

# Conditions 2026

For laboratories of seed companies conducting quality tests on:

- seeds
- (parts of) plants



**NAL**  
• naktuinbouw



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## Introduction

Naktuinbouw Authorized Laboratories (NAL) is an official authorization system of Naktuinbouw, based on annual external audits conducted by or on behalf of Bureau Authorizations, protocol review and proficiency tests. NAL is exclusively for seed companies: companies whose core business involves the production and marketing of seeds from their varieties. Their laboratories conduct sampling and quality tests on seeds and/or (parts of) plants. These NAL Conditions 2026 are an improved version of earlier editions of the NAL Conditions, starting in 1994.

When laboratories comply with the NAL Conditions, it assures them that their clients will receive reliable test results that accurately reflects the true quality of the seeds. The NAL authorization of a laboratory is demonstrated through the NAL certificate, which includes an appendix stating the tests for which authorization has been granted by Bureau Authorizations. This information is also displayed on the website of Naktuinbouw.

Sampling, testing, and the subsequent issuing of NAL Quality certificates is only permitted for crops under the supervision of Naktuinbouw inspections<sup>1</sup>.

The NAL system is a coherent framework based on:

- Guidelines for the company version 9
- NAL Authorization Board of Experts Regulations: 2015
- NAL Authorization Regulations: 2015
- NAL Board of Appeal Regulations: 2015
- NAL Conditions: 2026
- NAL Regulations on the use of the NAL Collective Trademark: 2015

The NAL Conditions 2026 are based on relevant criteria from:

- EPPO PM 7/84 (3), 2021, Basic requirements for QM in plant pest diagnosis labs
- EPPO PM 7/98 (5) 2021, Specific requirements for labs preparing accreditation for a plant pest diagnostic activity
- ISO 9001:2015 Quality Management Systems – Requirements
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISPM No. 31, 2008, Methodologies for sampling of consignments
- ISTA Laboratory Accreditation Standard version 8.0, 2026
- Miles S.R., 1963, Handbook of tolerances and measures of precision for seed testing. ISTA Statistics Committee, ISTA Proceedings 28: 525-686
- Regulation (EU) 2017/625 on official controls and other official activities
- Regulation (EU) 2016/2031 on protective measures against pests of plants

The NAL Conditions 2026 are divided into the following standard modules:

- Quality management system requirements
- Sampling requirements
- Testing requirements.

NAL authorization can only be granted when a laboratory complies with these three basic modules. Optional modules are NAL-DAFF of Australia and NAL-LEEZ.

Determined by the Board of Naktuinbouw  
Roelofarendsveen, 12 December 2025

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<sup>1</sup> See '[Regeling verhandeling teeltmateriaal](#)'



## NAKTUINBOUW MODULE QUALITY MANAGEMENT SYSTEM REQUIREMENTS

### 1. Identity

- 1.1 The participant must be legally identifiable (e.g. registered in a national chamber of commerce)

### 2. Scope

- 2.1 The participant must mention its scope in the quality manual, and make clear where which activities are carried out under authorization
- 2.2 The participant must keep this up to date

### 3. Quality management system (QMS)

- 3.1 The participant must develop, define, document and implement a QMS as a means of ensuring that all activities that are brought under authorization demonstrably satisfy specified requirements / conditions
- 3.2 The participant must improve this QMS continuously whenever there is a reason to, based upon the principle of the Deming circle: plan – do – check – act

### 4. Quality manual

- 4.1 The participant must have at least one quality manual
- 4.2 This quality manual can be either digital or a hard copy
- 4.3 Contents:
- 4.3.1 This quality manual must contain at least:
- Scope
  - QMS-documents (procedures, working instructions, protocols, format of forms), as required by the concerning scheme, or a reference to them
- 4.3.2 The quality manual must indicate which chapters from these NAL Conditions are excluded (only possible for: 17, 18, 19, 20, 23, 24, 26 and / or 27, as well as for items 1, 2, 3, 4, 5, 6 and / or 7 from Appendix II)
- 4.4 Language:
- 4.4.1 The quality manual and the QMS-documents must be written in Dutch or English
- 4.4.2 If the participant wants to have some documents (like working instructions) in the local language as well:
- This is only allowed when the format, the content and the revision indication are the same as the English revision; in case of differences between both versions, the English version will prevail
  - The participant must provide an interpreter during the audit
  - The above is not applicable for test protocols, sampling procedure/protocol and where relevant the procedure for issuing NAL Quality certificates or ASLN Laboratory reports, they must be written in Dutch or English at all times

### 5. Organization

- 5.1 The participant must (where and when necessary) explicitly have obtained the required approval of authorities involved
- 5.2 The participant must have a quality manager (irrespective of title), directly responsible for the QMS (regarding e.g. building, implementing, monitoring and maintenance of the QMS), including reporting to a technical managing director about its functioning
- 5.3 The participant must define tasks, responsibilities and competences needed (including substitution for key personnel), for ensuring proper functioning and control of all processes
- 5.4 The participant must appoint a process owner for each process
- 5.5 The participant's staff must be informed clearly about the tasks and responsibilities assigned to them, by means of: procedures / working instructions / protocols, job descriptions, qualification / training / experience / craftsmanship and / or adequate supervision
- 5.6 The participant's staff must be demonstrably competent for the tasks and responsibilities assigned to them
- 5.7 Even if certain tasks have been outsourced, the participant is still responsible for these outsourced processes; the participant must ensure that these have been carried out in compliance with the requirements of the concerning scheme at all times
- 5.8 The participant must determine any product / process requirements needed for specific or intended use, legal or statutory requirements

- 5.9 The participant must be organized in such a way that the employees are not under any financial, commercial, or other kind of pressure that could influence the performance of the work of that what is brought under authorization (in relation to its scope)
- 5.10 Every influence on results, by people / organizations outside the participant, must be excluded
- 5.11 The remuneration of employees involved in that what is brought under authorization (in relation to its scope), must not depend on the amount of work or the outcome of the work
- 5.12 The participant must refrain from activities that could endanger the trust in the independence of assessments and the integrity of its activities
- 5.13 In case of external service, the participant must deal with contract review, ensuring that only client requests are accepted when the participant knows the requirements / specifications and that she has the capability of meeting those requirements / specifications
- 5.14 In case of external service, the participant must deal with control of verification, storage and maintenance of all customer supplied products
- 6. Document control**
  - 6.1 Documents must be controlled
  - 6.2 Documents must be approved by a process owner, prior to use
  - 6.3 Documents must be implemented
  - 6.4 Each document must have a revision indication (either a date or a number)
  - 6.5 Relevant external documents must be controlled / implemented either
  - 6.6 Documents must be kept up to date
  - 6.7 Unintended use of obsolete documents must be prevented
  - 6.8 It must be clear which obsolete documents have to be kept (for how long and where) and that every obsolete document that is filed for legal purposes and / or to maintain knowledge, is identified in a suitable manner
  - 6.9 Obsolete documents have to be discontinued in myNaktuinbouw
- 7. Control of records**
  - 7.1 The participant must control all records
  - 7.2 Records must be kept in such a way that the participant is able to demonstrate its compliance to the requirements of the concerning scheme, that critical control points in the process have been monitored and that the outcome of this has led to a process / product within specifications / requirements. The period of keeping records may differ, but
    - local legal obligations must be fulfilled
    - must be kept for at least 5 years, unless local legal obligations prevent this
  - 7.3 The participant must deal with access to, and identifying, collecting, indexing, archiving, storing, storing term, maintaining and disposal of records
  - 7.4 The reliability of the quality records must be guaranteed
  - 7.5 Where systems for electronic data processing are used, the reliability and stability of the system must be tested demonstrably and a backup has to be made within determined intervals
  - 7.6 Data security must be ensured, including prevention or unauthorized access and unauthorized modification of data
  - 7.7 All calculations and data transfer must be subjected to suitable inspection
- 8. Audits**
  - 8.1 The participant must conduct internal audits to verify whether or not daily practices are in line with its QMS and the requirements of the concerning scheme
  - 8.2 Internal audits:
    - 8.2.1 Must be planned in good time for all processes
    - 8.2.2 Must be completed for secondary processes once per 3 years
    - 8.2.3 Must be completed for primary processes annually (where relevant)
    - 8.2.4 Furthermore the planning must be based upon all relevant aspects (e.g. outcome of earlier audits, ring tests, process performance, possible changes, etc.)
    - 8.2.5 Must be planned in good time for possible Multi Location Module-sites (for sampling):
      - If there are no NCs established during the external audit (once per 3 years), then there is no obligation to conduct an internal audit for this site; but of course it remains the responsibility of the participant to decide upon this, based upon their view / information gathered during monitoring of the process

- If there are NCs established during the external audit, Bureau Authorizations will then (given the weight and nature of the NCs) indicate to the participant whether it is required to conduct an internal audit in the next year
  - If an internal audit is required, the participant must determine, according to its own findings, whether it is necessary to conduct an internal audit in the following year
- 8.3 Internal auditors must be independent regarding the process which they have to audit
- 8.4 Internal auditors must have attended an auditor training course, which:
  - 8.4.1 Must last for four day parts at least
  - 8.4.2 Must deal with:
    - General information about the audit process
    - Drawing up an audit program
    - Conducting an audit
    - Interview techniques (dealing with personal communicative skills)
    - How to establish nonconformities
    - Reporting
- 8.5 The results of internal and external audits must be recorded and reported to the process owner
- 8.6 In case of a nonconformity established during internal and external audits, there must be drawn up a CAR (see chapter 10)
- 9. Complaints**
  - 9.1 The participant must deal with written or verbal (internal and external) complaints
  - 9.2 In the event of a connection between the complaint and the scope for the concerning scheme, the participant must draw up a CAR (see chapter 10)
- 10. Corrective (and / or Preventive) Action Requests (CARs)**
  - 10.1 The participant must deal with CARs adequately
  - 10.2 This chapter is applicable to various deficiencies, which become apparent e.g. by either observing / monitoring the process by staff, audits, calibration, ring tests, proficiency tests, clients and / or complaints
  - 10.3 All CARs must be analyzed to determine the root cause (underlying problem) and the impact
  - 10.4 The participant must determine an adequate corrective action to solve the underlying problem
  - 10.5 The participant must implement this corrective action
  - 10.6 The participant must be able to demonstrate evidence of this corrective action
  - 10.7 The participant must verify the corrective action after an appropriate amount of time, to understand if the corrective action itself was sufficient / effective in relation to the underlying problem
- 11. Management responsibility**
  - 11.1 Management must be able to demonstrate its commitment to comply with the requirements of the concerning scheme
  - 11.2 The management must conduct a management review annually
  - 11.3 The participant must determine, collect and analyse suitable data, in order to substantiate the suitability and efficacy of the QMS and its compliance to the requirements of the concerning scheme, to enable it to decide where improvements are necessary
  - 11.4 The input for the management review must therefore provide information on the following points as a minimum:
    - Outcome of internal and external audits
    - Outcome of job appraisals / need for training
    - Feedback from clients
    - Process performance and product conformity
    - Status of CARs
    - Follow-up on quality policy / objectives / measures / action points from previous management review(s)
    - Changes in / on the (environment of the) participant that will have an impact on the QMS
  - 11.5 The output of the management review must indicate conclusions of the management regarding all input, including decisions and measures with regard to the improvement of the QMS (e.g. the need for extra training, means, etc.) by means of quality objectives
  - 11.6 The management review must be demonstrable by means of minutes

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- 11.7 The participant must present an overview of results / process performance / product conformity to Bureau Authorizations on request

## **12. Human resources management**

- 12.1 The participant must ensure that suitable communication processes are established within and between the departments or functions in question
- 12.2 Staff must be demonstrably qualified (based upon suitable education, training and / or experience / craftsmanship)
- 12.3 The participant must identify whether there is a need for training
- 12.4 The participant must provide training where necessary

## **13. Equipment**

- 13.1 The participant must have access to all equipment necessary to perform its tasks, whenever and wherever needed
- 13.2 The participant must identify and keep a log of all equipment which may (even unintentionally) influence the quality and accuracy of results. This log makes reference to:
- A unique reference (name, identification, type, reference and / or serial number)
  - The condition in which it was received (e.g. new, used, overhauled)
  - The name of manufacturer / supplier
  - The service contractor for maintenance and / or calibration
  - The date of receipt and / or date of activation
  - The current location
  - The details of any maintenance and / or calibration carried out
  - The history of all damage, overload, faults, modification or repairs, incorrect handling, when it produces doubtful results or when it is defective and it has been taken out of use
- 13.3 All equipment which has been taken out of use:
- Must be clearly marked or stored at a designated location, until it has been repaired, calibrated and / or validation demonstrates that it is performing correctly again
  - The participant must draw up a CAR (see chapter 10)
- 13.4 The participant must at least for critical equipment (**see Appendix VIII**) ensure / manage / make demonstrable:
- Acceptance / release, based on tests. Before the test can be started, criteria must be set, concerning the allowed tolerance
  - Appropriate use
  - Maintenance and inspection
- 13.5 The participant must at least for critical equipment (**see Appendix VIII**) determine how and to ensure / manage / make demonstrable:
- Specified requirements, such as
    - Tolerances allowed by the participant itself
    - Measuring capacity / accuracy. The accuracy of devices used must be one digit more than the lowest value where it is used for (Example: if you need to measure exactly 1 gram, this scale needs to be able to measure 0,1 grams, where it matters if the quantity measured is 1,0 or 0,9 grams)
  - Monitoring indicated values (in relation to critical control points)
  - Calibration of the equipment:
    - At by the participant prescribed intervals
    - If the equipment is out of tolerance:
      - Adjustment of the device
      - Draw up a CAR (with the purpose of finding out what the impact is on the process where it has been used for in the period until the previous calibration, see chapter 10)
- 13.6 For the execution of calibration:
- It is allowed to subcontract calibration to a competent subcontractor that is accredited by an accreditation body (like a2La, COFRAC, DAKKS, ISRAC or Raad voor Accreditatie) to perform calibration services. In case a very high accuracy of the device is needed, the participant should ensure itself that the subcontractor uses sufficiently accurate calibration instruments
  - It is allowed to subcontract calibration to a non-accredited subcontractor, or calibration can be replaced by internal checks. In these cases

- The calibration instrument must be calibrated and proof must be demonstrable of its valid reference to (inter)nationally recognized standards; if such a reference is not applicable, the participant must provide sufficient evidence of conformity / accuracy of results
- Deviation of the calibration instrument must be max 10% of the tolerances as determined for the device that needs to be calibrated (Examples: if a scale does have tolerances of +/- 2 grams; the 'stones' itself used for calibration must have a max deviation of +/- 0,2 grams. If it is allowed that the temperature in a growth chamber may vary +/- 2°C, the thermometer or logger that is used for maintaining that temperature must be calibrated by a calibration instrument that itself is having a max deviation of +/- 0,2°C, when possible)
- Good practices must be used, such as:
  - Touching small stones: with a glove / tweezers
  - Repeatability and eccentric load: multiple measurements (measuring precision)
  - Calibration in the range of the intended use
  - Calibration of a pipette at proper temperature (e.g. 20°C)

#### 14. Purchasing

14.1 The participant must ensure the facilities, services and materials used are fit for purpose

14.2 The participant must where applicable and relevant:

- Provide purchase details of the product (on batch level) and / or service, giving consideration to the requirements
- Establish and introduce tests or other activities needed, to ensure that at least the critical products (**see Appendix VIII**) meet the requirements. Before the test can be started, criteria must be set, concerning the allowed tolerance
- Define the type and degree of inspection of critical products; this is dependent on the product, the influence that the supplied product has on the process where it will be used for and, in so far as applicable, on the reports of the quality audits and / or quality registrations and previous performance

14.3 The participant must:

- Evaluate suppliers and select them on the basis of their capacity to satisfy the requirements of the delivery contract
- Create and maintain quality registrations of accepted suppliers
- Maintain a list of approved subcontractors



