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DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Brussels,
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NOTE TO THE FILE

Subject: Report on the peer review on US National Organic Program, 6-9 May 2014

In the framework of the EU-US organic equivalence arrangement, unit AGRI.B4 carried out a peer review on the US National Organic Program covering the tree layers of the US organic system: organisation and procedures of NOP, control activities of a control body and field visits to three operators.

6 May 2014: visit to Washington State Department of Agriculture (WSDA) headquarters, Olympia (Washington State)

Participants: Joao ONOFRE and Manuel ROSSI PRIETO (AGRI.B4), Brenda BOOK and Scott RICE (WSDA), Renee MANN (USNOP)

The WSDA is a control authority listed in Annex III to Regulation (EC) No 1235/2008. It is a public body recognised by the US for the purposes of the EU-US equivalence arrangement. They can certify organic products intended to be exported to the EU in the framework of the arrangement.

The WSDA is based in Olympia and carries out organic certification activities primarily in Washington State, Alaska, California and Oregon. They certify around 11.000 operations per year from 7.000 producers. Washington State is the largest US state in organic certification. WSDA is certified ISO 65 and has 25 staff.

We met the Organic Program and Organic Accreditation and Quality Managers who explained in detail the WSDA organisation and procedures. We were introduced as well to the responsible staff for crops, processors and materials.

We had the opportunity to check several files that we had requested previously: some related to the operators we were going to visit, a file of an operator who surrendered the certification after being notified of an irregularity and a file of an operator exporting to the EU.

We checked as well the organic certification application forms for producers, handlers and processors.

After checking documents, we had a discussion with WSDA staff where we asked for additional information and clarification on some aspects.

Conclusion:

- WSDA staff was very cooperative and ready to give clear and thorough explanations on their procedures and control activities and on the files. They were aware of the content of the EU-US equivalence arrangement and in particular on the limitation concerning the use of antibiotics on organic apples and pears.

- Files were complete and easy to follow.

- Applications forms for operators were comprehensive and users friendly. International requirements as the prohibition of antibiotics in apples and pears for the EU were clearly indicated, including a reference to WSDA webpage where operators can find full details of requirements to export organic products to the EU.

- Some minor issues were spotted on the certificate of inspection form for imports into the EU. In certificates of inspection used in 2013, box 2 was incorrect because it did not make the difference between imports according to Art. 33(2) (recognised third countries) and Art. 33(3) (recognised control bodies) of Regulation (EC) No 1235/2008. WSDA detected this mistake and solved it. In the current form, there is a typo in box 9 (country of 'designation' instead of country of 'destination'). This will be solved immediately. The origin of these mistakes in the certificate of inspection may be the lack of an official EU form available on our website and ready to be filled in. Control bodies have to reproduce the certificate of inspection from Annex V to Regulation (EC) No 1235/2008. We could help operators and control bodies uploading a fillable PDF form on the EU organic website. Nevertheless, the e-certification project currently in development between AGRI, TAXUD and SANCO will certainly solve this issue.

7 May 2014: field visit to Wilcox Farm, Roy (Washington State)

Participants: Joao ONOFRE and Manuel ROSSI PRIETO (AGRI.B4), Renee MANN and Lisa BRINES (USNOP), Connie KARR (OTCO), Andy WILCOX and Jim MAHON (Wilcox Farms)

Wilcox Family Farms was founded in 1909. It is a family business run today by Wilcox fourth generation. This approximately 607 hectares (1.500 acre) facility is located along the north and east bank of the Nisqually River. They produce whole and liquid eggs and crops. In 2005, Wilcox started the conversion to cage-free systems and organic production.

During the field visit, we were guided by Wilcox staff and accompanied by staff from Oregon Tilth Certified Organic (OTCO), the certifier body for Wilcox organic certification. This control body is listed in Annex III and IV to Regulation (EC) No 1235/2008.

The field visit was focused on the organic eggs production, around 40% of the total egg production. Part of the production is in conversion. Production of organic eggs is around 10 million dozen eggs per year.

Some hectares of crops are certified for the production of organic feed that is used to cover part of their needs. The rest is purchased to some suppliers.

Laying hens are kept in houses according to their age. Pullets in the first weeks of life are kept in special houses with artificial lights and no outdoor access. These pullets are trained to jump with the help of a Dutch equipment. It is a multi-tier system that teaches pullets to move between the various levels and trains hens to jump and fly. These pullets spend more than 12 hours in darkness to avoid faster growing than needed.

As they grow, hens are moved to other houses with room according to their sizes where they can move and jump. Hens are grouped by species. Natural light and outdoor access are provided. Hens can lay in special areas.

The handling facility was arranged to separate organic from conventional production. Organic eggs were packaged with clear indications in green colour.

Wilcox staff showed us as well the liquid egg plant and the hard-boiled egg plant.

Conclusion:

- USNOP regulations do not establish detailed requirements concerning maximum numbers of animals per hectare or minimum surface areas indoors and outdoors for laying hens as EU regulations do. However, the conditions observed in Wilcox Farms can be judged as generally acceptable for EU standards. It is important to bear in mind that there are no exports of organic eggs from the US to the EU.

- Wilcox staff seemed very committed with the organic production as well as the Wilcox family. The fourth generation currently running this family business is the responsible of starting the conversion to organics.

8 May 2014: field visit to Zirkle Fruit Company, Selah (Washington State)

Participants: Joao ONOFRE and Manuel ROSSI PRIETO (AGRI.B4), Brenda BOOK and Scott RICE (WSDA), Renee MANN and Lisa BRINES (USNOP), Del LONG (WSDA inspector), Harold AUSTIN (Director of Orchard Administration, Zirkle Fruit Company)

Zirkle Fruit Company is the largest fruit producer in the US. It is a family-owned business founded in 1974 with several producing and handling facilities in Washington State. Zirkle grows apples, cherries, blueberries and wine grapes. Zirkle started the conversion to organic in 1995. They grow conventional and organic fruit and export organic apple to UK.

