

FINAL REPORT – December 18, 2014

USDA REVIEW OF THE EUROPEAN UNION ORGANIC PROGRAM

USDA Agricultural Marketing Service (AMS) National Organic Program's (NOP)

Peer Review of the European Union's Implementation of the US-EU Organic Equivalency Arrangement

DATES OF PEER REVIEW – July 21 – 25, 2014

1. INTRODUCTION

- 1.1. The U.S. Department of Agriculture (USDA) has an equivalency arrangement with the European Commission (EC) to recognize each other's organic production and handling standards for the purpose of international trade. To verify that the terms of the arrangement are being implemented correctly, each party periodically conducts a peer review of the other party's certification and accreditation system. Prior to this review, on May 5-9, 2014, members of an EC delegation conducted an onsite review of the USDA National Organic Program (NOP), accredited certifying agents, and operations certified under the NOP.
- 1.2. On July 21-25, 2014, representatives of the USDA Agricultural Marketing Service (AMS) reviewed organic accreditation and certification activities in the United Kingdom and France. Representatives of the Foreign Agricultural Service in the UK and France attended as observers. This report is an account of those activities and findings of the review.
- 1.3. Review team was comprised of:
 - 1.3.1. Betsy Rakola, Lead Auditor, AMS – NOP
 - 1.3.2. Cheri Courtney, Director of Accreditation and International Activities Division, AMS – NOP
 - 1.3.3. Jennifer Wilson, Observer, Foreign Agricultural Service – UK
 - 1.3.4. Laurent Journo, Observer, Foreign Agricultural Service – France

2. OBJECTIVES OF REVIEW

2.1. The objective of the review was to evaluate the system capabilities and performance of European Union (EU) authorities and Member States in controlling the proper application and enforcement of the US-EU organic equivalency arrangement.

3. LEGAL BASIS FOR THE REVIEW

3.1. The review was conducted based on US-EU Equivalency Arrangement conditions of periodic peer review assessments.

3.2. The following statutes, regulations, and standards were considered in the review:

3.2.1. U.S. Organic Foods Production Act of 1990

3.2.2. U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program

3.2.3. ISO/IEC 17011:2004(E) Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.

3.2.4. Council Regulation (EC) No 834/2007 on organic production and labeling of organic products and repealing Regulation (EEC) 2092/91.

3.2.5. Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products with regard to organic production, labeling and control.

4. PROTOCOL

4.1. The review was accomplished by observing competent authorities, control authorities, control bodies, and certified organic operations in two member states. In selecting competent authorities, control bodies and operations to be reviewed, the team worked with representatives of the EC to select operations representative of organic products produced in EU member states which are being exported to the United States.

4.2. The team reviewed various phases of the organic production, certification, and accreditation system to determine if the responsible authorities had the necessary controls in place to ensure traceability and compliance with the referenced organic standards. The team focused on the verification of the critical variance prohibiting antibiotic use in livestock production, as well as production and labeling of wine per USDA organic regulatory requirements.

4.3. At each member state competent authority office, the team discussed processes used to evaluate the competence of the control bodies. The team reviewed the functions of auditing bodies to determine whether they were evaluating whether control bodies were effectively implementing the terms of the arrangement.

4.4. The team visited five (5) organic production and handling operations to observe production, handling and labeling practices in order to determine the level of compliance accomplished by the certified operations. The team interviewed farmers, processors, and other responsible parties at each site, and participated in meetings with the farmers, production managers and the control body.

4.5. The team was accompanied by representatives of the EC throughout the review. At each of the certified organic operations visited, the team was also accompanied by at least one representative of the respective control body.

5. SUMMARY OF PREVIOUS REVIEWS

5.1. This was the first peer review of the EU program for the purpose of verifying that the terms of the organic equivalence are being met. The previous onsite review findings were addressed during the initial negotiations and therefore were not relevant for a follow-up response.

