



This draft procedure is being posted for public input for 30 days prior to final review and implementation by the National Organic Program (NOP). Interested parties are encouraged to provide substantive comments to the NOP by July 15, 2006. Comments will be considered and final procedures posted for use on the NOP website. Please submit written comments to the attention of the Associate Deputy Administrator, National Organic Program, 1400 Independence Avenue, SW; Room 4008-South, Washington, DC 20250; or by fax to (202) 205-7808.

DRAFT FOR COMMENT: Equivalence Determinations Procedures

Background

The Organic Foods Production Act of 1990 (OFPA), 7 U.S.C. Section 6501, *et. seq.*, as amended, regulates the production, handling, processing, and labeling of all raw or processed agricultural products to be sold, labeled, or represented as organic in the United States. Section 6505(b) of the law provides that “[i]mported agricultural products may be sold or labeled as organically produced if the Secretary determines that such products have been produced and handled under an organic certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of [OFPA].”

This document describes the procedures to be used by the United States (U.S.) to: 1) render equivalence determinations, in accordance with the U.S. Department of Agriculture’s (USDA) existing statutory and regulatory authority, for those countries seeking to export organic products to the United States; and, 2) gain recognition and acceptance, by importing countries, of U.S. organic exports produced in conformity with the USDA National Organic Program (NOP). The procedures described in this document will be adhered to in order to render an equivalence determination of another country’s organic program and to obtain separate acceptance of the NOP for any country seeking an equivalence agreement with the United States.

Policies

The burden of demonstrating equivalence rests with the exporting country. Equivalence means that the U.S. has determined that a foreign government’s technical requirements and conformity assessment system fulfills the objectives of the OFPA and its implementing regulations. The term ‘technical requirements’ refers to a system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products. The term ‘conformity assessment system’ refers to all activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural



products are fully and consistently applied from product to product. U.S. equivalence determinations will be transparent, enabling all interested parties and the public at large to understand the basis for U.S. actions.

The equivalence determination process includes a side-by-side comparison of the U.S. technical requirements and conformity assessment system with the foreign government's technical requirements and conformity assessment system to determine similarities and differences that may exist between the two countries. The side-by-side comparison will, in most instances, be conducted by the exporting country.

Whenever a country seeks U.S. determination on its organic standards, it is expected that the U.S. will request a similar determination of the NOP by the foreign government in order to facilitate U.S. organic exports.

In making an equivalence determination for the U.S. NOP, USDA may ask the foreign government for permission to engage in one or more on-site audits. The purpose of the on-site audit(s) is to verify that the foreign government's conformity assessment system for the country's production, handling, and processing of organic agricultural products is functioning as indicated in the document review.

Equivalence determinations could encompass some or all raw or processed organic agricultural products. Even within the category of products being examined (e.g., livestock products), equivalence may exist for some products but not for others.

Procedures

Foreign governments seeking an equivalence determination to the U.S. NOP should contact USDA in writing. The letter requesting a determination should be sent to:

USDA-AMS Administrator
1400 Independence Avenue, SW;
Room 4008 –So., Ag Stop 0268,
Washington, DC 20250,
Attn: NOP Equivalence Request.

The letter should be sent on the official letterhead of the foreign government's competent authority and should include the following information:



1. The competent authority's contact person(s) and contact information;
2. The legal basis for the foreign government's technical requirement(s), and conformity assessment system;
3. The scope of the requested determination, (e.g., all agricultural products, livestock products, crop products);
4. A detailed side-by-side comparison between the foreign government's technical requirements and those technical requirements set forth in the OFPA and its implementing regulations;
5. Detailed documentation supporting the foreign government's position that, where it uses different technical requirements, the different technical requirements satisfy the objectives set forth by the OFPA and its implementing regulations; and
6. Detailed documentation explaining the foreign government's conformity assessment program. The documentation should address:
 - a) The conformity assessment's program legal authority;
 - b) The conformity assessment program's documented specifications or procedures;
 - c) The conformity assessment program's compliance and enforcement process and procedures. The documentation should be sufficient to demonstrate the foreign government's ability to:
 - Identify and evaluate the degree of non-compliance related to the technical requirements;
 - Investigate non-compliances to determine what corrective or enforcement actions are necessary;
 - Issue corrective or enforcement actions in cases of violation;
 - Monitor implementation/closure of corrective or enforcement actions; and
 - Accurately and in a timely manner communicate with its regulated entities.

Documentation must be submitted in English. USDA will prepare and distribute a letter acknowledging the foreign government's request for equivalence determination. The letter will designate a USDA staff contact. During the interim period, USDA will examine the documentation for completeness and promptly inform the applicant in a precise and complete manner of all deficiencies.



Following discussions with the foreign government, the U.S. equivalence determination will be transmitted to the foreign government by letter from the appropriate U.S. official. The letter will recognize the equivalence of the foreign system and will include, at a minimum, the following:

1. The scope of agricultural products covered under the determination;
2. The obligation to notify USDA of any changes in the technical requirements and/or conformity assessment system that may affect the original determination of equivalence;
3. The obligation to provide USDA with information regarding corrective or enforcement actions imposed on certifying agents by the competent authority;
4. The obligation to cooperate with USDA, to the extent possible, when notified in advance, with any USDA inspections or audits; and
5. In the case of a limited equivalence determination, the obligation to adhere to any limitation or restrictions regarding the use of certain methods, procedures, processes, or substances in products to be sold, labeled, or represented as organic in the United States.
6. The equivalence determination may include additional obligations on a case-by-case basis. Obligations stated in equivalence determinations may vary in some respects depending on the circumstances of the particular determination.

Approval

[PENDING FINAL REVIEW]

Mark A. Bradley
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National Organic Program

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