

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

1 USDA REVIEW OF THE EUROPEAN UNION ORGANIC PROGRAM

2 DATES OF REVIEW – May 18-25, 2011

3 1. INTRODUCTION

4 1.1. The U.S. Department of Agriculture (USDA) is engaged in ongoing discussions with
5 representatives of the European Commission (EC) to establish a possible agreement to
6 recognize each other’s organic production and handling standards for the purpose of
7 international trade. To further inform these discussions, both parties agreed to conduct
8 onsite reviews of each other’s organic accreditation, certification and
9 production/handling systems. Prior to this review, on October 4-8, 2010, members of an
10 EC delegation conducted an onsite review of the USDA National Organic Program
11 (NOP), accredited certifying agents, and operations certified under the NOP.

12 1.2. On May 18-25, 2011, representatives of the USDA Agricultural Marketing Service
13 (AMS) and the Foreign Agricultural Service (FAS) reviewed organic accreditation and
14 certification activities in the Czech Republic and Spain. This report is an account of
15 those activities and findings of the review.

16 1.3. Review team was comprised of:

17 1.3.1. Miles McEvoy, Deputy Administrator, AMS – NOP

18 1.3.2. Ruihong Guo, Acting Associate Deputy Administrator and Director of
19 Accreditation and International Activities Division, AMS – NOP

20 1.3.3. Kelly Strzelecki, Senior Trade Advisor, FAS

21 2. OBJECTIVES OF REVIEW

22 2.1. The objective of the review was to evaluate the system capabilities and performance of
23 European Union (EU) authorities and Member States in controlling the proper
24 application and enforcement of the EC regulations for organic products.

25 3. LEGAL BASIS FOR THE REVIEW

26 3.1. The review was conducted at the invitation of the EC and was not part of a legal or
27 regulatory enforcement function of the USDA.

28 3.2. The following statutes, regulations, and standards were considered in the review:

29 3.2.1. U.S. Organic Foods Production Act of 1990

30 3.2.2. U.S. Code of Federal Regulations (CFR) Part 205, National Organic Program

31 3.2.3. ISO/IEC 17011:2004(E) Conformity assessment — General requirements for
32 accreditation bodies accrediting conformity assessment bodies.

33 3.2.4. Council Regulation (EC) No 834/2007 on organic production and labeling of
34 organic products and repealing Regulation (EEC) 2092/91.

35 3.2.5. Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down
36 detailed rules for the implementation of Council Regulation (EC) No 834/2007 on
37 organic production and labeling of organic products with regard to organic
38 production, labeling and control.

39 4. PROTOCOL

40 4.1. The review was accomplished by observing competent authorities, control authorities,
41 control bodies, and certified organic operations in two member states. In selecting
42 competent authorities, control bodies and operations to be reviewed, the review team
43 worked with representatives of the EC to select operations representative of organic
44 products produced in EU member states.

45 4.2. The team reviewed each phase of the organic production, certification, and accreditation
46 system to determine if the responsible authorities had the necessary controls in place to
47 ensure traceability and compliance with the referenced organic standards.

48 4.3. At each member state competent authority office, the team observed processes used to
49 evaluate the competence of the control bodies. The review team observed procedures
50 relating to the certification of organic operations according to EC regulations in order to
51 determine how compliance with the referenced organic production and handling
52 regulations would be carried out. The review team also interviewed personnel to
53 determine their knowledge of organic production, handling and certification practices
54 and their qualifications with respect to their duties and responsibilities.

55 4.4. The team visited eight (8) organic production and handling operations to observe
56 production, handling and labeling practices in order to determine the level of compliance
57 accomplished by the certified operations. The review team interviewed farmers and
58 other responsible parties at each site, and participated in meetings with the farmer,
59 production managers and the control body.

60 4.5. The review team was accompanied by representatives of the EC throughout the review.
61 At each of the certified organic operations visited, the team was also accompanied by at
62 least one representative of the respective control body.

63 5. SUMMARY OF PREVIOUS REVIEWS

64 5.1. This was the initial onsite review of the EU program for the purpose of informing
65 discussions on organic equivalence. There were no previous onsite review findings to
66 consider for follow-up response.