6. DEFINITIONS

6.1. For the purposes of this report, Council Regulation (EC) No 834/2007 Article 2 Definitions for competent authority, control authority and control body are followed when these terms are referenced in the report. Specifically,

(n) ‘competent authority’ means 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, 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;

(o) ‘control authority’ means 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 this Regulation; it shall also include, where appropriate, the

corresponding authority of a third country or the corresponding authority operating in a third country;

(p) ‘control body’ means an independent private third party carrying out inspection 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.

7. OBSERVATIONS

7.1. Overview of the United Kingdom (UK) Organic Industry – in the UK, 551,000 hectares of land are certified organic, with an additional 24,000 in transition. The sector reached £1.8 billion in 2009, with 5,156 certified producers on 739,000 hectares. As of 2013, the sector had declined to only 3,918 producers on 575,000 hectares and declining sales in the intervening period but restored back to £1.8 billion in 2013. The organic industry is beginning to rebound after the UK’s recession, with dairy leading the growth.

Crops harvested after the first 12 months of conversion may be labeled ‘produced under conversion to organic farming.’ The UK requires certification for producing or processing organic food or products, importing organic food from third countries (those outside the EU), producing organic animal feeds, and relabeling organic products at any stage of the distribution chain.

7.2. Observations on United Kingdom Competent Authority – the United Kingdom (UK), as a member of the European Union (EU), applies the EU regulations for organic agriculture. The Department for Environment, Food, and Rural Affairs (DEFRA) holds primary responsibility for guaranteeing the control system. DEFRA currently has five full-time and three part-time organic staff members dedicated to the competent authority function. A Government Agency, Natural England, provides technical expertise to both DEFRA and UK control bodies. There are currently eight control bodies authorized and supervised by DEFRA to conduct organic certification activities in the UK. The United Kingdom Accreditation Service (UKAS), a non-profit organization overseen by the UK Department for Business, Innovation and Skills, accredits control bodies according to EN 45011 transitioning to standard ISO/IEC 17065 between 1 July 2014 and 1 September 2015. UKAS audits all control bodies annually and sends its draft reports to DEFRA at the end of each calendar year. These may show some unresolved

non-compliances. UKAS receives and approves corrective actions, and it then submits a final report to DEFRA in April. UKAS refers only major violations to DEFRA for resolution. DEFRA and UKAS meet quarterly to discuss issues of comment interest or concern, and DEFRA also meets quarterly with the UK Organic Certifiers Group (UKOCG), which includes all authorized UK-based control bodies. On occasions DEFRA, UKAS and UKOCG will meet together. The UKOCG Technical Working Group analyzes organic regulatory information and attempts to harmonize policies on technical matters amongst the various control bodies to ensure consistency.

UKAS was not present at the review team's meeting, and DEFRA representatives were not sure how UKAS provided training to its auditors on the organic standards. DEFRA was unable to share UKAS' reports from control body audits, since they were considered proprietary business information. Therefore, the team could not determine whether UKAS reviews the terms of the US-EU equivalency arrangement during its audits of control bodies. DEFRA committed to following up with UKAS to request permission to share a sample audit report with the USDA. (NOTE: DEFRA has checked whether they can provide this but confidentiality agreements between UKAS and the client mean that they are not able to share it more widely.)

DEFRA provides an annual report to the EC on their organic activities. FVO reviewed DEFRA's organic activities in 1999 and 2013. FVO plans to increase its oversight of organic agriculture by visiting all competent authorities, as well as third countries where the EC has trade arrangements, every 2-3 years. Results of the FVO reviews are published online.