## NAKTUINBOUW MODULE SAMPLING REQUIREMENTS NAL

### 15. General

- 15.1 Leading thought must be that a good representative sample is essential for obtaining a good and reliable test result
- 15.2 The sampling procedure / protocol (and related documents) must be approved by Bureau Authorizations through myNaktuinbouw and deal with the relevant requirements of the concerning scheme, including the requirements laid down in **Appendix II**
- 15.3 It must be ensured that sampling is not affected by any (preconceived) information, outside influences or improper pressure
- 15.4 Samples must be taken according a predefined schedule / assignment
- 15.5 Both the function drawing up the sampling schedule as well as the sampler can in no way be someone that has an interest in the outcome / result of the test
- 15.6 The participant must deal with receipt, handling, storage and appropriate disposal of samples, to protect the participant's integrity / the environment
- 15.7 The participant must decide how they want to deal with samples by indicating:
  - Whether they want to keep a sample
  - How big the sample needs to be
  - How long they want to keep the sample
- 15.8 At all stages of transport, storage, handling and preparation of samples, measures must be taken to prevent loss, damage and / or deterioration
- 15.9 *Not applicable for NAL*

### 16. Sampler

- 16.1 The sampler must have adequate sampling expertise / techniques and the skills to apply these
- 16.2 The sampler must be demonstrably trained at an approved training organization:

Scope of sampling	Approved training organizations
<ul style="list-style-type: none"> <li>• Leaf material of mother plants to determine the seed health status</li> <li>• Leaf or other plant material for plant health testing</li> </ul>	<ul style="list-style-type: none"> <li>• Naktuinbouw ('Professional Plant Sampling')</li> <li>• Participants whose training is approved by Bureau Authorizations through myNaktuinbouw</li> </ul>
<ul style="list-style-type: none"> <li>• Pollen for pollen (plant) health testing</li> </ul>	<ul style="list-style-type: none"> <li>• Participants whose training is approved by Bureau Authorizations through myNaktuinbouw</li> </ul>
<ul style="list-style-type: none"> <li>• Fruits for seed health testing</li> </ul>	<ul style="list-style-type: none"> <li>• Naktuinbouw ('How to sample fruits, small seed lots and compartments')</li> <li>• Participants whose training is approved by Bureau Authorizations through myNaktuinbouw</li> </ul>
<ul style="list-style-type: none"> <li>• Seed lots larger than 30.000 seeds</li> </ul>	<ul style="list-style-type: none"> <li>• Naktuinbouw ('Professional Seed Sampling')</li> <li>• Participants whose training is approved by Bureau Authorizations through myNaktuinbouw</li> <li>• ISTA</li> <li>• NIAB (UK)</li> <li>• Nébih (HU)</li> <li>• SGS Brookings (US)</li> <li>• SEMAE/ASFIS (FR)</li> </ul>
<ul style="list-style-type: none"> <li>• Small seed lots</li> <li>• Seed sampling per compartment</li> </ul>	<ul style="list-style-type: none"> <li>• Naktuinbouw ('How to sample fruits, small seed lots and compartments', or in case the sampler is not responsible for determining the sample size: 'Professional Seed Sampling')</li> <li>• Participants whose training is approved by Bureau Authorizations through myNaktuinbouw</li> </ul>
<ul style="list-style-type: none"> <li>• <i>(not applicable for NAL)</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>(not applicable for NAL)</i></li> </ul>

- 16.3 The sampler must attend a refresher course
  - The sampler must maintain his / her expertise / techniques and attend a refresher course at least once every 4 years, relevant for his / her scope
  - The refresher course may be attended at an approved training organization. In-company organization is allowed as an alternative.

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- Possible input for an in-company refresher course (not obligatory / exhaustive):
  - Sharing experiences of samplers in a meeting; what do they face (method, material, instructions, daily practices, etc.) and where did it perhaps go wrong earlier?
  - Discussing possible nonconformities from internal or external audits, adapted procedures, instructions or forms
  - Witnessing together a sampling being performed, followed by a discussion of the observations
- 16.4 The sampler can be assisted by a trainee, as long as the trainee is working under his / her supervision on the job; the sample administration must make demonstrable who the sampler was and who the trainee
- 17. Multi location module (MLM) and subcontracting of sampling**
  - 17.1 The multi location module is optional and relevant for participants that want to produce and communicate test results on samples taken by a sampler who is not working under the supervision / control of this authorized participant itself (e.g. because this sampler is working on remote facilities or in a different site abroad)
  - 17.2 Each MLM site must comply with all relevant requirements of this scheme
  - 17.3 Sampling of seed may be subcontracted, as described in **Appendix IV**
    - To a sampler in the scope of a companies' ISTA accreditation
    - To a company NAL authorized for sampling of seed
  - 17.4 *Not applicable for NAL*
  - 17.5 The participant must inform the Bureau Authorizations if they want to use the MLM option or if they want to subcontract sampling
- 18. Sampling of (parts of) plants**
  - 18.1 Requisites:
    - The correct sampling equipment must be available (e.g. gloves, knife, disinfection, clean bags)
    - The sampling equipment must be designed in such a way that it is possible to:
      - Sample and obtain a sample from every required type / piece of tissue
      - Clean it effectively afterwards (to avoid cross contamination)
  - 18.2 It must be indicated and / or reference must be made regarding (along with the assignment):
    - The required type of tissue (e.g. stem, root, leaf, pollen, fruit)
    - The required stage / age of this tissue
    - The size of the lot and / or plot (e.g. the number of mother plants per lot)
    - The minimum / proportionate sample size (e.g. volume / weight / number)
    - The sampling intensity (e.g. minimum number of primary samples per sample, lot and / or plot)
    - The division of primary samples over the lot and / or plot (if relevant)

The above specifications for leaf material, pollen and fruits must comply with **Appendix II**
  - 18.3 Regarding sampling:
    - 18.3.1 Hygiene:
      - The sampler must be able to draw a representative sample
      - The sampler must have a clean work environment, including sampling equipment
      - The sampler must avoid cross contamination between the several lots and / or plots which need to be sampled
    - 18.3.2 Sampling method:
      - The sampler must be able to draw every primary sample that is needed and how is needed (complying with **Appendix II**)
      - The sampler must check all information on the assignment with information regarding the lot and / or plot, sample bag and circumstances in the field
      - Every sample must be labelled with all relevant information
    - 18.3.3 Irregularities:
      - Irregularities (e.g. incorrect information) must be brought to the attention of a function which is appointed to manage such irregularities
    - 18.3.4 There must be adequate administration, indicating or making a reference to the following information:
      - The name and address and / or co-ordinates (e.g. client, location of the plot)

- The drawing of the plot and / or a scheme indicating the relation between sample and lot and / or plot (tracking & tracing)
- The assignment
- The crop and variety
- The lot and / or plot number
- The lot and / or plot size
- The number and identification of samples
- The sample size
- The relevant information / observations of the sampler
- The initials of the sampler
- The date of sampling
- The tests which must be completed
- The test result

## 19. Sampling of seeds

### 19.1 Requisites:

- The correct / dedicated sampling equipment must be available (e.g. probes, triers, carts, bench, mixing equipment, clean bags)
- When sampling bins / large bags with potentially non-homogeneous seed lots (e.g., when received from production, and/or after transport), a sampling stick with compartments or a spiral trier must be used
- The sampling equipment must be designed in such a way that it is possible to:
  - Sample and obtain seed from almost every place in the unit
  - Clean it effectively afterwards (to avoid cross contamination)

### 19.2 It must be indicated and / or reference must be made regarding (along with the assignment):

- The maximum lot size per sample
- The minimum / proportionate sample size (e.g. volume / weight / number of seeds)
- The division of primary samples over the unit / lot
- The sampling intensity (e.g. minimum number of primary samples per sample, lot and / or plot)

The above specifications must comply with **Appendix II**

### 19.3 Regarding sampling:

#### 19.3.1 Hygiene:

- The sampler must be able to draw a representative sample
- The sampler must have a clean working place (regarding sampling equipment) and
- The sampler must avoid cross contamination between the several lots that need to be sampled

#### 19.3.2 Sampling method:

- The sampler must be able to draw each primary sample that is needed and how is needed (complying with **Appendix II**)
- The labels / information on every unit must be visible to the sampler
- The sampler must check all information on the assignment with info on the unit and sample bag
- Every sample must be labelled with relevant information

#### 19.3.3 Irregularities:

- Irregularities (e.g. incorrect information, seed does not seem to be homogeneous) must be brought to the attention of a function that is appointed to deal with such irregularities, see also **Appendix II**

#### 19.3.4 There must be an adequate administration, indicating or making a reference to the following information:

- The origin (producer / supplier) of the seeds
- The date of arrival
- The crop
- The variety
- The lot number
- The lot size
- The relation between sample and seed lot (tracking & tracing)

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- The lot quality (stage of processing)
- The number of units
- The weight of the sample or number of seeds
- The relevant information / things the sampler noticed (e.g. when the lot appears not to be homogeneous, wet seeds, noxious weeds, etc.)
- The initials of the sampler
- The date of sampling
- The tests which must be completed
- The test result

**20. Not applicable for NAL**

## **NAKTUINBOUW MODULE TESTING REQUIREMENTS NAL**

### **21. Facilities**

- 21.1 The environment where the test is conducted must ensure that the results of the tests are reliable and that there is no negative influence on the required accuracy (of both measurements and testing itself)
- 21.2 If necessary, the participant must organize that testing facilities have additional protection against extraordinary conditions, such as extreme temperature, dust, moisture, steam, vibration, DNA-fragments, electromagnetic disturbance or interference, and must be maintained appropriately with specific attention to hygiene issues in order to prevent cross-contamination
- 21.3 Access to and use of all testing facilities must be controlled
- 21.4 The participant must offer sufficient space for the employees carrying out the work to make practical and accurate movements and also provide adequate health and safety provisions
- 21.5 The facilities must be equipped with appropriate instruments and power sources required for the tests

### **22. Applied protocols and testing**

- 22.1 The participant must have suitable documents for the use and operation of all relevant equipment for handling and preparing samples (if applicable) and for accepted testing techniques according the scope
- 22.2 The participant must carry out the testing according to by Bureau Authorizations approved protocols (either the Naktuinbouw standard protocol or an in-house company method / protocol)
- 22.3 In case the number of seeds to be tested is lower than the minimum validated sample size in a seed health test:
  - Previously tested negative seeds may be added to the sampled seeds to reach the validated sample size
  - Samples from multiple seed lots may be combined prior to testing. In this case, the result (positive or negative) is valid for all seed lots represented in this sample
    - In case of a positive test result, seed lots can be retested as single lots to identify the infected seed lot(s)
    - When the infected seed lot(s) is identified, the remaining seed lots tested negative for the target pathogen can be regarded as free from the pathogen
- 22.4 New (or changes in earlier approved) in-house company methods / protocols in the scope of the NAL authorization must be assessed and approved by Bureau Authorizations through myNaktuinbouw, before taking them into use
  - After approval, the participant must regularly review its seed health / plant health protocol to assure that the protocol is still fit for purpose
- 22.5 When the participant is to the opinion that the already approved method / protocol (the one that is in force) is no longer fit for purpose and must be replaced by a next revision immediately, the following steps must be taken:
  - The participant must inform Bureau Authorizations about this intention, indicating the reason why
  - Bureau Authorizations will consult her expert for a quick scan a.s.a.p.
  - Bureau Authorizations will inform the participant whether this request can be approved provisionally (if that provisional consent cannot be given, no claim can be set here)
  - If this next revision has been approved provisionally, the participant can start issuing NAL Quality certificates if needed

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- The next revision will be studied more carefully by our expert later on, and the participant will be informed about the outcome (as usual)
  - When the new revision will be approved, everything is OK. But when the new revision cannot be approved, the results that are obtained with the new revision in the meantime cannot be regarded as valid anymore, so they must be withdrawn
- 22.6 The in-house company method / protocol must indicate at least:
- Scope (pathogen(s) (scientific name(s)) / plant species (scientific name(s)) / matrix (seed, leaf, etc.) / test)
  - Indication of the applied technique / method (plating, PCR, ELISA, UPT, germination (light / dark, temperature), etc.)
  - Meaning of abbreviations
  - Execution of the test (providing clarity (or making a reference to) where relevant for: used equipment, usage of equipment, (sub-) sample size, the making of a working- or subsample, weighing, purifying, drying, back weighing, fractions (unharmful impurities, other seeds, pure seeds, etc.), counting days, grinding, spin (in g), number of isolates, primer sequences, kits (type and supplier), antibodies (supplier), reagents, buffer composition, medium composition, positive-/negative controls, warnings, etc.)
  - Decision scheme describing the criteria to define the test result (extinction / Ct threshold, reaction of controls standard (normal, abnormal, not germinated), calculation of results, closing / repeating, etc.)
  - Reference to literature (where relevant)
  - In case of revisions: a log indicating the changes to all former versions. All changes to the last accepted version have to be marked in the text, or the revision log must be complete in all details (except changes in formatting)
- 22.7 For approval: if the participant has chosen for a structure in modules, all relevant modules have to be sent to Bureau Authorizations for making an appropriate evaluation possible. Documents describing the execution of the test as well as the decision scheme need to be included and need to be evaluated. Documents describing supporting processes (e.g. preparation of buffers or antibiotics, qualification matrix of personnel) can be included for clarification of a protocol, but do not need protocol review in itself.
- 22.8 For approval:
- 22.8.1 For seed analysis:
- For new protocols: supporting data demonstrating the reliability and reproducibility of the method is required. Supporting data can consist of a comparison between the old and new situation, reproducibility of the method and/or the experiments performed in the development of the method.
  - For previously approved protocols which have been updated:
    - If it involves a major change (such as changes in light, temperature or moisture conditions, laboratory facilities, substrate, crop or seed treatment): supporting data is required
    - If it involves a minor change: supporting data is not required
    - If it involves a textual change or editorial without consequences for the test result: the protocol is sent to Bureau Authorizations, but no further review is necessary
- 22.8.2 For seed health / plant health testing:
- For new protocols: a validation file is required
  - For previously approved protocols which have been updated:
    - If it involves a minor change: a comparison / experiment in which the old and new situation are compared with each other is sufficient
    - If it involves a major change (e.g. when changing media): a validation file is required
    - If it involves a textual change or editorial without consequences for the test result: the protocol is sent to Bureau Authorizations, but no further review is necessary.
- 22.8.3 A validation file consists of:
- Validation protocol
  - Validation report
  - Data dossier (raw data)

- 22.8.4 The participant must determine the requirements for the testing protocol (e.g. minimal sensitivity, specificity), prior to validation
- 22.8.5 Validation consists of determination of the relevant performance criteria as described in EPPO Standard PM 7/98:
  - Analytical sensitivity
  - Analytical specificity: inclusivity
  - Analytical specificity: exclusivity
  - Selectivity: all plant species for which the protocol is suitable. A representative set of species can be validated, when substantiating in the validation file why these species were chosen
  - Repeatability
  - Reproducibility
  - Robustness
- 22.8.6 The validation report consists of:
  - The testing protocol which has been validated
  - The scope of the test, including the validated (sub-)sample sizes
  - Relevant performance characteristics (together with a plausible explanation when certain performance characteristics have not been determined)
  - Conclusion on whether:
    - The requirements have been met
    - The protocol is fit for its purpose
- 22.9 The participant must identify the need for and if necessary apply statistical techniques required for determining, managing and verifying test results
- 22.10 There must be adequate planning, including the priority of tests, availability of staff and facilities/equipment, to ensure that the testing is carried out under controlled conditions
- 22.11 At all stages of storage, handling and preparation of samples measures must be taken to prevent damage and/or deterioration that would make results invalid
- 22.12 Anonymity of samples must be ensured as far as possible in order to prevent any influence on the results. The participant must ensure that evaluation of tests can be done without information about the background (origin, complaints, etc.) only, e.g. by coding, in order to avoid preoccupation that could influence test results (to ensure impartiality)
- 22.13 If the test shows abnormalities and / or deviates from what is expected, management must be informed and appropriate action undertaken, possibly leading to a CAR (see chapter 10)
- 22.14 The results of testing (of the samples) are compared with the original sampling schedule, for inspection of completeness of sampling and analysis
- 22.15 The lab technician evaluating the test must not have any interest in the outcome or result of the test
- 22.16 There must be full traceability at all stages in the process (e.g. from receiving and sampling of the seed lot, handling samples, storage of samples, the conducting of all tests, all test evaluations and all NAL Quality certificates issued)

## **23. Subcontracting**

- 23.1 If a NAL participant wishes to subcontract a test to Naktuinbouw Laboratories, with the intention to issue a NAL Quality certificate based upon a test result obtained from Naktuinbouw Laboratories this is allowed
- 23.2 If a NAL participant wishes to subcontract a test to another NAL or ASLN participant, with the intention to issue a NAL Quality certificate based upon a test result obtained from the other NAL or ASLN participant, this is allowed as long as the other NAL or ASLN participant has the test in their scope of authorization
- 23.3 If a NAL participant subcontracts a test to another laboratory, with the intention to issue a NAL Quality certificate based upon a test result obtained from this subcontracted laboratory this is allowed when the subcontracted laboratory has an accreditation for NEN-EN-ISO 17025. Condition 5.7 is applicable.  
This subcontracted laboratory must:
  - 23.3.1 Have the subcontracted test in their scope of accreditation;
  - 23.3.2 Have the proof of accreditation and results from relevant audits available for Bureau Authorizations
  - 23.3.3 Have the protocol for the concerning test and its revisions approved by Bureau Authorizations Naktuinbouw. The protocol must be written in Dutch or English



23.3.4 Take part in proficiency testing between laboratories for the concerning test when organized by Bureau Authorizations and inform the NAL participant when a minor or major card is issued. Condition 25.3 is applicable

The NAL participant must:

23.3.5 Inform Bureau Authorizations about the test and subcontracted laboratory it will use, independent from incidental or structural subcontracting.

