New Zealand Food Safety Authority
PO Box 2835, Wellington, New Zealand

Third Party Agency Responsibilities – Organic Products (NZFSA Standard OP2)

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Contents

1 Background

The NZFSA Standard on Third Party Agency Responsibilities – Organic Products was developed as part of the NZFSA system for official assurances for organic products. It describes acceptable criteria for the responsibilities of Third Party Agencies (TPAs) providing assessment and verification services to operators participating in the official organic assurance programme.

Under this programme TPAs will assume responsibilities for registering operators, assessing and verifying registered operators' compliance with Organic Management Plans (OMPs), reporting on their assessments, and verifying consignment eligibility for an official assurance.

2 Summary

This Standard specifies requirements relating to the responsibilities of TPAs providing assessment and verification services to the organic industry.

Appendix One outlines criteria for demonstrating that the outcomes in the Standard are achieved, including:

- operator registration;
- assessments and verification of operator compliance with regulatory standards, overseas market access requirements, and assessment frequency determinations;
- management of resolution of operator non-compliance, including follow-up of corrective actions with persons accountable for organic management plans and notifications to NZFSA of any critical non-compliance;
- chemical residue testing of product; and
- verification of consignment eligibility for official assurance.

Proposals for alternative criteria may be approved by NZFSA, provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved.

Appendix Two provides the review process for assessment frequency reclassification for a registered operator participating in the official organic assurance programme.

3 Outcome

All TPAs and their personnel providing assessment and verification services to organic operators on NZFSA's behalf operate in conformance with these requirements, and provide quality assessment and verification services consistently.

That NZFSA is confident the official assurance programme for organic products ensures that all organic product covered by an official assurance for organic production has been produced in accordance with NZFSA Standards for this Programme, which are based on the overseas market access requirements.

4 Effective changes

This standard introduces requirements for Third Party Agencies providing assessment and verification services on behalf of NZFSA for the Official Assurance Programme for organic products. This is a new programme developed at the request of the New Zealand Organic Products Exporters Group.

5 Implementation

This Standard will apply from the date of its issue by Circular or other means of official promulgation by NZFSA.

NZFSA Standard OP2, "Third Party Agency Responsibilities - Organic Products"

1.0 SCOPE

This Standard contains the outcomes for Third Party Agencies (TPAs) providing assessment and verification services to the New Zealand organic export industry members who participate in the NZFSA Official Organic Assurance Programme.

It also specifies the responsibilities of TPAs servicing the New Zealand organic export industry, and how these must be discharged to accord with the requirements of the NZFSA Official Organic Assurance Programme.

The criteria outlined in Appendix One of this Standard were developed in consultation with industry to establish clear rules for TPAs when assessing organic management plans and verifying registered operators compliance with these plans.

All Third Party Agencies recognised by NZFSA to provide assessment and verification services for organic products intended for export must comply with this Standard.

2.0 PURPOSE

This standard provides a framework for the delivery of services by TPAs and their individuals, and ensures consistent service delivery by NZFSA accredited individuals.

3.0 OUTCOME

All TPAs and their personnel providing assessment and verification services to organic operators on NZFSA's behalf operate in conformance with these requirements, and provide quality assessment and verification services consistently.

4.0 INTERRELATED REQUIREMENTS

The following standards must be read in conjunction with this Standard.

- AS/NZS ISO/IEC Standard 17020:2000, "General Criteria for the Operation of Various Types of Bodies Performing Inspections" (EN 45004:1009).
- "NZFSA Technical Rules for Organic Production" (NZFSA Standard OP3, Appendix Two). .
- NZFSA Standard OP1, "Accreditation, Recognition, and Performance Measurement Criteria for Third Party Agencies and their Personnel – Organic Products".

- NZFSA Standard OP3, "Registration and Performance Measurement Criteria for Operators – Organic Products." .

- *Pesticide Residues in Food: Codex Alimentarius, volume two.* Codex Alimentarius Commission, 1993.

5.0 ADDITIONAL RESOURCES

The following documents are useful resources.

- "Guide to the NZFSA Official Organic Assurance Programme".
- "NZFSA Official Organic Assurance Programme, A Guide to the performance measurement of Third Party Agencies and their individuals".

