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Enviado el: jueves, 28 de diciembre de 2017 04:11 p. m.
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Asunto: Comentarios al Expediente 12/0109/271016
Datos adjuntos: Comentarios 12 0109 271016.pdf

Estimado COFEMER,

Adjunto a este correo electrónico se encuentra una carta de OMRI con comentarios referentes al expediente 12/0109/271016. En el mismo archivo se incluyen dos documentos citados en dicha carta.

De antemano agradezco la inclusión de estos comentarios en la página de COFEMER.

Saludos cordiales,

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Comentarios al anteproyecto "*Acuerdo por el que se modifican, adicionan y derogan diversas disposiciones del diverso por el que se da a conocer los lineamientos para la operación orgánica de las actividades agropecuarias*"
No. Expediente 12/0109/271016

28 de diciembre de 2017

A quien corresponda,

OMRI (el Instituto de Revisión de Materiales Orgánicos) agradece a COFEMER por la oportunidad de proporcionar comentarios en relación a los Lineamientos para la Operación Orgánica de las Actividades Agropecuarias. OMRI es una organización independiente sin fines de lucro que ofrece una revisión experta y transparente de insumos para determinar su compatibilidad en la producción de fibras y alimentos orgánicos. OMRI se fundó en 1997 a partir de los esfuerzos de agencias de certificación y otras organizaciones que vieron la necesidad de abordar inconsistencias con respecto a la revisión de materiales proporcionando a la industria un programa de revisión de insumos exhaustivo y transparente.

Lista de Formulados (insumos comerciales)

Las enmiendas a los Lineamientos presentadas por el Grupo de Trabajo Marco Regulatorio e Invitados (B000173817) proponen que las agencias de certificación sean responsables de determinar que los insumos comerciales cumplan con los estándares orgánicos. OMRI apoya firmemente esta revisión. Este modelo es consistente con otros programas orgánicos (por ej. el Programa Orgánico Nacional del USDA y el Régimen Orgánico Canadiense). Sin embargo, no está claro si estas enmiendas permitirán que los insumos comerciales sean evaluados por otras organizaciones, tales como OMRI, que se dedican a esta labor. OMRI recomienda que se realicen modificaciones adicionales a los Lineamientos para permitir que organizaciones dedicadas a la revisión de materiales puedan evaluar que los insumos comerciales cumplan con los estándares orgánicos.

OMRI cuenta con acreditación ISO 17065 para la revisión de insumos de acuerdo con el Programa Orgánico Nacional del USDA (7 CFR Parte 205) y el Régimen Orgánico Canadiense (CAN/CGSB 32.311). Aunque ambos estándares designan a las agencias de certificación como las entidades responsables de verificar que los insumos utilizados en las operaciones orgánicas cumplan con los estándares, también permiten a dichas agencias consultar con organizaciones, tales como OMRI, dedicadas a la revisión de materiales. Esta opción alivia la carga colocada en el proceso de certificación y permite que la revisión de materiales se realice de manera eficiente por organizaciones expertas en el tema. El Programa Orgánico Nacional del USDA y el Régimen Orgánico Canadiense han formalizado esta práctica al publicar los documentos a continuación,

donde se detallan las opciones disponibles para las agencias de certificación en la labor de verificar la compatibilidad de un insumo:

- Instrucción provisional del Programa Orgánico Nacional del USDA para la revisión de materiales: https://www.ams.usda.gov/sites/default/files/media/NOP%203012%20Material%20Review.pdf
- Memo del Régimen Orgánico Canadiense con respecto a la verificación de insumos: http://www.inspection.gc.ca/food/organic-products/certification-and-verification/guidance-documents/input-verification/eng/1398872788692/1398873007130

Bajo estos dos programas, las agencias de certificación tienen la opción de: (1) hacer la verificación ellos mismos, (2) consultar con otras agencias de certificación que ya hayan evaluado el producto y aceptar la decisión de esa agencia, o (3) consultar con una tercera parte (por ej. organizaciones dedicadas a la revisión de materiales). Tanto el Programa Orgánico Nacional del USDA como el Régimen Orgánico Canadiense permiten a las agencias de certificación aceptar las decisiones de organizaciones dedicadas a la revisión de materiales que cuentan con acreditación ISO 17065 como es el caso de OMRI.