23.4 When the above is satisfied, it is allowed to issue a NAL Quality certificate based upon a test result obtained from this subcontractor (including Naktuinbouw or another NAL or ASLN participant), provided that on the certificate, under 'additional information' is stated: 'test result obtained from an approved subcontractor'. When the subcontractor belongs to the same holding such additional information on the NAL Quality certificate is not obligatory.

## **24. NAL Quality certificates**

24.1 Bureau Authorizations must approve the procedure (and related documents, including the format of the certificates) for issuing NAL Quality certificates through myNaktuinbouw, before NAL Quality certificates can be issued

24.2 The participant can only issue NAL Quality certificates if:

24.2.1 The sample is taken in compliance with the NAL Conditions (including **Appendix II**)

24.2.2 The test result is based upon fully completed tests compliant with the NAL Conditions (also for e.g. purity determinations in fruity crops)

24.2.3 The test has been carried out according to approved protocols for which the participant is authorized

24.2.4 When a test in the scope of the participants' NAL authorization is being used to meet phytosanitary requirements, minimally these phytosanitary requirements have to be met with respect to sample and subsample size and the method applied

24.2.5 The issuance is according to **Appendix IV**

24.3 When the participant receives a major (due to the results of a proficiency test or post-control), the authorization for the relevant test is temporarily withdrawn, in such cases it is no longer permitted to issue a NAL Quality certificate for this test, until written permission is given by Bureau Authorizations, showing explicitly that authorization for the test has been granted again

24.4 The NAL Quality certificate must be in a standard format (see **Appendix V**) and must contain the following information:

- The participant name and address and / or trademark of the NAL authorized participant (reference to other brand names is not allowed)
- A clear identification of the batch (crop in Latin, crop in English / other language, variety, lot number)
- Additional information (subcontracting or information on the seed lot, e.g. seed treatments)
- A unique NAL Quality certificate number
- Test result
  - Germination and UPT: written in integers
  - Purity:
    - a. report with one decimal
    - b. report traces (written as TR) in case percentage is between 0.00 and 0.05% and add description of kind of inert matter or other seeds
  - Seed count: in kg or grams
- A NAL year stamp in red ink or digital, the name and signature of the person issuing the certificate, in blue ink or digital
- The date of issue
- If the NAL Quality certificate has two pages, pages have to be linked by a footer. Both pages have to be signed and sent

24.5 A NAL Quality certificate must not contain:

- Any advice or recommendation based on the test results
- A reference to ISHI or ISTA
- Any information regarding the test method
- Any test data

Only if export requires information regarding the test method and/or test data (like number of seeds) can be added. This is only allowed:

- When the text has been approved by Bureau Authorizations

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- When it is put in the optional 'Remarks' section for the specific quality aspect
- 24.6 A NAL Quality certificate can be issued in English, English / French, English / German, English / Spanish, English / Russian and English / Arabian only
- 24.7 In the event a test result issued with the NAL Quality certificate is incorrect, the NAL Quality certificate must be retrieved from the recipient and replaced with a new NAL Quality certificate with the correct test result
- 24.8 In the event authorization is withdrawn with a retrospective effect (even when temporary), the participant must determine if a recall or informing clients is necessary
- 24.9 If the participant wishes to issue a NAL Quality certificate with a test result for seed analysis, it must comply with the requirements of the document NAL Quality score from June 2012 (**Appendix III**)

## **25. Monitoring test quality**

The participant must ensure the quality of test results over time.

### **25.1 Test**

25.1.1 The participant must draw up a program for monitoring test quality and register the results of this monitoring.

25.1.2 For germination and UPT under well-controlled circumstances no additional monitoring of tests is needed, other than monitoring the equipment (see chapter 13) and monitoring the lab technicians by means of internal ring tests (see paragraph 25.2)

25.1.3 At least one of the following measures must be implemented for UPT with limited control of temperature, humidity and/or light:

- use of reference samples in all tests
- testing of blind samples with known germination levels
- replicate testing of the same sample using the same method, either by different lab technicians or at different times

25.1.4 The following measures must be implemented for seed health testing:

- positive and negative controls must be included in all tests. The participant may substantiate (e.g., by a risk analysis) that the use of controls in a specific test is not feasible or less relevant
  - positive controls must be relevant to all pathogens targeted in the test
  - positive controls must have a representative pathogen load
  - positive and negative controls must be introduced into the process as early as possible
  - controls must be monitored in time. Criteria must be set, concerning the allowed tolerance. Appropriate action must be taken when a control is out of tolerance
- a program for testing blind (e.g., spiked) samples with a representative pathogen load and/or replicate testing of the a sample from the same batch with the same method

25.1.5 The following measures must be implemented for plant health testing:

- positive and negative controls must be included in all tests. The participant may substantiate (e.g., by a risk analysis) that the use of controls in a specific test is not feasible or less relevant
  - positive controls must be relevant to all pathogens targeted in the test
  - positive controls must have a representative pathogen load
  - positive and negative controls must be introduced into the process as early as possible
  - controls must be monitored in time. Criteria must be set, concerning the allowed tolerance. Appropriate action must be taken when a control is out of tolerance
- a program for testing blind (e.g., spiked) samples with a representative pathogen load and/or replicate testing of a sample from the same batch with the same method

25.1.6 *Not applicable for NAL*

25.1.7 The following measures must be implemented for genetic tests:

- positive and negative controls must be included in all tests. The participant may substantiate (e.g., by a risk analysis) that the use of controls in a specific test is not feasible or less relevant
  - controls must be relevant to all genetic expressions targeted in the test
- a program for testing blind samples and/or replicate testing of the same sample with the same method

## 25.2 Internal ring test

- 25.2.1 The participant must draw up a program for internal ring tests, to demonstrate the individual skills and expertise of the lab technicians. Internal ring tests should guarantee reproducibility. All critical steps of the protocol that require human intervention should be covered by the internal ring test, unless steps other than evaluation are demonstrably assured through alternative procedures
- 25.2.2 The participant must make a program for 3 years, based upon the scope
- 25.2.3 Categories
- 25.2.3.1 Each test within the participant's scope for seed analysis will belong to one of the categories as mentioned under 25.2.4
- 25.2.3.2 Each test within the participant's scope for seed health / plant health will belong to one of the categories as mentioned under 25.2.5
- 25.2.3.3 *Not applicable for NAL*
- 25.2.3.4 Each category that is relevant for its scope for NAL must be completed at least annually
- 25.2.3.5 Each test that is within its scope for NAL must be completed at least once per three years
- 25.2.3.6 If this leads to a very high number of internal ring tests for the same group of lab technicians a risk-analysis can be performed to show that a lower frequency is acceptable.
- 25.2.3.7 For germination and UPT: tests of crops of which the seedlings can hardly be distinguished from each other and which have the same evaluation criteria (e.g. pepper and hot pepper) can be considered as one test when drawing up the program for internal ring tests
- 25.2.3.8 For physical purity and other seeds: tests of crops which have the same definition of pure seed can be considered as one test when drawing up the program for internal ring tests
- 25.2.4 Categories for seed analysis; examples per category are an indication and not exhaustive:
- Category A: Physical purity, Determination of other seeds
  - Category B: Thousand seed weight, when executed manually
  - Category C: Moisture, when executed manually
  - Category D: Germination and UPT of monocotyledons with primary root essential for evaluation, e.g. Allium, Asparagus, Freesia
  - Category E: Germination and UPT of monocotyledons with secondary roots that may compensate primary roots, e.g. Zea
  - Category F: Germination and UPT of dicotyledons with primary root essential for evaluation, e.g. Anethum, Apium, Beta, Borago, Brassica, Capsicum, Cichorium, Coriandrum, Daucus, Foeniculum, Fragaria, Lactuca, Pastinaca, Petroselinum, Raphanus, Scorzonera, Solanum, Spinacia, Thymus
  - Category G: Germination and UPT of dicotyledons with secondary roots that may compensate primary roots, e.g. Cucumis, Cucurbita, Helianthus, Phaseolus, Pisum, Vicia
  - Category H: Germination and UPT of dicotyledons with several equal seminal roots, e.g. Cyclamen
- 25.2.5 Categories for seed health / plant health:
- 25.2.5.1 Categories for bacteria:
- Dilution plating and identification of suspected colonies
  - Grow out (sweat box or green house)
  - Molecular assays (BioPCR / seed extract PCR)
  - Other
- 25.2.5.2 Categories for viruses / viroids:

- ELISA
  - Bioassay
  - Molecular assays (RT-PCR)
  - Other
- 25.2.5.3 Categories for fungi:
- Agar plating
  - Blotter
  - Grow out
  - Other
- 25.2.6 *Not applicable for NAL*
- 25.2.7 This program for internal ring tests must be based upon other relevant aspects as well, including e.g. outcome of earlier internal ring tests, proficiency tests, relevant CARs and process performance / product conformity
- 25.2.8 Each lab technician that is responsible for evaluation of those tests is obliged to participate in the internal ring tests
- 25.2.9 If in a certain case obliged participation is not possible (for any reason whatsoever), the participant must consider and determine in each case whether the concerning employee can be maintained as an evaluator for the concerning test (one of the considerations must be whether it is necessary to have the results confirmed by another lab technician)
- 25.2.10 Before the internal ring test can be started, criteria must be set, dealing with e.g. (when and where relevant):
- The object that needs to be recognized
  - The percentage of the object that needs to be found
  - The allowed deviation between the lab technicians from average and which relevant table will be used to determine this
  - It is also possible that 'average' will be determined after the test and after discussion with participants
- 25.2.11 When deviation between participants is larger than acceptable, the participant must draw up a CAR (see chapter 10).
- 25.3 External proficiency tests
- 25.3.1 Each participant is obliged to take part in external proficiency tests (or testing of a blind sample) when organized by Bureau Authorizations, for those tests that are within their scope for NAL.
- 25.3.1.1 Participation in the NAL proficiency test Physical purity / Determination of other seeds is obligatory when the species is in the scope of the participant
- 25.3.1.2 The organization of NAL proficiency tests for seed health is described in **Appendix VI**
- 25.3.2 Participation in other proficiency tests is encouraged
- 25.3.3 In the event of a minor or major in a proficiency test or post-control, the participant must:
- Draw up a CAR (see chapter 10)
  - Inform Bureau Authorizations about the outcome of this within two months (minor) of two weeks (major)
- 25.3.4 In the event of a major:
- The authorization for the concerning test will be withdrawn temporarily
  - Until resolved, it is not possible for the participant to issue NAL Quality certificates for this test on any possibly affected seed lot, or state otherwise that possibly affected seed lots are healthy
  - The participant must determine if a recall or informing clients is necessary
  - Bureau Authorizations will inform within two weeks after receiving the corrective action if authorization for this test can be granted again

## MODULE NAL-DAFF OF AUSTRALIA

### 26. Participation

- 26.1 Participation in this module is possible for NAL authorized companies with purity and determination of other seeds in their scope for NAL regarding seed analysis.
- 26.2 Participants must fully comply with the conditions and requirements as mentioned in the current version of 'The Netherlands Inspection Service for Horticulture and Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) agreement' (see **Appendix VII**)

## MODULE NAL-LEEZ

### 27. Participation

- 27.1 Participation in this module is required for NAL authorized companies that are also part of the LEEZ (Laboratoria erkend voor export van zaaizaden) system by NVWA. Participants must be based in the Netherlands and have seed health testing in their scope for NAL
- 27.2 Participants must fully comply with the NAL Conditions as identified in LEEZ – bijlage 1
- 27.3 Bureau Authorizations must approve the procedure (and related documents) for using test results for export certification, through myNaktuinbouw
- 27.4 The participant can only use their own test results for export certification if:
  - 27.4.1 The participant has a LEEZ-authorization for the test at the moment of export certification
  - 27.4.2 The sample is taken in compliance with the NAL Conditions (including article 4, 5, 6 and 7 of **Appendix II**) at a location in the Netherlands.
    - If samples are taken at a location in the Netherlands, but not by the participant itself, this location must fulfill the same sampling requirements and must be audited by NAL with the same frequency as the participant itself
  - 27.4.3 The test is conducted in the Netherlands, fully completed, and compliant with the NAL Conditions
  - 27.4.4 The test has been carried out according to approved protocols for which the participant is authorized
  - 27.4.5 When a test in the scope of the participants' NAL authorization is being used to meet phytosanitary requirements, minimally these phytosanitary requirements have to be met with respect to sample and subsample size and the method applied
  - 27.4.6 If the participant's own results do not comply with the requirements above, export certification must be based on the original test result of a Dutch official laboratory, or of a foreign laboratory registered by NVWA as specified in register 18 05c
- 27.5 When the participant receives a major (due to the results of a proficiency test or post-control), the NAL authorization for the relevant test is suspended. Test results produced during the suspension period cannot be used for export certification purposes
- 27.6 Participants must participate in post-control, organized by Bureau Authorizations Naktuinbouw, as described in 'Officiële nacontrole Laboratoria Erkend voor Export Zaaizaden (LEEZ), versie 1 januari 2025'



## MISCELLANEOUS

### 28. Definitions / references

#### 28.1 Abbreviations:

- ASLN: Authorized Service Laboratories Naktuinbouw
- CAR: Corrective (and / or Preventive) Action Request
- DAFF: Department of Agriculture, Fisheries and Forestry
- ELISA: Enzyme-Linked Immuno Sorbent Assay
- EN: Europese Norm (European Standard)
- EPPO: European Plant Protection Organization
- ISHI: International Seed Health Initiative
- ISO: International Standardization Organization
- ISTA: International Seed Testing Association
- MLM: Multi Location Module
- Naktuinbouw: Netherlands Inspection Service for Horticulture
- NAL: Naktuinbouw Authorized Laboratories
- NC: Nonconformity
- NEN: Nederlandse Norm (Dutch Standard)
- PCR: Polymerase Chain Reaction
- PT: Proficiency Test
- QMS: Quality Management System
- UPT: Usable Plant Test (see 28.4)