6.0 DEFINITIONS

NZFSA definitions of terms can be found in their "Glossary of Terms", available on the NZFSA website (http://www.nzfsa.govt.nz/dairy/publications/information-papers/glossary.htm).

Accreditation - Formal granting of recognition of competency for specified categories, following assessment against a standard, by an accreditation body or NZFSA.

Accreditation body - An internationally recognised, independent organisation which is authorised to accredit organisations to certain ISO standards in New Zealand.

Accredited individual - A person who has demonstrated that they meet NZFSA competency standards, and has subsequently been formally accredited by NZFSA to undertake prescribed activities.

Assessment - Systematic examination of an individual, organisation, plan, programme, or system against regulatory requirements.

Assessor - A person who carries out an examination to determine the degree of conformity with prescribed criteria (ie documents and procedures).

Conflict of interest - Any circumstance that may undermine or detract from the impartiality and/or independence of an individual or organisation.

Contracting party - An organisation which has contracted the TPA to provide specified services as detailed in a contract.

Critical non-compliance - Any identified non-compliance is defined as critical if it affects the system's ability to continue to provide confidence that the product meets the requirements of the relevant NZFSA Programme.

e.g. An action, event or omission which may result in:

- Failure of organic product to comply with the importing country requirements;
- Failure to identify when organic product is not conforming;
- Failure to identify or rectify a non-compliance;
- Failure to keep accurate and complete records;
- Failure to provide accurate, complete and timely reports;
- Failure to identify and segregate non-conforming organic product in accordance with the requirements of the Official Organic Assurance Programme;
- Failure to comply with an Organic Management Plan;
- Failure to prevent recurrence of non-compliance; and/or
- Failure to rectify non-compliance within the specified timeframe.

Critical situation – Any situation which, in the professional judgement of the Assessor, places public health, animal welfare, market access, official assurances, national good, or NZFSA's credibility at risk, or where an offence is suspected.

Director - Director, Export Standards & Systems , NZFSA.

Facilities - Machinery, equipment, premises, packaging and transport containers used during the production, harvesting, processing and handling of organic agricultural product and foodstuffs.

Full assessment - An assessment to confirm that staff, facilities, operations and procedures comply with regulatory requirements and documented procedures are followed. Information gathered will include, but need not be limited to, records, discussions with management and personnel, and the observation of activities.

IANZ - International Accreditation New Zealand. An accreditation body.

ILAC - International Laboratory Accreditation Cooperation.

JAS-ANZ - Joint Accreditation System of Australia and New Zealand. An accreditation body.

MAF - Ministry of Agriculture and Forestry, New Zealand.

Non-compliance - Any failure to comply with the requirements of the Official Assurance Programme.

Operator - A natural or legal person or business entity who has completed the registration process with a TPA and has the day to day management and/or contractual control of an organic management plan.

Organic Management Plan (OMP) - A programme of conditions, processes, procedures, measures, and standards to be complied with, performed, undertaken, taken or met in relation to:

- any process or activity related to organic products, ingredients used in the processing of organic products, or both; and
- sampling, examination, inspection, and testing, or any of those actions relating to any such process or activity; and
- the recording and inspection of information relating to any such action;

and (without limiting the generality of the foregoing) may include conditions, processes, procedures, measures, or standards relating to the production, processing, storage, and/or transport of organic products.

Overseas market access requirement - official sanitary, truth of labelling, and/or related specifications set by the relevant competent authority for the importation of animal or plant products.

Recognised - Recognised by the Director General of MAF.

Surveillance assessment - A partial assessment to confirm selected components of a programme comply.

Third Party Agency (TPA) - An organisation recognised by NZFSA to carry out assessment (evaluation and/or verification) services.

Verification - Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with NZFSA-approved plans, programmes and systems, and to confirm the ongoing applicability of those.