67 6. DEFINITIONS

68 6.1. For the purposes of this report, Council Regulation (EC) No 834/2007 Article 2

69 Definitions for competent authority, control authority and control body are followed
70 when these terms are referenced in the report. Specifically,

71 (n) ‘competent authority’ means the central authority of a Member State competent for
72 the organization of official controls in the field of organic production in accordance
73 with the provisions set out under this Regulation, or any other authority on which that
74 competence has been conferred to; it shall also include, where appropriate, the
75 corresponding authority of a third country;

76 (o) ‘control authority’ means a public administrative organization of a Member State to
77 which the competent authority has conferred, in whole or in part, its competence for the
78 inspection and certification in the field of organic production in accordance with the
79 provisions set out under this Regulation; it shall also include, where appropriate, the
80 corresponding authority of a third country or the corresponding authority operating in a
81 third country;

82 (p) ‘control body’ means an independent private third party carrying out inspection and
83 certification in the field of organic production in accordance with the provisions set
84 out under this Regulation; it shall also include, where appropriate, the corresponding
85 body of a third country or the corresponding body operating in a third country.

86 7. OBSERVATIONS

87 7.1. Report on Czech Republic Competent Authority and Control System

88 Competent Authority

89 The Czech Republic, as a member of the European Union (EU), applies the EU
90 legal framework for organic agriculture. The Ministry of Agriculture holds primary

91 responsibility for applying and supervising the EU and national regulations, guaranteeing
92 the control system, and administering the national logo. The Unit of Organic Farming,
93 within the Ministry's Department of Environment and Agriculture, performs the day-to-
94 day competent authority oversight over organic agriculture. There are currently three
95 control bodies authorized and supervised by the Ministry to conduct organic certification
96 activities in the Czech Republic. The Czech Institute for Accreditation accredits control
97 bodies according to the norm EN 45 011.

98 The European Commission conducts several meetings per year in Brussels to
99 which all member states send representatives from the competent authority. For the
100 Czech Republic, the Ministry of Agriculture is the competent authority. Meetings are
101 held for training, and for discussing and agreeing to proposed amendments to the
102 Commission regulation. Competent authorities are required to send organic production
103 statistics to the Commission on a regular basis. They must also send a seed report, noting
104 the organic seeds available and the conventional seeds used through derogations. Control
105 oversight for the competent authorities is the responsibility of the EC's Directorate
106 General for Health and Consumers (DG SANCO), which requires each member state to
107 submit a manual for control oversight for all agriculture. The Unit of Organic Farming is
108 included in this report. DG SANCO conducts regular audits of competent authorities in
109 member states. DG SANCO conducted an audit of the Czech Ministry of Agriculture
110 oversight within the last year. It was noted that the Czech Unit of Organic Farming was
111 not included in the DG SANCO audit.

112 The Unit of Organic Farming consists of five employees – four
113 officials/specialists and one administrative assistant. The Ministry of Agriculture
114 requires that all its official/specialists have a bachelor's degree related to a field of
115 agriculture. The Organic Unit follows this general requirement and seeks additional
116 qualifications related to its specialty when hiring staff members. All four specialists have
117 bachelor's and master's degrees in agriculture-related fields and all had at least two years
118 of experience working in the organic area at the time of hiring. Specialists are required to
119 not have any interest in any private business enterprises and to sign declaration of
120 confidentiality and disclose any conflicts of interest. The personnel files were complete
121 and contained up-to-date resumes, training records, confidentiality agreements and

122 disclosure forms. Specialists attend various training throughout the year, such as relevant
123 technical training, annual training conducted for certification bodies, and training
124 conducted by certification bodies.

125 The Organic Unit tracks written complaints it receives. In 2010, one complaint
126 was received, investigated and resolved.

127 The Organic Unit does not have a quality manual.

128 Overview of Industry

129 In the Czech Republic, organic farming is called "ecological farming" and the
130 organic products are called "bio products." According to the Czech Act on Ecological
131 Agriculture No. 242/200, a bio product is a raw material of plant or animal origin or of an
132 animal obtained from ecological agriculture in accordance with the relevant EU
133 regulations. Bio foodstuff is a foodstuff produced in accordance with the EU regulations
134 and the general Czech food legislation (Food Act No. 1997/110, Decree No. 304/2004 on
135 Food Additives, Decree No. 205/2004 on contaminants, and Decree No. 446/2004 on
136 adding food supplements).

137 In 2010, area under certified organic production totaled 448, 202 hectares, and
138 comprised 10 percent of total agricultural land. Permanent grassland comprised 82
139 percent of the land, followed by 12 percent arable, and 1.3 percent permanent crops, such
140 as orchards. Organic production includes fruits, vegetables, grains, dairy products, meat,
141 and herbs and spices. Products are intended primarily for domestic processors or for
142 local consumption. In 2010, there were 3,517 organic farms and 626 organic food
143 producers. Organic foods generated 0.75 percent of total food sales in 2010. Organic
144 milk and dairy products account for more than one - fifth of the Czech organic market in
145 value.

