



**OECD Schemes
For the Varietal Certification or the Control of Seed
Moving in International Trade**

**GUIDELINES
FOR THE AUTHORISATION
OF SOME CERTIFICATION ACTIVITIES
UNDER THE OECD SEED SCHEMES
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Foreword

1) These Guidelines were prepared as part of the initial temporary OECD experiments that were similar to and legally equivalent to those undertaken in the European Community in the 1990s. As a consequence, the role of authorised seed personnel, seed testing laboratories and surveillance bodies undertaking seed certification activities on behalf of an OECD Designated Authority and the approach to monitoring their compliance to requirements are therefore similar to those used in the EC experiment.

2) The governments of the countries participating in the OECD Seed Schemes designate authorities (Designated Authorities) that are responsible for implementing the Schemes. When certain activities that are essential components of the Schemes are delegated to other parties, a number of requirements should be met to ensure that the parties are competent to carry out specific tasks. There may also be legal, financial, organisational and other criteria involved in the process of delegating authority.

3) These Guidelines specifically relate to the OECD Seed Certification Schemes and OECD Designated Authorities. They provide for a generic approach which includes monitoring and the requirement that authorised seed personnel and laboratories operate within the framework of a documented quality system based on appropriate ISO or EN/ISO Accreditation Standards. Designated Authorities may adapt or build on these Guidelines to meet their specific needs so long as they comply with the legal basis and conditions for delegation of authority defined in the rules and procedures of the OECD Seed Schemes [*Council Decision C(2000)146/FINAL as amended to date, available in English and in French at www.oecd.org/agr/seed*].

4) Terms such as “accredit” and “license” are sometimes used in the process of delegating authority. For the purposes of these guidelines the term “authorisation” has been adopted to best describe the process under which an OECD Designated Authority may delegate its authority to other individuals, organisations, entities and /or bodies.

5) These Guidelines are strictly voluntary and have been written in the interest of co-operation and harmonisation through sharing experiences. In addition to them, Designated Authorities may find the following international standards useful as a means to manage their authorisation process:

- ISO/IEC 17020:1998 “General criteria for the operation of various types of bodies performing inspection”. *This may be useful for individuals and/or entities undertaking seed inspection and/or surveillance activities.*
- ISO/IEC 17025:2005 “General requirements for the Competence of Testing and calibration laboratories”. *This may be useful for laboratories undertaking seed testing.*
- ISTA Seed Testing Laboratory Accreditation Standard. *This standard is based on ISO/IEC 17025:2005 to meet the specific needs of ISTA, its member laboratories and the international seed trade.*
- EN 45011:1998 “General requirements for bodies operating product certification systems”. *This may be useful for formulating the basis of a system for delegating authority to surveillance bodies undertaking supervision, surveillance, verification and audit activities on behalf of the Designated Authority.*
- ISO 9001:2000 “Quality management system requirements”

6) The present document is also available on line, in French and in English, at www.oecd.org/agr/seed

**GUIDELINES
FOR THE AUTHORISATION OF SOME CERTIFICATION ACTIVITIES
UNDER THE OECD SEED SCHEMES**

1. INTRODUCTION AND SCOPE OF APPLICATION

1.1 These voluntary Guidelines are recommended for implementation by the Designated Authorities to formalise the delegation of authority to individuals, and/or organisations to undertake field inspection, seed sampling (including labelling and sealing) and seed testing within the framework of the OECD Seed Schemes.

1.2 The authorisation process may include all species in all OECD Seed Certification Schemes or may be limited as deemed appropriate by Designated Authorities to meet their national circumstances.

1.3 The Guidelines introduce the concept of an authorised "*Third Party Seed Inspection Organisation*" (ATPSIO), that may act officially on behalf of an OECD Designated Authority under formal delegated authority. However, Designated Authorities will retain overall accountability for the operation of the system and the delivery of OECD seed certification. The approach outlined in these Guidelines is flexible, and does not preclude Designated Authorities from undertaking the full range of seed certification activities themselves, and it is open to Designated Authorities to make whatever arrangements they want within this framework.