7.0 REQUIREMENTS

Recognised TPAs must:

- register operators for participation in the NZFSA official organic assurance programme;
- assess organic management plans (OMPs) against NZFSA Standard OP3, "Registration and Performance Measurement of Operators – Organic Products";
- verify operator compliance with OMPs and criteria specified in NZFSA Standard OP3;
- assign assessment frequency categories to operators;
- conduct regular and surveillance assessments of operators at frequency assigned;
- collect samples and arrange chemical residue testing of soil, water, ingredients and/or organic products produced or used by operators participating in this programme;
- manage resolution of operator non-compliance and critical non-compliance, including follow-up of corrective actions with persons accountable for OMPs;
- manage de-registration of operators;

- verify consignment eligibility for official assurance; and
- make available to NZFSA registration details of operators to facilitate the issue of official assurances,

in order to give NZFSA confidence that the NZFSA Official Organic Assurance Programme is providing the truth of labelling outcomes required by the overseas market.

8.0 VERIFICATION

Verification of compliance of TPAs with this Standard is undertaken annually by the accreditation body in conjunction with a technical expert appointed by NZFSA.

8.1 Criteria

The criteria for assessing TPA compliance with the Standard are as follows.

- The TPA operates in accordance with the requirements of ISO Standard 17020, NZFSA Standard OP1, "Accreditation, Recognition and Performance Measurement Criteria for Third Party Agencies & Personnel – Organic Products", and this NZFSA Standard.
- The TPA does not misuse or abuse its accreditation status.

8.2 Decision

The TPA is non-compliant if one or more of the criteria for assessing compliance is not met.

8.3 Result

8.3.1 Compliant TPAs

Compliant TPAs continue to be recognised by NZFSA to provide assessment and verification services to the New Zealand organic export industry if they also comply with the requirements of NZFSA Standard OP1, "Accreditation, Recognition and Performance Measurement Criteria for Third Party Agencies and their Personnel – Organic Products".

8.3.2 Non-compliant TPAs

- Non-compliant TPAs have recognition to provide assessment and verification services for the official organic assurance programme withdrawn until the issue has been resolved to the satisfaction of NZFSA.
- The reports from non-compliant TPAs are not accepted by NZFSA.

9.0 VERSION CONTROL

Version	Date	Status	By
Draft 000510	23 June 2000	Issued for internal comment	TA-OPP, NZFSA: Dairy & Plants
Draft 000711	11 July 2000	Issued for external comment	TA-OPP, NZFSA: Dairy & Plants
Draft 001016	16 October 2000		TA-OPP, NZFSA: Dairy & Plants
Draft 010216	16 February 2001		TA-OPP, NZFSA: Dairy & Plants
Version One	March 2001	Approved	Directors, NZFSA: Dairy & Plants and NZFSA: Animal Products

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Appendix One

CRITERIA FOR THIRD PARTY AGENCIES

Following are criteria by which a TPA may be judged to achieve satisfactorily the requirements described in section 7 of this Standard. TPAs that have demonstrated that they meet each of the criteria will be recognised by NZFSA.

Proposals for alternative criteria will be accepted by NZFSA, provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by NZFSA to assess proposals can be obtained from NZFSA.

1.0 ASSESSMENT OF OMPS

The TPA assesses and verifies operators' OMPs for compliance with NZFSA Standard OP3, "Registration and Performance Measurement Criteria for Operators – Organic Products" prior to registering operators for participation in this programme.

The assessment is undertaken by an individual accredited by NZFSA.

An individual that has undertaken the initial assessment and verification of an organic management plan does not undertake the on-going on-site verification of operator compliance with that plan.

2.0 OPERATOR REGISTRATION

The TPA registers an operator when there is no unresolved critical non-compliance.

De-registration of operators, or registration with conditions (eg time limit) is undertaken when appropriate (e.g. operator or NZFSA request).

The TPA maintains an up to date register of operators participating in the programme and provides NZFSA with on-line access to the register.

3.0 ON-GOING VERIFICATION OF OPERATOR COMPLIANCE WITH OMPS

The TPA continues to verify the operator's compliance with the OMP at the assigned frequency.

The verification is undertaken by an individual accredited by NZFSA.

4.0 CATEGORISATION OF OPERATOR ASSESSMENT FREQUENCY

Following the verification and operator registration, the TPA assigns the assessment frequency category to the operator in accordance with the criteria specified in NZFSA Standard OP3.

The TPA advises the accountable person of the category to which they have been assigned, the frequency of assessments and the date of effect.