The European Commission conducts regular training called "Better Training for Safer Food," which is held in different locations around the continent each year. The training lasts 4-5 days and covers a variety of topics, including organic. Team members are expected to attend these courses and to share their knowledge with others. DEFRA also sits on the Regulatory Committee on Organic Production (RCOP) (formerly known as SCOF). RCOP provides occasional "notes" to member states with written interpretations of organic regulatory issues. DEFRA circulates summary information to control bodies after each meeting with the EC. The team saw an example of these explanatory notes during visits with UK control bodies, viewing a note about the prohibition on antibiotics

use in organic livestock destined for export to the US. Both DEFRA and representatives of the control bodies expressed an interest in learning how US farmers successfully raise organic livestock without the use of antibiotics.

7.3. Observations from Control Body #1 –The CB has been providing organic certification for several decades and currently certifies over 3,000 operations. The CB has a certification staff of about 100 people. Most certified operations are located in the UK, with a few clients in other countries. UKAS accredits the CB to the EU organic regulations, as well as multiple other schemes. The CB performs additional and unannounced inspections on many of its certified operations.

The CB provides regular training to its inspectors on certification schemes. It holds 2-3 days of training annually on a national level, as well as regional trainings, webinars, Skype, and written training documents. The CB participated the USDA's equivalence webinar to understand equivalence arrangement.

The CB's technical team receives regular updates from DEFRA. The US team evaluated several export certificates and two labels destined for the US market, one for crackers and one for cheese. All of them complied with USDA requirements for organic product labels. The CB estimates that it has about 20 clients exporting to the US.

The CB has developed specific producer and processor questionnaires to collect information on how operations verify, trace, and segregate livestock products produced without antibiotics. The questionnaires also ask about recordkeeping procedures and training procedures for workers. The team viewed two examples of completed producer and handler questionnaires, as well as inspection reports which specifically addressed questions of antibiotic use in livestock production.

Based on observations on a dairy farm, inspection reports, and interviews with staff, it appears that the CB considers the following livestock to be compliant with the terms of the equivalency arrangement: cows never treated with antibiotics, the offspring of cows which were managed organically during the last third of gestation, and cows not treated with antibiotics in the 12 months prior entering a dairy herd. The CB stated that, once a heifer has been treated with antibiotics, the CB would not consider that cow to be eligible for USDA organic production again. However, calves treated with antibiotics may be

brought into the milking herd, as the CB does not consider the calves to have been part of the herd until they have been bred.

- 7.4. Observations from Control Body #2 – The CB has been in operation for several decades and certifies over 1,000 operations. The CB is currently accredited by UKAS under EN 45011, and it receives an annual audit. It certifies 1,074 certified producers and 260 processors.

The CB has a staff of 16 full-time employees, as well as 23 subcontracted inspectors. It holds an annual training for inspectors, and its certification officers provide significant training and oversight for the contracted inspectors. The CB conducts targeted, risk-based unannounced inspections. It is currently in the process of developing procedures for residue testing. The CB has reviewed the requirements of the equivalency arrangement with its inspectors.

The team viewed four files for operators exporting to the US: a trader of frozen blackberries, a bulk yellow corn handler, and two dairies. Labels complied with US requirements. The CB received guidance from DEFRA and the EC on antibiotic-free milk. The CB forms indicate that it requires an animal to be antibiotic free for its entire life in order for a livestock product to be approved for export as organic to the United States. The dairy files had sufficient evidence of milk segregation, labeling treated cows with tail tape, milking into separate lines, and storing milk in separate tanks.

- 7.5. Observations from Certified Operation #1 – The operation is a parallel cheese-making operation in southern England. The operation has been certified organic for over a decade, but currently, it only produces one organic cheese under a private label contract with an organic milk cooperative. The cheese is all exported to the US and distributed by a certified US dairy cooperative. The cheese is labeled “organic.” The product label includes the USDA seal and displays the name of the certifier of the final handler on the information panel.