1.4 A glossary of terms used in this document and their definitions is provided in Appendix. It is based on ISO terminology but tailored to be relevant to OECD Seed Schemes.

2. REQUIREMENTS

2.1 General

2.1.1 All persons or seed testing laboratories associated with field inspection, sampling, seed testing and/or Third Party organisation activities (henceforth referred to as "seed persons and/or laboratories and/or organisations" within this section) seeking to be authorised must have access (for advice and information) to the services of the Designated Authority. There must not be undue financial or other conditions for authorisation. The Designated Authority shall require that all authorised seed persons and/or laboratories and/or organisations maintain their expertise, are notified of changes in the OECD Seed Schemes Rules, technical methodology and the authorisation system, and that their training is timely and appropriate. The Designated Authority shall require that all authorised seed persons and/or laboratories and/or organisations are regularly employed in the activities for which they are authorised.

2.1.2 Confidentiality of the information obtained in the course of the Designated Authorities' authorisation activities, at all levels of its organisation, needs to be maintained.

2.1.3 The Designated Authority should assure itself that all authorised seed persons and/or laboratories and/or organisations are free from pressures which might adversely affect the quality of their work, independence of judgement and maintenance of integrity when undertaking activities for which they are authorised.

2.1.4 All authorised seed persons and/or laboratories and/or organisations should be familiar with the implementation of the OECD Seed Schemes as per their scope of authorisation through training and experience.

2.1.5 The Guidelines incorporate rules and methods for inspection, seed sampling and seed testing such as those of the OECD Seed Schemes and the International Seed Testing Association (ISTA) or the Association of Official Seed Analysts (AOSA).

2.1.6 As sampling, sealing and labelling activities are closely linked, one authorisation procedure will cover all of them. Henceforth any reference to "seed samplers" also covers control of labelling and sealing. This does not prevent a Designated Authority from restricting the scope of the authorisation to only one or two of these activities.

2.1.7 The Designated Authorities, or their ATPSIO(s) where appropriate, must:

- carry out official assessments of competence for authorisation of seed persons and/or laboratories;
- ensure that seed sampling and/or seed testing is done according to OECD Seed Certification Schemes Rules and methods as indicated in paragraph 2.1.5;
- provide OECD seed certification labels to seed companies with authorised seed samplers and any other authorised person within the company;

2.2 Documentation and change control

A system for the control of all documentation relating to the authorisation system should be considered and developed by the Designated Authority appropriate for all authorised seed persons and/or laboratories. For example a workable system might include:

- a) current issues of the appropriate documentation;
- b) a process to ensure that changes or amendments to documents are authorised, processed and implemented in a quick and efficient manner;
- c) an effective process to ensure that all authorised seed persons and/or laboratories are notified of changes.

2.3 Surveillance and audit facilities

2.3.1 The Designated Authority, or its ATPSIO where appropriate, should have available the required resources in terms of technical expertise and equipment to undertake the authorisation, surveillance and audits of all applicants. This does not preclude the use of external resources when necessary.

2.3.2 If assessment, surveillance or auditing is carried out on behalf of the Designated Authority by an external body such as an ATPSIO, the Designated Authority should ensure that this external body conforms to the requirements of 2.1.3 and 2.3.1. A properly documented agreement covering these arrangements, including a confidentiality clause, and provisions for regular audits of the ATPSIO, is advisable.

2.3.3 The Designated Authority, are to ensure regular surveillance and audits of all authorised seed persons and/or laboratories and/or organisations are conducted to ensure the requirements of OECD varietal certification are being met. Surveillance and audits are described in more detail under the relevant chapters concerning authorisation of field inspectors, seed samplers, seed testing laboratories and third party seed inspection organisations.

Note: Additional requirements and methods for monitoring to reduce the risks of non-compliance may be introduced.

