavy metals remain in the organic product until the next step.

Organic product (eg, organic rice syrup)

Acids/impurities ↓ ↑ hydroxide ions

Ion exchange resin bed

The second stage is the **Anion Process** where the ion exchange filter takes hydrogen that was added in the first stage as well as organic acids and other impurities from syrup and replaces them with hydroxide ions (OH-) from sodium hydroxide, which is on the National List, 205.605.

What remains is the Organic syrup in water with no salts and minimal amount of organic acid and other impurities. The original product remains unchanged aside from a removal of impurities. This is the same result of any filtration system.

Please let me know if you have any follow-up questions and thank you for your time and consideration.

Sincerely,
QUALITY ASSURANCE INTERNATIONAL (QAI)

Jessica Walden
Senior Technical Reviewer

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August 7, 2019

Devon Pattillo, Materials Specialist
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Re: May 7, 2019 Notice to Certifiers - Ion Exchange

Oregon Tilth is requesting further clarification regarding the National Organic Program's (NOP) May 7, 2019 Notice to Certifying Agents regarding the use of ion exchange. Specifically regarding the new requirement for 'ion exchange resins', as defined in the notice, to be on the National List for continued use in organic production. The information provided contradicts previous trainings provided by the NOP, and the Food and Drug Administrations (FDA) classification of these substances as 'Secondary Direct Food Additives' at 21 CFR 173.

Oregon Tilth has historically required the recharging and sanitizing materials used in ion exchange to be on the National List at §205.605, but considers the resins and membranes to be food contact equipment, per NOP trainings and Frequently Asked Questions (FAQ). The recharging and sanitizing materials are the substances of concern and may be added or incorporated into food. The resins are insoluble and designed to be sanitized, recharged and reused repeatedly to remove contaminants that build up during food processing or are naturally present in food or water. The insoluble ion exchange resins and membranes are never incorporated into food products. This review process ensures that anything exchanged or added to an organic product is an approved substance at §205.605 (e.g., sodium hydroxide, sodium chloride). Please see the attached slides from the 2010 NOP Certifier Training, which includes examples of allowed substances for recharging ion exchange resins when used in organic production. If this change is implemented, please allow adequate time for the petition process for ion exchange resins as part of the implementation timeline.

Please note the following FDA references for ion exchange resins as Food Contact Substances:

- FDA's Food Ingredient & Packaging Terms with regard to 'Secondary Direct Food Additives', which states: *"This term is in the title of 21 CFR 173, which was "created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program".*

- **FDA approved ion exchange resins for use as Food Contact Substances**: Search FDA Inventory of Effective Food Contact Substance Notifications for 'ion exchange resin'. These are used to selectively remove contaminants from liquid water based food materials, such as milk, whey, fruit juice, beer and wine, as well as for demineralizing sugar, softening water for food and beverage production, extracting individual proteins or substances present in liquid water based food materials, and food enzyme solutions. The Food Contact Substance Notifications (FCS), FCS 45, FCS 52 and FCS 74, are examples of the specific ion exchange resins listed at 21 CFR 173.25 and used in food production. None of the synthetic resins listed in section A are currently on the National List. Section B of this part details the types of materials that are used to exchange or replace the less desirable ions found in foods. Some of these materials are listed at §205.605 as allowed ingredients in organic production.

The Notice from NOP states that ion exchange resins and membranes are not food contact substances and requires them to be added to the National List for their continued use in organic production. This change will have a significant impact on our clients and the industry at large. Many organic products currently on the market cannot be produced without this technology. It is unlikely that the NOP or certifiers fully comprehend the extent of the impact without the opportunity for public comment or stakeholder input.

A public comment period for such changes assures adequate participation and feedback from stakeholders and ensures understanding of the technology involved and potential impact on the industry. It also provides adequate time to prepare for and adapt to these changes. This process was not followed and the implementation requirements are not reasonable for the industry to adjust to such a drastic change. We urge the NOP to reconsider their new stance on ion exchange and consider existing technical reviews of other substances that use ion exchange already in section §205.605(a) of the National List.

Thank you for your time and attention to this important matter.

Sincerely,

Erin Bardagjy
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Ion Exchange

Situation: Certifiers are asking if ion exchange is allowed in organic handling. Specific questions are what materials may be used to charge the ion exchange columns.

Ion Exchange

NOP Guidance:

- NOP has posted policy that ion exchange technology is allowed, as long as materials used are on the National List.
- For example-
  - Listed items:
    - Sodium hydroxide
    - Sodium chloride
  - Not listed:
    - Hydrochloric acid

CCOF
Advancing organic agriculture through certification, education, advocacy, and promotion.

Paul Lewis, Ph.D.
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August 9, 2019

RE: CCOF Comments on the May 7th notification on the ion exchange process

Dear Dr. Lewis:

Thank you for the opportunity to comment on the May 7th notification from the National Organic Program (NOP) to USDA accredited certifying agents clarifying that all nonagricultural substances used in the ion exchange process must be on the National List of Allowed and Prohibited Substances (National List).

California Certified Organic Farmers (CCOF) supports NOP's decision to delay implementation of the May 7th notification. Seeking National Organic Standards Board (NOSB) input and gathering stakeholder feedback through a public comment process is critical to ensuring a transparent and well-grounded outcome.

CCOF remains concerned with NOP's decision outlined in the May 7th notification and recommends NOP reconsider the requirement that all nonagricultural substances used in the ion exchange process be on the National List. CCOF developed an approach to resin filtration and ion exchange review after thoughtful consideration of the process and discussion with other accredited certification agents. The ion exchange process involves a combination of equipment (resin and membrane) and recharge materials. When reviewing an ion exchange process for compliance, CCOF requires the recharge materials to be on the National List and the resin to be FDA approved as a food contact substance. CCOF does not require the resin or membrane to be on the National List as they are analogous to other types of equipment used to process products.

The full impact of the May 7th notification is uncertain. CCOF reviewed an application for certification from a sugar cane processor using ion exchange with sodium hydroxide as the recharge material. The operation's ion filtration system would be noncompliant under the new notification as there are no ion exchange resins on the National List. It is unclear whether the operation could transition to an alternate filtration system.

In addition, there may be implications for other filtration systems that involve resins. We are uncertain how many CCOF certified operations could be affected by NOP's May 7th notification since we have reviewed each ion exchange resin, membrane and recharge material as part of the operation's Organic System Plan, but only recorded recharge materials in our database.

CCOF appreciates the opportunity to comment and urges NOP to address our concerns.

Sincerely,

Sarah Reed

Sarah Reed
Handler Certification Director
CCOF Certification Services, LLC

CC: April Crittenden, Chief Certification Officer, CCOF Certification Services, LLC
Rebekah Weber, Policy Director, CCOF, Inc.