



Australian Quarantine and Inspection Service (AQIS)

RESPONSE

to

European Commission

**On the Implementation of Recommendations Arising
from Mission Report (XXIV/1093/99) on Organic
Farming in Australia**

and

**On the Supervision of Organic Inspection Bodies
Operating in Australia**

1. BACKGROUND

From 8 to 19 March 1999, a review team from the European Commission, Directorate-General XXIV, Consumer Policy and Consumer Protection carried out a review of organic farming in Australia. The review encompassed visits to three Approved Certifying Organisations and two certified organic producers of each organisation. At the conclusion of the review, the EU Mission Report (XXIV/1093/99) identified eight (8) recommendations to the competent Australian authority – the Australian Quarantine and Inspection Service (AQIS).

On 9 June 1999, AQIS formally responded to those recommendations. The thrust of the Original AQIS Response was to accept all of the Mission Report's recommendations.

Since that time, AQIS in partnership with the Australian organic industry has implemented the measures necessary to bring the recommendations of the Mission Report into practice as indicated in the original response.

This report to the EU Commission details the actions taken by AQIS and the Approved Certifying Organisations with respect to each individual recommendation of the Mission Report. Additionally, this report provides information on each of the AQIS-Approved Certifying Organisations with respect to their administration (head office and structure), scope of operations, number of inspectors, number of organic operators certified, number of inspections carried out, and a brief description of their manual.

2. IMPLEMENTATION OF RECOMMENDATIONS ARISING FROM MISSION REPORT (XXIV/1093/99) ON ORGANIC FARMING IN AUSTRALIA

2.1 The Competent Authority should collect more information.

Mission Report Recommendation

The Competent Authority should collect more information on the operators and on inspection bodies and hold this information on file. In particular the following information should be available: the list of processors and exporters and, if possible, an estimate of agricultural products and foodstuffs intended for export to the Community; the annual reports of the inspection bodies; the overview of the sanctions applied by the inspection bodies to the operators; reports on the audits carried out by the Competent Authority on the inspection bodies.

Original AQIS Response

AQIS accepts this recommendation and is in the process of implementing the necessary administrative arrangements. Each of the approved organic certifying bodies will be required to provide AQIS with an annual report which will include the information required by the Commission. AQIS will maintain these reports on file

and provide the Commission with a consolidated annual report at the end of each financial year.

Implementation

AQIS has directed that each Approved Certifying Organisation provide an annual report to AQIS as per Article 9 (8) (b) of Council Regulation (EEC) No 2092/91. This report must include information relating to certified organic operators and estimates on production and prospective exports. AQIS will maintain these reports on file and provide the Commission with a consolidated annual report shortly thereafter.

Additionally, AQIS has also directed that each Approved Certifying Organisation document in their QM manual, a sanctions policy/procedures for the purposes of audit. Approved Certifying Organisations sanctions policy and procedures, as well as records of sanctions applied, is audited by AQIS staff as part of the annual audit of each Approved Certifying Organisation and their operators. Additionally, each Approved Certifying Organisation must include a summary report of sanctions imposed on certified organic operators in their annual report to AQIS. As mentioned above, AQIS will maintain these annual reports on file and provide the Commission with a consolidated report.

AQIS auditors enter information on audit scheduling into the AQIS Quality Assurance Audit Tracking System (QAATS) database. QAATS is able to provide all relevant AQIS staff with final reports following audits of each of the Approved Certifying Organisations. Additionally, the information stored on QAATS is available to all AQIS staff throughout Australia and negates the need to forward confidential information via the postal service.

2.2 Continuous supervision of the approved certifying bodies.

Mission Report Recommendation

The Competent Authority should assure a continuous supervision of approved inspection bodies. It would be appropriate to organise a better follow up of the audits of the inspection bodies. Some EN 45011 requirements like full-time staff and training of staff need more attention.