#### 28.2 QMS

- Scope: the total of all tests for which NAL authorization has been granted, as stated on the NAL authenticated register of tests
- Procedure: a document (can be either digital or a hard copy, either in a flowchart or in wording) indicating the flow (of a part) of the laboratory's process, along with the responsibilities and remarks (reference to documents, relevant time frames) per process step. Answering the question who does what, where and when. Also about the competencies and responsibilities for the relevant tasks / process steps. It is relevant to distinguish:
  - The responsible function for a process step (e.g. initiating, coordinating, delegating work to competent employees, compliance with requirements/procedure, etc.)
  - The function involved in completing the task/process step (responsible for their work)
  - The function which must be consulted during a process step
- Work instruction: a document (can be either digital or a hard copy) that describes how a specific part of the laboratory's process must be executed, when there is a risk that absence of this can lead to significant variation and that the process will not be adequately controlled.
- Process owner: the individual (function, employee or manager) responsible for control of the process (e.g. initiation, flow, appointing staff, training).
- Impact analysis: next to an analysis of the root cause (the basic cause or core issue of a problem) one should analyze the impact. At least two questions must be posed: The problem seen at "this point x", can it happen at "point y" too? What was the effect of the problem on previous tests?
- MyNaktuinbouw: online tool through website Naktuinbouw for protocol review
- Critical control point:
  - A specific step (in a procedure, instruction or protocol) for which the laboratory has determined that control is critical to the outcome of the process
  - That therefore needs to be monitored, in order to reduce, eliminate or prevent the possibility that it will not be controlled
  - Applicable and relevant
- Primary process: the chain of activities (like for ASLN: sampling and testing) that must be carried out in order to be able to deliver a result / product to an internal or external customer; this must be seen in relation to the scope of the concerning scheme / existence of a business (like for ASLN: a test result; for a seed company: a bag of seeds)
- Secondary process: all other activities that are supporting the primary process (like: calibration, document control, internal auditing, training of staff)

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### 28.3 Equipment and products

- Accuracy: measure of statistical bias (how close or far off a given set of measurements (observations or readings) are to their true value) with a description of systematic errors
- Adjustment: adjusting the device within appropriate tolerances, ensuring the metrological performance, and making it fit for purpose (again)
- Calibration:
  - Determining the value of the deviation of a device from a calibration instrument
  - Where it consists of:
    - Applying test loads to the device under specified conditions
    - Determining the error and/or variation of the indication and
    - Evaluating the uncertainty of measurement to be attributed to the NAL test results
- Calibration instrument:
  - The standard, known to have a valid reference to (inter)nationally recognized standards (if possible or feasible) and  
The means intended to conduct calibration of a device; this is understood to mean both a material measure as well as a measuring device
- Critical equipment: listed in Appendix VIII. Must be calibrated (when possible) at certain intervals to assure its functioning from the start
- Critical product: listed in Appendix VIII. Needs an entry control to assure its functioning from the start
- Deviation: difference between the calibration instrument (e.g. regarding indicated temperature, wavelength, dispensed volume or the control weight used) and the corresponding settings or reading on the device that needs to be calibrated, including possible systematic and random errors
- Equipment: apparatus / device / instrument / machine used in a process under NAL authorization, which needs to operate within certain tolerances to enable a controlled process. E.g., balance, datalogger, pipette. Precision: measure of statistical variability (how close measurements are together) with a description of random errors
- Product: means and reference materials / controls used in a process under NAL authorization.
- Tolerances: permissible deviation from a certain temperature, wavelength, volume or weight, because the permissible deviation does not or hardly affect the outcome of the intended use / concerning test
- Uncertainties: uncertainties as determined by publication reference EA-4 02 from the European co-operation for accreditation; in short: addition of possible systematic and random errors
- Vision equipment: equipment that uses image processing technology (such as cameras, sensors, and software) in seed analysis

### 28.4 Sampling and testing

- Seed lot or seed batch: an amount of seeds, produced at the same time within one process step all at one time (like: cleaning, grading, enhancing) / delivered as a single unit
- Small seed lot: a lot that consists of less than or equals 30.000 seeds. See **Appendix II**
- Unit: seeds that are packed together (in a box, bag, bucket etc)
- Small unit: a unit that is under 15 kg
- Primary sample: a portion taken from a (seed) lot or (seed) batch during a single sampling action (e.g. one trier probe or one hand probe).
- Compartment: (part of) a greenhouse or field in which the plants are exposed to the same environmental conditions and which is clearly separated from other compartments by a physical barrier, time or space.
- Compartment sample: a sample collected from seed/plant/pollen lots produced in a compartment, based on the number of mother plants from which the seeds/plant parts/pollen were harvested.
- Mother plant: plant from which seeds/plant material/pollen are harvested.
- Test: method (from A – Z, see NAL Condition 22.5), laid down in an unambiguous protocol (so written that an appropriately qualified person can perform the complete test), for which authorization has been granted

- Germination test: determination of the emergence and development of seedlings grown under optimal circumstances where all essential structures (root system, hypocotyl/epicotyl and cotyledons/coleoptile) can be evaluated
- Usable plant test: determination of the development of seedlings grown under practical circumstances where at least the cotyledons and/or the first real leaf can be evaluated.
- Physical purity test: determination of the percentage of pure seeds, the percentage of inert matter and the percentage of other seeds. Often combined with determination of other seeds.
- Determination of other seeds: test in which the number of other seeds is reported per species or genus. Often combined with a physical purity test, but on a (in general 10 times) larger amount of seeds.
- Protocol: a document which describes how a test needs to be conducted, by indicating the consecutive steps and also (where necessary) the different roles / responsibilities; in case the participant has divided a test into distinctive parts (modules), the protocol must indicate how this all together is build up; this must be in line with requirement 22.5.

#### 28.5 Monitoring test quality

- NAL Proficiency testing: a test of skill and an evaluation of the capability of an NAL authorized laboratory to achieve a correct test result for the tests for which it is authorized, by a system to objectively compare the laboratory's results with other laboratories' results by an independent organization (e.g. Bureau Authorizations). The main objective being the establishment of trueness. This is achieved by using the laboratory's personnel, materials, equipment, environmental conditions and quality management system, through the analysis of (to the participating laboratory) unknown specimens, prepared and distributed by an external source (e.g. Bureau Authorizations). An 'external check', a third line control.
- Internal ring test: a test to see to what extend all lab technicians within a laboratory (that are 'mature' and responsible regarding evaluation of a test) are coming to more or less similar test results when testing the same sample. An 'internal check', a second line control.
- Blind sample: a sample from a lot that has been tested in an earlier stage, and that is brought to the laboratory (again) on purpose, to see whether the laboratory comes to the same / expected test result. For health tests this can be a spiked sample. This can be organized internally (→ second line control) or externally (→ third line control). Constraint: the blind sample must fit in the routine flow of testing, so that a lab technician does not have a clue that he / she is dealing with a blind (!) sample.
- Major: notification by Bureau Authorizations to a participant whose results in a NAL proficiency test demonstrate an underperformance based on statistical analysis.
- Minor: notification by Bureau Authorizations to a participant whose results in a NAL proficiency test indicate a (minor) deviation based on statistical analysis.

## **29. Revision history (NAL Conditions 2026 v14 compared to NAL Conditions 2025 v13.1 )**

We made the following changes through the document:

Throughout the Conditions sampling of soil and testing soil is deleted. It concerns paragraph 16.2.3, 17.4, 20, 22.8.2, 25.1.6, 25.2.3.3 and 25.2.6.

Throughout the Conditions consequently 'chapter' and 'paragraph' are applied.

Introduction has been updated with correct references.

### **4.3.2**

Added: some items from Appendix II

### **13 and 28**

Deleted 'means, devices and reference materials' through the Conditions, and use only 'equipment'.

### **13.1**

Textual change

### **13.4**

Deleted: where relevant.

Added: at least for critical equipment (see Appendix VIII)

Moved: bullet 4 moved to 13.5

Deleted: bullet 5 storage and bullet 6 appropriate disposal

### **13.5**

Deleted: where relevant.

Added: at least for critical equipment (see Appendix VIII)

Moved: bullet 1 comes from 13.4

### **13.6**

Deleted: bullet 2, third round: The requirement above is not applicable for the following devices.....to specifications. This information has been moved to Appendix VIII.

### **14.2**

Added 'at least critical (see Appendix VIII)'

### **16.2**

Added: table with approved training organizations per scope

### **16.3**

Added to first bullet: , relevant for his / her scope

Second and third bullet: Textual changes

### **17.3**

Added: to a company NAL authorized for sampling of seed

### **19.1**

Added second bullet: When sampling bins / large bags with potentially non-homogeneous seed lots (e.g., when received from production, and/or after transport), a sampling stick with compartments or a spiral trier must be used

### **22.4**

Added a bullet: After approval, the participant must regularly review its seed health / plant health protocol to assure that the protocol is still fit for purpose.

### **22.6**

Added: scientific names. Both for pathogen(s) and crops/plant species.

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#### 22.8.5

Added to fourth bullet on selectivity: all plant species for which the protocol is suitable. A representative set of species can be validated, when substantiating in the validation file why these species were chosen

#### 22.17

Deleted (not applicable for ASLN anymore)

#### 25.1

Rewrote this requirement. Only 25.1.1 did not change.

#### 25.2.1

Deleted: 'regarding evaluation of the concerning tests', 'should be inherent to the end of result' and 'and focus on the variable part of assay'.

Added: 'skills' to 'individual expertise'. All critical steps of the protocol that require human intervention should be covered by the internal ring test, unless steps other than evaluation are demonstrably assured through alternative procedures

#### 25.2.11

Deleted: Drawing up a CAR may not be needed when a re-test shows a good result

#### 28.3

Changed title into Equipment and products.

Added definition of critical equipment: listed in Appendix VIII. Must be calibrated (when possible) at certain intervals to assure its functioning from the start

Added definition of critical products: listed in Appendix VIII. Needs an entry control to assure its functioning from the start

Added to the definition of equipment: E.g., balance, datalogger, pipette.

Added definition of product: means and reference materials / controls used in a process under NAL

Added definition of vision equipment: equipment that uses image processing technology (such as cameras, sensors, and software) in seed analysis

#### 28.5

Changed in the definition of internal ring test: evaluating changed in testing

Added to the definition of blind sample: For health tests this can be a spiked sample.

#### APPENDIX III

Deleted at Determination of other seeds 1.: part 1, 2 or 3.

#### APPENDIX IV

Changed in line 4: Company B: NAL-authorized for sampling

#### APPENDIX VI

Replaced reg erk zz into LEEZ in the flow chart

#### 2a

Deleted 'method' from '....test (pathogen, crop, method)'

Added: Constraint: if the authorized laboratory applies a method with a different subsample size, participation may be possible in consultation with Bureau Authorizations.

#### 3

Added 'for this method' to Pre-screening is performed using above mentioned guidelines using the Naktuinbouw standard protocol.

#### 4

Added: A datalogger is added to the package, at least when it is expected that temperature may have influence on the results

Added: The datasheet includes participant information, including critical control points for the specific test method. Participants are obliged to enter all details

#### 5

Added: Critical control points and temperature recorded by dataloggers are checked and analyzed.

6

changed version 2026

7

Added: and except obligatory participants who apply a different method for that crop/pathogen-combination (such as SE-PCR versus ELISA or agar plating versus blotter)

NEW APPENDIX VIII

Overview of critical equipment (part 1) and critical products (part 2)



**Appendix I discarded. See [Regeling verhandeling teeltmateriaal](#)**

## **APPENDIX II SAMPLING INTENSITY AND OTHER REQUIREMENTS**

### **1. Sampling of leaf material of mother plants to determine the seed health status**

Samples must be collected according to an approved sampling strategy. Samples must be representative; every primary sample must be represented in the submitted sample equally.

- 1.1 The stage and type of plant material must be relevant for the produced seed
- 1.2 In case of seed productions of up to 10 mother plants, all mother plants must be sampled
- 1.3 In case of seed productions of more than 10 mother plants, at least 10% of the mother plants must be sampled, with a minimum of 10 and a maximum of 200 plants per line and/or compartment
- 1.4 In case of compartment sampling, at least 10% of the mother plants must be sampled, with a minimum of 10 and a maximum of 200 plants

### **2. Sampling of leaf or other plant material for plant health testing**

Samples must be collected according to an approved sampling strategy. Samples must be representative; every primary sample must be represented in the submitted sample equally.

- 2.1 The stage and type of plant material must be relevant for the pathogen to be tested
- 2.2 In case of plant numbers of up to 10 plants, all plants must be sampled
- 2.3 In case of more than 10 plants, at least 10% of the plants must be sampled, with a minimum of 10 plants and a maximum of 200 sampled plants per line and/or compartment
- 2.4 In case of compartment sampling at least 10% of the mother plants must be sampled, with a minimum of 10 and a maximum of 200 plants

### **3. Sampling of pollen for pollen (plant) health testing**

- 3.1 The sample must be taken after drying of the pollen
- 3.2 Pollen must be mixed thoroughly before the sample is taken
- 3.3 Per male line, 10% of the volume or weight must be sampled, with a maximum of 200 µl pollen
- 3.4 Multiple small pollen samples may be combined up to a volume of 200 µl. In this case, the result (positive or negative) is valid for all pollen samples represented in this volume
- 3.5 In case of compartment sampling, a relative (to the number of male plants in that compartment) representative sample size (volume or weight) of each pollen lot must be sampled to create a sample with a minimum volume of 200 µl (per compartment)

### **4. Sampling of fruits for seed health testing**

- 4.1 At least one fruit must be collected from each individual plant from which seeds will be harvested
- 4.2 The collected fruit should contain mature or close to mature seeds and should be the upper fruit (or originate from the upper truss) that meets this criterium
- 4.3 The fruit should be collected at the time of harvest or after final harvest of the seeds.
- 4.4 A sample for testing shall be taken from the seeds extracted from these fruits according to Table 1

	<b>Sample size</b>
Bacteria	Minimal 10 seeds per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds
Virus/Viroid	Minimal 3 seeds per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds
Fungi	Minimal 1 seed per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds

Table 1: Submitted seed samples for testing from fruits

- 4.5 The test result is valid only for seeds harvested before or at the time of fruit collection. A new sample is required for seeds harvested after this moment

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## 5. Seed sampling of seed lots larger than 30.000 seeds

- 5.1 When a seed lot has been received from a third party (e.g. when bought or received from production):
- 5.1.1 Each unit needs to be sampled, with a minimum of one primary sample per unit
  - 5.1.2 Furthermore Table 2 is applicable (because of the minimal number of primary samples to be taken for e.g. 1-4 units)
- 5.2 When a seed lot is known to be completely homogeneous (at least, regarding appearance), e.g. after thorough mixing during the cleaning or pelleting process:
- 5.2.1 Taking of one primary sample per unit / batch is sufficient
- 5.3 When a seed lot has been received from another department / site of the company itself (e.g. after cleaning or enhancement and / or when ready for shipment to customer):
- 5.3.1 The minimum number of primary samples to be taken in relation to the number of units / kilograms of the seed lot is indicated in Table 2:

Units < 100 kg			Units ≥ 100 kg		
Number of units in the lot	Number of units to be sampled	Minimal number of primary samples	Lot size in kilograms	Number of primary samples	Min. number of primary samples
1 / 4	each unit	3 / unit	100 / 500	5	5
5 / 8	each unit	2 / unit	501 / 3.000	1 / 300 kg	5 - 10
9 / 15	each unit	1 / unit	3.001 / 20.000	1 / 500 kg	10 - 40
16 / 30	15	15 (1 per sampled unit)	≥ 20.001	1 / 700 kg	40
31 / 59	20	20 (1 per sampled unit)			
≥ 60	30	30 (1 per sampled unit)			

Table 2: number of primary samples depending on number and size of units / lots

- 5.3.2 In case of irregularities (e.g. a less homogeneous appearance), Table 2 is still applicable, but all units must be sampled.
- 5.4 When it involves seed lots in small units (under 15 kg capacity), the units (e.g. 20 units of 5 kg or 100 units of 1 kg) can be combined into one compound unit, which altogether cannot exceed 100 kg.
- 5.5 When it concerns seed mats, tapes, small packets or reels, the units can be combined into one compound unit, which must not exceed 2 million seeds
- 5.6 For each compound unit, sampling must be carried out as indicated in Table 2 (e.g. for a compound unit existing out of 20 units of 5 kg, at least 3 primary samples must be taken)
- 5.7 The sampler must be able to draw a representative sample:
- 5.7.1 To avoid systematic errors, the sampler must change the place of sampling between the different units regularly (e.g. different layers; near the wall / in the centre; different angles)
  - 5.7.2 Every unit must be represented in the submitted sample equally
  - 5.7.3 The primary samples collected must be mixed thoroughly before taking a submitted sample out of the composite sample

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## 6. Seed sampling of small seed lots

6.1 Sample sizes for individual seed lots are in accordance with Table 3

Lot size:	≤150 seeds	151 - 300 seeds	301 - 3.000 seeds	3.001 < seeds < 30.000
Minimum infection rate to be detected:	10%, with 95% probability	10%, with 95% probability	10%, with 95% probability	1%, with 95% probability
<b>Bacteria</b>	5 seeds	15 seeds	30 seeds	300 seeds
<b>Virus/Viroid</b>	5 seeds	15 seeds	30 seeds	300 seeds
<b>Fungi</b>	5 seeds	15 seeds	30 seeds	200 seeds <sup>2</sup>

Table 3. Minimum test sample sizes for small seed lots.