The cheese is processed, aged, and stored on site. The only ingredients are organic milk, rennet, salt with a caking agent, and cultures. The CB verified all ingredients during the annual review. The operation sanitizes all equipment, followed by a potable water rinse, prior to each organic product run. All organic records are kept on green paper, from bulk tank temperature records to final bulk tags, and the cheese is wrapped in green plastic so

that it can be easily identified as organic. The operation had documentation to show that the contracted pest management service was aware of their organic status. Their records showed excellent traceability from receiving through shipment. NOP import certificates accompanied each shipment. Staff members were highly knowledgeable and promptly produced all the records requested during the onsite visit.

- 7.6. Observations from Certified Operation #2 – This operation is a dairy farm with about 100 cows in southwest England. The operation supplies milk to the organic milk cooperative which contracts with Certified Operation #1. Representatives from the milk cooperative, which has about 200 members, also participated in the visit. The cooperative provided copies of instructions for milk tankers, which specified dates for pick up, clean-out procedures, and requirements for the segregation of USDA organic-eligible milk and EU organic milk. The farm sold all its milk as USDA organic-compliant.

The operation had a variety of pastures available for grazing, most of which were buffered by hedgerows or trees. The cattle were all on pasture during the visit. The calves were in housed pens with clean bedding, ample space, light, and fresh air. The operation raises all replacement livestock on the farm.

The inspector verified animal healthcare records and audited the stocks of medications. The farm plan stated that heifers, if treated, would be marked with tail tape. No heifers had been treated since the equivalency arrangement came into effect.

The farmer had recently treated three calves with antibiotics due to eye infections and pneumonia. He recorded these treatments in his healthcare records and on his master animal ID list. The CB considered these calves to be eligible for USDA organic production, since they would not enter the milking herd for more than twelve months after the date of antibiotic treatment. The farmer reported few health problems due to early intervention and the use of homeopathic remedies.

- 7.7. Overview of French Organic Industry – organic agriculture in France has grown quickly in recent years. In 2012, there were 24,425 farms growing organically on about 1 million hectares, as well as 12,341 processors. These figures represent 4.7% of French farms and 3.7% of French agricultural land, respectively. Since 2007, the number of certified operations has doubled, and the quantity of certified or in-conversion land has increased

by 85%. The French Ministry of Agriculture, Food, and Forestry (MAAF) hopes to double organic acreage again by 2017.

Organic consumption in France doubled from 2007-2012. In 2014, the size of the organic market is about €4.17 billion, consisting of 25% imported food. Most organic food is sold through wholesale or retail channels. 12% is sold directly to the consumer, and 5% is sold by “artisanal traders.”

- 7.8. Report on French Competent Authority – Ministry of Agriculture, Food, and Forestry: MAAF oversees the organic, or “biologique,” system in France. France first codified the term “organic” in the Agricultural Orientation Law of 1980, and they now follow the EU organic regulations. The French control system incorporates a number of government agencies. The Ministry of Agriculture oversees policy, participates on the EU RCOP, and oversees the other organizations involved in organic agriculture. The Direction Générale des Politiques Agricole, Agroalimentaire et des Territoires (DGPAAT) oversees import authorizations and derogations (variances from the EU organic regulations). The Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) is the anti-fraud agency with general oversight of the food system in France, and it may inspect any organic operation based on complaints of regulatory violations. The Institut National de l’Origine et de la Qualité (INAO) is the competent authority which conducts approval assessments of all French control bodies according to the EU organic regulations. The Comité Français d’Accréditation (COFRAC) is the accreditation authority, and it is a non-governmental, non-profit organization. The Direction Générale des Douanes et Droits Indirects (DGDDI) oversees customs and imports, and the Groupement National Interprofessionnel des Semences et Plants (GNIS) provides organic seed waivers and maintains a seed database. Lastly, Agence BIO is a public interest group responsible for marketing and promotion, as well as the registration and tracking of organic operators.
- COFRAC has 140 staff and over 1,000 inspectors and technical experts. It oversees 126 certifying bodies, 8 of which are organic CBs. COFRAC also audits the CB's activities outside of France. COFRAC accreditation is a prerequisite for INAO approval of a control body, and approval from both agencies is required before an organic control body may operate in France.