Original AQIS Response

AQIS accepts this recommendation and with the formation of the Organic Produce Export Certification Program, AQIS has taken steps to enhance its supervision of the approved organic certifying bodies. Additional management and auditing resources have already been allocated to this Program. Additionally, a team of regulatory auditors has also been assigned to the Program. AQIS is firmly committed to a process of continuous improvement in the operations of this Program including better coordination and follow up of AQIS audits on the approved organic certifying bodies. Additionally, AQIS will be ensuring that it can demonstrate that attention is paid by the approved organic certifying bodies to all of the requirements of EN-45011 and/or ISO 65.

Implementation

AQIS has formed the Organic Produce Export Certification Program as a standard operational program within its Quarantine and Export Operations Division. The sole responsibility of this program is enforcement of the Export Control (Organic Produce Certification) Orders under the *Export Control Act 1982*. Under this legislation program auditors carry out annual and, if required, special (either unannounced or as part of a specific investigation) audits of the Approved Certifying Organisations. Additionally, under this legislation program staff supervise the distribution and reconciliation of organic produce certificate forms to the Approved Certifying Organisations and regularly review the certificates issued. All program auditors are fully trained in both auditing and organic inspection techniques.

As with all other AQIS programs, the Organic Produce Export Certification Program has a Business Plan covering the period 1999/2000 to 2001/2002. This Business Plan outlines the directions for the program including an overview, the program's mission, required outcomes, responsibilities, activities and functions. Additionally, the Business Plan describes the program's resources, key performance indicators, and environmental analysis. The Business Plan also provides detailed information on the program's key strategies for export program integrity, financial management, information technology, improving client satisfaction, and human resources management.

As previously described, AQIS auditors use QAATS for audit scheduling and subsequent reporting. This data base system will allow for all reports to be accessed by users anywhere in Australia. This was considered necessary to allow enhanced supervision of the Approved Certifying Organisations as these bodies operate across State/Territory borders. This electronic medium will ensure that previous audit reports and Corrective Action Request (CAR) forms can be reviewed by AQIS staff before they audit Approved Certifying Organisations certified operators located in other States.

Under the program all Approved Certifying Organisations must be audited every year. The outcome of this auditing will be reported to the Commission.

AQIS has provided the EN-45011 document to all of the Approved Certifying Organisations. This European Standard and ISO 65 will be used as a guide by AQIS staff during audits of these organisations. Additionally, the staff of the Approved Certifying Organisations are required to demonstrate their awareness of these standards whilst being audited by AQIS.

2.3 Separation of activities

Mission report recommendation

The auditors should re-examine the activities carried out by inspection bodies to ensure the correct separation between activities such as consultancy, marketing and representation of operator groups, in order to demonstrate inspection bodies' impartiality and objectivity.

Original AQIS Response

AQIS accepts this recommendation and will implement arrangements to ensure that the approved organic certifying bodies can demonstrate the correct separation between activities such as consultancy, marketing and representation of organic operators and their certification and inspection role.

Implementation

AQIS has directed Approved Certifying Organisations to identify and document those activities such as consultancy, marketing and representation of organic operators in their respective quality manuals to ensure separation of functions and impartiality. Furthermore, AQIS has instructed that the Approved Certifying Organisations pictorially display in their quality manual, their organisational structure including such areas as, marketing, consultancy, inspection and decision making.

AQIS confirms impartiality and objectivity of Approved Certifying Organisations through a verification process which entails documentation review and practical demonstrations.

Some of the measures adopted by the Approved Certifying Organisations include confidentiality agreements which must be signed by their organics inspectors; documenting the specific roles and responsibilities of inspectors; requiring inspectors to complete pecuniary interest forms (specifying any interests inspectors may have which could impact on their impartiality); and directives prohibiting inspectors from entering into any sales, pricing or commercial activities.

2.4 Monitoring of organic produce certificates

Mission report recommendation

The Competent Authority should establish a more rigorous monitoring of the use of organic produce certificates.

Original AQIS Response

AQIS accepts this recommendation and is currently implementing a system for reporting on the provision of organic export certificates by the approved organic certifying bodies. This system will include having the blank individually numbered certificate forms issued to approved organic certifying bodies as fully accountable documents. The Approved Certifying Organisations will be required to regularly forward copies of all certificates they issue to AQIS as well as providing a consolidated report each year.