146 Certification Process

147 To become certified, an operation applies with one of the three Czech control
148 bodies. Certification activities, including document review and an onsite visit, verify
149 compliance with organic regulations. When the operation is found to be compliant, the
150 next step is to register with the Ministry. All agricultural land is registered. The Ministry
151 maintains a real-time database of all organic operators and detailed information about
152 organic farms, such as maps, types of products grown, and size by product categories.

153 When the registration is complete, the control body may issue the organic certificate.
154 Once certified, a certificate is issued for one year and subsequently, the operation is
155 inspected annually. Control bodies conducted a total of 35 sample tests in 2010.

156 Nonconformities fall into three categories:

- 157 1. Minor non-conformities – written notice, correction demanded and checked
- 158 2. Moderate non-conformities – conditional certificate or certificate issued after
159 corrections are taken
- 160 3. Serious non-conformities – refusal to issue certificate or certificate removed,
161 and/or loss of subsidy

162 The control body must notify the Ministry of Agriculture for infringements
163 mentioned in Organic Farming Act.

164 Penalties include removal of product or farm from organic certification and
165 monetary fines. When a control body issues a non-conformance, a certified operation can
166 appeal the decision to the control body. If operation is not satisfied with the appeal
167 decision, an appeal can be filed with the Minister of Agriculture. Such appeals are
168 reviewed by an advisory group of lawyers in terms of legal and regulatory procedures,
169 rather than factual content. For example, certified operations can appeal the amount of
170 penalties and the review would ensure that consistency with other cases is exercised.

171 Authorization and Supervision of Control Bodies

172 Requirements for control body authorization include accreditation by the Czech
173 Institute of Accreditation and demonstration of appropriate technical and administrative
174 infrastructure and staff expertise. Control bodies are supervised through annual office
175 visits and witness audits (50 annually – 1.5%). Results are shared on the spot and also
176 included in the annual report from the Ministry to the control bodies. In 2010, Central
177 Institute for Supervising and Testing in Agriculture (UKZUZ), which executes state
178 official controls, conducted 200 (5% of certified operations) unannounced inspections.
179 UKZUZ also collected and tested 30 samples in 2010.

180 The USDA review team reviewed the 2010 audit report of KEZ, one of the three
181 authorized control bodies. The audit was conducted in December 2010 and noted no
182 noncompliances. The report documented the review of five areas:

- 183 1. Organization of staff and changes to management

- 184 2. Operator files
185 3. Audit conducted by the Czech Institute of Accreditation
186 4. Inspection schedule
187 5. Sampling and testing

188 The team also reviewed the files of four witness inspections conducted by the
189 Ministry. The witness inspections evaluated inspectors' performance related to the EU
190 organic regulations. The witness inspections were well-documented, thorough and
191 complete.

192 Derogations:

193 Seeds: UKZUZ maintains the Czech database for all seeds, organic and non-organic.
194 The Ministry of Agriculture depends on UKZUZ to maintain this database and supplies a
195 list of organic seeds to the EC. Producers must use organic seeds if available in the
196 required variety in their country or EU member states that border their country.
197 Producers can request to use conventional, non-treated seeds through their certifier. The
198 certifier makes the request through the Ministry for approval. During audits, control
199 bodies verify seeds purchased and derogation approval. The Ministry submits a list of
200 seed derogations to the Commission on a regular basis.

201 Livestock: Derogations can be permitted for outside access during extreme weather
202 (hot/cold), for the health of the animals.

203 Conversion period: Under the EU organic standards, conversion times are 2 years from
204 planting or 3 years from harvest for perennial crops. Control body supervision and
205 inspections are required during the conversion period. Under the Czech national rule, the
206 requirement for control body supervision and inspection can be reduced after the first
207 year of registration, and must be approved by the Ministry. This derogation is typical for
208 grasslands. It is allowed in EC 889-Article 36.