2.4 Documented procedures

2.4.1 It is suggested that the Designated Authority should have documented procedures which describe the way in which it applies its authorisation criteria for seed persons and/or laboratories and/or organisations. Suggestions for inclusion are:

- a) procedures for training and assessing applicants for authorisation;
- b) procedures followed when auditing and monitoring the competence of all authorised seed persons and/or laboratories and /or organisations;
- c) a list of the ATPSIO(s) which have been assessed as competent in accordance with the activity areas described in this Guideline and authorised to operate on behalf of the Designated Authority;
- d) procedures for withdrawal, suspension and cancellation of authorisation;
- e) appeals procedures.

2.4.2 A published description of the:

- authorisation system is advised;
- rules and methods recommended in paragraph 2.1.5 relevant to seed sampling, labelling, sealing, and testing within the framework of implementing the OECD Seed Certification Schemes is available.

2.5 Non-compliance procedures

2.5.1 Withdrawal of authorisation

If required the Designated Authority or its ATPSIO may suspend or withdraw authorisation. The following are examples where authorisation may be suspended or withdrawn;

- a) false or misleading information has been provided in the application for authorisation;
- b) false or misleading information has been provided in a report associated with or leading to OECD varietal certification;
- c) authorised seed persons and/or laboratories and/or organisations have not followed correct procedures;
- d) there is evidence from surveillance and/or audit activities that authorised seed persons and/or laboratories and/or organisations do not meet the required standard of competence;
- e) there is evidence from surveillance and/or audit activities that authorised seed persons and/or laboratories have yielded to pressures which have adversely affected the quality of their work, independence of judgement and maintenance of integrity when undertaking activities for which they are authorised.

2.5.2 Other action

In some cases the Designated Authority or its ATPSIO may require authorised seed persons and/or laboratories and/or organisations to undergo corrective training and re-examination.

2.5.3 Appeals

The Designated Authority or its ATPSIO may operate an appeals procedure to enable a review of decisions to suspend or withdraw authorisation.

The appeal process should not have costs or procedures which discriminate against any person, company or entity.

3. AUTHORISATION OF FIELD INSPECTORS

3.1 Training

Applicants for authorisation should undergo training appropriate to the crops which they would be authorised to inspect.

3.2 Knowledge and Skill Requirements

Applicants should have the following knowledge and skills;

3.2.1 Knowledge of:

- a) the OECD Seed Schemes;
- b) the methods of field inspection and field standards appropriate for the crop species for which authorisation is sought;
- c) the varietal characteristics of the varieties to be inspected.

3.2.2 Skills in:

- a) use of varietal characteristics to confirm varietal identity of seed crops;
- b) detection, characterisation and quantification of varietal impurities in seed crops.

3.3 Competency Assessment

Applicants should satisfy the Designated Authority of their competence to become authorised through the following two methods of assessing competence:

- a) a written examination to test knowledge of the methods and norms for field inspection;
- b) a practical examination through observation of the applicant in operation to confirm the correct application of field inspection methods.

3.4 Conditions for Maintaining Knowledge and Skills

Authorised field inspectors need to maintain their knowledge and skills by:

- a) undertaking regular inspection of crops and,
- b) participating in periodic retraining and,
- c) keeping up-to-date copies of OECD Seed Scheme Rules and crop inspection procedures and being familiar with any changes to these.

3.5 Surveillance and Audit Procedures

3.5.1 Check-inspections

A proportion of crops inspected by authorised field inspectors are to be check-inspected by official field inspectors, as specified in the conditions of the OECD Seed Schemes. The exact method used can be determined by the Designated Authority. Options include:

- a) check-inspecting a proportion of crops for each authorised field inspector;
- b) check-inspecting a proportion of crops selected randomly from all crops which are inspected by authorised field inspectors;
- c) check-inspecting a proportion of crops selected randomly from all authorised field inspectors and additional monitoring of authorised field inspectors with a higher risk of non-compliance.