Implementation

AQIS has disallowed the use of electronic organic produce certificates and has re-issued these certificates as individually numbered and fully accountable “blank” forms.

AQIS has directed Approved Certifying Organisations to document, in their quality manual, organic produce certificate procedures. This export documentation procedure then forms part of the scope of the annual audits of each Approved Certifying Organisation conducted by AQIS staff.

AQIS has implemented “reconciliation and issuing” procedures for the distribution of organic produce certificates to approved certifying bodies. Approved certifying bodies are required to return to AQIS the triplicate copy of the “endorsed” organic produce certificate.

2.5 Annual report from Approved Certifying Bodies

Mission report recommendation

The Competent Authority should request an annual report from the inspection bodies as foreseen in Article 9.8 of Council Regulation 2092/91.

Original AQIS Response

AQIS accepts this recommendation and, as described above under recommendation (1), AQIS is in the process of implementing the necessary administrative arrangements. Each of the approved organic certifying bodies will be required to provide AQIS with an annual report which will include the information required by the Commission. AQIS will maintain these reports on file and provide the Commission with a consolidated annual report at the end of each financial year.

Implementation

AQIS has directed that Approved Certifying Organisations provide an annual report detailing their policies and operations, certified operators, and estimated export quantities. AQIS has provided a format to each Approved Certifying Organisation that requires the details for each certified operator be completed and returned to AQIS as per Article 9 (8) (b) of Council Regulation (EEC) No 2091/92.

AQIS will maintain a copy of these reports on file as well as forward a consolidated report to the EU Commission every year.

2.6 Ensuring that certified products are exported to EU

Mission report recommendation

Unless a similar control system is set up for the domestic market of organic products, it needs to be clarified which guarantees can be given that organic products intended for domestic sales or imported organic products do not end up as an ingredient in processed products for export to the EU.

Original AQIS Response

AQIS accepts this recommendation and will be working with its recently established Organic Produce Export Committee on an appropriate mechanism to ensure that only

properly export certified/certifiable products are used in preparing export consignments. However, it should be noted that exports of processed organic products form only a very minor portion of organic produce exports from Australia.

Implementation

AQIS has worked with the Organic Produce Export Committee to develop mechanisms to ensure that only certified organic products are used in processed products for export. Under these arrangements, Approved Certifying Organisations are required to ensure that producers of organic processed foods have in place mechanisms which demonstrate that only properly certified organic raw materials are used to make organic processed foods. In some instances, the Approved Certifying Organisations formally approve the use of imported organic produce and subsequently advise the certified processor. This involves maintaining accurate records of incoming products to be reconciled against outgoing product. Approved Certifying Organisations are required to audit these arrangements during their inspections and AQIS will ensure, through its own auditing practices, that these procedures are being adhered to.

Examples of the specific measures implemented by the Approved Certifying Organisations are to require processors to complete a declaration for each processed product detailing the ingredients with regards to supplier, weights/percentages, and name of certifying organisation; verification of input/output balances during audits of certified operators; and development of processing and preparation standards which specify requirements with regard to segregation of product, processing and labelling.

2.7 Inspection bodies to take samples for analysis

Mission report recommendation

The Competent Authority should request that the inspection bodies take samples for residue analysis in cases where there is any suspicion of the use of unauthorised products, as foreseen in Article 6 of Annex III of Council regulation 2092/91.

Original AQIS Response

AQIS accepts this recommendation and will initiate changes to the approved organic certifying bodies' inspection arrangements to ensure that appropriate samples are collected and analysed.

Implementation

AQIS has verified through audit, that soil and tissue samples have been taken by Approved Certifying Organisations and subsequently analysed. Analysis reports have been checked and noted by AQIS staff during recent audits. AQIS is working with the Approved Certifying Organisations to broaden the range of chemicals that are analysed and to adopt under the National Standard for Organic and Bio-dynamic Produce, the Australian Standard for Risk Management - AS/NZI 4360. This Australian Standard incorporates the elements of risk analysis, risk assessment and

review and will require each Approved Certifying Organisation to document its own risk management process.