This field visit was requested by DG AGRI to check how US operators and control bodies deal with the prohibition of using antibiotics on apples/pears intended to be exported to the EU.

We visited the orchards and the handling facility.

In the orchards, apple trees are organised by blocks depending on the production method (conventional or organic) and the market of destination (US or EU). Blocks are identified by a Z (US) or by an X (EU). To avoid contamination, organic blocks are surrounded by buffer zones consisting of non-cultivated land and a row of trees. The apples from these trees are sold as conventional.

In the organic blocks, weeding is done with propane flamers.

Apple trees producing apples for EU market must not be treated with antibiotics in case of fire blight. In case of treatment with antibiotics, those apple trees can qualify again for EU market only 36 months after last treatment.

We checked as well the place where substances for treatments are stored. Those for organic production were clearly identified and acceptable for organic production.

In the afternoon, we visited the handling facility in Prosser. Staff in charge of the reception of the apples from the orchards explained their procedures to ensure that apples for EU market are clearly identified and separated from the others. Apples for EU market are classified, washed (with organic cleanser) and packed avoiding any contact with other apples. They are handled in first place in the day. They are identified by an X in the boxes.

We had the opportunity to witness an audit from a WSDA inspector. Due to time limitations, the audit was partial.

Audit started with a document review where the inspector checked the sites, varieties and acres and the applied treatments. Inspector keeps records of all treatments applied in the last three years to check the compliance with EU, Canada and Japan requirements. He checked that the 36 months limit without antibiotics treatment was fulfilled. Then the inspector visited some blocks with us and checked buffer zones, weeding, water treatment for irrigation, etc.

The audit in the handling facility turned into a simple visit of the premises. The inspector come with us and was ready to answer our questions on the handling methods but he did not carry out an audit. This was mentioned to WSDA staff and to USNOP in the closing meeting.

During lunch, we exchanged views with Harold Austin (Zirkle) who is also a member of the National Organic Standards Board, a Federal Advisory Committee comprised of members of the organic community that advises USDA on which substances should be allowed or prohibited in organic farming and processing. We discussed on alternatives to antibiotics to fight against fire blight once they will be prohibited as from October 2014. An Austrian product called Blossom Protect is being tested with good results. It is a biotechnological plant protection product containing microorganisms which block the fire blight pathogen, *Erwinia amylovora*, from colonizing the apple blossom. There are other methods as copper applications at a very low degree to avoid toxicity, control of humidity, use of resistant varieties…

The issue of fire blight was also discussed during a dinner with David Granatstein, a researcher from the Washington State University. We learnt that a research project is in development to find reliable solutions to fight fire blight. However, Mr Granatstein

acknowledged serious delays in the completion of the project. He estimated that a couple of years more would be necessary.

Conclusion:

- The orchards and the handling facility seemed to be properly organised. Organic fruit was clearly separated from conventional and identified. The systems and procedures in place to prevent commingling with conventional apples or with organic apples treated with antibiotics seemed effective.

- Very committed staff. In particular, Harold Austin was a useful source of information about organics in US due to his knowledge and to his role as a member of the NOSB.

- The EU agreed to a partial witness audit, however this was not satisfactory. At the handling facility, the inspection was limited due to the noise of the manufacturing facility and the lack of time. In the future, a full audit should be observed. Additionally, Zirkle staff showed a familiarity with the inspector that may put into question the inspector rotation policy of WSDA.

9 May 2014, morning: field visit to Snoqualmie Vineyards, Prosser (Washington State)

Participants: Joao ONOFRE and Manuel ROSSI PRIETO (AGRI.B4), Brenda BOOK and Scott RICE (WSDA), Renee MANN and Lisa BRINES (USNOP), Joy ANDERSEN (Senior Winemaker, Snoqualmie)

Washington State's wine industry is growing very fast. The number of wineries has grown from 24 to more than 700 in 25 years. Snoqualmie started in 1983 under the leadership of Joy Andersen. Since the beginning, this winery is committed to sustainable and organic practices.

This producer makes conventional and organic wine. Organic wine, both labels considered ("organic" without added sulphites and "made with organic grapes" with up to 100 ppm), is around 1% of the total production and nearly all is labelled "made with". The annual production of "organic" wine is around 50 cases. This "organic" wine is sold in farmer markets. We did not find a single bottle of "organic" wine in restaurants or shops and not even in this winery’s shop.

We visited the vineyards and the production facility. At the vineyards, organic grapes are clearly identified by signs indicating "Organic vineyard, do not spray". Buffer zones consisting of non-cultivated land are in place and are subject to regular testing.

At the production facility, we visited the lab where the level of sulphites is controlled. If the maximum level of 100 ppm authorised for wines "made with organic grapes" is exceeded, wine is mixed with others with less content of sulphites. Excess sulphites are not removed.

On the production practices, very restricted under EU rules but all allowed under US regulations, we realized that it is not a real problem. This producer explained that they do

not use any of the practices that are not allowed in the EU. The only practice they apply is centrifugation, which is allowed in EU.

The absence of added sulphites in organic wine is not counterbalanced by heat treatments or ultrafiltration. They produce just a few cases per year and do not intend to make more.

Conclusions:

- The issue of the restriction of production practices in EU regulations seems not to be a problem in practice, at least in Washington State.

- During the visit to the vineyards, a member of the staff referred to the WSDA inspector as "our inspector". Furthermore, it was the same inspector as the one of the apple company. Again, too familiarity between the company staff and the inspector.