209 7.1.1. Report Observations from Czech Control Body: KEZ CZ-BIO-001

210 Founded in 1999, KEZ was the first control body in the Czech Republic
211 authorized to certify operations engaged in organic agriculture. It is accredited under EN
212 45011 (ISO Guide 65) by the Czech Institute for Accreditation. There is an annual
213 focused evaluation and complete evaluation every 5 years. KEZ currently has 13 staff
214 members (5 inspectors and 3 certification staff), certifying 1,650 organic farms and 200

215 organic processors, distributors, importers, and seed producers. KEZ also has private
216 certification programs, such as natural organic cosmetics, inputs, feed, and certification
217 of natural programs. KEZ maintains a quality management system, including staff
218 qualification requirements, resumes, training records, and declarations of confidentiality
219 and conflict of interests. KEZ requires its inspectors and certification staff to possess a
220 relevant university degree plus a minimum of three years of experience. KEZ maintains
221 a complaint log. KEZ conducted 17 sample tests in 2010.

222 The review team reviewed five certification files (one new producer, two certified
223 producers, and two certified processors). Files were complete and thorough. Detailed
224 maps and complete land history were available for all farm parcels through the Ministry
225 of Agriculture web portal. The KEZ database recorded many details for organic
226 operations and information is easily retrievable. Inspection reports utilize checklist
227 format and do not include comments or details concerning the audits conducted or the
228 input materials used. There is no record of input materials used or labels in the files.

229 7.1.2. Report Observations from Certified Operation #1

230 Operation #1 is a farm of 50 hectares with beef cattle and arable land, certified by
231 KEZ. The review team conducted a witness audit of a KEZ-inspector's inspection of the
232 farm. The inspector conducted a comprehensive inspection. First, the fields and crops
233 were checked against records and maps of the farm. The inspector also checked
234 inventory of silage. Products grown are fed to the operator's own cattle and sold to local
235 organic mills. Because the neighboring farm is conventional, a 6-meter buffer zone is
236 maintained. The operator reported that, by agreement, his neighbor does not spray in the
237 buffer zones. Generally, neighbors reach case-by-case agreements to reduce the potential
238 for contamination, because detected residues can be reported to the phytosanitary agency
239 and conventional neighbors are responsible for damages.

240 The inspector checked the condition of the cattle, pasture health, stocking rates,
241 and asked questions about how the cattle were fed, watered, and sheltered against bad
242 weather. The cattle were in good condition. The cattle stay indoors for the winter and
243 outdoors the rest of the year. Forage makes up 50% of the dry matter intake. The cattle
244 receive bluetongue vaccination. Antibiotics were used to treat navel infections, which
245 was followed by doubling of the withdrawal period.

246 At the operator's office, the inspector checked all relevant records, including
247 planting and harvest records, seed records, including derogations requested and approved,
248 and records on yields and sales activities. Exit interview reviewed all critical criteria for
249 the operator, explained the certification process, and noted no noncompliances. A copy
250 of the inspection report was provided to the operator at the end of the inspection.

251 7.1.3. Report Observations from Certified Operation #2

252 Operation #2 is a goat farm of 170 hectares and 700 goats. In addition to pasture,
253 the farm produces oats, wheat and barley for the goats. The farm is set in an idyllic
254 environment and the animals were in good condition. All milk is processed at its own
255 processing facility located onsite. The operator produces 10 types of products, including
256 milk, yogurt and various cheeses. Antibiotics are not used. The goats are wormed with
257 approved parasiticides (ivermectin) every 3 years based on veterinarian's diagnosis.

258 The operator conducts organic workshops and seminars, and hosts farm tours.

259 7.1.4. Report Observations from Certified Operation #3

260 Operation #3 is a dairy farm of about 200 hectares (half pasture and half crops),
261 certified by Abcert, another of the three control bodies in the Czech Republic. It has 43
262 milk cows and 74 heifers. All farm production is related to milk production. Peas, oats,
263 and various grasses are grown as feed for the cows. Grazing season lasts from end of
264 April to end of October. A milk processor comes twice a week to pick up the milk.

265 Operator reported that there are usually two inspections a year, one announced
266 and one unannounced. The announced one includes an inspection of the fields and cows,
267 and complete audit of records and documentation. The unannounced visit is usually a
268 shorter visit in winter and checks housing condition and makes sure there is enough space
269 and straw for the cows.

270 The operator reported that antibiotics are used only when there are serious
271 infections, and, in such cases, a double withdrawal period is required. Minor infections
272 are treated with homeopathic methods. Vaccinations are given in accordance with
273 veterinary advice.