COFRAC and INAO both require an application for accreditation and for approval respectively stating the scopes of activities. They conduct one witness audit per scope per year. Certifiers receive audits from both agencies annually during the initial cycle and every twelve to eighteen months thereafter. Additional audits may be conducted in response to complaints. COFRAC shares all of its reports and significant communication with INAO, and the two bodies have an annual joint meeting. All organic auditors are trained annually and receive information on regulatory clarifications. COFRAC bases its audits on ISO standards, reviewing the overall system, conflicts of interest, staff training, and organizational structure. INAO looks more specifically at the proposed control plan of a control body, and it may also examine individual organic operator files. Neither agency had conducted training on the US-EU organic equivalency arrangement, and their auditors did not systematically review the activity of control bodies in relation to the arrangement.

- 7.9. Report Observations from Control Body #3 – The CB is headquartered in France and has offices and subsidiaries worldwide. The CB is accredited by numerous organizations, including the French National Institute for Origin and Quality and the USDA National Organic Program. The CB is accredited by COFRAC and approved by INAO, and it is also audited by the EC's FVO. It has 30 certification staff and 100 inspectors in France to certify 17,000 French producers and 7,000 processors. Nearly all inspectors are full-time employees. Since the equivalency arrangement, the CB's USDA-organic certified operations have declined by over 80%.

The CB covers the US-EU organic equivalence arrangement in their policies, quality manual, and during the shadowed and observed inspections. All inspectors received training on the equivalence arrangement in January 2013. The CB's EU expert is in direct contact with the Commission to receive changes, and it has worked with the US-based Accredited Certifiers Association and the European Organic Certifiers Council to get more information.

The CB conducts an annual risk assessment of its clients to identify high-risk operators. INAO requires the CB to conduct a second, unannounced inspection for about half of its certified operations. High-risk operators may receive more than one inspection, as well as sampling tests, traceability audits, and a more frequent rotation of inspectors.

The CB verifies 103 winemakers for exports to the US. The team viewed labels for three wines exported to the US. Some wineries use different principal display panel (PDP) labels for the US and EU markets, using the "made with organic grapes" term on the US label. Others use the term "biologique" instead of "organic" on the PDP, and state "made with organic grapes" only on the back information panel. This allows them to customize only the information panels for the EU and US markets. The CB reviews all labels at its offices, and inspectors verify all inputs on site. The inspection report included extra questions on wine to ensure that inspectors verify that the wine is eligible for export the US market.

The CB certifies two operations which handle livestock products for export to the US. In order to address the critical variance prohibiting antibiotic use in livestock destined for the US, the CB requested an attestation stating that the products were produced without the use of antibiotics. However, the CB did not verify this claim through document reviews or inspections prior to approving an NOP import certificate for the livestock products. Instead, the CB instructed its inspectors to review the attestation statements during the operations' next annual inspection. Therefore, the CB did not verify that antibiotics had not been used until after the product had accessed the US market.

7.10. Report Observations from Certified Operation #3 – this operation is a vineyard in the Minervois region of southern France, which has been certified organic for over a decade. The grower used sheep manure and compost to build soil fertility. Weeds were controlled mechanically with tillage. The inspector reviewed all inputs, including sulfur, Bt, and pyrethroid products to control fungus, worms, and blight from leaf hoppers (respectively). The inspector verified buffers, which consisted of three rows of vines which the grower did not harvest. In addition, the grower attempted to prevent contamination through cooperation with neighbors and the analysis of prevailing winds during pesticide applications.