3.5.2 Inspection Audits

Authorised field inspectors may be audited by official field inspectors during field inspections. The audits should be carried out by a qualified auditor or a person with audit experience.

3.5.3 Re-examination

The Designated Authority may require authorised field inspectors to re-qualify for authorisation in periodic competency assessments. The suggested interval is 3-5 years.

3.5.4 Documentation

Examination of field inspection report forms will enable the Designated Authority to monitor the standard of completion of documentation.

3.5.5 Use of pre- and post-control plot assessment results

The results of control plot assessments can be compared with authorised field inspectors' field inspection reports as an indicator of performance.

4. AUTHORISATION OF SEED SAMPLERS (including Sealing and Labelling)

4.1 Training

The Designated Authority, or ATPSIO where appropriate, must be satisfied that applicants have been sufficiently trained and are competent.

4.2 Knowledge and Skill requirements

4.2.1 Applicants should:

- be trained and competent in taking seed samples for seed certification purposes;
- have knowledge of and work according to current international methods;
- have sufficient knowledge of OECD Seed Certification Schemes (e.g. relevant to sampling, testing and labelling);

- have access to appropriate equipment; and
- maintain their expertise.

4.2.2 Sampling Equipment

Any equipment which is used for seed sampling must fulfil the requirements of the rules and methods as indicated in paragraph 2.1.5.

4.3 Competency assessment

The competency of applicants may be assessed by:

- a written examination to test knowledge of OECD Seed Certification Schemes, and principles and procedures of seed sampling, sealing and labelling;
- a practical examination of the application of seed sampling methods; and
- re-examination in case of recognised deficiencies of the authorised seed sampler.

4.4 Conditions for maintaining knowledge and skills

Authorised seed samplers need to maintain their knowledge and skills by:

- undertaking regular seed sampling work; and
- keeping up-to-date the documentation and being familiar with the appropriate operating procedures and methods based on the OECD Seed Certification Schemes and the seed sampling rules and methods as indicated in paragraph 2.1.5;
- participating in periodic retraining may also be required.

4.5 Surveillance and audit procedures

4.5.1 Audits of seed samplers

Audits of authorised seed samplers are to examine adherence to the appropriate sampling procedures and methods and include checks on documentation, as well as the examination of company records on label and seal usage. The use of official labels and systems of traceability for the use of these should also be examined.

4.5.2 A proportion of seed lots sampled by authorised seed samplers must be check sampled by official seed samplers and check-tested in an official seed laboratory respectively. In the case of automatic seed sampling the check-sampling will not be relevant and should be replaced by audits, process monitoring and other relevant tests according to the international rules and standards.

5. AUTHORISATION OF SEED TESTING ANALYSTS AND SEED LABORATORIES

5.1 Training

The Designated Authority, or ATPSIO where appropriate, must be satisfied that staff of the applicant laboratory have been sufficiently trained and are competent.

5.2 Knowledge and Skill Requirements

Seed testing laboratories must:

- have a qualified laboratory manager (analyst in charge);
- have enough qualified seed analysts in relation to the volume of tests carried out, with the appropriate technical qualifications in accordance with the rules and methods as indicated in section 2.1.5, confirmed by official examinations;
- be situated in appropriate premises and have appropriate calibrated and well maintained equipment which fulfil the requirements of the international methods and rules and;
- work according to international methods and rules for seed testing.

5.3 Competency assessment

The following methods may be used to assess the competency of applicants:

- Laboratory management examination for seed analyst in charge:

An examination to assess laboratory management skills, particularly control of testing conditions and documentation, in addition to a seed testing examination.

- Seed testing examination for all seed analysis staff:

After completion of a training course, a practical examination relating to seed testing in respect of the species that will be tested.

A written examination to test knowledge of principles and procedures of seed testing according to the international rules and methods.

Note: The examinations must be appropriate to the seed species for which the seed testing laboratory is seeking authorisation for.

- Re-examination in case of recognised deficiencies of the authorised seed testing laboratory staff.

