

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