9 May 2014, afternoon: closing meeting at WSDA offices in Yakima (WA)

Participants: Joao ONOFRE and Manuel ROSSI PRIETO (AGRI.B4), Brenda BOOK and Scott RICE (WSDA), Miles MCEVOY, Betsy RAKOLA, Renee MANN and Lisa BRINES (USNOP)

A conference call was held to allow the participation of USNOP staff based in Washington DC.

JO summarized the peer review and thanked Miles McEvoy and his staff and the WSDA staff for the outstanding organisation. JO stressed the great interest of all the farms we visited and also the opportunity we had of meeting remarkable people from the organic sector.

JO regretted that the witness audit was not carried out as planned. The doubts about the inspector rotation policy of WSDA were also mentioned. Brenda Book (WSDA) explained and justified this on the basis of the geographical extension, the increasing number of operators and the small number of full time inspectors (8), 2 part-time inspectors and 3 contract inspectors.

The peer review that the USNOP will carry out in the EU by the end of July was discussed as well. Cheri Courtney and Betsy Rakola will come to Europe in the week starting the 21st July. The peer review will take place in France and UK. In France, they will visit an organic wine producer and ECOCERT headquarters. In UK, a visit will be organised to an organic cheese producer in southern England that is exporting to the US in the framework of the equivalence arrangement. Visits to control bodies and competent authorities will be scheduled as well.

THE EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate H. Sustainable development and quality of agriculture and rural development
H.3. Organic farming

Brussels, 10 MAI 2011
AGRI H.3/HVB/rm/D(2011) 541906

MISSION REPORT

ORGANIC FARMING

UNITED STATES

MISSION DATE : **4-8 OCTOBER 2010**

LEGAL BASIS : **Council Regulation (EC) No 834/2007 and Commission Regulation (EC) No 1235/2008**

SCOPE : **Organic products of plant and animal origin and organic processed products of plant and animal origin**

MISSION TEAM : **Herman VAN BOXEM (Commission, AGRI/H.3)**
Paul AXMANN (Commission, AGRI/H.3)
Felix BLOCH (Commission, AGRI/A.2)
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Table of contents

ABBREVIATIONS USED

ACA	Accredited Certifying Agent
AMS	Agricultural Marketing Service
ARC	Audit, Review and Compliance Branch of AMS
CB	Certifying Body
CFDA	California Department of Food and Agriculture
DG AGRI	Directorate-General for Agriculture and Rural Development
IOIA	International Organic Inspectors Association
NOP	National Organic Program
OFPA	Organic Food Production Act
USDA	United States Department of Agriculture
SOP	State Organic Program

EXECUTIVE SUMMARY

A peer review mission on organic production was carried out in United States from 4 to 8 October 2010. The mission was carried out in the framework of the assessment of the application of the United States to be included in the list of equivalent third countries according to Article 33(2) of Regulation No 834/2007. The objective was to verify in practice the application of the US standard for organic production and the functioning of the control system, including supervision of Certifying Bodies (CBs).

The mission included discussion with representatives from the United States Department of Agriculture (USDA) and it's National Organic Program (NOP), with the California Department of Food and Agriculture (CFDA) and its California State Organic Program, two visit to CBs, as well as visits to five certified organic operators.

Conclusions of the mission:

- The US has established an overall and coherent legal framework and control system for organic production that has many strong legislative and administrative characteristics but is still undergoing major changes and improvements. It is not clear whether all aspects of the control system with its current performance as observed by the mission team can at this time be considered to have an equivalent effectiveness as those in the EU legislative framework. However, further consideration will need to be given to the improvements currently taking place.

- The mission has identified a number of issues on the practical application of the US organic standards that are relevant for the ongoing equivalence determination and will require further discussion during ongoing talks.

1. INTRODUCTION

The mission took place from 4 to 8 October 2010. The objectives were to verify the application of the United States production and inspection rules for organic production in practice and to provide an opportunity to discuss how the relevant authorities carry out supervision of the Certifying Bodies (CBs).

The mission was carried out by four officials of the Directorate-General for Agriculture of the European Commission (two from Unit H.3 "Organic Farming", one from Unit A.2 "Industrialised Countries, OECD" and one from the EU Delegation in the US) and by two organic production experts from Member States, one from the UK Department of Environment, Food and Rural Affairs and one from the Danish Veterinary and Food Administration.

2. MISSION PROGRAMME

During the mission, meetings were held with representatives from the United States Department of Agriculture (USDA) and its National Organic Program (NOP) at the premises of the USDA in Washington D.C. as well as with the California State Department of Agriculture and its State Organic Program at their offices in Sacramento.

Two Certification Bodies (CBs) and five certified organic operators were visited.

The detailed mission programme can be found in the Annex.

3. ORGANIC PRODUCTION IN US

The 2008 Organic Production Survey carried out in 2007[1] counted 14,540 organic farms in the United States, comprising 1.66 million hectares of land, of which 45% is grassland. Of those farms, 10,903 were USDA certified and 3,637 were exempt from certification because they had a turnover of less than 5,000 US$.

A wide variety of organic crops is grown: 127,000 ha of wheat, 57,000 ha of corn, 53,000 ha of vegetables (including potatoes), 39,000 ha of soy beans and 31,000 ha of fruit.

As regards livestock, the census counted 220,000 milking cows, 48,000 beef cows and 14,000 pigs. There were 4.5 million laying hens and 6.4 million broilers.

4. REGULATORY FRAMEWORK FOR ORGANIC PRODUCTION AND CERTIFICATION IN THE US

Legislation

- Organic Foods Production Act of 1990,

[1] http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Organics/index.asp

- National Organic Program, Title 7 of the Code of Federal Regulations, Part 205. 21 December 2001, last updated 17 June 2010.