274 7.1.5. Report Observations from Certified Operation #4

275 Operation #4 is a dairy processor certified by Abcert. The processor also handles
276 conventional milk. The operator receives organic milk from 10 suppliers certified by

277 KEZ and Abcert, and 95% of the milk is made into cheese products. Certificates are
278 maintained on file. Organic milk is accompanied with supplier signatures, brought in
279 through dedicated containers, and received at Tank 4, which is dedicated to organic milk.
280 Every container is tested for prohibited substances per government requirement. Organic
281 milk maintains a separate identity through the whole process and organic products are
282 processed at the beginning of the day. The review team conducted a complete tour of the
283 production process, from receiving to storage of finished products, and reviewed the most
284 recent inspection report. Organic products and ingredients are clearly labeled. The team
285 also checked ingredients of enzymes in storage. Operator reported that the last inspection
286 lasted over 4 hours and included inspection of production process, records of milk
287 purchased and products sold, cleaning process and agents, and inputs.

288 7.2. Report on Spanish Competent Authority - Ministry of Agriculture

289 Competent Authority:

290 In Spain, there are two levels of oversight – the competent authority of Spain,
291 which is the Ministry of Environment and Rural and Marine Affairs (MARM,) in Madrid,
292 and the 17 autonomous communities which are competent authorities in their respective
293 communities.

294 MARM serves the central function of coordinating with the EU and other member
295 states on behalf of Spain, and channels information between the EU and the autonomous
296 communities. The EC Directorate-General for Agriculture and Rural Development,
297 Organic Farming – Unit H.3, has no direct relationship with the communities. MARM
298 conducts regular meetings to coordinate a Spanish position on EC regulations, exchanges
299 information from the EC to the communities and from the communities to the EC, and
300 issues import permits for organic products from third countries. MARM represents Spain
301 at EC meetings and at international institutions with representatives from the regional
302 authorities attending on a rotating basis. Before the meetings, MARM sends all
303 documents to be discussed to the regional authorities and industry sector for input.
304 Following the meetings, MARM reports back to all parties. MARM collects and submits
305 information from the communities to the EC on statistics, evaluation work, seed
306 derogations, and control visits. MARM also establishes guidelines for food quality
307 control, promotion of food stuffs, and coordinates the Spanish position to represent the

308 regional competencies. MARM indirectly provides training for regional competent
309 authorities through a contract with Inter Eco.

310 DG SANCO is responsible for auditing control systems for all EU member states.
311 It appears the last performance audit of MARM's control system from DG SANCO was
312 in 2000. In 2009, MARM received a visit from DG Agriculture and the EU Court of
313 Auditors. DG SANCO is also responsible for auditing all of Spain's competent
314 authorities.

315 The autonomous communities are independent competent authorities and
316 authorize public and private control bodies to certify organic production in their
317 communities. Of the 17 communities, 14 communities authorize only government
318 control bodies to operate, two (Andalucia and Castilla La Mancha) utilize private control
319 bodies, and one (Aragon) has both. The regional competent authorities authorize and
320 supervise the public and private control bodies, and handle infringements and complaints
321 in their communities. Autonomous communities maintain databases of operators and
322 control bodies. Operations that operate in multiple regions have to be registered in all
323 regions. MARM has no official relationship with regionally authorized control bodies,
324 and its relationship with the regional competent authorities is one of coordination rather
325 than supervision.

326 Overview of Industry:

327 In 2009 (the latest data available), Spain's area in organic production totaled 1.6
328 million hectares, and represents the largest of any EU member state. 571,000 hectares
329 are cultivated. Production in Spain has shown steady growth from just 4,235 hectares in
330 1991. However, not much growth is expected from 2010 figures. The regions with the
331 largest production acreage include Andalucia, Castilla-La Mancha, Extremadura,
332 Catalonia, and Aragon. Of the total area under organic production, 45 percent is pastures
333 and prairies, 35 percent is crops, and the rest is woodlands. The number of certified
334 organic operations in 2009 totaled 27,627. Products include cereals, olives, olive oil,
335 dried fruit, livestock, milk and dairy products, and other fruits and vegetables. According
336 to the EC report "An Analysis of the EU Organic Sector," Spain has the largest area
337 under certified organic production and in-conversion combined, but consumption of
338 organic products within Spain remains low. Eurostat data from the same report notes that

339 the organic share of total food expenses in Spain amounted to 0.2 percent in 2007. About
340 50 percent of organic food consumption in Spain is from imported products. Another
341 limiting factor in Spain is that only 20 percent of conventional supermarkets carry
342 organic products. However, this leads to a strong export market for Spanish organic
343 products. MARM estimates Spain's exports at approximately 980 million Euros
344 (\$1,412.8 million). Of that total, approximately 36 percent is fresh product and 46
345 percent is processed.