2.8 Advice to Commission Services undertaken

Mission report recommendation

The Competent Authority should inform the Commission Services of the actions undertaken to bring the recommendations of this report into practice by 1 December 1999.

Mission report recommendation

AQIS will provide the Commission Services with a report on how it has brought the missions report's recommendations into practice by 1 December 1999.

Implementation

This report outlines the actions AQIS and the Australian organic industry have undertaken to effect the recommendations of the Mission Report.

3. SUPERVISION OF ORGANIC INSPECTION BODIES OPERATING IN AUSTRALIA

3.1 General

All of the AQIS-Approved Certifying Organisations are not-for-profit entities. These organisations are approved by AQIS under the jurisdiction of the *Export Control Act 1992* through its subordinate legislation the Export Control (Orders) Regulations and the Export Control (Organic Produce Certification) Orders.

AQIS carries out audits of each Approved Certifying Organisation, annually. These audits involve an audit of the organisation's head office as well as visits to observe the organisation's inspectors in action at certified operators in at least two locations in Australia. The scope of these annual audits encompasses all elements of the organisation's quality system with regards to carrying out organic inspections and issuing organic export documentation. This includes confirming compliance with the relevant EU Commission requirements - EN45011 and Council Regulation (EEC) No 2092/91 (including subsequent amendments).

All AQIS organics auditors are qualified to ISO-level standards as well as being trained as organics inspectors.

The information provided below is a general description of each of the AQIS-Approved Certifying Organisations with respect to their administration (head office and structure), scope of operations, number of inspectors, number of organic operators certified, number of inspections carried out, and a brief description of their manual.

3.2 National Association for Sustainable Agriculture, Australia Ltd (NASAA)

Head Office

NASAA's head office is located at Mount Barker Road, Sterling, South Australia.

Structure

NASAA is a not-for-profit company limited by guarantee comprising Director members located throughout Australia. These Directors represent either State Councils or are nominated by licensees to represent a specific State. The Board, which is comprised of nine Directors, meets twice yearly. The Executive Committee is comprised of a Chairperson, Secretary, Treasurer and Vice President and it meets an additional three times per year. The NASAA Administrator attends all of these meetings. In addition to their AQIS accreditation NASAA is also accredited by the non-government organisation, the International Federation of Organic Agricultural Movements (IFOAM).

Scope of operations

NASAA is listed under Commission Regulation (EC) No 1367/98. Their certification program covers production, processing, import/export/wholesaling, packing/handling and input manufacturing. All commodities are covered. NASAA accredits operators as organic but does not currently accredit operators as bio-dynamic.

Number of inspectors

NASAA has 22 trained inspectors operating throughout Australia and conducts regular training courses to ensure the availability of suitably qualified inspectors.

Number of organic operators certified

As of 30 June 1999, NASAA had 364 certified producers and 104 certified processors.

Number of inspections carried out

NASAA inspects all operators annually as well as carrying out random unannounced audits on an additional 5 percent of operators. Furthermore, NASAA carries out additional audits of operators where reports from other operators or directions from AQIS indicate that this is necessary.

Inspection reports are signed by the organic operator being inspected after an inspection.

NASAA's Inspection Review Committee meets every 2 months to review these reports.

Brief description of their manual

NASAA has a comprehensive quality manual. Its Standards (which are consistent with the National Standards for Organic and Bio-dynamic Produce) comprise two volumes (*Standards for Organic Agricultural Production* and *Preparation and Processing Standards for Food and Fibre*). Their quality manual includes sections on their operations, their standards and controls, their business, the certification process, the inspection process, and administration.

3.3 Biological Farmers of Australia Co-operative Ltd (BFA)

Head Office

BFA's head office is located at Ruthven Street, Toowoomba, Queensland.

Structure

BFA is a not-for-profit Co-operative. Its Board of Directors is comprised of seven Directors and is responsible for managing and controlling the business and operations of the Co-operative, development of organisational policy and for ensuring implementation of the quality system. Their structure includes a Chairman, Executive Officer and Certification Officer. There are committees on Certification Review, Standards Review and Appeals Review.

In addition to their AQIS accreditation BFA has also achieved ISO9002 accreditation.