7.11. Report Observations from Certified Operation #4 – this operation is a cooperative producing both organic and conventional wine in southern France. The cooperative purchased grapes from Operation #3. It had dedicated equipment for organic receiving, pressing, fermentation, and storage. The cooperative kept all organic records on green paper for easy identification, and it verified the organic status for each field through

annually-updated certificates. The team viewed examples of receiving tags and lot numbers for each organic shipment, which demonstrated full traceability of products. The cooperative added enzymes and sulfur dioxide to the wine as processing aids, and its technical staff frequently conducted tests to verify that the total sulfite concentration was below 100 ppm. The inspector identified a minor weakness in the record keeping system, which she cited as a finding on her report.

7.12. Certified Operation #5 – This operation is a winery in southern France which purchased organic wine from operation #4. The winery again verified organic certificates for all grape growers to determine whether the grapes and the resulting wine were compliant with USDA organic requirements. Technical staff showed the team a print-out from the CB, which listed processing aids that were allowed for EU organic wine. The print-out identified the subset of these processing aids which were allowed for use in wine to be exported to the US. The list was updated weekly.

7.13. The winery sanitized and rinsed all tanks and lines prior to organic runs. the CB had previously approved all sanitizers and processing aids. Bottles were rinsed with water prior to filling. Wine labeled "made with organic grapes" was placed in dedicated organic storage and labeled as "NOP eligible."

8. FINDINGS

- 8.1. EU competent authorities are not systematically verifying that certifying bodies are correctly implementing the US-EU equivalency arrangement. They stated that auditors may happen to select files which pertain to the arrangement, but they could not state affirmatively whether this verification had occurred. As a result, there may be differences among certifying bodies with respect to their level of understanding and ability to correctly implement the equivalency arrangement.
- 8.2. EU competent authorities are not providing training to accreditation auditors on the terms of the equivalency arrangement.
- 8.3. The USDA considers the term "biologique" equivalent to the term "organic" from a product labeling perspective. In the EU products labeled with "biologique" on the PDP may also list "made with organic [ingredient(s)]" on the information panel. These labels do not conform to the USDA labeling requirements.

8.4. Certifying bodies are applying different requirements for the critical variance prohibiting antibiotic use for livestock and livestock products destined for export to the US. One certifier prohibited antibiotic use for the life of the animal, another prohibited it for 12 months prior to use and allowed a flexible interpretation of a cattle herd, and a third only required a self-attestation on the part of the exporter stating that antibiotics had not been used.

8.5. The French competent authority had not shared the European Commission's 2012 guidance on the critical antibiotic variance with certifying bodies. Representatives from DGPAAT stated that they would resend the guidance immediately following the closing meeting of the peer review, and the Commission planned to review the topic during their upcoming RCOP meeting on September 22.

COM: it was discussed with Member States during the September and November RCOP meetings (SCOF has changed its name to RCOP, Regulatory Committee on Organic Production). The French delegation explained the failure in the communication with their control bodies and confirmed that the guidance was immediately sent to all of them after the peer review. COM stressed the importance of this guidance and required Member States to check that control bodies are well aware of its content, that they understand it and they put it into practice. COM sent the guidance again to MS competent authorities.

9. CLOSING MEETING

The team conducted a closing meeting with EC and French MAAF officials in Paris, France on July 25, 2014. At the meeting, the U.S. team provided a summary and discussion of all findings in this report. The EC team also provided a preliminary response.

10. CONCLUSIONS AND OBSERVATIONS

10.1. The overall EC certification system is robust. Member states appear to work well together, and all of the participants in the peer review were well-organized and well-prepared. Certifiers are verifying EC organic compliance in a sound manner.

10.2. The requirements for USDA organic wine were well-understood and correctly implemented. Control body staff members were knowledgeable on the topic and accurately applied the requirements of the trade arrangement.

10.3. All inspectors accompanied by the team were precise and thorough in their duties, while remaining professional and courteous.

10.4. The frequent onsite audits conducted by competent authorities and control authorities resulted in sound oversight of control bodies.

10.5. The system of risk assessments and unannounced inspections is working well. Based on the communication between operators and inspectors, it appears that producers and handlers accept unannounced inspections as part of the normal course of business.

END OF REPORT