5. MISSION FINDINGS

5.1. Production standard

Documentary assessment of the US regulatory framework has been carried out prior to the mission through several rounds of meetings and exchange of correspondence between the USDA's NOP and the services of DG AGRI. The EU raised a number of questions on the equivalence of certain elements in the US organic production rules. US provided more information on these elements. The assessment is ongoing and is as such not part of this report.

As to the application of the standard, the mission team observed that the US organic standard was correctly applied by the small sample of operators visited on the spot. A number of organic farming practices observed, as reported in sections 5.5 and 5.6 of this report, illustrated the practical application of the US organic standard in the US and will be taken into account in the ongoing equivalency determination.

5.2 Control system

5.2.1 Competent Authority USDA / NOP

The National Organic Program (NOP) is a program under the United States Department of Agriculture (USDA) Marketing and Regulatory Programs mission area and is placed within the Agricultural Marketing Service (AMS) agency.

The NOP uses the services of two of the ten other AMS programs, i.e. the Audit, Review and Compliance Branch (ARC) of the Livestock and Seed Program and the Appeals Branch of the Compliance and Analysis program.

The NOP has three divisions: Standards, Accreditation & International Activities and Compliance & Enforcement. At the time of the mission the NOP employed 30 people. This is a significant increase in a relatively short period. In addition, eight ARC auditors of the Livestock and Seed Program carry out audits on CBs.

The NOP accredits[2] Certifying Agents, also known as Accredited Certifying Agents (ACAs), Certifiers or Certifying Bodies (CBs); the latter term that will be used further in this report. CBs can be private organizations or public authorities. The NOP has accredited 55 CBs in the US; worldwide, including US, NOP has accredited 97 certifiers.

The NOP is undergoing major and dynamic changes since mid 2009, shortly after the new administration took office. Major changes take place in staffing, including strong growth in staff and in development of the NOP procedures, which have been put together in a "Handbook" in September 2010. The NOP organizes regular training for CBs. The communication between CBs and NOP was reported to have largely improved over the

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[2] The term "accreditation" in this context is used as a synonym of "approval" or "determination that authorizes an entity to conduct certification activities". It is defined in § 205.2 of the NOP.

last year. The NOP is showing a high level of transparency, mainly through the NOP website.

The report of the Office of the Inspector General on the functioning of the NOP[3] identified a number of weaknesses of the program that are currently being addressed.

5.22 California State Authority

States can take over the enforcement of the NOP within the border of that State. For a State to assume NOP enforcement and appeal functions, NOP needs to grant the State Organic Program (SOP) status to that State. Only the State of California has set up such a State Organic Program. In 2004 the USDA approved the California Department of Food and Agriculture (CDFA) as a State Organic Program under the NOP. The Program concentrates on compliance. It delegates most of these activities to the 58 counties of the State in the Program.

The program carries out market surveillance mainly and may be partially overlapping with the NOP. It carries out some sampling of organic products based on risk analysis. It may also generate information that is useful for the NOP supervisory activities on the CBs.

After a report by the Office of the Inspector General of USDA on the functioning of the NOP, the Californian State program was reviewed by the NOP in December 2009[4] and is undergoing major changes.

Such programs do not exist in any of the other States of the US.

5.3 **Supervision**

Since the launch of the program, the NOP supervises the CBs. The NOP has established a systematic approach to supervision of accredited CBs. It uses the services of the ARC for auditing the CBs. The CBs are assessed every 2.5 years and are completely reviewed and re-accredited every 5 years. CBs pay ARC for the cost of its audit services.

The NOP carries out similar supervision on CBs applying the NOP outside the US, but these activities are not covered by this report.

Apart from a desk-audit, an on-site audit is carried out at the head offices of the CB. During the audit the quality manual, the records, the staff qualifications and training, possible conflicts of interest, fairness and completeness of certification decisions are checked. Witness-audits to operators subject to the controls of the CB are also carried out. A list of non-compliances is established and followed up.

The main findings of the audits were variations in how the standards were applied in some areas such as the access to the outdoors for poultry, the incompleteness of some Organic Systems Plans, which describes how the operator will carry out his activities in compliance with NOP and some cases of conflicts of interest.

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[3] http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.

[4] Report available on NOP website at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5084990&acct=noprulemaking

The supervision has been reinforced following the report of the Inspector General. Additional assessments outside the normal audits are carried out by the NOP.

The withdrawal of the approval of a CB can take several years due to the lengthy appeal process. During the appeal the CB can continue its activities. Recently, the accreditation of one CB had been withdrawn in mid 2010 after initial findings in 2007; the accreditation of a few other CBs is in the process of being withdrawn.

5.4 Enforcement

Both the NOP and the CBs have the competence and authority to suspend or revoke operators. The majority of suspensions and revocations are proposed and effectuated by the CBs. "Suspension" or "Revocation" are applied to certified operators who are in violation of the regulations depending upon the degree of severity and is determined on a case-by-case basis. "Suspension" can be levied for up to three years, for violations such as non-payment of fees, failure to submit renewal application, failure to correct non-compliances, incomplete OSPs, and record keeping issues. "Revocation" is for major violations, such as willful application of prohibited materials, commingling and false organic product claims.

In addition to suspension and revocation, the NOP has greatly increased use of its authority to levy civil penalties, and pursue criminal charges through working closely with other federal authorities.[5]

When a CB intends to apply a sanction to an operator subject to its control, i.e. suspension or revocation, it has to follow several procedural steps. The decision on revocation rests with the NOP.

The operator can appeal the suspension or revocation, because the NOP regulations, based on the US constitutional framework, grant the right to appeal "adverse actions" to the recipients of such actions. The appeal process has several steps and can take between one and two years. The appeal right is not always exercised. Many proposed suspensions and revocations are not appealed. In such situations, the CBs proceed to suspend or revoke the operators. For cases that are appealed, the NOP is currently taking steps to shorten and streamline the appeal process. The appeal process had recently been improved due to the addition of a program assistant and a second appeal team member. Additionally, the NOP encourages CBs to use informal negotiation and settlement mechanisms to reduce the number of appeals filed.