Calculated sample sizes are based on hypergeometric distribution (ISPM No. 31- Methodologies for sampling of consignments (2008)). Data supporting the infection rates are presented in the Questions section of <https://www.naktuinbouw.com/inspections/erkenningen/nal>.

6.2 If all seed lots are harvested from one compartment in the same harvest period, seed sampling per compartment (item 7) can be applied

## 7. Seed sampling per compartment

- 7.1 There must be a complete registration for each compartment that contains the number and identity of the lines, number of mother plants at time of harvest, and dates of harvests of the compartment
- 7.2 From each harvest a unique seed lot is made per line
- 7.3 A random sample must be taken from each seed lot. The sample size from this small lot is based on the number of mother plants from which the lot is produced, and according to Table 4.

	Sample size
Bacteria	Minimal 10 seeds per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds
Virus/Viroid	Minimal 3 seeds per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds
Fungi	Minimal 1 seed per mother plant, maximum (but not limited to) the number of seeds used for seed lots of >30.000 seeds

Table 4: Submitted seed samples for testing from a compartment

<sup>2</sup> The 200 seed sample is a generally accepted sample size for seed health testing for fungal seed transmitted pathogens.

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## NAL Quality score

### Germination

**In order to come to a reliable NAL Quality score for germination, we have determined the following requirements / constraints for issuing a NAL Quality certificate with a NAL Quality score:**

1. There has to be a procedure for obtaining the NAL Quality score, which (and with all relevant related documents and references (as tolerance table)) has to be evaluated and approved by the Bureau Authorizations through myNaktuinbouw.
2. This procedure must deal with all items of this paragraph
3. The NAL Quality score can be based upon results from a germination test on/between paper, in sand, a grow out test/UPT or a combination of these, as long as the same type of observations (e.g. 'normal seedlings') are averaged
4. It is not allowed to use data older than one year in this matter regarding the last test result (it does not matter how old the previous ones are, as long as both are within tolerances)
5. For some product forms the shelf life will be shorter and therefore needs to be determined by the company per crop / product form
6. There have to be tested 400 seeds as a minimum always
7. This can be done in one germination test on 400 seeds from the lot that will be packed, as long as all repetitions (e.g. 4x 100) are within allowed tolerances
8. It is also allowed to do the last germination test on the previous ( $\neq$  last) product form, in case the laboratory did demonstrably carry out a risk analysis on the last process step:
  - (where relevant, but not limited to) considering processing, crop, treatment, enhancement and the effect thereof on the germination figure
  - which must lead to the conclusion whether the risk of the last process step can be neglected (meaning that the process step does not / hardly affects the germination figure)
  - there is no threshold in this matter; the decision must be plausible and needs to be sustained by evidence of analysis of data present
  - in case the risk analysis led to the conclusion that the risk of the last process step in this matter can not be neglected, or in case of a *a priori* risk, the laboratory must have a fail-safe system, or the results of this product form can not be used for determining a NAL Quality score
  - if the process step alters, or when the company introduces a new product form, this risk analysis needs to be carried out again
  - in case there is evidence or an assumption that the conclusion in the risk analysis was not correct (e.g. by monitoring the process, by complaints or otherwise), the risk analysis needs to be carried out again
  - all the above is not applicable if the last process step concerns packing only
  - all the above is only applicable for NAL Quality certificates, and not for all processed seed lots
9. It is allowed to use results of more than one germination test; the examples underneath (these are all before the actual packing) are allowed:
  - 200 seeds on the last product form (to be packed) and 200 seeds on the previous product form (vertical in pedigree), but only when:
    - each test result (if applicable, regarding repetitions) itself is within allowed tolerances
    - as well as between the two tests results

	○	
○	○ 200 seeds	○
	○ 200 seeds	

- 200 seeds on the last but one product form and 200 seeds on the previous product form (vertical in pedigree), but only when:
  - each test result (if applicable, regarding repetitions) itself is within allowed tolerances
  - as well as between the two tests results
  - and if this is OK according the outcome of a risk analysis where this product form is considered (according 8)

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	○ 200 seeds	
○	○ 200 seeds	○
	○ next product form	

- 200 seeds on the product form and 200 seeds on the same product form (a sister lot, horizontal in pedigree), but only when:
  - each test result (if applicable, regarding repetitions) itself is within allowed tolerances
  - as well as between the two tests results

	○	
○ 200 seeds	○ 200 seeds	○

- 200 seeds on each input for a blend and 200 seeds on the blend, but only when:
  - each test result (if applicable, regarding repetitions) itself is within allowed tolerances
  - as well as between the tests results

○ 200 seeds	○ 200 seeds	
○ 200 seeds		○

- 400 seeds on each input for a blend and not on the blend itself (theoretical germ), but only when:
  - each test result (if applicable, regarding repetitions) itself is within allowed tolerances
  - as well as between the tests results
  - and if this is OK according the outcome of a risk analysis where blending is considered (according 9)

○ 400 seeds	○ 400 seeds	
○		○

10. For the cases under 9 it is allowed to use any result, as long as it is within the acceptable tolerance range (see Miles, 1963)

### **Determination of other seeds**

**In order to come to a reliable NAL Quality score for determination of other seeds, we have determined the following requirements / constraints for issuing a NAL Quality certificate:**

1. An other seed determination by numbers must be performed on a minimum working sample as stated in the ISTA rules on Sampling Table 2C Lot sizes and sample sizes. A relevant AOSA table is acceptable too. The maximum weight to be examined is 1 kilogram. For fruity crops for which the seed lots are produced in a greenhouse (or other clean environment) the minimum working sample is 2500 seeds (or a weight equal to that)
2. It is also allowed to do the test on the previous (≠ last) product form, in case the laboratory did demonstrably carry out a risk analysis on the last process step:
  - (where relevant, but not limited to) considering processing, crop, treatment, enhancement and the effect thereof on the test result
  - which must lead to the conclusion whether the risk of the last process step can be neglected (meaning that the process step does not / hardly affects the test result)
  - there is no threshold in this matter; the decision must be plausible and needs to be sustained by evidence of analysis of data present
  - in case the risk analysis led to the conclusion that the risk of the last process step in this matter can not be neglected, or in case of a *a priori* risk, the laboratory must have a fail-safe system, or the results of this product form can not be used for determining a NAL Quality score
  - if the process step alters, or when the company introduces a new product form, this risk analysis needs to be carried out again
  - in case there is evidence or an assumption that the conclusion in the risk analysis was not correct (e.g. by monitoring the process, by complaints or otherwise), the risk analysis needs to be carried out again
  - all the above is not applicable if the last process step concerns packing only
  - all the above is only applicable for NAL Quality certificates, and not for all processed seed lots

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## **Moisture determination**

Moisture should be determined in duplicate and communicated as a percentage using one decimal. The difference between duplicates should be <0.25%.

### **Definitions:**

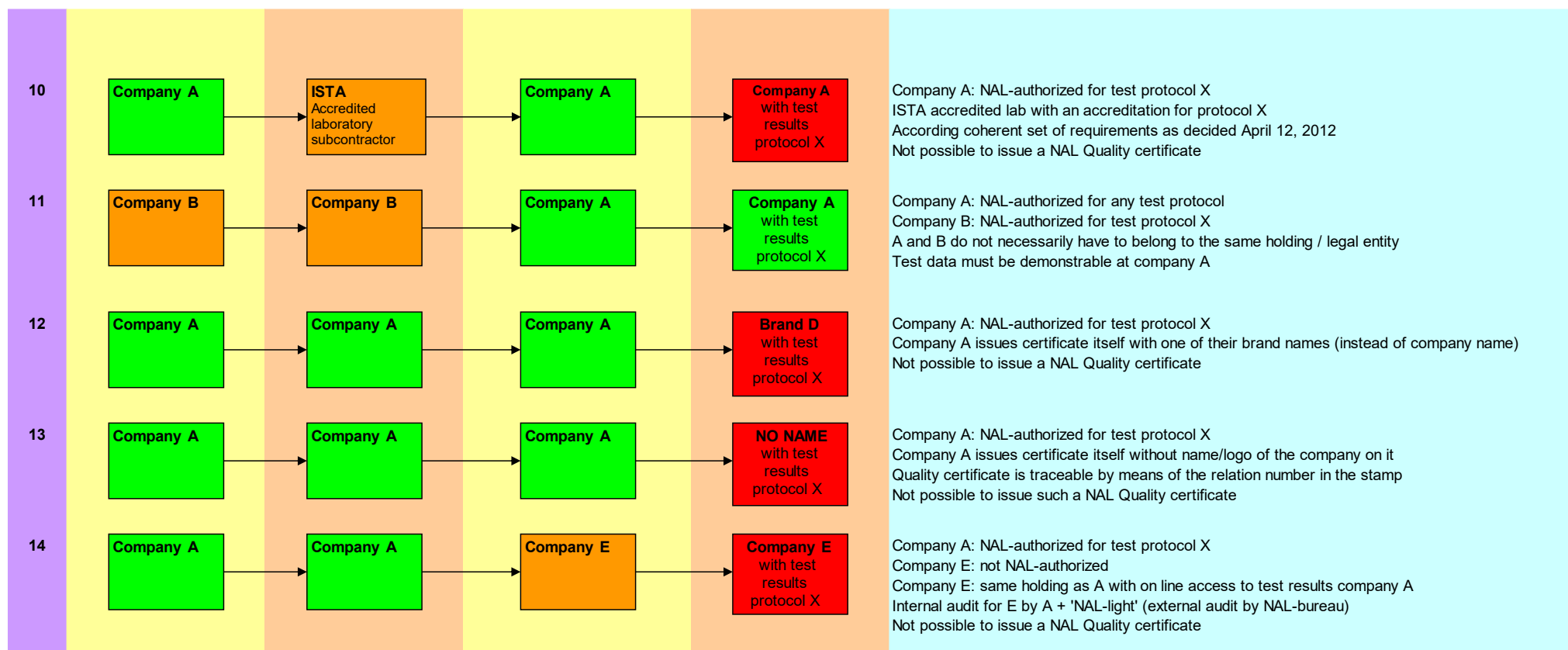
- a. Acceptable tolerance (table):
  - i. indicating which range can be accepted between replicates or tests, because there is no significant difference between the same type of observations
  - ii. this has to be based upon a 2-way test equivalent at 2.5% or 5% significance level
  - iii. the proper table has to be used, e.g.:
    - 1. for tests in 1 laboratory
    - 2. regarding the number of seed in repetitions in the concerning test
    - 3. regarding the total number of seeds tested in the concerning test
    - 4. when there is more than 1 laboratory in the company: for tests in different laboratories
- b. A priori risk:
  - i. risk that is already known to exist in advance
- c. Fail-safe system:
  - i. does not mean that failure is impossible / improbable
  - ii. but rather that the system's design prevents or mitigates unwanted consequences of the system's failure, because it responds appropriately and adequately
- d. Mother lot / original seed lot / seed lot of origin:
  - i. an amount of seeds as a direct result from a harvest of a production field (in some companies even per harvested cluster)
  - ii. sometimes a harvest is divided into more than one part, because the quantity of the harvest itself is too big to handle, which leads to more than one mother lot for this production
- e. Pedigree:
  - i. a means (e.g. an ERP-system) for indicating how different seed lots are related to each other
- f. Product form:
  - i. a description of the product, often reflecting a stage in the production process, e.g.:
    - 1. raw seeds (harvested seeds)
    - 2. cleaned seeds (e.g. clipper)
    - 3. graded seeds (e.g. grade I, grade II, etc.)
    - 4. treated seeds (e.g. with fungicide, primed, pelleted, etc.)
    - 5. blended seeds
    - 6. packed seeds
- g. Risk analysis:
  - i. identifying possible risks in the process which can affect the test result
  - ii. analyzing the identified risks (cause, chance of occurrence / possible impact)
  - iii. determining the need for adapting existing / establishing new control measures to control the identified risks
- h. Seed lot (number):
  - i. a certain amount of seeds, which is traceable / can be distinguished (from e.g. other crops, varieties, harvests, product forms) throughout the production chain (by means of an unique seed lot number)
  - ii. therefore the seed lot number of a certain amount of seeds is changing after each processing step, when it becomes a new product form
- i. Shelf life:
  - i. the period of time that a quality score after that it has been determined for a certain seed lot (crop / product form) is expected to remain stable
- j. Sister lots:
  - i. parts of a seed lot that have been processed in the same way, in most cases on different moments

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## OVERVIEW ISSUING NAL QUALITY CERTIFICATES

	SAMPLING	TESTING	CERTIFICATE ISSUED BY	TEXT CERTIFICATE	REMARKS / CONSTRAINTS
1	Company A	Company A	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X
2	Company C	Company A	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X Company C: not NAL-authorized / no Multi Location Module for company A Not possible to issue a NAL Quality certificate
3	Company C MLM for company A	Company A	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X Company C: Multi Location Module for company A
4	Company B	Company A	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X Company B: NAL-authorized for sampling A and B do not necessarily have to belong to the same holding / legal entity
5	ISTA Accredited laboratory subcontractor	Company A	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X Sampling is carried out by a sampler in the scope of a laboratories' ISTA accreditation At the start of using this option the ISTA audit report to be submitted to Bureau Authorizations
6	Company A	Lab Z subcontractor	Company A	Company A with test results protocol X	Company A: NAL-authorized for test protocol X Lab Z: if not in line with NAL Conditions in chapter 23 Not possible to issue a NAL Quality certificate
7	Company A	Naktuinbouw subcontractor	Company A	Company A with test results protocol X	Company A: NAL-authorized for any test protocol Naktuinbouw: see conditions in chapter 23.1 and 23.4 Test data must be demonstrable at company A
8	Company A	ASLN or NAL Authorized laboratory subcontractor	Company A	Company A with test results protocol X	Company A: NAL-authorized for any test protocol Company ASLN or NAL authorized for test protocol X, see conditions in chapter 23.2 and 23.4 Test data must be demonstrable at company A
9	Company A	ISO 17025 Accredited laboratory subcontractor	Company A	Company A with test results protocol X	Company A: NAL-authorized for any test protocol ISO 17025 accredited lab for test protocol X, see conditions in chapter 23.3 and 23.4 Test data must be demonstrable at company A

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Issued by Naktuinbouw Authorized Laboratory (NAL)

## Quality Certificate

Certificate number

Latin name :

Crop, Variety :

Lot / batch number :

Additional information :

## QUALITY INFORMATION

GERMINATION		
Normal seedlings	Abnormal seedlings	Non germinated seeds
%	%	%
Remarks:		

PHYSICAL PURITY		
Pure seeds	Inert matter	Other seeds
%	%	%
Kind of inert matter		Other seeds (species)
Remarks:		

DETERMINATION OF OTHER SEEDS BY NUMBER
In the test were found (size of working sample [xxx] gr.): [no other seeds / ... ]
Remarks:

SEED HEALTH
Lot has been tested for [pathogen]: pathogen not detected
Remarks:

Stamp	Date
	Signature
	Name

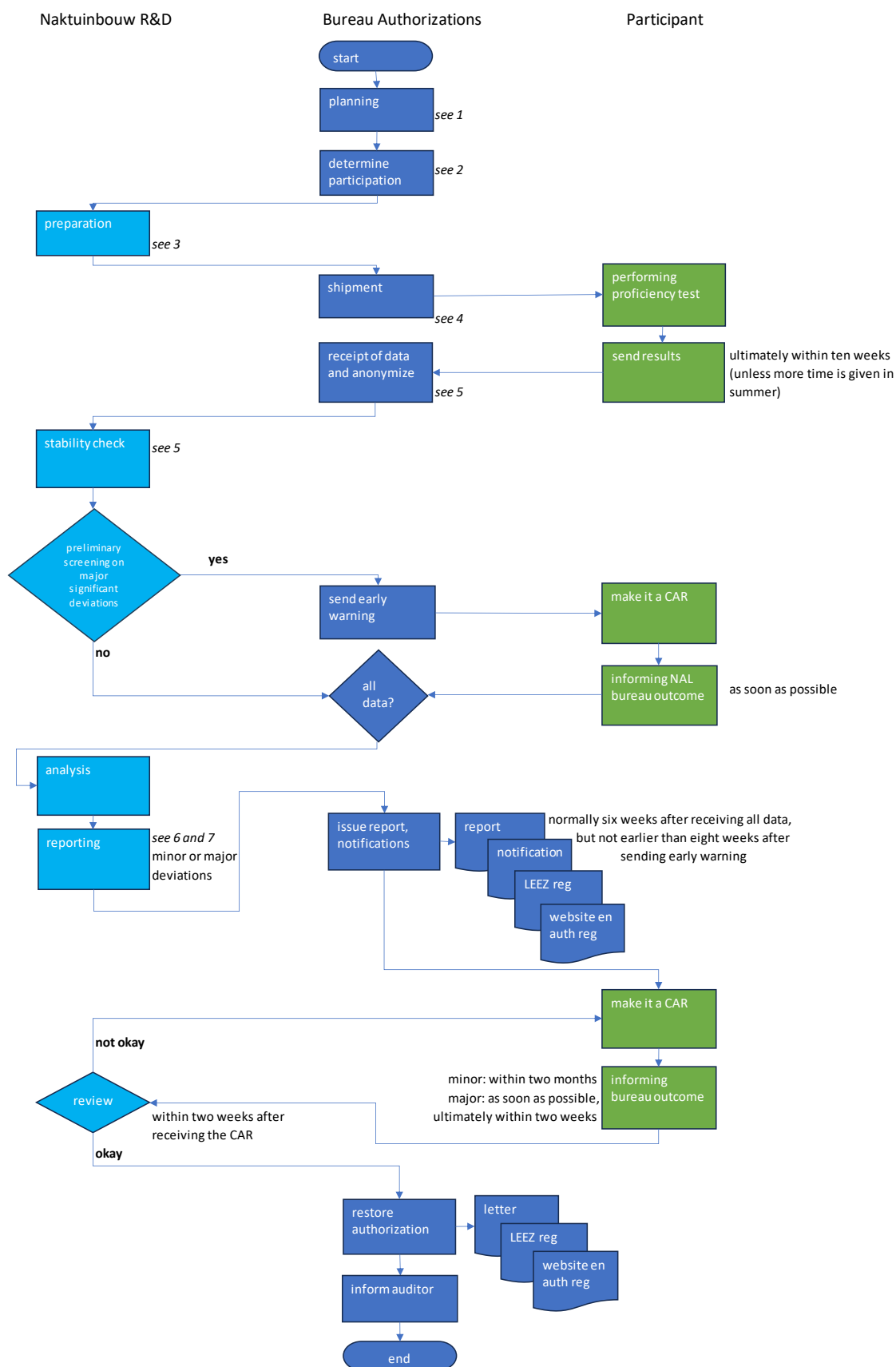
## Quality Certificate

PLANT HEALTH
Production from which this lot origins has been tested for [pathogen]: pathogen not detected
Remarks:

SEED COUNT OR THOUSAND SEED WEIGHT
[xxx] seeds / gr. or kg 1.000 seeds = [xxx] gr. or kg
Remarks:

MOISTURE CONTENT
%
Remarks:

Stamp		Date
		Signature
		Name

**APPENDIX VI ORGANIZATION OF PROFICIENCY TESTS SEED HEALTH NAL**

## 1 Planning

The Bureau Authorizations will make a proposal for a long term plan:

- a. overview for 3 years.
- b. dealing with categories as mentioned in NAL condition 25.2.5.
- c. dealing with history (results of earlier proficiency tests).
- d. dealing with developments / actual problems.
- e. dealing with the scope of NAL authorized laboratories:
  - i. for tests for which  $< 4$  laboratories are NAL authorized → blind samples.
  - ii. for tests for which  $\geq 4$  laboratories are NAL authorized → proficiency test.
- f. dealing with plans for proficiency tests organized by other organizations (when known, such as GEVES).

This long term plan is shared with the NAL Board of Experts in October/November and updated at every meeting, including the status of the preparation of each test. The plan for the ongoing year is mentioned on the website of Naktuinbouw.

The proficiency tests are spread over the year. The week number when test sets are planned to be sent is communicated in December.

An important constraint is the availability of naturally infected seed lots. Seed lots should be made available by NAL-authorized laboratories at least nine months before the proficiency test can be sent. It may take up to nine months to prepare the test sets. If during that preparation phase, the seed lot appears to be not suitable the proficiency test plan cannot be fulfilled.

## 2 Participation

Obligatory participation:

- a. Each NAL (or ASLN) authorized laboratory with the concerning test (pathogen, crop) in the scope of their NAL authorization. Constraint: if the authorized laboratory applies a method with a different subsample size, participation may be possible in consultation with Bureau Authorizations.
- b. Each laboratory with a pending request for authorization of the concerned test.
- c. Each by Bureau Authorizations approved subcontractor with the concerning test in the scope of their approval.
- d. Naktuinbouw laboratory.

Voluntary participation:

- a. Any laboratory that wants to participate for benchmarking their method to that of others. Constraint: Bureau Authorizations must be informed about the protocol and the laboratory must have routine expertise for this test. The number of available test sets may be a limiting factor.

In December all NAL-authorized laboratories and known voluntary participants are invited to indicate their wish/must to participate in the proficiency tests (pathogen, crop, method, and for information subsample size) in the next year. The laboratory performs the PT according to their in-house, NAL-approved, company protocol.

If a laboratory wants to participate with more than one method (e.g. one obligatory and one voluntarily) this is possible without extra costs when the same test set is being used. A second test set may be available if needed in such case, for extra costs.

## 3 Preparation

The preparation starts approximately nine months before sending the test sets to all participants. It starts with selection and testing of naturally contaminated and healthy seed lots. New seed lots are only suitable when an MUA has been signed, allowing the use in a proficiency test.

### Pre-screening

- Negative samples: Test at least three times the sample size of a standard test according to the Naktuinbouw standard protocol. All subsamples must test negative to be considered as a suitable seed lot for the negative category.
- Heavily contaminated samples: All subsamples of a ten times dilution from the selected seed lot must be positive. In the proficiency test, the seed lot is used undiluted to provide the heavily contaminated samples.
- Medium-contaminated samples should not be close to the detection limit of the Naktuinbouw standard protocol, but there isn't a fixed number. Depending on the type of test (and answers we need) we decide how many subsamples of a certain seed lot must be tested to get a good overview of the homogeneity. Not all subsamples must test positive, however  $>70\%$  is desirable.

The organization of proficiency test for a specific seed/pathogen combination depends heavily on the availability of suitable seed lots. Pre-screening is performed using above mentioned guidelines using the Naktuinbouw standard protocol for this method. If the quality of the available seed lot doesn't meet the guidelines it may be needed to postpone the PT until suitable seed lot(s) comes available. Other options are a PT without heavily contaminated samples or the use of heavily contaminated samples that are just not matching the guideline.

The sample size is based on the subsample size used in the standard protocol of Naktuinbouw.

The number of negative, heavily contaminated and medium-contaminated samples in a PT set may differ and depends on the expected workload for the participants, availability of seeds and/or statistical considerations.

For a last stability check, we test a complete set, after preparation of all the sets, and before sending the sets to the participants.

#### **4 Shipment of the proficiency test set**

The test set is sent together with an instruction. The instruction is also sent by e-mail. The instruction mentions objective of the PT, contents of the package, storage conditions, and deadlines.

The test set is sent under cooled conditions only when needed. A datalogger is added to the package, at least when it is expected that temperature may have influence on the results. It is sent by a courier service with track and trace code. When phytosanitary documents are needed these are provided whenever possible.

The material is addressed to the contact person for proficiency tests at the company.

By e-mail also datasheets are sent. The datasheet includes participant information, including critical control points for the specific test method. Participants are obliged to enter all details. A deadline of 10 weeks is given to provide the results. The deadline will be adapted if the set is sent around the summer period. Extra sets will normally not be available for a participant before analysis of the results of all participants, since spare sets are limited and possibly needed for resolving potential cards after evaluation of all the results.

#### **5 Reporting process**

Analysis of results starts as soon as all results have been received. Missing results of delayed laboratories will not be taken into account for the analysis. Results of the delayed laboratories will be analysed at a later point and may lead to extra costs. Two days before the deadline a reminder will be sent. If results of obligatory participants are not available the authorization will be temporarily withdrawn, unless there is a valid reason.

The overall results are compared with our pre-screening data in order to confirm the stability. If there is a stability issue, we may decide not to give minors or majors.

A preliminary statistical check is performed to see if any obligatory laboratory does not meet the requirements. In case a major is expected the laboratory receives an "early warning" by e-mail.

In the complete report all details of the participant results are checked and commented. Results of voluntary participants are included. Critical control points and temperature recorded by dataloggers are checked and analyzed. In case of no early warning: the report (and minors) can be sent when finished, normally this is within 6 weeks. In case of an early warning: the report and the majors/minors will be sent 8 weeks after the early warning. The report is sent to all participants (obligatory and voluntary), the notification of a deviation to the laboratory concerned.

#### **6 Impact of deviations**

The required action on a minor is described in the NAL Conditions, version 2026, paragraph 25.3.3.

The required action on a major is described in the NAL Conditions, version 2026, paragraph 25.3.3 and 25.3.4. As long as the notification has not been issued, but an early warning only, acting as described in 25.3.4 is not needed.

- Bureau Authorizations comments on the CAR asap, ultimately within two weeks. If Bureau Authorizations doesn't agree with the CAR this will be substantively argued.
- In case Bureau Authorizations and the participant disagree on the root cause analysis and the corrective action a decision on the authorization of the concerning test will be made by Naktuinbouw unit manager Authorizations.

The auditor is informed of a minor and may give attention to the CAR. The auditor is informed of a major (including an early warning) and the status of it. The auditor will spend extra time during the audit to verify whether the laboratory has followed the correct process and, depending on the status, the problem with the test has been solved.



## 7 Statistics

The threshold is determined by the analysis of obligatory participants only.

- Heavily contaminated samples  
The participant must be able to detect all samples from this category. If not, an obligatory participant will receive a major.
- Medium-contaminated samples
- Thresholds are based on the binomial distribution of obligatory participants (except 2b and except obligatory participants who apply a different method for that crop/pathogen-combination (such as SE-PCR versus ELISA or agar plating versus blotter)). An obligatory participant will receive a minor when the probability of receiving a set with the number of their reported positive samples is lower than 0.1 ( $0.1 > p \geq 0.01$ ). In case of a probability lower than 0.01 the obligatory participant will receive a major. For example for a sample set with 20 medium contaminated samples with an overall mean of 15.6, participants with 11 or 12 positive samples will receive a minor. Obligatory participants with less than 11 positive samples will receive a major (table 1).
- Healthy samples  
False-positives are less critical from the NAL point of view, only a minor will be issued to obligatory participants when the probability of the reported positive samples is smaller than 0.01. Thus the probability of receiving three positive samples in the healthy category with an overall mean of 0.4 is  $<0.01$  (table 1).

Table 1. Example of number of positive samples per laboratory, overall mean and limits per contamination level

Contamination level	n	Laboratory (obligatory participants)							Mean	Minor	Major
		1	2	3	4	5	6	7			
Healthy	5	0	3	0	0	0	0	0	0.4	>2	-
Medium	20	14	18	11	14	18	17	17	15.6	11, 12	<11
High	5	5	5	5	5	5	5	5	5	-	<5

## THE NETHERLANDS INSPECTION SERVICE FOR HORTICULTURE AND AUSTRALIAN GOVERNMENT DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY AGREEMENT

The Netherlands Inspection Service for Horticulture (Naktuinbouw) and the Australian Government Department of Agriculture, Fisheries and Forestry (the department),

**RECOGNISING** the role of the department in protecting Australia's agriculture, food, fisheries and forestry industries, human health and the health of Australian flora and fauna through effective quarantine and biosecurity systems;

**RECOGNISING** the mutual benefits gained through a cooperative initiative for the certification of seed exports to meet the department's import requirements and to facilitate trade between the Netherlands and Australia.

**PURSUANT** to their prevailing laws and regulations, **HAVE REACHED THE FOLLOWING UNDERSTANDING:**

### 1. PURPOSE

- 1.1 The purpose of this Agreement is to facilitate and promote cooperation between the department and Naktuinbouw (NAL Bureau) and allows Naktuinbouw Authorised Laboratories (NAL) to certify the purity of seed lots for export to Australia without the requirement for routine ISTA sampling and purity analysis in Australia.

### 2. DEFINITIONS

Naktuinbouw	Also known as the Netherlands Inspection Service for Horticulture. Naktuinbouw is an independent non-profit inspection service in the Netherlands and authorises seed companies if their Quality System and laboratory tests meet the "NAL conditions"
NAL	Naktuinbouw Authorised Laboratories
NAL Bureau	The board overseeing, auditing and approving Naktuinbouw Authorised Laboratories
The department	Australia Government Department of Agriculture, Fisheries and Forestry
ISTA	International Seed Testing Association
Company	A NAL – Authorised laboratory seeking approval under the NAL- Department of Agriculture, Fisheries and Forestry protocol
Participants	The NAL Bureau and Australian Department of Agriculture, Fisheries and Forestry
NAL – Authorised Company	A NAL – Authorised laboratory officially recognised and approved under the NAL- Department of Agriculture, Fisheries and Forestry protocol

### **3. PROCESS FOR COMPANIES TO BE APPROVED UNDER THE NAL - DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY PROTOCOL**

- 3.1 The NAL Bureau will establish and administer the approval process in line with Schedule 1 for applicants seeking approval under the NAL - Department of Agriculture, Fisheries and Forestry protocol - 'Detection of other seeds and inert matter in seeds for export to Australia', hereinafter referred to as the "NAL - Department of Agriculture, Fisheries and Forestry protocol".
- 3.2 Refer to **Appendix 1** for an outline of the NAL - Department of Agriculture, Fisheries and Forestry protocol.
- 3.3 Refer to **Appendix 2** for the flowchart relating to the process for checking seed analysis reports for seed to Australia.
- 3.4 This Agreement outlines the procedures for:
- auditing and approving companies under the protocol;
  - proficiency and verification testing by the NAL – Bureau;
  - NAL-Authorised Companies not compliant with requirements.