Teniendo en cuenta la información dispuesta anteriormente, OMRI recomienda que se brinde más orientación con respecto a las opciones disponibles para las agencias de certificación en la tarea de verificar que los insumos comerciales cumplan con los Lineamientos para la Operación Orgánica de las Actividades Agropecuarias. Los Lineamientos deberían permitir la evaluación de insumos comerciales por parte de organizaciones que revisan materiales.

Anexo 2 de los Lineamientos

Las enmiendas también proponen eliminar los requisitos de información enumerados en el Anexo 2. OMRI está de acuerdo con estos cambios. Los requisitos de información en el Anexo 2 a menudo exceden lo que sería necesario divulgar según la descripción, los requisitos de composición o condiciones de uso de los materiales listados en el Anexo 1. Esto impone una carga innecesaria a los productores orgánicos y fabricantes de insumos que intenten aprobar materiales según los Lineamientos para la Operación Orgánica de las Actividades Agropecuarias.

Gracias por la oportunidad de poder compartir estos comentarios. OMRI agradece a SENASICA, a los miembros del Consejo Nacional de Producción Orgánica (CNPO) y a todas las partes involucradas en este proceso por su arduo trabajo.

Sinceramente,

Peggy Miars
Directora Ejecutiva/CEO

Ana Negrete
Administradora del Programa Internacional

Interim Instruction
Material Review

1. Purpose and Scope

This instruction specifies the criteria and process that accredited certifying agents (certifiers) must follow when approving substances for use in organic production and handling. This instruction is directed at certifiers, who must meet certain terms and conditions as part of their accreditation (see 7 CFR 205.501(a)(21)).

2. Definitions

Material Review Organization (MRO). An entity with expertise in verifying compliance of production and handling materials with the U.S. Department of Agriculture (USDA) organic regulations. MROs provide certifiers, input manufacturers, suppliers, and organic operations with an independent review and assessment of materials intended for use in organic production and handling.

Materials. Substances to be used as an input in organic production and handling. Materials include, but are not limited to: 1) fertilizers, soil amendments, potting soil, crop production aids, and pest control materials used in crop production; 2) feed supplements, feed additives, medications, and livestock production aids used in livestock production; and 3) ingredients, processing aids, post-harvest handling substances, sanitizers, and facility pest control materials used in processing and handling.

3. Background

The National Organic Standards Board (NOSB) and organic community have historically supported the accreditation of MROs to ensure consistency, uniformity, and predictability of review programs for materials used in organic production and handling. The Organic Foods Production Act of 1990, as amended, (7 U.S.C. § 6501) does not provide authority to accredit MROs; the International Organization of Standardization (ISO) accreditation process has, however, been identified as being able to provide adequate oversight and enforcement of MROs to ensure consistency of material review by different organizations.

Section 205.201 of the USDA organic regulations requires organic producers and handlers to provide a list of each material in their Organic System Plans (OSP).

Certifiers must evaluate this list to determine compliance with the USDA organic regulations. Certifiers either approve or reject a material and communicate their findings to the applicant for certification or the certified operation. Prior to a material being used in organic production or handling by an applicant or certified operation, the certifier must approve the use of the material in the context of the operation's OSP.

In January 2011, the NOP requested that the NOSB provide recommendations on the review of materials by certifiers and MROs. In July 2011, the NOP issued Policy Memorandum 11-4 that outlined criteria for MROs.

