



DATE: October 20, 2009

TO: Accredited USDA ISO Guide 65 Program Clients

FROM: Dana K. Stahl, Acting Accreditation Program Manager

SUBJECT: European Union Organic Regulations

On May 6, 2009, Samantha Simon, the USDA ISO Guide 65 Program Accreditation Manager distributed a memorandum regarding changes to the European Union (EU) Organic Regulations. This memorandum provides further clarification for USDA ISO Guide 65 Program Certification Bodies wishing to export organic products to the European Union.

First, it is important to understand the definitions used within the EU Organic Regulations and how they apply to the USDA and USDA ISO Guide 65 Program Certification Bodies.

Accreditation Body – an independent third party who meets the requirements of ISO 17011 and who provides the assessment report referenced under EC No 1235/2008 Article 11(3) and EC No 834/2007 Article 33(3). The ARC Branch is an accreditation body recognized by the National Institute of Standards and Technology (NIST) under the National Voluntary Conformity Assessment Systems Evaluation (NVCASE) Program. The recognition is specific to our accreditation of certification bodies to the NOP (7 CFR Part 205) and the EU Organic Regulations: EEC No 2092/91, EC No 834/2007, and EC No 899/2008.

Competent Authority – *the central authority of a Member State competent for the organization of official controls in the field of organic production in accordance with the provisions set out under this Regulation (834/2007, Article 2.(n)), or any other authority on which that competence has been conferred to; it shall also include, where appropriate, the corresponding authority of a third country;* The ARC Branch is recognized by the EU as a competent authority for evaluating the EU Organic Regulations through the USDA ISO Guide 65 Program.

Control Authority – *a public administrative organization of a Member State to which the competent authority has conferred, in whole or in part, its competence for the inspection and certification in the field of organic production in accordance with the provisions set out under the Regulation; it shall also include, where appropriate, the corresponding authority of a third country or the corresponding authority operating in a third country.* This is a Certification Body in an EU Member State or their designee.

Control Body – *an independent private third party carrying out inspections and certification in the field of organic production in accordance with the provisions set out under this Regulation; it shall also include, where appropriate, the corresponding body of a third country or the corresponding body operating in a third country.* This is a Certification Body outside an EU



Member State. This includes Certification Bodies accredited by USDA, whose assessment scope includes the EU Organic Regulations.

Third Country – Countries (including Switzerland) who have been evaluated against Article 33(1) of Regulations (EC) No 834/2007 and are included on Annex IV of Third Countries for equivalency. The United States is not included on Annex IV.

Compliance – Control Bodies (Certification Bodies – CB’s) must be formally accredited against ISO Guide 65 with ongoing surveillance and must meet the EU Organic Regulations in their entirety. The EU Organic Regulations require the government of these CB’s to maintain an electronic seed database. Since USDA does not maintain an electronic seed database, CB’s accredited under the USDA ISO Guide 65 Program are not able to seek compliance.

Equivalence – There are two options for EU Organic Equivalence Recognition.

1. Equivalence Option 1: EC No 834/2007, Article 33(2) – recognition of a Third Country and published in Annex III of EC No 1235/2008. The Third Country must be recognized, and is responsible for providing a yearly annual report to the EU Commission regarding implementation and enforcement of control measures established within the country. The EU regularly reviews Third Countries and only products produced within the Third Country are eligible for certification as organic in the EU.
2. Equivalence Option 2: EC No 834/2007, Article 33(3) – individual CB’s can apply for recognition as providing equivalent controls. CB’s must submit evidence to the EU Commission of equivalence to the standards being applied, to ISO Guide 65, and to special inspection measures specified in the regulation. The EU Commission then makes the decision to recognize (or not) a CB. The recognized CB’s are published on Annex IV of EC No 1235/2008. This is the option that applies to CB’s accredited under the USDA ISO Guide 65 Program.

Secondly, there are several dates of significance importance that apply to CB’s seeking Equivalence Option 2.

- **January 1, 2009** - Products certified on or after January 1, 2009, must meet the requirements of the new EU Organic Regulations to be eligible for import into the EU as organic.
- **October 31, 2009** – This is the first deadline for CB’s to submit a request for inclusion onto Annex IV to the EU Commission. Once a CB is included on Annex IV, the CB may export organic products in accordance with the EC No 1235/2008. CB’s not included on Annex IV may continue to export organic products through agreements with individual member states that grant individual approval through January 1, 2013, or until included on Annex IV.



- **December 31, 2009** – Product certified to EU Regulation EEC No 2092/91 before January 1, 2009, can be exported to the EU (regardless of if the CB's is included on Annex IV or if the CB's exports directly to individual member states) through December 31, 2009. After this date, products must be certified to the new EU Organic Regulations: EC No 834/2007, EC No 889/2008.
- **January 1, 2013** – This marks the end of the transition period between the old and new EU Organic Regulations. After this date, all organic products must be imported in accordance with EC No 1235/2008.
- **March 31 (annually)** – CB's shall submit a conscience report to the EU Commission, the annual report shall update the information of the technical dossier referred to in Article 11(3) of EC No 1235/2008. (Article 12(1) of EC No 1235/2008)
- **October 31 (annually)** – After October 31, 2009, CB's must submit a request for inclusion onto Annex IV to the EU Commission. The EU Commission will review the request and make the final decision. (Article 11 of EC No 1235/2008.)

Thirdly, the ARC Branch would like to provide additional information on submission requirements and the sufficiency of the USDA ISO Guide 65 Program assessment report.

In order for CB's to be added to Annex IV, they must submit information as outlined in Article 11 of EC No 1235/2008. On December 12, 2008, the EU Commission issued [*Guidelines on imports of organic products into the European Union*](#) to provide guidance on submission requirements for imported organic products. Section 4 of this document applies to CB's.

Once a CB is included on Annex IV, they may export organic products in accordance with EC No 1235/2008. CB's not included on Annex IV may continue to export organic products through agreements with individual member states that grant individual approval through January 1, 2013, or until included on Annex IV.

The ARC Branch believes that the assessment report issued through the USDA ISO Guide 65 Program meets the requirements of the EU Commission. However, if the EU Commission requests additional information regarding the assessment report, notify the ARC Branch and we will accommodate their request.