While operators maintain certification during the appeal period and can thus continue to sell organic products, they receive a warning that willful violations of the regulations during the appeal will incur additional penalties when unfavorable appeal decisions are rendered. During the appeal period, CBs continue to conduct normal certification and monitoring activities over the operators. The likelihood of integrity compromise is also mitigated by the fact that many adverse actions are for violations of an administrative nature.

The above finding appears to be in contradiction with the requirements of ISO Guide 65[6], which states that a CB must be able to control the use of its certificates by the operator,

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[5] **NOP response: Fourteen civil penalties were levied between January 2010 and February 2011.**

including the withdrawal of the right of the operator to use the certificate on his products.[7]

The NOP also operates an elaborated complaint system that systematically deals with all complaints received from the public (between 160 and 200 a year). In that way it functions as a market surveillance system and enforcement tool.

5.5 Certification Bodies

At the time of the mission, there were 55 "domestic" CBs accredited and listed by the NOP. In addition there are several NOP accredited Canadian CBs with activities in US.

The NOP also accredits CBs for activities outside US; these activities are not within the scope of this report.

Many CBs use free-lance, contracted inspectors. Some inspectors work for more than one CB, they often followed training coursed offered by the US-based International Organic Inspectors Association (IOIA).

Appropriate procedures have been established for the transfer of an operator from one CB to another.

During the mission two CBs were visited.

5.5.1 Certification body 1

This CB is a long-standing private organization with control activities in organic production only. It certifies 2,150 operators. It has a sister trade organization with the same name that undertakes advocacy and communication work, which is partly financed by the returns from the certification activities of the CB.

The CB applies well documented procedures. It maintains very detailed paperwork with a large emphasis on the Organic Systems Plan of the operator, which describes how the operator will carry out his activities in compliance with the NOP. The files also contain detailed inspection questionnaires and well documented findings.

It carries out an annual on-the-spot inspection, which is announced to the operator. There is a tendency to carry out the inspection each year at the same time[8]. Additional and unannounced inspections are carried out on 4 to 5% of operators according to a risk-assessment. However, this is not documented. Such recent inspections were for instance verifying the access to pasture.

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[6] General Requirements for bodies operating product certification systems.

[7] **NOP response: CBs do control the use of their certificates, including withdrawing use through suspension or revocation. In situations where the appeal right is exercised, such control is achieved with an additional step, thereby in line with the ISO requirements.**

[8] **NOP Response: Inspections by certifiers are carried out during periods of organic activity to determine compliance with NOP regulations. For many certified operations, this period normally occurs during the summer months.**

Until recently, the CB was hardly carrying out any sampling for pesticide residue analysis. An NOP sampling policy was now under development after the report of the Inspector-General on the NOP highlighted the requirement to carry out such test in the Organic Foods Production Act. The CB did not carry out any sampling for GMO analysis. The CB explained that it had no operators subject to its control that grew corn or soybeans. The NOP staff clarified that there was at the moment no requirement for sampling for GMOs as there were no tolerance levels set for GMOs.[9]

The mission team noted that the CB recently stopped the supervision of its inspectors by accompanying them during some control visits[10].

When checking an operator file of a poultry (laying hens) producer at the CB office, the mission team found that the provisions of NOP §205.239 accommodating health and natural behaviour of poultry were not implemented or were applied in a very minimal way, at least as regards the access to the outdoors. The CB had notified an adverse action to the operator for not providing sufficient access to the outdoors. The operator invoked a multitude of reasons why he should not give the birds access to the outdoors, such as his policy to keep the birds indoors until they reached 80% of their maximal egg production capacity, which is not a reason listed in §205.239 for allowing temporary confinement. Although the CB did not agree with the position of the operator, it stated that it was not in a position to enforce its adverse action due to a lack of direction of the NOP on this issue and, several months after the first issuing of the notification of adverse action, issued a "continuation of non-compliance" statement, while the operator could carry on his organic activities. Moreover, it was noted in the same operator file that the outdoor area was smaller than the indoor area and that the operation also was keeping non-organic birds of the same breed at the same operation.

As many other CBs, the CBs is a member of the voluntary association of accredited CBs, which facilitates the communication between them.

The CB is audited by the USDA every two and a half years, typically by two ARC auditors accompanied by one NOP auditor. The audit would take four to five days in the office and would include witness audits for every products scope: plant, livestock and wild products. The last audit report resulted in three corrective actions. The team noted that the USDA ARC report on this CB dating July 2010 referred to similar cases of non-compliance as regards other organic poultry operations.

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[9] **NOP response: NOP regulations at 205.670 state that pre- or post- harvest tests may be conducted when there is reason to believe that an agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods.**

[10] **NOP response: The NOP regulations require certifiers to conduct an annual performance evaluation of all inspectors (7 CFR 205.501(a)(6)). The NOP regulations also require certifiers to describe the qualifications, including experience, training and education for all inspectors (7CFR 205.504(a)(3)). Certifiers do not normally directly supervise inspections by accompanying inspectors during the inspection. Certifiers must maintain oversight and responsibility over the inspectors. The CB observed during the EU mission continued to maintain supervision over the inspectors.**

5.5.2 Certification body 2

This CB is part of the Agricultural Commissioner's Office of the Department of Agriculture of a Californian County; in that sense it would be rather called a Control Authority in the vocabulary of the EU organic legislation. In California there are two more Counties deploying these control activities on organic production. The Office has a wide range of responsibilities including pesticide and plant health law enforcement.

The Office currently certifies 17 organic operators (growers and processors). The inspectors are employed by the office and have a very good knowledge of the general characteristics of the agricultural production in the region, which is very intensive and using a high number of pesticide applications.

