



DATE: May 6, 2009

TO: Accredited USDA ISO Guide 65 Programs

FROM: Samantha J. Simon, Accreditation Program Manager

SUBJECT: European Union Organic Regulations

On January 1, 2009, new European Union (EU) regulations went into effect for the production, control, and labeling of organic products. However, some of the new provisions on labeling do not take effect until July 1, 2010; and labeling remains optional for imported organic products. *EC No 834/2007* provides the basis for organic production and labeling and repealed *EEC No 2092/91*. *EC No 889/2008* establishes the detailed rules for the implementation of *EC No 834/2007*; and *EC No 1235/2008* establishes the detailed rules for the importation of organic products. Products certified on or after January 1, 2009 must meet the requirements of the new regulations to be eligible for import into the EU as organic.

The Audit, Review, and Compliance (ARC) Branch has worked closely with the USDA Foreign Agricultural Service to determine the affect of the new regulations on U.S. certification bodies. The ARC Branch is pleased to confirm that the EU continues to recognize the ARC Branch as the assessment body within the U.S. As such, the ARC Branch will continue to conduct assessments of certification bodies under the USDA ISO Guide 65 Program to ensure that the certification bodies are meeting the requirements of the new regulations.

The ARC Branch understands that many U.S. certification bodies conduct activities outside of the U.S. We have been working to ensure that those activities are accepted by the EU as well. Last year we sought recognition as an accreditation body under the National Institute of Standards and Technology (NIST) National Voluntary Conformity Assessment Systems Evaluation (NVCASE) Program. We are proud to announce that we have received that recognition. This recognition provides confirmation that the ARC Branch is operating in accordance with *ISO 17011:2004*. Currently, 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*) under the USDA ISO Guide 65 Program. The ARC Branch is in the process of requesting a scope extension to include the new regulations.

The ARC Branch has also confirmed that certification bodies who wish to import organic products into the EU must apply to the European Commission to be recognized as a control body as outlined in *EC No 834/2007*, Article 33 (3). The process to achieve and maintain this recognition is further defined in *EC No 1235/2008*, Articles 11 and 12. As outlined in Article 11, the application must include a copy of the USDA ISO Guide 65 Program assessment report issued by the ARC Branch. The ARC Branch will ensure that the report contains the specific information request. In addition, the certification body must specify the products that it will certify and from which countries. Each product-country combination must be clearly specified



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in the application. In addition, certification bodies must notify the ARC Branch that they are submitting an application to the Commission.

Applications must be received by October 31, 2009 to be considered for the first list. For the following calendar years, the Commission will update the list as appropriate on the basis of applications that have been received prior to October 31 of each year. Even after the list of control bodies is published, the EU is allowing a transition period where it will still be possible to import organic products under the original process. However, this possibility will be phased out, ending January 1, 2013. Once a certification body is recognized and placed on the list, it must meet the requirements outline in *EC No 1235/2008*, Article 12 to remain on the list.

As previously announced, the ARC Branch will verify conformance to the new regulations during the certification body's next surveillance audit. If the certification body needs approval prior to its next surveillance audit, it may submit an application to extend the scope of its accredited program. The application for extension of scope must be submitted to ARCBranch@ams.usda.gov and must include supporting documents and records. Refer to *ARC 1012 Procedure*, Clause 15.4 for additional information.

For questions or additional information, please contact me at 540-361-7640 x103 or Samantha.Simon@ams.usda.gov.