Reclassification of operator assessment frequency is undertaken in instances as described in NZFSA Standard OP3. Information to support operator reclassification is recorded (Appendix Two to this standard contains an example of a report format for operator reclassification).

5.0 ARRANGEMENT OF CHEMICAL RESIDUE TESTS

Testing for residues to determine the use of prohibited substances is undertaken in accordance with the following.

5.1 Random testing

It is intended that a requirement for random testing will be incorporated once the programme has been implemented.

The scope of random testing is restricted to prohibited pesticide and veterinary drugs.

If the operator is participating in any other residue programmes, results from these programmes may be presented to the TPA for consideration and acceptance by the TPA in place of the random test. Acceptance of such results is dependent on determining that the samples were collected by a third party and tested in accordance with point 5.4 below.

5.2 Testing as required by the TPA

Testing is undertaken at the initial on-site assessment to establish a base level of any prohibited substances that may be present in the system at the time of entry into the programme.

Testing is also undertaken when the TPA has reason to believe that unauthorised substances may have been used in the production of the product(s). Examples of such instances are:

- when evidence indicates prohibited substances have been purchased by the operator;
- when an operator conducts both conventional and organic production (i.e. parallel production); or
- where the operation is under conversion to organic production.

5.3 Sampling

The sampling methods and sample sizes adopted by the TPA are in accordance with CODEX recommended methods of sampling products for the determination of pesticide residues.

5.4 Testing

Samples are analysed by a laboratory holding ISO Guide 25 accreditation from an ILAC member for the scope of the proposed tests, using screening methods appropriate for the product, and the prohibited substances likely to be found on or associated with that product.

5.5 Results

The production system associated with any residue test result indicating a prohibited substance has been used is investigated and an investigation report documented by the TPA. The investigation determines:

- Why the residue is present;
- Degree of operator compliance with OMP;
- Product status/eligibility for official assurance.

Records of test results and investigation reports are kept for 2 years.

5.6 Test costs

Test costs are the responsibility of the operator participating in the programme.

6.0 MANAGEMENT OF RESOLUTION OF OPERATOR NON-COMPLIANCE

When managing resolution of operator non-compliance, the TPA also follows-up on corrective actions with persons accountable for OMPs.

The TPA:

- reports all observed non-compliance to the operator;
- agrees corrective actions and date for resolution for all instances of non-compliance (except critical situations);
- takes the action necessary to obtain resolution;
- confirms resolution;
- reports all critical non-compliance and critical situations to NZFSA;
- in all critical situations, fully briefs and hands control over to NZFSA; and

- ensures all non-conforming product is managed in accordance with NZFSA Standard OP3 and the Operator's OMP.

Any identified non-compliance is defined as critical if it affects the system's ability to continue to provide confidence that the product meets the requirements of the NZFSA Programme.

6.1 Classifying non-compliance

Where non-compliance is identified the TPA establishes the degree of non-compliance, e.g. by assessing:

- the intent of the operator to deviate from the organic management plan ,
- the extent of the system breakdown, or
- whether it was a one-off error

and classifies the non-compliance as critical or non-critical accordingly. The impact of the non-compliance on products and production areas/premises is considered.

6.2 Reaction to non-compliance

Where the non-compliance has an impact on the eligibility of any products for an official assurance, the TPA ensures such product is not verified as eligible for an official assurance.

Instances of non-compliance identified during any audit results in reclassification to a category with higher levels of assessment.

6.3 Corrective action timeframe

A corrective action and time frame for its implementation are agreed between the TPA assessor and the operator for each instance of non-compliance. The TPA verifies that the corrective action has been implemented and is operating effectively within the agreed time frame.

The TPA records all agreed corrective actions taken to correct identified operator non-compliance. Corrective actions outline:

- what is to be done;
- person responsible for ensuring action is taken and is effective;
- the time frame for implementation of the corrective action; and
- the verification activities to be undertaken to ensure that corrective action has been successfully implemented.

All corrective actions shall be reviewed and their effectiveness in addressing non-compliance and its root cause verified.

7.0 ELIGIBILITY FOR OFFICIAL ASSURANCE

7.1 Production and control

NZFSA assurances for organic products are produced and controlled by the systems currently operating for the issue of NZFSA assurances for plant, animal and dairy products.