346 Authorization and Supervision of Control Bodies

347 Provisions of regional laws specify requirements for the authorization of control
348 bodies. Entidad National de Accreditation (ENAC), supervised by MARM, is the official
349 accreditation body in Spain, and accredits organic control bodies under EN 45011,
350 laboratories and other certification bodies in Spain. ENAC receives a peer review every
351 4 years and was last reviewed in February 2011. The review was conducted based on
352 EC765, and covered review of staff resources, quality management system, equipment
353 and methods, and reporting activities. ENAC has about 450 auditors, 10 of whom are
354 organic auditors. There are also five organic technical experts. Qualification
355 requirements for organic auditors and experts include related academic degrees, five
356 years of experience in related fields, and observation of five audits.

357 ENAC accreditation is required for private control bodies and voluntary for public
358 authorities. Accreditation process includes evaluation of all application materials, a desk
359 audit, an onsite audit, office visit, and witness inspections. To maintain accreditation,
360 control bodies are audited again at 18 months and reevaluated after 4 years, followed by a
361 5-year cycle thereafter.

362 Currently, ENAC has accredited 6 control bodies and one public control authority
363 in Spain. Five additional public control authorities are in the process of being accredited.
364 Not all control authorities operating in the autonomous communities are ISO 65 or EN
365 45011 accredited.

366 Derogations:

367 The regional competent authorities maintain lists of approved seed and seed
368 potato derogations. These lists are provided to MARM, which creates an annual report
369 for the EC. Producers are required to use organic seeds if available in the required

370 variety in their country or EU member states that border their country. Producers can
371 request to use conventional, non-treated seeds through their control bodies. During
372 audits, control bodies verify seeds purchased and derogation approval.

373 It did not appear that other derogations on shortening the conversion period are
374 approved on a routine basis in Spain. However, much of the production witnessed on this
375 trip was in perennial horticulture crops, which take several years to reach full production,
376 unlike land being converted to row crop production.

377 7.2.1. Report on Competent Authority of Castilla – La Mancha

378 Castilla - La Mancha is one of Spain's 17 autonomous communities. There are
379 about 4700 certified operations in this region. A database of certified operations is
380 maintained and updated annually. The Consejeria de Agricultura oversees environmental
381 and agricultural matters, and serves as the competent authority. A regional law, based on
382 EU regulations and similar to those of other regions, regulates all aspects of agricultural
383 production, food quality, and the authorization of control bodies. The competent
384 authority is audited by an EU audit team every 4 years. An audit was conducted last
385 year. Staff qualification requirements include academic studies, relevant work
386 experience and regular annual training.

387 In Castilla - La Mancha, four control bodies have been authorized to certify
388 organic production. All four are accredited by ENAC. Two additional requests for
389 authorization are being reviewed. Control bodies are audited by the competent authority
390 once a year. The audit consists of file review and witness inspection. A draft report is
391 issued for response. Currently, 2010 reports are being drafted.

392 The competent authority requires that sampling and testing be conducted by
393 ENAC-accredited labs. Sampling and testing has been done, but data on tests results are
394 not maintained. Positive results were reported to be fairly low. Enforcement sanctions
395 against violations of organic regulations include issuance of noncompliance notice,
396 withdrawal of certificates, and withdrawal of EU financial aids. The Department of
397 Quality Control can levy fines for frauds. Last year, in transition phase for EC
398 regulations, no certificates were withdrawn; however, 327 noncompliances were issued,
399 citing mostly administrative irregularities. Complaints are tracked and investigated. In
400 2010, there were about five complaints.

401 Derogations from EU regulations, such as use of conventional seeds and
402 shortening conversion period, are granted by the control bodies. Operators have to
403 request use of conventional seeds, approvals may be granted, report forwarded to
404 MARM, and then forwarded to EU annually. The conversion period may be reduced by
405 control bodies, but there are very few requests - 1% of 4910 operators in 2009. For
406 example, a research project that has been controlled all along can be certified upon
407 request.

408 7.2.2. Report Observations from Control Body - SOHISCERT S.A.