Most organic growers in the region also produce non-organic crops. Most growers use separate companies for harvesting and cooling.

The Office uses appropriate inspection documents. It was audited by USDA in 2007 and 2009 and a number of non-compliances had to be corrected. The low number of operators under its control is seen as problematic for the future viability of the Office.

5.6 Operators

Five organic operators were visited during the mission.

In general, the organic farms visited operate at a larger scale than in the EU, employ farm managers and farm workers, operate on different locations and typically contract out several activities to contractors. In California a high proportion of crop farmers practice both organic and conventional farming, albeit on different locations or "ranches".

While two farmers visited applied an appropriate multi-annual rotation, one farmer visited applied a very narrow rotation. However, green manure crops, also known as "cover crops", seem widely applied. They exist of legumes, grasses and other plants and are used as a rotational crop, in some cases only during a few months.

The farming operations visited generally do not apply livestock manure, out of fear for food safety (E. coli and others), but mainly use composted manure, either horse or cattle manure or poultry manure. These manures originate from non-organic farming, in some cases from large entities that could be described as "factory farming"[11]. The commercial composts and other fertilisers on the market are reviewed by the Organic Material Review Institute (OMRI)[12] or Washington State Department of Agriculture. Incidents in the past were reported when such composts were detected to contain synthetic nitrogen[13].

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[11] As defined in Codex Alimentarius Guidelines for the production, processing, labelling and marketing of organically produced foods (CAC/GL32), Table 1, first entry: "Factory farming refers to industrial management systems that are heavily reliant on veterinary and feed inputs not permitted in organic agriculture".

[12] www.omri.org.

[13] **NOP response: while a few commercial liquid fertilizers have been found to contain a prohibited synthetic, there is no evidence that synthetic nitrogen has been detected in composts.**

As regards conversion, as stated in the NOP, no controls are required during the transition (or conversion) period. The mission team observed a two year transition being applied to fallow or cover crops in a verifiable way. However, in a more intensive cropping system, it was not clear to the mission team how transition could be performed in a verifiable way based on written declarations only[14].

5.6.1 Operator 1

This is a large walnut grower, processor and exporter. Compost from poultry manure from intensive "factory farmed" operations is applied. Some plant protection products allowed in organic production are applied by helicopter. In winter cover crop is grown in between the trees.

The operator processed his own walnuts as well as the walnuts of some 60 organic walnut growers. A traceability system was in place. The nuts were stored at freezing temperature.

The CB appeared to carry out appropriate controls but did not take any samples in 20 years. The team noted that a large quantity of redundant, non-allowed pesticides was stored on the premises, which the farmer claimed he was not able to dispose of in an economical way. This situation was known to and verified by the authorities. The NOP regulations do not prohibit the presence of non-allowed pesticides on an organic operation.

5.6.2 Operator 2

This is a dairy farmer producing organic milk since 2007. 280 milking cows on 160 ha of mostly irrigated land and 120 ha of natural grassland rented from the State. Apart from the intensive pasture system, feed consisted of organic alfalfa hay, cereals, and a concentrate made from corn, barley, soybean meal and a mineral mix, fed in a Total Mixed Ration system.

From mid November to end of March the winter rains make the pasture land too wet for grazing and vulnerable to poaching. During that period the cows stay in the open loose housing stable bedded with sand.

The calves stay in individual cubicles until they are three to three and a half months old, which may not be considered equivalent to EU organic farming legislation which forbids the housing of calves in individual boxes after the age of one week. The calves are fed with natural fresh milk and cereals.

As regards identification of animals, the cows had individual ear tags, but it was underlined that ear tagging of cows is not a legal obligation in the US. NOP standards require operators to implement and maintain livestock identification measures.

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[14] **NOP response: to be certified for organic production, operations must demonstrate that the land was free from prohibited inputs or farmed organically during the transition period. NOP control is exercised in collaboration with various federal and state authorities that require land use registration and maintain database tracking land use. For example, California law requires all producers to register and submit monthly "Pesticide Use Permits" for all pesticide inputs. These documents can be obtained from the Agriculture Commissionaires office and used as additional sources for verifying compliance during the transition period.**

Identification of livestock may be done by ear tags, photos or drawings, branding, tattoos, leg bands, or other methods.

5.6.3 Operator 3

This is a grower of organic vegetables and fruit for 20 years at a medium to large scale on irrigated land. 60 to 70 different crops are grown in a three to five year crop rotation based on plant families. Farm made compost from mainly non-organic cow and horse manure is the main fertilisers. Cover crops are grown in the autumn every second year. For crop protection, a mix of measures was applied: resistant varieties, biological control through hedgerows and owl boxes, trap crops, vacuum sucking of insects, lime sulphur, Neem, soap, pyrethrum, Bacillus thuringiensis, spinosad and plant growth stimulators.

Additional land was in transition for two years while being fallow.

5.6.4 Operator 4

This is a large scale specialised broccoli grower who has two non-organic ranches in the valley and two organic ranches on the hill. All the land is irrigated. Up to four crops can be grown per season. For the organic ranches he exchanges land with an organic strawberry grower nearby to implement a rotation. The rotation used is three times broccoli in a row, followed by a cover crop (vetch, beans or peas), followed by 12 months strawberry.

He uses granulated dry chicken manure on the soil and fish emulsion fertilisers in drip irrigation systems. These fertilisers are approved for use in organic farming but the chicken manure is likely to originate from intensive "factory farmed" operations. Pyrethrum and insecticidal soap are used against aphids.

He uses contractors for irrigation, fertilising and harvesting. These contractors are also inspected by the CB.

The CB is carrying out an extensive annual inspection as well as unannounced spot inspections.