Scope of operations

BFA is listed under Commission Regulation (EC) No 1367/98. Its operations cover all commodities. They accredit operators as organic but do not currently accredit operators as bio-dynamic.

Number of inspectors

BFA has 21 trained inspectors located throughout Australia.

Number of organic operators certified

BFA covers 648 certified operators.

Number of inspections carried out

In addition to auditing each operator annually, up to 10 additional audits are carried out each year for compliance purposes.

Brief description of their manual

BFA has applied the elements of National Standard for Organic and Bio-dynamic Produce directly to their documented quality system. Their quality manual comprises sections on organisation; quality system; contract review; design control; document and data control; purchasing; customer supplied product; product identification and traceability; process control; inspection and testing; inspection, measuring and test

equipment; inspection and test status; control of non-conforming products; corrective and preventative action; handling, storage, packing and delivery; control of quality records; internal quality audits; training; servicing; and statistical techniques.

3.4 Bio-Dynamic Research Institute (BDRI)

Head Office

BDRI's head office is located at Main Road. Powelltown, Victoria.

Structure

BDRI is a non-profit company limited by guarantee. The seven BDRI Directors are responsible for managing the business and developing policy for the organisation. BDRI has nominated a specific person who is responsible to "give effect" to the day-to-day operations of their quality system.

Scope of operations

BDRI is listed under Commission Regulation (EC) No 1367/98. BDRI certifies organic produce to bio-dynamic standards (ie Demeter). Their certification program incorporates the elements of production, processing, import/export requirements, packing and handling, transportation, and labelling. All commodities are covered by this certification system.

Number of inspectors

BDRI has 17 trained/registered inspectors operating throughout Australia. Additionally, BDRI insists that people wishing to become inspectors must have a minimum of 4 years bio-dynamic farming experience before they are eligible for additional inspector training.

Number of organic operators certified

As of November 1999, BDRI has 150 certified operators.

Number of inspections carried out

BDRI inspects all of their certified operators' annually as well as conducting unannounced inspections. During the past 12 months, BDRI has conducted a total of 166 inspections (this incorporates 16 unannounced inspections).

Brief description of their manual

BDRI has applied the elements of the National Standard for Organic and Bio-dynamic Produce to their quality manual. This comprises of 3 manuals which encompass the elements of inspection procedures; sampling procedures; inspection report forms (ie farm, rangeland, manufacturer, wholesaler, retailer); sanctions; export requirements; processing/manufacturing; wholesaling/retailing; farming; labelling; certification procedures; assessment of inspection reports; and issuing export documentation.

3.5 Organic Vignerons Association of Australia (OVAA)

Head Office

OVAA registered head office is located at Payneham Road, Stepney, South Australia and the secretariat is located at 1B Gawler Street, Nuriootpa, South Australia.

Structure

OVAA comprises 5 Executive Committee members (including a President and Vice President), who are responsible for managing the business and developing organisational policy. OVAA employs the services of an Office Manager/Quality Manager who is responsible for the management and maintenance of the quality system.

Scope of operations

OVAA is listed under Commission Regulation (EC) No 1367/98. Their certification program encompasses all elements of the National Standard for Organic and Bio-dynamic Produce in relation to wine growing and wine production only. OVAA does not accredit operators as bio-dynamic.

Number of inspectors

OVAA has 6 trained inspectors located throughout Australia.

Number of organic operators certified

There are 27 vineyards and 5 wine producers accredited with OVAA.

Number of inspections carried out

In addition to auditing each certified operator annually, a further six (6) supplementary inspections are carried out to determine compliance to OVAA manuals.

Brief description of their manual

OVAA has three manuals which cover (1) the Certification and Control of Organic Grapes and Wine, (2) Quality Manual and (3) Office Procedures Manual. OVAA manuals have incorporated the essential elements of the National Standard for Organic and Bio-dynamic Produce, these include administrative procedures; levels of organic certification; wine-making processes; penalties; auditing; soil/tissue sampling; quality records; annual reports; wine and vineyard inspection procedures; organisational structure; staff training and development; document control; and corrective action.