409 SOHISCERT S.A. is headquartered in Seville. Its main certification activity is
410 organic farming. It also certifies wine for Global GAP. Accredited by ENAC since
411 2000, it has 28 staff members. Staff qualification requirements include college degree in
412 agricultural engineering, veterinary science, environmental sciences, food technology or
413 biology, as well as 2 years of experience. Regular training is conducted and documented.
414 Staff qualifications, training records, and conflict of interest and confidentiality
415 documents are well documented. SOHISCERT S.A. is audited by ENAC annually and
416 by the Regional competent authority annually. The audits generally last two days, one
417 day at the office and one day at witness inspections.

418 SOHISCERT S.A. certifies about 3,500 operations. The certification process
419 consists of review of application materials, desk audit, onsite audit, corrective action
420 process (if relevant) and granting of certification. Subsequently, an annual inspection is
421 conducted. Enforcement actions include issuance of noncompliance notices and
422 withdrawal of products from the certificates. SOHISCERT S.A. maintains a live system
423 of certified operations. SOHISCERT S.A. defines and tracks complaints at three levels:
424 1. Appeals by operators of Sohiscert decisions, which are handled by the Commission of
425 Advisors, an outside organization that reviews the appeals and makes decisions; 2.
426 Operator complaints against Sohiscert; 3. Third party complaints. Complaints average
427 about five or fewer each year, and are investigated and resolved.

428 7.2.3. Report Observations from Certified Operation #5

429 Operation #5 is an olive farm of 100 hectares, 75% of which, half organic and
430 half conventional, is in production. The operation also processes organic and
431 conventional products. Between products, the machines are washed with pressured hot

432 water. The review team reviewed the buffer zones and asked questions about soil, weed
433 and pest management. Operator reported use of approved fertilizers, use of copper to kill
434 diseases and fungi, and scale treatment with garlic extract. The conventional portion of
435 the farm, managed by the same operator, does not spray. Operator reported that the last
436 inspection was in May 2011 and included a complete review of borders, buffer zone, soil
437 and disease management, and complete review of production and sales records. Two
438 samples have been taken by the control body and both were negative. Operator also tests
439 samples regularly.

440 7.2.4. Report Observations from Certified Operation #6

441 Operation #6 is an organic citrus operation. The review team asked questions
442 about disease treatment and soil management. Red scale, white fly and fungi are
443 common problems. Operation uses sheep manure, and liquid fertilizer, delivered through
444 the irrigation system. Bleach is used to clean the system. The liquid fertilizer is certified
445 for organic production; if not, the control body would check and evaluate the ingredients.

446 7.2.5. Report Observations from Certified Operation #7

447 Operation #7 is an apricot farm and became organic in 1997. The operator uses
448 composted sheep manure as fertilizer. Sulfoluq from limestone is used to control fungi
449 and has to be authorized by the control body. Ground covers are not grown because they
450 absorb water from the trees. In this particular region, due to the extremely low rainfall in
451 this area, the groundcover is ploughed in March. The operator stated that in these
452 climatic conditions, keeping the groundcover the whole year leads to premature
453 defoliation and general deterioration of the trees. The operator is not sure whether the
454 neighboring farm is conventional or organic, but because the neighboring field is lower
455 (on a separate terrace), there is less concern about drift.

456 7.2.6. Report Observations of Certified Operation #8

457 Operation #8 is an almond processor. It is a cooperative of 6,500 producers and
458 60,000 hectares. Of these, about 850 are organic producers, cultivating about 8,000
459 hectares.

460 7.2.7. Report on Control Authority and Control Body in the Valencia Autonomous 461 Community

462 The Generalitat Valenciana, Conselleria d'Agricultura, Pesca i Alimentació
463 (CAPA) is the competent authority in the Valencia region. Comitè d'Agricultura
464 Ecològica de la Comunitat Valenciana (CAEVA) is the control authority for organic
465 production, promotion, and regulation enforcement in this region. CAEVA is public and
466 nonprofit. Staff qualification requirements include, at a minimum, degree in agriculture
467 engineering, related experience, in-house training focused on specific areas, and refresher
468 courses to keep up with changes.

469 The control body, CAEVA ES-ECO-020-CV, is an independent body within
470 CAEVA and oversees organic certification in the Valencia region. It reported that it has
471 a quality management system, operates in compliance with EN45011-ISO65, and has
472 applied for accreditation by ENAC, although not yet accredited. ENAC has conducted
473 onsite and witness audits. Corrective actions are being reviewed and another visit will be
474 conducted. The competent authority does not conduct witness inspections of the control
475 body. Currently, there are 1,853 certified operations, and around 65.647 hectares of
476 certified land in the Valencia region.