5.6.5 Operator 5

This is a specialised strawberry farmer practising organic production for more than 20 years. Other crops are raspberries, several types of other berries, peas, broccoli and cauliflower. The rotation for strawberry is 1 in 5. Each year "dry fallow" is applied to half of the land, i.e. sowing cover crops in winter (legumes and grasses), letting the land dry and ploughing the crops under in autumn.

The cover crops get composted cow manure, while the strawberries get a mixture of guano, feather meal, fish meal, seaweed (kelp) and micro-nutrients through the drip irrigation. As plant protection predator mites are released and soap and plant soils are used. The strawberry plants used were organically grown, except for the latest planting when they were not available. The young plants for the broccoli and the cauliflower were organically grown.

6 COMMENTS AND DISCUSSION

6.1 General issues

The US government strongly supports the development of the NOP.

The NOP is undergoing major and dynamic changes, growth and improvement since mid 2009. The further development of the production standard is progressing.

The report of the Inspector General on the functioning of the NOP identified a number of weaknesses of the program that are currently being addressed.

One state, California, has developed a State compliance and enforcement program that is integrated in the general State food control system. Such systems do not exist in any of the other States.

6.2 Effectiveness of the control system

The CBs seem to be well-organized and capable. However, they have shown a number of important weaknesses.

The CBs visited hardly carried out any sampling and analyses of prohibited pesticides and other substances, thereby not using a significant and powerful tool to detect potential non-respect of organic standards. Such testing is required by the Organic Food Production Act of 1990. Moreover, NOP §205.671 enables exclusion of a product if pesticide residues are found above 5% of the EPA tolerance for food. It is not clear how this can be applied when the CBs do not apply sampling for pesticide residue analysis[15].

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[15] **NOP response: the NOP is a process-based system that establishes proactive control measures through the development, approval and implementation of organic system plans (OSP). The OSPs describe detailed practices and procedures for production and handling, all inputs used and their source/composition/application, monitoring practices and procedures, record-keeping system, and management practices to prevent contamination and commingling. Implementation of the OSP is verified through annual onsite inspections.**

It is augmented by the NOP requirement under §205.670 that CBs may conduct pre- or post-harvest tests based on suspected use of prohibited materials or excluded methods. In practice, such tests are often conducted in the process of complaint investigation and utilized as a tool to verify compliance, enabling NOP §205.671 Exclusion from Organic Sale to be applied where applicable.

Although the NOP has not collected and consolidated data, residue testing is conducted through a variety of channels. For instance, some CBs have robust residue testing programs and conduct testing on random or risk bases. The NOP collaborates with the AMS Science & Technology Programs to conduct tests in several ways. A recent study focuses on fresh organic produce in the U.S. The produce was tested for about 180 synthetic pesticides. Test results are forthcoming and will be followed up in accordance with §205.671 procedures if applicable. Over the last 16 years, the AMS Pesticide Data Program has tested 1,351 organic samples of mostly fruits and vegetables, representing 1.3% of the total number of samples tested (107,503).

To further leverage testing as a tool, the NOP is currently engaged in rule-making to require mandatory periodic residue testing, and has already provided training to CBs on sampling procedures and lab requirements.

It is not clear how compliance with the rule that GMOs can not be applied (NOP §205.105) is being assured and verified, as no testing takes place[16].

The high proportion of mixed organic and non-organic farms requires special attention.[17]

The typical use of several subcontractors for fertilizing, irrigation or harvesting calls for a good definition of responsibilities and appropriate attention to correctly maintain the chain of custody.

In the poultry sector, as described in section5.5.1 of this report, the mission team noted that a CB was not in a position to stop operators applying living conditions to poultry not in line with the NOP-rules or to deny certification to these operations within a reasonable time period. The CB stated that this was due to a lack of direction of the NOP. [18]

The enforcement procedure is very lengthy. Moreover, when a sanctioned operator appeals to the sanction, the proposed sanction is suspended. This construction inevitably leads to non-organic products being sold as organic and thus questions the credibility of the control system. (Immediate denial of certification is only foreseen for 1st applicants (NOP §205.405(g)) and was not reported being used). This lack of ability to withdraw certification appears to be in conflict with the requirements of ISO Guide 65. [19]

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[16] **NOP response: regarding GMOs, organic producers utilize a variety of methods to avoid contact or the unintentional presence of GMOs including testing seed sources for GMO presence, delayed or early planting to get different flowering times for organic and GMO crops, cooperative agreements with neighbours to avoid planting GMO crops adjacent to organic crops, cutting or mowing alfalfa prior to flowering, posting signs to notify neighbouring farmers of the location of organic fields, and thorough cleaning of farm equipment that has been used in non-organic crop production. In order to become a certified organic operation, a producer must submit an organic system plan to a NOP accredited certifying agent for approval. The producer's organic system plan must include a description of management practices and physical barriers established to prevent contact of organic crops with prohibited substances. Certifying agents evaluate the preventative practices and buffer zones to determine if the producer has taken reasonable steps to avoid contact with GMOs.**

[17] **NOP response: mixed operations establish control mechanisms to ensure organic integrity. These are elaborated in the operation's OSP, reviewed and approved by the CBs, and inspected annually.**

[18] **NOP response: The CBs are continually making interpretations of the NOP regulations based on their authority as accredited certifying agents. The NOP works closely with the CBs to answer questions and ensure consistent application of the requirements.**

The NOP is providing tools for consistent interpretation and application of the regulations. The NOP has issued a "Program Handbook" for CBs and operations that provides additional guidance and greater clarity in many areas to ensure consistency. The NOP continues to develop standards and provide clarifications through an open and transparent system.