3.6 Eco-organics of Australia Inc (EO)

Head Office

The main office of EO is located at 105 Richmond Terrace Road, Coraki, New South Wales.

Structure

EO is accredited by both AQIS and the Therapeutic Goods Administration - a Commonwealth government department responsible for therapeutic goods. The EO business structure is composed of a Chairman and three member of the Review Committee. In addition, EO employees one inspector to conduct inspections of certified operators. Management representatives are responsible for developing organisational policies and ensuring operation procedures are maintained. The Chairman does not vote on matters relating to certification approval/review.

Scope of operations

EO is not listed under Commission Regulation (EC) No 1367/98. Their certification program encompasses those elements of the National Standard for Organic and Bio-dynamic Produce in relation to tea tree growing, harvesting and oil production only. No other organic produce is certified. The sourcing of all tea tree plants is performed within Australia, no tea tree products are imported and used in processing operations.

Number of inspectors

EO has one trained inspector located in Coraki, New South Wales.

Number of organic operators certified

EO has 2 certified processors and 4 certified producers which are audited annually.

Number of inspections carried out

EO audits each operator at least once per year.

Brief description of their manual

The EO quality system is composed of 3 sections, (1) producer documents (including producer certification standards, inspection and testing procedures, production records, training, standard operating procedures); (2) processor documents (including processor certification standards, inspection procedures and reports); and (3) system documents (including confidentiality agreements, operation of the inspection system and board of review).

3.7 Organic Food Chain (OFC)

Head Office

OFC head office is located at Mail Service 222 Oakey, Queensland.

Structure

In addition to their AQIS accreditation, OFC has also achieved ISO9002 accreditation. OFC comprises a Chairman, Secretary, Directors and a General Manager who are responsible for managing the business and scheduling audits. OFC is a non-profit organisation.

Scope of operations

OFC is not listed under Commission Regulation (EC) No 1367/98. The OFC quality system accredits all commodities but does not accredit operators to bio-dynamic standards. Their certification encompasses production, processing, handling, storage delivery, product identification and verification.

Number of inspectors

OFC has 2 trained inspectors located in Queensland and Victoria.

Number of organic operators certified

OFC covers 21 certified operators.

Number of inspections carried out

OFC conducts annual inspections on all certified operators.

Brief description of their manual

OFC has a comprehensive quality manual based on the National Standard for Organic and Bio-dynamic Produce. Elements of this manual relate to broad acre and horticultural production; storing and preservation; animal husbandry; processing, manufacturing and packing of food, beverages and animal and vegetable fibre; audit; management responsibility; quality policy; management review; design control; document and data control; internal review; training; corrective and preventative action; product identification and traceability; process control; control of quality records; handling, packaging, storage, preservation and delivery; and control of non-conforming product.

3.8 Organic Herb Growers of Australia Inc (OHGA)

Head Office

OHGA is now located at Cellulose Technology Park, Southern Cross University, East Lismore, New South Wales.

Structure

OHGA has a management structure which includes the appointment of an Executive Officer with responsibilities for managing the inspectorate and quality system as well

as a formal structure which clearly defines the roles and responsibilities of their executive committee members.

Scope of operations

OHGA is listed under Commission Regulation (EC) No 1367/98. Their Standards (which are in full compliance with the National Standard for Organic and Bio-dynamic Produce, Australian legislation and EN45011) are designed to ensure that ethical concepts of organic production principles are followed in the interest of protecting against deception, fraud and misrepresentation.

Number of inspectors

OHGA has 20 trained inspectors located throughout Australia.

Number of organic operators certified

OHGA has 438 certified operators.

Number of inspections carried out

All of the OHGA certified operators have an annual inspection. There is an additional 5% random inspections carried out every year based on the total number of certified operators.

Brief description of their manual

The OHGA quality manual ensures transparency of all stages of procedures with efficient cross-referencing and maintenance of member certification. It is comprised of two sections. The first section on management guidelines includes descriptions of their structure, officers and duties, the certification review committee, inspector qualifications and procedures, and testing. The second section on procedures for certification includes descriptions of procedures for application, assessment, renewals, export documentation, certifying operators, and handling non-compliance.