### **4. NAL BUREAU ROLES AND ACTIVITIES**

#### **Prior to approval**

- 4.1 The NAL Bureau will confirm that the company is NAL authorised (with purity + determination of other seeds by number in their scope) and has a Quality Management System prior to approval.
- 4.2 The NAL Bureau will undertake an initial desk audit on the procedures, work instructions and protocols provided by the company.
- 4.3 The NAL Bureau will ensure that the company has implemented and adopted the NAL – Department of Agriculture, Fisheries and Forestry protocol for a minimum of 3 months into their standard operating procedures prior to an audit by the NAL Bureau.
- 4.4 The NAL Bureau or Authorised Auditor will then conduct an audit on the company to verify implementation of the NAL - Department of Agriculture, Fisheries and Forestry protocol.
- 4.5 On completion of the audit, the NAL Bureau will send the audit report and all relevant documents (in English) to the International Systems Manager for review.
- 4.6 Once the associated audit documentation has been finalized, the NAL Bureau will send the audit report and all relevant documentation (in English) to the department.

#### **Once approved**

- 4.7 Once approved the NAL Bureau will ensure that each NAL - Authorised Company continues to comply with the requirements in this Agreement and the NAL - Department of Agriculture, Fisheries and Forestry protocol.

- 4.8 The NAL Bureau (or appointed inspector) will verify consignments through sampling prior to exporting to Australia. The NAL – Authorised Company must notify the appointed inspector prior to shipping seed with a NAL Quality Certificate to Australia. Samples must be taken in line with the following:
- a) For seed lots destined for Australia with a NAL Quality Certificate, annually:
    - ii. For non-pelleted seed lots, a minimum of 5% of **all** shipments greater than 10 kgs
    - ii. For pelleted seed lots, a minimum of 5% of **all** shipments greater than 250 kgs  
(*Note: This 250kg weight threshold for pelleted seed applies only to check sampling. Australia's requirements remain that mandatory purity analysis is required for all imported pelleted seed lots greater than 10 kg*).  
This sample is referred hereafter as a 'Check Sample'.
  - b) Randomly select the shipment to be sampled.
  - c) Send the sample to the Naktuinbouw laboratory for testing.

## 5. VERIFICATION PROCESS

- 5.1 The NAL Bureau will ensure that the NAL – Authorised Company will notify the NAL bureau or appointed inspector of every shipment accompanied with a NAL Quality Certificate exported to Australia. Where a NAL-Authorised Company does not notify the NAL Bureau, the NAL Authorised Company will be issued with the following:
- a) 1<sup>st</sup> offence: written warning + **Yellow card**;
  - b) 2<sup>nd</sup> offence within 12 months of 1<sup>st</sup> offence: written warning + **Red card**;

Refer to Schedule 1, Point 1 (table for 'Notification of shipments') for a further explanation on process if requirement to notify NAL Bureau is not met.

- 5.2 On completion of testing the Check Sample, the NAL Bureau and NAL – Authorised Company will be notified by the Naktuinbouw laboratory whether the result is compliant or not. Refer to Schedule 1, Point 1 (table for 'Check sampling') for a further explanation on check sampling not meeting requirements.
- 5.3 If the result meets the requirements as mentioned in the department's seed contaminants and tolerance tables and the department's BICON database requirements, the situation of approval will continue. Refer to Appendix 1 for direct links to these websites.
- 5.4 The NAL Bureau will issue a Yellow card or Red card to a NAL - Authorised Company not meeting protocol requirements. Refer to Schedule 1, Point 1 (table for 'Check sampling') for a further explanation on check sampling not meeting requirements.
- 5.5 The NAL Bureau will notify the department when a Yellow card or Red card is issued in either of the cases outlined above.
- 5.6 The NAL Bureau will ensure that all NAL - Authorised Company seed samplers attend a seed sampling refresher course once every four years.

## 6. PROFICIENCY TESTS

- 6.1 The Naktuinbouw ISTA Laboratory will arrange for each NAL - Authorised Company to participate in a Naktuinbouw proficiency test on physical purity annually.

- 6.2 The Naktuinbouw ISTA Laboratory will notify the NAL Bureau of the results of the proficiency test.
- 6.3 The NAL Bureau will provide a copy of the proficiency test results to the department.
- 6.4 The NAL Bureau will issue a Yellow card or Red card to a NAL - Authorised Company where proficiency results are not accurate. Refer to Schedule 1, Point 1 (table for 'Proficiency tests') for a further explanation on process for proficiency tests.

## **7. THE DEPARTMENT'S ROLES AND ACTIVITIES**

- 7.1 The department will approve the NAL – Authorised Company based on the provided audit report and all relevant documentation from the NAL Bureau.
- 7.2 The department will list the approved NAL – Authorised Company on the department's BICON database and will notify NAL Bureau on completion of review.
- 7.3 The department will remove NAL – Authorised Companies from the department's BICON approved list when notified from the NAL Bureau that the company has received a red card.
- 7.4 The department will add NAL – Authorised Companies to the department's BICON approved list once notified by the NAL Bureau that the corrective actions have been resolved.
- 7.5 The department will promptly notify the NAL Bureau of any non-compliant consignments accompanied with NAL Quality Certificates and will advise the NAL Bureau of any remedial action taken. Refer to Schedule 1, Point 1 (table for 'Non-compliant shipments') for further information).

## **8. SYSTEM REVIEWS AND AUDITS**

- 8.1 Procedures herein established are subject to revision as situations warrant; however, they will remain in effect until revised.
- 8.2 Unless otherwise negotiated, periodic reviews and audits of the Protocol and Agreement will be conducted at times mutually determined by both the NAL Bureau and the department.

## **9. MAINTENANCE OF RECORDS**

- 9.1 The NAL Bureau will maintain all records relating to the assessment and authorisation of companies for a period of six years.
- 9.2 The NAL Bureau will keep one central document, in which there is an overview regarding all notified + sampled shipments + test result (and follow up).

## **10. INTELLECTUAL PROPERTY**

- 10.1 Intellectual property of all material provided or created for the purpose of this Agreement, or derived from such material, will remain or vest with the Participants who created or provided the material, consistent with international law.

## **11. CONTACT PERSONS**

11.1 The NAL Bureau and the department will nominate a contact person(s) to act as a liaison point on all matters relevant to this Agreement.

11.2 The NAL Bureau and the department will exchange information through their designated contact person(s) on any matters affecting the operation of this Agreement.

## **12. COSTS**

12.1 The NAL Bureau and the department will be responsible for any costs they incur in carrying out their activities under this Agreement.

## **13. DIFFERENCES OF INTERPRETATION AND APPLICATION**

13.1 The Participants will resolve any difference regarding the interpretation or application of this Agreement by consultation.

## **14. MODIFICATIONS**

14.1 This Agreement may be modified at any time with the written consent of the Participants.

## **15. STATUS OF THE AGREEMENT**

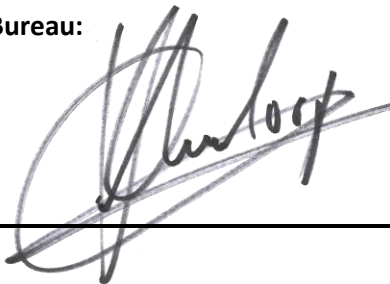
15.1 This Agreement is not legally binding.

## **16. DATE OF IMPLEMENTATION, DURATION AND TERMINATION**

16.1 This Agreement will come into effect upon signature by both the NAL Bureau and the department.

16.2 This Agreement will remain in effect until terminated by mutual written consent of the Participants. Either may also terminate this Agreement by giving the other 180 days' written notice of its intent to terminate.

For the NAL Bureau:



SIGNATURE

Peter van Nieuwkoop

NAME

Head of Inspections Department

TITLE

22 December 2022

DATE

For the Australian Department of Agriculture, Fisheries and Forestry:



SIGNATURE

Jenna Roberts

NAME

Director, Plant Import Operations

TITLE

19 December 2022

DATE

## Version history

The following table details the published date and amendment details for this document.

Version	Date	Amendment details
1.0	24/03/2016	First publication of this agreement.
2.0	01/09/2016	<p>The following minor edits were made to the agreement:</p> <ul style="list-style-type: none"> <li>Point 5.1: Reworded to include reference and that the NAL – authorised company will notify the NAL Bureau and ‘appointed inspector’ for every shipment that is accompanied with a NAL Quality Certificate to Australia. Previously this point indicated that the NAL Bureau must be notified of every shipment exported to Australia.</li> <li>Reference to ‘DAWR’ has been amended to ‘the department’.</li> <li>Schedule 1: Restructured and reworded Point 1 to Point 4 to assist in making these sections clearer. Removed Point 1 bii – reference to prohibited species listed on BICON.</li> <li>Appendix 2: Updated links in flowchart.</li> </ul>
3.0	24/10/2016	<p>The following minor edits were made to the agreement:</p> <ul style="list-style-type: none"> <li>Appendix 1: Point 5 – All links were rearranged to align with the Appendix 2 flowchart. This will assist in making this section clearer. The Noxious Weeds Database was also updated to reflect a recent change made to the database.</li> <li>Appendix 2: Updated the Noxious Weeds Database link in the flowchart.</li> </ul>
4.0	06/02/2018	<p>The following minor edits were made to the agreement:</p> <ul style="list-style-type: none"> <li>Schedule 1: Point 1 b.iii – updated to reflect changes made to the Seed contaminants and tolerance tables website</li> <li>Appendix 2 flowchart: updated to reflect changes made to the Seed contaminants and tolerance tables website</li> </ul>
5.0	21/12/2020	<p>The following edits were made to the agreement:</p> <ul style="list-style-type: none"> <li>References to the ‘Department of Agriculture and Water Resources’ have been updated to the ‘Department of Agriculture, Water and the Environment’</li> <li>Section 4.8 was updated to increase the weight threshold for pelleted seed lots to 250 kg before check sampling is required on 5% of consignments</li> <li>Appendix 2 was updated to provide a process that aligns with current Australian requirements and assessment practices, and to provide working hyperlinks.</li> </ul>
6.0	08/12/2022	<p>The following minor edits were made to the agreement:</p> <ul style="list-style-type: none"> <li>References to the ‘Department of Agriculture, Water and the Environment’ have been updated to the ‘Department of Agriculture, Fisheries and Forestry’.</li> </ul>

		<ul style="list-style-type: none"> <li>• Appendix 2 was updated to provide clarity around Australia's requirements for sclerotia, ergot, smut and choke, and provide reference to the seed contaminants and tolerance webpage.</li> <li>• Converted information contained within Schedule 1, Sections 1 through 3, into table format.</li> <li>• Revised the Department's requirements for NAL quality certificates in Schedule 1, Section 2 (previously Section 4), to align with requirements listed in BICON.</li> </ul>
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# **SCHEDULE 1**

## **1. PROCESS AND FOLLOW UP ACTIONS FOR NON-COMPLIANCE WITH REQUIREMENTS ADMINISTERED BY NAL BUREAU**

	Requirement not met	Type of card (warning)	Action by Authorised Company	Approval by NAL bureau	Status of DAFF Approval
<b>Notification of shipments</b>	Notification to NAL bureau (or appointed inspector) of shipments prior to export to Australia	<ul style="list-style-type: none"> <li>- 1<sup>st</sup> offence: Yellow card</li> <li>- 2<sup>nd</sup> offence within 12 months of 1<sup>st</sup> offence: Red card</li> </ul>	<b>Yellow or Red Card:</b>	<b>Yellow or Red Card:</b>	<b>Yellow Card:</b> approval maintained conditional, until follow up is regarded as sufficient by NAL Bureau
<b>Check sample</b>	Number of other seeds <i>Note: Apply ISTA table 4A (Miles F1b)</i>	<ul style="list-style-type: none"> <li>- 1 or 2 out of 5 consecutive tests: Yellow card</li> <li>- 3 or more out of 5 consecutive tests: Red card</li> </ul>	Comment upon the deviation. Carry out a root cause analysis and indicate whether corrective action is required.	NAL bureau to approve the root cause analysis and evidence of eventual corrective action.  If NAL bureau does not regard the follow up as sufficient, the company must take other corrective action.	<b>Red Card:</b> approval withdrawn temporarily, until the follow up (corrective action) is regarded as sufficient by NAL bureau
	Determination of other seeds:  Weed seed not mentioned in Australia's seed contaminants and tolerance tables and BICON database requirements	<ul style="list-style-type: none"> <li>- 1 out of 10 consecutive tests: Yellow card</li> <li>- 2 or more out of 10 consecutive tests: Red card</li> </ul>			
	Determination of other seeds:  Weed seed exceeds tolerance for Restricted seeds ( <i>Table 1, Maximum contaminant seeds per kg for restricted seeds</i> )	<ul style="list-style-type: none"> <li>- 1 out of 5 consecutive tests: Yellow card</li> <li>- 2 or more out of 5 consecutive tests: Red card</li> </ul>			
	Determination of other seeds:  Weed seed mentioned under section 'Seeds with Nil Tolerance'	<ul style="list-style-type: none"> <li>- 1 out of 10 consecutive tests: Yellow card</li> <li>- 2 or more out of 10 consecutive tests: Red card</li> </ul>			

	Inert matter	<ul style="list-style-type: none"> <li>- 1 or 2 out of 5 consecutive tests: Yellow card</li> <li>- 3 or more out of 5 consecutive tests: Red card</li> </ul>			
<b>Proficiency tests</b>	Minor deviation	Yellow Card			
	Major deviation	Red Card			
<b>Non-compliant shipment</b>	Non-compliant NAL Quality Certificate at arrival in Australia	<ul style="list-style-type: none"> <li>- 1<sup>st</sup> offence: Yellow card</li> <li>- 2<sup>nd</sup> offence within 12 months of 1<sup>st</sup> offence: Red card</li> </ul>			

## 2. DEPARTMENT'S REQUIREMENTS FOR NAL QUALITY CERTIFICATES ACCOMPANYING CONSIGNMENTS TO AUSTRALIA

The following is an outline of the information required to be included on a NAL Quality Certificate for seed exported to Australia. The NAL Quality Certificate must include the following:

- Be issued, signed, and stamped by a NAL accredited seed laboratory representative.
- Include the date of issue.
- Record the botanical name (genus and species) of the crop.
- Record the distinguishing marks of the seed lot e.g. seed lot identifier, lot number, or batch number.
- Record the quantity of the seed lot/batch that has been tested e.g. number of containers, total weight.
- Record the actual weight of the submitted sample (i.e. bulk sample) and the working sample (or the number of pellets examined).
- Must give a description of inert matter.
- Record the botanical name and the number of each identified species of seed found per kilogram (any identified genera or species are to be recorded as such).
- Record the percentage of any soil found in the sample (soil < 0.05% can be recorded as "Trace" or "TR").
- Record the percentage and description of fungal particles and animal faecal matter.

**NOTE:** If seed is coated the following must also be included:

- Record whether seed has been coated (such as seed pellets, encrusted seeds, seed granules

etc).

- b) Record the weight of lot for raw seed and/or coated seed. If seed is coated and the weight of lot is on raw seed, the weight difference will need to be recorded. Bulk search determined by examination of 7,500 depelleted will need to be recorded.

Refer to 'Appendix 2: Assessing seed lot purity results for Australia' for more information relating to this process.

### **3. DEPARTMENT'S PROCEDURES FOR SEED LOTS ACCOMPANIED BY NAL QUALITY CERTIFICATES**

The following is an outline of the onshore procedures that will be undertaken by the department when seed lots arrive in Australia accompanied with a NAL Quality Certificate.

- a) All documentation will be examined on arrival.
- b) Each NAL Quality certificate will be assessed to ensure it meets the department's requirements in terms of purity and weed seed tolerances.
- c) If a NAL Quality certificate identifies a prohibited contaminant, the corresponding seed lot will be directed for cleaning, export or destruction.
- d) Where the department is satisfied the certificates are acceptable, the following inspection procedures apply:
  - i. The department will physically inspect the consignment to reconcile bag markings and line or lot numbers against the certification.
  - ii. A random sample will be drawn by the department from each seed lot and inspected for live insects, signs of disease and to confirm the contents matches the accompanying certification.
- e) The department reserves the right, at any time, to draw samples in accordance with ISTA procedures and submit them to an onshore ISTA accredited seed testing laboratory for analysis.

# **APPENDIX 1**

## **Standard Protocol NAL – Australian Department of Agriculture, Fisheries and Forestry**

### ***Detection of other seeds and inert matter in seeds for export to Australia***

#### **1. Aim**

Determination of other seeds (like weeds) and soil particles in seed lots meant for export to Australia.