[19] **NOP response: As stated previously, the CBs do have the ability to withdraw certification through suspension or revocation. The NOP regulations are based on the US constitutional framework which presumes innocence until proven guilty. The appeal system ensures that due process is afforded to affected parties and decisions are fair, correct and consistent throughout the system. As most adverse actions are due to administrative violations, there are not many cases involving fraud. There is little (or no) evidence to support the claim that operations under appeal have "inevitably" released non-organic products into the marketplace. The NOP has instituted various practices, such as the publication of adverse actions notices, lists of certified operations,**

6.3 Conclusion

6.3.1 Equivalence of the production rules

The overall determination of whether the US production rules can be considered to be equivalent to rules applied in the EU is the subject of a separate exercise which has not been finalized.

However, this peer review has addressed a number of issues on the practical application of the NOP production rules which are relevant for this equivalency determination:

(1) The rules on organic poultry living conditions are too vague and lead to practices that seem to go against the NOP production rules and cannot be considered equivalent to EU production rules.

NOP response: Since the writing of this report, NOP has issued draft guidance on Poultry access to the outdoors to provide greater consistency in the application of the rules.

The practices of keeping calves in cubicles cannot be considered equivalent to EU production rules.

NOP response: The NOP regulations are fundamentally equivalent to the EU standards in ensuring healthy animals and environmental benefits.

(2) The practice of crop rotation is not sufficiently defined to determine equivalence.

NOP response: Crop rotation is required by NOP standards and equivalent to EU rules. Crop rotation rules are performance based and ensure that the intended results of crop rotations are accomplished, rather than just meeting a 3, 5, or 7 year rotation requirement which would not necessarily accomplish the goals of conservation, pest control or nutrient management. Because of the wide variety of growing conditions, the NOP adopts a less prescriptive approach and allows crop rotation plans to be developed based on local site specific conditions and considerations. Crop rotation is verified through inspections and NOP audit, and generally practiced in a manner that maintains or improves soil organic matter, manages deficient or excess plant nutrients and provides erosion control.

(3) It is not clear whether the transition period is applied correctly in all cases.

NOP response: The NOP regulations require a transition period of 36 months during which an operator can be voluntarily controlled by a CB. During application for certification, an operator must provide verifiable proof that the land was farmed organically and without the use of prohibited inputs. If the operator does not have adequate documentation to verify that the land has had no applications of prohibited substances within 36 months, then the land is not eligible for organic certification. In those cases, the certifier could provide supervision through inspections during the transitional time period.

(4) Manure from factory farming is used in many instances.

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and lists of suspended/revoked/surrendered operations and CBs, to increase the effectiveness of market control mechanisms in regulating trade of organic products.

NOP response: Under NOP standards, manure may be used as long as it is composted or applied according to prescriptive NOP standards.

6.3.2 Equivalence of the control measures

It is not clear whether certain aspects of the control system with its current performance as observed by the mission team can be considered to have an equivalent effectiveness as those in the EU legislative framework:

(1) In case of operators appealing a sanction applied to them, the control system does not appear to be effective, as the sanctioned operators can in principle continue to sell their products as organic during the lengthy appeal process. The NOP is however taking steps to shorten the appeal process and acts against willful violations during the appeal process.

(2) The withdrawal of accreditation of a CB is not efficient, as it takes several years.

NOP response: As stated previously, the NOP regulations are based on the US constitutional framework which presumes innocence until proven guilty. The appeal system ensures that due process is afforded to affected parties and decisions are fair, correct and consistent throughout the system.

(3) The general lack of sampling for analyzing pesticide residues seems not in line with the US legal framework and neglects an efficient control tool.

NOP response: The NOP is a process-based system that establishes proactive control measures through the development, approval and implementation of organic system plans (OSP). The OSPs describe detailed practices and procedures for production and handling, all inputs used and their source/composition/application, monitoring practices and procedures, record-keeping system, and management practices to prevent contamination and commingling. Implementation of the OSP is verified through annual onsite inspections.

The process approach is augmented by the NOP requirement under §205.670 that CBs may conduct pre- or post- harvest tests based on suspected use of prohibited materials or excluded methods. In practice, such tests are often conducted in the process of complaint investigation and utilized as a tool to verify compliance, enabling NOP §205.671 Exclusion from Organic Sale to be applied where applicable.

To further leverage testing as a tool, the NOP is currently engaged in rule-making to require mandatory residue testing, and has already provided training to CBs on sampling procedures and lab requirements.

(4) It is not clear how the NOP requirement that GMOs cannot be used is being assured and verified, as no testing takes place.

NOP response: The NOP is a process-based system that establishes proactive control measures through the development, approval and implementation of organic system plans (OSP). The OSPs describe detailed practices and procedures for production and handling, all inputs used and their source/composition/application, monitoring practices and procedures, record-keeping system, and management practices to prevent contamination and commingling. Implementation of the OSP is verified through annual onsite inspections.

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or excluded methods. In practice, such tests are often conducted in the process of complaint investigation and utilized as a tool to verify compliance, enabling NOP §205.671 Exclusion from Organic Sale to be applied where applicable.

To further leverage testing as a tool, the NOP is currently engaged in rule-making to require mandatory periodic residue testing, and has already provided training to CBs on sampling procedures and lab requirements.

Annex : Mission Programme

Monday, October 4

- Opening meeting in Washington D.C.

1. Welcome remarks by US
2. Opening remarks by EC
3. NOP update
4. Discussion

Tuesday, October 5

- Meeting in Sacramento (State Authority))
- Site visit in Sacramento area (2 operators)

Wednesday, October 6

- Site visit in Santa Cruz (1 CB)
- Site visit in Santa Cruz area (1 operator)

Thursday, October 7

- Site visit in Monterey (1 Control Authority)
- Site visits in Monterey area (2 operators)

Friday, October 8

- Closing meeting in San Francisco

1. Comments by EC
2. Comments by US
3. Closing remarks by US