In December 2011, the NOSB recommended that:

- MROs be defined as entities accredited or authorized to review and approve materials as compliant with the USDA organic regulations;
- The NOP provide guidance and criteria on the material review process;
- The NOP require MROs to make their review processes transparent;
- Certifiers accept decisions made by other certifiers and MROs;
- The NOP maintain a single, national, generic materials list;
- The NOP maintain a consolidated brand name materials list as an aggregation of materials approved by certifiers and MROs;
- Manufacturers and suppliers of materials partially fund the cost of managing MROs; and
- The NOP hold MROs and material manufacturers/suppliers accountable for violations of the USDA organic regulations.

In May 2012, the NOSB made additional recommendations related to MROs, specifically that:

- Material decisions should only be made by NOP-authorized entities;
- MROs should only make synthetic vs. nonsynthetic determinations based on NOP guidance;
- ISO Guide 65: 1996 General requirements for bodies operating product certification systems (now ISO 17065: 2012 Conformity assessment—requirements for bodies certifying products, processes and services) accreditation should be required for all MROs; and
- The NOP should approve a specific number of criteria for MROs.

In August 2013, the NOP revised Policy Memorandum 11-4 to include procedures for addressing inconsistent interpretations by certifiers and MROs of allowed materials.

4. Policy

Certifiers must review all materials used by organic producers and handlers for compliance with the USDA organic regulations. *See* 7 CFR § 205.201(a)(2). All certifiers must verify that materials used by certified operations comply with the regulations, including the National List of Allowed and Prohibited Substances, and any annotations provided therein (see 7 CFR §§ 205.601-606).

Certifiers have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:

1. Certifiers can verify that the material complies with the regulations by evaluating the product, all of the ingredients within the product, and, if applicable, the manufacturing

processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).

2. Certifiers may consult with another certifier who has already evaluated the product and accept that certifier's determination of the product's compliance with the regulations. The Washington State Department of Agriculture, as an accredited certifying agent, has a publicly available list of approved products available at http://agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx.

3. Certifiers may accept pesticides that have been determined by the U.S. Environmental Protection Agency (EPA) to comply with the USDA organic regulations.

4. Certifying agents may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials. The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for crop and livestock materials, as well as for materials used in organic handling.

In all cases, a certifier must:

1. Maintain documentation to support its determinations about the status of a product's compliance with the regulations, including those products that are approved based on prior determination by another certifier, MRO, or the EPA;

2. Make synthetic vs. nonsynthetic or agricultural vs. nonagricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials;

3. Demonstrate appropriate education, training, and experience levels for personnel conducting material reviews; and

4. Create clear written protocols and procedures outlining the expectations regarding the depth and frequency of the review, and providing clear direction for the evaluation of ingredients, sub-ingredients, processing aids, and manufacturing methodologies at all stages associated with the production of the formulated product.

Products with Multiple Reviews

Some manufacturers may submit their products for review to more than one certifying agent or MRO. In the majority of cases, certifying agents and MROs reach the same determination regarding the allowance or prohibition of a product. On rare occasions, certifying agents and

MROs reach different conclusions on whether the product complies with the USDA organic regulations.

In cases where different certifying agents, alone or in consultation with MROs, reach different conclusions on the allowance of a material, the NOP must be notified for a final determination on proper application of the regulations according to the following steps:

1. When a certifying agent concludes that a product may not comply with the regulations, and that product is allowed by another certifying agent, the certifying agent must notify the NOP at NOP.Guidance@ams.usda.gov.

2. The NOP will review information from both parties and determine whether the regulations have been properly applied. The NOP's determination will be limited to the application of the USDA organic regulations for generic materials; the NOP does not approve or endorse branded (formulated) input products.

3. If the NOP determines that the regulations have not been properly applied and, therefore, the product does not comply with the regulations, the NOP will instruct the certifying agent to rescind its approval of the product.

4. The NOP will communicate the determination to all certifying agents and MROs with a timeline, if appropriate, for the discontinuation of product use by organic operations.

A decision made by certifying agents about the status of a branded (formulated) product remains in effect until the NOP notifies all certifying agents about the status of a material under the regulations.