477 Certification is accomplished through the certification committee composed of 8
478 members with various expertise and background. Certification process includes review
479 of application materials, document audit, onsite audit, and certification decision. The
480 Committee of Parties, nominated and elected every 4 years, representing producers,
481 industry, and consumers, oversees the work of the control body and ensures that rules are
482 applied consistently. Noncompliances are usually detected during inspections, and
483 operators have 15 days to correct or present additional information. If product integrity is
484 compromised, a case can be initiated to stop the sale of the implicated product(s) as
485 organic. Operations have 30 days to appeal, during which the certificate is temporarily
486 suspended. Appeals are filed with the Committee of Parties and reviewed for procedural
487 correctness. Decisions are not changed unless procedures are not followed. Maximum
488 penalty is withdrawal of certificate. Frauds are handled by a separate unit which deals
489 with frauds of all types.

490 A complaint log is maintained. In 2010, four third party complaints were
491 received and resolved. A sampling plan is prepared on an annual basis, based on a risk
492 analysis of all operators (1-5 levels). Risk levels of 3-5 are sampled and tested. In 2010,

493 155 samples collected from 1832 inspections were tested, and 42 showed positive
494 residues and were addressed depending on the situations.

495 8. CLOSING MEETING

496 The review team conducted a closing meeting with EC officials in Albal (Valencia), Spain on
497 May 25, 2011. At the meeting, the U.S. review team provided a complete summary and
498 discussion of all findings in this report.

499 9. INTRODUCTION TO FINDINGS

500 The assessment activities took place in two of the EU's 28 member states.

501 10. FINDINGS

502 10.1. Finding 1. The European Commission's Organic Farming Program (section H.3)
503 does not conduct on-site audits of competent authorities' organic programs. . The
504 Commission supervises the control systems set up by the Member States. In particular :

- 505 ○ Organic controls form part of the Official Food and Feed Controls (OFFC) that are
506 governed by Regulation (EC) No 882/2004 on official controls performed to ensure
507 the verification of compliance with feed and food law, animal health and animal
508 welfare rules. Implementation of the OFFC in the Member States is supervised by
509 the FVO of DG SANCO. The FVO carries out audits in the Member States to verify
510 that official food and feed controls, including organic controls, are carried out in
511 accordance with the Community law.
512
- 513 ○ The audit service of DG AGRI carries out audits of agricultural expenditures that
514 are paid to MS from the Community budget. Organic farming is also supported,
515 mainly through rural development aid paid in the form of agri-environmental
516 measures. Therefore organic farming is in the scope of audits of agri-environmental
517 measures.
518
- 519 ○ Unit H.3 provides assistance to the services mentioned above in relation to specific
520 issues with regards to organic farming. It also carries document reviews of reports
521 and notifications from MS and in case of doubts concerning application of organic
522 farming legislation by a MS, it follows-up the issue with Unit M.3 (Monitoring of
523 application of agricultural legislation, infringements and complaints). Unit H.3
524 carries out a regular review of information available (notifications and reports from
525 MS, audit reports from other Commission services) and takes action in respect to a
526 particular MS when necessary.
527

528 10.2. Finding 2. The inspection reports reviewed in the Czech Republic relied on
529 check boxes. There was a lack of observations and evidence recorded in the inspection
530 reports. We observed a thorough inspection during the witness audit in the Czech
531 Republic but there was a lack of detail within the inspection report. The lack of detail

532 and the reliance on check boxes make it difficult for control bodies and competent
533 authorities to fully evaluate organic operations' compliance with the EU requirements.

534 10.3. Finding 3. Government certifying agents (control authorities) are not required to
535 be accredited under the EU organic regulations. In Spain, Valencia's control authority
536 (CAECV) voluntarily agreed to be accredited by ENAC, Spain's accreditation authority.
537 Most government certifying agents operating in Spain are not accredited.

538 10.4. Finding 4. Antibiotics are used in organic livestock production.

539

540 10.5. Finding 5. Inert ingredients are not reviewed or restricted in pesticide or fertilizer
541 inputs.

542

543 11. CONCLUSIONS AND RECOMMENDATIONS

544 General Observations:

545 1. Producers and processors appear to comply with EU organic standards. Records
546 are thorough and complete.

547 2. Inspections are conducted by qualified personnel. Inspections are thorough and
548 complete and note all non-compliances found.

549 3. Samples are collected, and risk assessments and unannounced inspections are
550 conducted.

551 END OF REPORT