5.4 Conditions for maintaining knowledge and skills

5.4.1 Authorised seed testing laboratories need to ensure that their staffs maintain their knowledge and skills by:

- undertaking regular seed testing work; and
- keeping up-to-date the documentation and being familiar with the seed testing rules and methods as indicated in section 2.1.5;
- participating in periodic retraining may also be required.

5.4.2. Any premises and equipment which is used for seed testing must fulfil the requirements of the appropriate rules and methods as indicated in paragraph 2.1.5.

5.5 Surveillance and Audit Procedures

5.5.1 Check testing

A proportion of samples tested by authorised seed testing laboratories must be check tested in an official seed laboratory.

5.5.2 Audits of seed testing laboratories

Audits of authorised seed testing laboratories are to examine adherence to the appropriate testing procedures and methods and include checks on documentation, as well as the examination of laboratory records. The audits should be carried out by a qualified auditor or a person with audit experience

5.5.3 Authorised seed testing laboratories may be required to test and report on specially prepared samples of seed, i.e. ring tests.

6. AUTHORISATION OF THIRD PARTY SEED INSPECTION ORGANISATIONS

6.1 Independence

The Designated Authority must be satisfied that authorised Third Party Seed Inspection Organisations (ATPSIOs) meet the "Independence criteria for Type A inspection body", as specified in ISO/IEC 17020:1998 *General criteria for the operation of various types of bodies performing inspection*.

6.2 Training

The Designated Authority must be satisfied that Third Party Seed Inspection Organisations have been sufficiently trained and are competent in terms of sections 3.2, 4.2 and 5.2 as appropriate to the scope of authorisation being sought.

6.3 Knowledge and Skill Requirements

Third Party Seed Inspection Organisations must:

- have a qualified manager who is technically competent in seed certification requirements;
- have enough qualified seed certification staff (field inspectors, sampling, testing and audit personnel) in relation to the volume of inspections, sampling, tests and audits carried out, with the appropriate technical qualifications in accordance with the rules and methods as indicated in section 2.1.5 and confirmed by official examinations;
- be situated in appropriate premises and have appropriate equipment which fulfil the requirements of the Rules of the Seed Schemes and;
- work according to the Rules of the Seed Schemes.

6.4 Competency assessment

The following methods may be used to assess the competency of applicants:

- Examination of the manager's knowledge and understanding of the seed certification Rules:

An examination to assess applicants management skills, particularly control of seed certification activities, conditions and documentation, in addition to an auditor examination.

- Seed certification examination for all seed inspection, sampling, testing and auditing staff:

After completion of a training course, a practical examination relating to seed certification activities in respect of the species that will be included within the scope of the applicants operation.

A written examination to test knowledge of principles and procedures of seed certification according to the Rules of the Seed Schemes.

Note: The examinations must be appropriate to the seed species for which the applicant organisation is seeking authorisation for.

- Re-examination in case of recognised deficiencies of the authorised Third Party Seed Organisation's seed certification staff.

6.5 Conditions for maintaining knowledge and skills

6.5.1 Authorised Third Party Seed Inspection Organisations need to ensure that their staffs maintain their knowledge and skills by:

- undertaking regular seed certification work; and
- keeping up-to-date the documentation and being familiar with the appropriate operating procedures and methods based on the OECD Seed Certification Schemes Rules as indicated in section 2.1.5;
- participating in periodic retraining may also be required.

6.5.2 Any premises and equipment which is used for seed certification must fulfil the requirements of the appropriate Seed Scheme Rules as indicated in paragraph 2.1.5.

6.6 Surveillance and Audit Procedures

The Designated Authority must ensure the requirements of sections 3.5, 4.5 and 5.5 are undertaken through audits of authorised Third Party Seed Inspection Organisations (ATPSIOs) to examine their adherence to the appropriate inspection, sampling and testing procedures and methods in accordance with the scope of their authorisation. These audits are to also include checks on documentation, as well as the examination of appropriate seed certification records.