7.1.1 Plant products

Assurances are produced and controlled in accordance with the requirements in the MAF Plants Biosecurity Standard, PEO.MMR: "Design, Production, Distribution and use of MAF Plants Marks – Certificates and Seals".

7.1.2 Dairy products

Assurances are produced and controlled by the Export Standards & Systems Group of NZFSA.

7.1.3 Animal products

Assurances are produced and controlled by the Export Standards & Systems Group of NZFSA.

7.2 Completion of assurances

Where a TPA has been authorised by NZFSA to prepare official assurances for submission to NZFSA for endorsement, all materials submitted accordingly are:

- completed in accordance with the overseas market access requirements;
- legible;
- typed;
- traceable to the TPA individual verifying the assurance; and
- presented on the approved certificate format (refer to the example in the "Guide to the NZFSA Official Organic Assurance Programme");

Completed assurances contain all the information required on the assurance certificate including a unique reference number.

7.3 Verification of assurances

The TPA procedures for verification of assurances include:

- communication of the assessment information required for the verification of assurances, including transfer of information to other TPAs and NZFSA;
- confirmation that the products in the consignment meets the requirements of the official organic assurance programme;

- confirmation that the overseas market access requirements stated on the certificate are those which have been validated by NZFSA; and

- confirmation that the certificate has been produced and completed in accordance with the requirements in this NZFSA Standard.

Verification notices are supplied in either a manual or electronic form as required by NZFSA.

Annex A

RECLASSIFICATION OF A REGISTERED OPERATOR PARTIPATING IN THE OFFICIAL ORGANIC ASSURANCE PROGRAMME

Registered operator:

Accountable person:

Street address:

Postal address:

Telephone number: **Fax number:**

Current category: (Please circle current category)

Reduced Assessment	**Standard/Entry Assessment**	**Increased Assessment**

Date assigned to current category:

Reclassified category: (Please circle recommended category)

Reduced Assessment	**Standard/Entry Assessment**	**Increased Assessment**

Date for reclassification:

Describe current performance by ticking the appropriate boxes in the table below:

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Production Unit/Premises	Production units/premises operating in accordance with the OMP assessed and verified by the TPA for two (2) or more seasons and all significant changes assessed and verified by the TPA prior to the change.	All production units/premises operating under an OMP assessed and verified by the TPA and all significant changes assessed and verified by the TPA.	Production units/premises conditionally operating under an OMP, or OMP assessed and verified by the TPA subject to certain conditions.
Organic Management Plan	The OMP is assessed and verified by the TPA, is current and is reviewed by the operator.	The OMP is assessed and verified by the TPA, and is current.	- The OMP is deficient, - the OMP is not fully implemented, - the OMP is not current, - the OMP requires assessment or verification, or - the OMP is in the process of assessment or verification.
Verification of compliance with OMP	Full compliance with OMP demonstrated for two years.	Isolated non-compliance with OMP, corrected by operator as required by TPA.	- Regular or persistent non-compliance with OMP, or - failure to complete corrective action required by TPA.
Reporting	- Regular and exception reports complete, accurate and on time for at least two years, and - proactively advises the TPA of any non-compliance identified and corrected.	- Regular and exception reports complete, accurate and on time for at least one year, or - regular reports occasionally incomplete or late and exception reports are complete accurate and on time.	- Regular or exception reports contain incomplete information or factual errors or are persistently late; or - exceptions are not reported.
Management of critical non-compliance	- Critical non-compliance identified, - full traceback completed to identify root causes, - corrective actions completed in a timely manner, - full analysis of the risk to the operation from this type of non-compliance completed, and - actions taken to eliminate the risk of potential non-compliance or monitoring systems implemented to identify	Critical non-compliance identified and managed according with NZFSA requirements.	- Critical non-compliance not identified, or - critical non-compliance are identified and inadequately managed.

Area	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
	potential non-compliance in the operation.		
Control of non-conforming product	All non-conforming product disposed of in accordance with the OMP.	All non-conforming product disposed of in accordance with the OMP.	Non-conforming product **not** disposed of in accordance with the OMP.

Information considered by TPA in the review: (Please attach reports or any other relevant information)

TPA:

Contact person:

Signed: _____

Date: _____