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Instruction **Equivalence Determination Procedure**

1. **Purpose and Scope**

This instruction describes the procedure to be followed by the United States to: 1) render equivalence determinations in accordance with the U.S. Department of Agriculture's (USDA) statutory and regulatory authority, for those countries seeking to export organic products to the U.S.; and 2) if determined to be in the interest of the U.S., gain recognition and reciprocal acceptance by importing countries of U.S. organic exports produced in conformity with the USDA National Organic Program (NOP).

This instruction applies to countries seeking an equivalence arrangement with the U.S.

2. **Background**

The Organic Foods Production Act of 1990 (OFPA; 7 U.S.C. § 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 U.S. Section 6505(b) of the OFPA provides that "imported 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."

3. Policy

Equivalence means that the U.S. has determined that a foreign government's technical requirements¹ and conformity assessment system² meet or exceed the requirements of the OFPA and its implementing regulations.

The burden of demonstrating equivalence rests with the exporting country. To evaluate equivalence, the NOP will conduct a side-by-side comparison of the U.S. and the foreign government's technical requirements and conformity assessment systems to determine similarities and differences that may exist. U.S. equivalence determinations will be transparent, enabling all interested parties and the public to understand the basis for its actions.

In making an equivalence determination for the NOP, USDA may ask the foreign government for permission to engage in one or more onsite audits to verify that the foreign government's

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¹ "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.

² "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.

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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 can 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.

4. **Procedure**

4.1 **Equivalence Determination Request**

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

USDA-AMS Administrator 1400 Independence Avenue, SW Room 2642-S, 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 set forth in the OFPA and the USDA organic regulations;
- 5. Detailed documentation supporting the foreign government's position that, where the technical requirements differ, its technical requirements meet or exceed the OFPA and the USDA organic regulations; and
- 6. Detailed documentation explaining the foreign government's conformity assessment program:
 - a. The documentation should address the conformity assessment program's:
 - i. Legal authority;
 - ii. Documented specifications or procedures; and
 - iii. Compliance and enforcement process and procedures.
 - b. The documentation should be sufficient to demonstrate the foreign government's ability to:
 - i. Identify and evaluate the degree of noncompliance related to the technical requirements;
 - ii. Investigate noncompliances to determine what corrective or enforcement actions are necessary;
 - iii. Issue corrective or enforcement actions in cases of violations;

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- iv. Monitor implementation/closure of corrective or enforcement actions; and
- v. Accurately and in a timely manner communicate with its regulated entities.
- 7. Documentation must be submitted in English.

4.2 Acknowledgement

USDA will prepare and distribute a letter acknowledging the foreign government's request for equivalence determination, and 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.

4.3 **Determination**

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 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 limitations or restrictions regarding the use of certain methods, procedures, processes, or substances in products to be sold, labeled, or represented as organic in the U.S.

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.

5. References

Organic Foods Productions Act of 1990, as amended

7 U.S.C. § 6501 Purposes.

7 U.S.C. § 6505(b) Compliance Requirements: Imported Products.