APPENDIX

GLOSSARY OF TERMS AND THEIR DEFINITIONS IN AUTHORISATION OF SOME CERTIFICATION ACTIVITIES

The following commonly used terms associated with the authorisation process in seed certification and their definitions have been developed as a means of encouraging a uniform understanding amongst Designated Authorities whenever they are used. Where possible and appropriate, definitions from ISO 9000:2005 have been utilised, with some slight adjustment at times to reflect the needs and role of seed certification.

Authorised

Having been formally recognised by the Designated Authority, or the legal person to whom the tasks provided for in the Rules and Directions have been delegated by the Designated Authority, as competent to act on its behalf to provide a service in accordance with the requirements specified in the Scheme Rules.

Note: Where a Designated Authority implements the authorisation as defined in the OECD Seed Schemes, the authorisation to carry out activities pursuant to the Schemes shall be granted subject to its surveillance (i.e. Authorisation status is subject to ongoing review).

Authorised field inspector, seed sampler and seed testing laboratory

A person and/or seed testing laboratory and/or entity authorised by the Designated Authority, or authorised third party seed organisation as appropriate, as being competent to carry out an activity for the purposes of seed certification.

Authorised Third Party Seed Inspection Organisation (ATPSIO)

A technical body or entity acting under official delegated authority to undertake specific activities associated with seed certification on behalf of the Designated Authority.

Field Inspection, Seed Sampling, Seed Testing authority

A document issued by the Designated Authority or authorised third party seed organisation indicating that the named person is authorised to perform an activity for the OECD Seed Schemes.

Note: An authority will normally specify the scope of activities for which the holder is recognised as competent to undertake and conditions with which the holder must comply.

Applicant (for authorisation)

Person and/or seed testing laboratory and/or third party seed inspection organisation seeking authorisation from the Designated Authority to undertake seed certification activities.

Audit

Evaluation to determine the degree of compliance with documented procedures and required levels of competence.

Check-inspection, -sampling, -testing

A method of surveillance used by the Designated Authority; where both authorised and official inspectors carry out the activity with respect to the same crop.

Note: The two inspections should be conducted independently and the results compared, to assess the competence of the authorised person or entity.

Compliance

Fulfilment of specified requirements.

Corrective Action

Action taken to eliminate the causes of non-compliance, defect or other undesirable situation in order to prevent re-occurrence.

Note: The corrective actions may involve changes in procedures and systems, to achieve quality improvement at any stage of the quality management loop.

There is a distinction between "correction" and "corrective action": "Correction" refers to rework or adjustment and relates to the disposition of an existing non-compliance. "Corrective action" relates to the elimination of the causes of a non-compliance.

Field Inspection, Seed Sampling and Seed Testing Procedure

Specified way to perform an activity.

Note: In many cases procedures are documented. When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used.

A written or documented procedure usually contains the purposes and scope of an activity; what shall be done and by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; and how it shall be controlled and recorded.

Independent

Organised in such a way that confidence in its independence of judgement and integrity is maintained at all times.

Field inspection, seed sampling, seed testing

Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with the specified requirements in order to establish whether compliance is achieved for each characteristic.

System for Field Inspection, Seed Sampling, Seed Testing

The organisational structure, responsibilities, operational procedures, processes and resources for implementing activities associated with an activity under authorisation. Internal audits or the preparation of documents for the provision of Seed Certification.

Legal entity

The company/organisation, governed by public or private law, to which the Designated Authority has delegated the tasks provided for in the Rules and Directions. This legal entity and its members shall derive no private gain from the outcome of the measures it takes.

Non-Compliance

Non-fulfilment of a specified requirement. This definition covers quality characteristics, activity procedures and authorisation conditions.

Surveillance

A system of monitoring the competence of an authorised legal entity and/or persons and adherence to their conditions of authorisation and documented procedures including reporting.

Note: Surveillance activities include check inspections, -sampling or -testing, inspection, sampling or testing audits, re-examination of knowledge and skills, and document checks.