#### **2. Abbreviations**

- TPW: Thousand Pill Weight
- TSW: Thousand Seed Weight

#### **3. Materials**

- Bags
- Balance
- Binocular
- Drying equipment
- Filter paper
- (Flat edged) spatula
- (Flat edged) spoon
- (Flat) tray
- Measuring jug
- Reference collection
- Sampling apparatus (scoops and triers)
- Screens
- Vortex

#### **4. Working procedure**

Each lot must not exceed the maximum lot weight for that species. The maximum lot weight can be found in Table 2C (part 1, 2 or 3) of the ISTA-rules. If the seed lot exceeds the maximum lot weight, that seed lot must be divided into sub-lots of an appropriate size. Each sub-lot must be clearly defined and labelled uniquely (e.g. A and B).

#### **4.1 Sampling (to be linked with / taken up in the company instruction for sampling)**

##### **4.1.1. Sampling intensity:**

- For seed lots in containers or bags < 15 kg:

These containers or bags shall (unless the sampling intensity is more than prescribed by ISTA) be combined into sampling units not exceeding 100 kg. After the determination of the number of sampling units (by using the formula: *number of sampling units = number of containers x size of container / 100*), apply the sampling intensity as if it concerns containers of 15-100 kg.

- For containers 15-100 kg:
  - 1 -4 containers: min. 3 primary samples from each container
  - 5-8 containers: min.2 primary samples from each container
  - 9-15 containers: min.1 primary sample from each container
  - 16-30 containers: min.15 primary samples in total
  - 31-59 containers: min.20 primary samples in total
  - 60 or more containers: min. 30 primary samples in total
- For containers > 100 kg and < 20.000 kg:
  - Lot size up to 500 kg: at least 5 primary samples
  - Lot size 501-3.000 kg: one primary sample for each 300 kg (min. 5 samples)
  - Lot size 3.001-20.000 kg: one primary sample for each 500 kg (min. 10 samples)
- Lot size above 20.000 kg:
  - One primary sample for each 700 kg (min. 40 samples)

## **4.2 Separation**

- Make a working sample out of the submitted sample.

**Note:** If the submitted sample is going to be used entirely as a working sample, the sample size of the submitted sample must not exceed the required volume +10%. If the sample size of the submitted sample is bigger than the required volume +10%, the working method underneath has to be applied.

### **4.2.1 Seeds**

- The submitted sample and working sample have to be produced in accordance with ISTA Table 2C Part 1. Agricultural and vegetable seeds (column: minimum submitted sample and min. working sample: other seeds by number).
  - Determination of Soil use Minimum working sample Purity (g) (column Purity analysis, based upon 2.500 seeds);
  - Determination of Purity use Minimum working sample Purity (g) (column Purity analysis, based upon 2.500 seeds);
  - Determination of Ergot use Minimum working sample Purity (g) (column Purity analysis, based upon 2.500 seeds) and the all other seeds found in the determination of Other seeds by number;
  - Determination of other seeds use the Minimum working sample of other seeds by number (g) (column Other seeds by number, based upon 25.000 seeds).
- For the fruit crops where no weight is given in column 5 of ISTA Table 2C part 1 (e.g. *Cucumis sativus* L.), it is allowed to give a result of other seed determination within the NAL-Department of Agriculture, Fisheries and Forestry framework, if the test is carried out on a working sample with a size as indicated in column Purity analysis of ISTA table 2C part 1, based upon 2.500 seeds.
- Determine how to reduce the submitted sample to the appropriate working sample.
- Remove inert matter by sieving or by hand and set inert matter aside for determination

- (4.3).
- Check sample on presence of naked seeds of any species and set aside for other seed determination (4.3)

#### **4.2.2. For coated seed (excluding seed tapes and seed mats)**

- Submitted sample must contain 10.000 seeds for seed pellets or 25.000 seeds for encrusted seeds or seed granules (check this by TSW; Table 2D Part 1).
- Remove inert matter by sieving or by hand and set inert matter aside for determination (4.3).
- Check sample on presence of naked seeds of any species and set aside for other seed determination (4.3)
- Remove the enhancements.
- For pelleted seeds it is also allowed to conduct a test on the previous product form, the raw seeds batch. If this is the case, the following sentence must be placed under 'additional information' on the NAL Quality certificate:

*This consignment of ... kgs pelleted seeds with batch number [number], derives from raw seeds batch number [number]. The latter has been sampled and examined, which results can be found on this NAL Quality certificate under 'physical purity'.*

#### **Determination**

- Examine the working sample.
- Use a binocular for determination of other seeds using a reference collection or internet data bank.
- In case it is not possible to name a certain other seed, send the sample to a specialist for further examination.
- Divide the sample in fractions:

Pure seeds	Pure pellets
Other seeds	Unpelleted seeds
Inert matter	Inert matter

- Determine the weight of these fractions and indicate with the number of decimal places as stated below:

Weight of working sample or subsample (g)	Minimum number of decimal places
<1.000	4
1.000 – 9.999	3
10.00 – 99.99	2
100.0 – 999.9	1
≥ 1000	0

- Determine the identity of the pure seed (pure pellet), the other seeds (unpelleted seeds) and inert matter (work according ISTA-rules, chapters 3.5, 3.6 and 3.7).
- Make records of the findings:
  - Date of examination
  - Name of employee
  - The weight of the working sample
  - The weight of the three fractions found
  - The scientific name of the pure seed (pure pellet) fraction

- The scientific name on species level and number of seeds of each species found in the other seed fraction
- Description of inert matter
- Enter data in computer. Determine per species the number of other seed per kg of pure seed, the percentage of soil and inert matter as indicated in ISTA chapter 3.6.
- Enter data in computer. Determine per species the number of other seed per kg of pure seed, the percentage of soil and inert matter as indicated in ISTA chapter 3.6.

## 5. Issuing NAL Quality certificates

Prior issuing NAL Quality certificates: check the results of other seed determination and inert matter against the 'Department of Agriculture, Fisheries and Forestry Standards for Seed Contaminants and Tolerances'.

Use the following as references:

- Appendix 2: Assessing seed lot purity results for Australia
- Permitted seed for sowing BICON case:  
<https://bicon.agriculture.gov.au/BiconWeb4.0/ImportConditions/Questions/EvaluateCase?elementID=0000068166>
- Seed Contaminants and Tolerance tables:  
<http://www.agriculture.gov.au/import/goods/plant-products/seeds-for-sowing/contaminants-tolerance>
- BICON database: <https://bicon.agriculture.gov.au/BICONWeb4.0/>

The results must comply with these standards. If the seed lot does not comply, no NAL certificate for Australia can be issued.

## 6. References

- NAL-conditions (Naktuinbouw, Netherlands)
- ISTA International Rules for Seed Testing (ISTA, Switzerland)
- ISTA Handbook on seed sampling (ISTA, Switzerland)
- Reference collection of seeds
- Digital reference collection of seeds (<http://seeds.eldoc.ub.rug.nl/>)

## 7. History and revisions of the NAL – Department of Agriculture, Fisheries and Forestry Protocol

- 27-04-2011. Concept version 8: Based on ISTA rules for Seed testing, NAL Handbook and Department of Agriculture and Water Resources Standards for Seed Contaminants and Tolerances.
- 17-05-2011. Concept version 9: Brackets added for (Flat edged) spatula, (Flat edged) spoon, (Flat) tray.
- 27-07-2011. Version 1.0 - Concept version 9 converted to final version 1.0.
- 08-02-2012. Version 1.1 - At 4.2.1 Seeds, the first bullet is described in more detail.

- 09-02-2015. Version 1.2 - AQIS changed to Australian Government Department of Agriculture and Water Resources. Updated all Hyperlinks.

Added to 4.2.1. For the fruit crops where no weight is given in column 5 of ISTA Table 2A part I (e.g. *Cucumis sativus* L.), it is allowed to give a result of other seed determination within the NAL- Department of Agriculture and Water Resources framework, carried out on a working sample with the size as indicated in column 4 (purity analysis) of ISTA Table 2A part I.

Added to 4.2.2. For pelleted seeds it is also allowed to conduct a test on the previous product form, the raw seeds batch. If this is the case, the following sentence must be placed under 'additional information' on the NAL Quality certificate: This consignment of... kgs pelleted seeds with batch number [number], derives from raw seeds batch number [number]. The latter has been sampled and examined, which results can be found on this NAL Quality certificate under 'physical purity'
- 01-12-2022. Version 1.3 – Updated instances of ISTA table 2A to 2C, and 2B to 2D.

Updated Section 4.2.1 for fruit crops where no weight is listed in Table 2C to allow results for other seed determinations to be recorded if the test is carried out on a working sample with a size as indicated in column Purity analysis of ISTA table 2C part 1, based upon 2.500 seeds.



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graph TD
    Q1{Does the seed lot contain more than 0.14% soil?}
    A1[YES] --> R1[The seed lot does not meet Australian requirements. The seed lot needs cleaning to reduce soil contamination below 0.14%.]
    A1 -- NO --> Q2{Does the seed lot contain any sclerotia, ergot, smut or choke?}
    A2[YES] --> Q3{Is the contamination listed as non-actionable or permitted in the section 'Sclerotia, ergot, smut and choke' (including Table 3) of the Seed contaminants and tolerance tables and within the specified tolerances?}
    A2 -- NO --> Q4{Does the seed lot contain any animal material (e.g. faeces)?}
    A3[YES] --> Q3
    A3 -- NO --> Q5{Does the seed lot contain any contaminant seed?}
    A4[YES] --> Q6{Are all contaminant seeds listed in Table 1 of the Seed contaminants and tolerance tables and within the specified tolerances?}
    A4 -- NO --> Q7{Is the contaminant seed identified to species level?}
    A5[YES] --> Q8{Is the species listed on the BICON case 'Permitted seed for sowing'?}
    A5 -- NO --> Q9{Is the contaminant seed listed in BICON as not permitted entry. Or listed in Table 23 and being imported into a defined State listed as not permitted.}
    A6[YES] --> R2[The seed lot does not meet Australian requirements. The seed lot needs cleaning to remove contaminant seeds.]
    A6 -- NO --> Q10[Contact the department for advice. Email: imports@agriculture.gov.au Subject line: "Plant T2 – NAL Certificate Assessment"]
    R1 --> Q10
    R2 --> Q10
    Q10 --> Q3
    Q10 --> Q7
    Q10 --> Q9
    Q3 -- YES --> Q4
    Q3 -- NO --> Q10
    Q4 -- YES --> Q10
    Q4 -- NO --> Q5
    Q5 -- YES --> Q6
    Q5 -- NO --> R3([The seed lot meets Australian requirements])
    Q6 -- YES --> R3
    Q6 -- NO --> Q7
    Q7 -- YES --> Q8
    Q7 -- NO --> Q10
    Q8 -- YES --> R3
    Q8 -- NO --> Q9
    Q9 -- YES --> R2
    Q9 -- NO --> Q10
    
```

The flowchart outlines the process for assessing a seed lot against Australian requirements. It begins with a decision on soil content. If soil is above 0.14%, the lot fails. If not, it checks for sclerotia, ergot, smut, or choke. If present, it checks if they are non-actionable or permitted within tolerances. If not, it checks for animal material. If present, it checks if it's within tolerances. If not, it checks for any contaminant seeds. If present, it checks if all are within tolerances. If not, it checks if the contaminant is identified to species level. If not, it checks if the species is on the BICON 'Permitted seed for sowing' list. If not, it checks if the contaminant is listed in BICON as not permitted or in Table 2 and imported into a defined State listed as not permitted. If any of these checks fail, the lot fails and needs cleaning. If all checks pass, the lot meets Australian requirements.

<https://www.agriculture.gov.au/import/goods/plant-products/seeds-for-sowing/contaminants-tolerance>

<https://bicon.agriculture.gov.au/BiconWeb4.0/ImportConditions/Questions/EvaluateCase?elementID=0000068166>

NAL – Department of Agriculture, Fisheries and Forestry Agreement  
Version 6.0  
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**Overview of critical equipment (part 1) and critical products (part 2)**

Type of Process or Test		Critical equipment (13.4 and 13.5)	Remarks
<b>General</b>		Calibration instruments	
Sampling	Leaf and other plant material		
	Seeds		
Seed Analysis	Physical purity, Determination of other seeds	<ul style="list-style-type: none"> <li>• Balance</li> <li>• Vision equipment</li> </ul>	
	Thousand Seed Weight	<ul style="list-style-type: none"> <li>• Balance</li> <li>• Counting machine</li> </ul>	
	Moisture	<ul style="list-style-type: none"> <li>• Oven</li> <li>• Moisture device</li> <li>• Balance</li> </ul>	
	Germination	<ul style="list-style-type: none"> <li>• Equipment with temperature control</li> <li>• Vision equipment</li> </ul>	
	UPT	<ul style="list-style-type: none"> <li>• Equipment with temperature control (climate chamber)</li> <li>• Vision equipment</li> </ul>	
Seed, Plant and Soil Health	<b>Seed and Plant Health (General)</b>	<ul style="list-style-type: none"> <li>• Stomacher / bag mixer / genogrinder</li> <li>• Pipettes up to 5 ml</li> <li>• Pipetting robot</li> <li>• Balance and counter used for determining the number of seeds</li> <li>• All equipment with temperature control</li> <li>• All equipment with RH control</li> <li>• pH meter</li> </ul>	<ul style="list-style-type: none"> <li>• Only 13.4 for stomacher / bag mixer / genogrinder</li> <li>• pH meter can be calibrated with calibration fluid that is on the market, e.g. pH 4,01, pH 7,00 or pH 10,01. That what is on the market is okay and sufficient. Good practices are nevertheless important (e.g. preventing contamination of the calibration fluid by means of dirty sensors, storage in a dark place and application by proper temperatures)</li> </ul>
	Bacteria Plating	Balance for antibiotics	
	Bacteria PCR	<ul style="list-style-type: none"> <li>• DNA extraction platform</li> <li>• PCR device</li> </ul>	<ul style="list-style-type: none"> <li>• PCR device: calibration by an appropriate calibration service (like CYCLERtest or instrument performance verification), which enables laboratories to assure its thermocyclers to perform according to specifications</li> </ul>
	Bacteria Grow-out		
	Virus ELISA	<ul style="list-style-type: none"> <li>• Plate washer</li> <li>• ELISA reader</li> </ul>	<ul style="list-style-type: none"> <li>• Only 13.4 for plate washer</li> </ul>
	Virus Bio-assay		
	Virus PCR	<ul style="list-style-type: none"> <li>• RNA extraction platform</li> <li>• PCR device</li> </ul>	

	Fungi Agar	Incubator	
	Fungi Blotter	Incubator	
	Fungi Grow-out		
Genetic Tests	Genetic purity/true-to-type	<ul style="list-style-type: none"> <li>• PCR device</li> <li>• Flow cytometer</li> </ul>	

Type of Process or Test		Critical Products (14.2)	Remarks
Sampling	Leaf and other plant material		
	Seeds		
Seed Analysis	Physical purity, Determination of other seeds		
	Thousand Seed Weight		
	Moisture	Sample bags	
	Germination	Paper, sand, organic substrate	unless controls are included
	UPT	Organic substrate, rock wool	unless controls are included
Seed, Plant and Soil Health	<b>Seed and Plant Health (General)</b>	Controls	
	Bacteria Plating	Media	
	Bacteria Grow-Out		
	Bacteria PCR	<ul style="list-style-type: none"> <li>• Mastermix</li> <li>• Primers, probes</li> </ul>	
	Virus ELISA	<ul style="list-style-type: none"> <li>• Antisera</li> <li>• ELISA plates</li> </ul>	
	Virus Bio-assay	Test plants	
	Virus PCR	<ul style="list-style-type: none"> <li>• Mastermix</li> <li>• Primers, probes</li> </ul>	
	Fungi Agar	Media	
	Fungi Blotter	Blotter paper	
	Fungi Grow-Out		
Genetic Tests	Genetic purity/true-to-type		