5. References

USDA Organic Regulations (7 CFR Part 205)

7 CFR 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.
7 CFR 205.201 Organic production and handling system plan.
7 CFR 205.203 Soil fertility and crop nutrient management practice standard.
7 CFR 205.600-607 The National List of Allowed and Prohibited Substances

NOSB Recommendations

NOSB Formal Recommendation, Proposed Recommendation on Evaluation of Materials Review, May 22, 2012.
NOSB Formal Recommendation, Evaluation of Material Review Organizations, December 2, 2011.

Other Laws and Regulations

Pesticide Registration Number 2003-1: Labeling of Pesticide Products under the National Organic Program

International Standards

ISO 17065: 2012 Conformity assessment—requirements for bodies certifying products, processes and services

Document Control: This document supersedes Policy Memorandum 11-4 Evaluation of Materials used in Organic Crop, Livestock and Handling Operations, dated January 21, 2011, and the revisions dated October 31, 2011 and April 6, 2013. This document also supersedes "Verification of Materials Memo" dated March 5, 2008, and "Documented Source of Approved & Prohibited Materials for Use in Organic Operations" dated July 16, 2004. These documents are now obsolete.

Input Verification under the Canada Organic Regime

Date: May 7, 2014

To: Certification Bodies accredited by the CFIA (Canadian Food Inspection Agency)

Subject: Input verification under the Canada Organic Regime

As per Section 13(1) of the *Organic Product Regulations*, CFIA (Canadian Food Inspection Agency)-accredited certification bodies (CBs) must verify that all inputs used in the production and processing of organic agricultural products are those permitted, and used in the manner described, in CAN (Canada)/CGSB (Canadian General Standards Board) 32.311. Producers and processors of organic products must provide a complete list of input materials used in production and/or processing within their Organic System Plan. The inputs materials list includes: fertilizers, soil amendments, planting media, crop production aids and pest control products used in crop production; livestock feed supplements, feed additives, medications and livestock production aids used in livestock production; and ingredients, processing aids, post-harvest handling substances, cleaners, sanitizers and facility pest control products used in processing and handling as defined in Section 3 of the CAN (Canada)/CGSB (Canadian General Standards Board)-32.310-2006.

It is the role of CFIA (Canadian Food Inspection Agency)-accredited CB (Certification Body)s to ensure that inputs in the production of organic products they certify comply with CAN (Canada)/CGSB (Canadian General Standards Board) 32.311. CB (Certification Body)s have three options available for determining compliance:

1. CB (Certification Body)s can verify that the input material comply by evaluating the product and all of the ingredients within the input. The CB (Certification Body) shall contact the supplier/formulator/manufacturer to obtain full disclosure of the ingredients in the input material and the processes used to produce the ingredients and the input material.
2. CB (Certification Body)s may consult with another CFIA (Canadian Food Inspection Agency)-accredited CB (Certification Body) or input evaluation program who has evaluated the input material and accept that CB (Certification Body)'s evaluation of the input's compliance with CAN (Canada)/CGSB (Canadian General Standards Board) 32.311. Input evaluation programs must be accredited to ISO (International Organization for Standardization) 17065.
3. CB (Certification Body)s may consult with a third party to obtain technical information necessary for the CB (Certification Body) to make a compliance determination on the input. These parties must be accredited to ISO (International Organization for Standardization) 17065.

In all cases, the CB (Certification Body) shall take responsibility for all activities outsourced to another body. The CB (Certification Body) must maintain a procedure and documentation to support its determinations about the status of input compliance. CB (Certification Body)s must periodically confirm that product formulations and processes have not changed. This will generally be annually,

but where a longer interval can be justified, must be at least once every three years.

In cases of dispute between CB (Certification Body)s regarding input verification, the CB (Certification Body)s shall inform their respective CVB (Conformity Verification Bodies)s. The CVB (Conformity Verification Bodies)s shall come to a collective decision about the status of the input material.

Valeriya Staykova
Lead Auditor
Canada Organic Office

Date modified:

2014-05-11