NAFI naktuinbouw

NAFI Conditions 2025

for the monitoring of seed production

Naktuinbouw - Quality in Horticulture

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Introduction

It is intended that Naktuinbouw Authorized Field Inspection (**NAFI**) will become a voluntary module under the **Verification Program (VP)** of Naktuinbouw, a verification program for seed production and market access. This alongside other modules, like Naktuinbouw Authorized Laboratories (**NAL**). It will be monitored by or on behalf of Bureau Authorizations. The standard is developed by the participants in conjunction with Naktuinbouw. From 2017 onwards, it is possible to participate officially. The participants in conjunction with Naktuinbouw will evaluate this module, and ensure that the standard will be adapted when necessary.

Why NAFI?

1. It is in the participants' interest to ensure that monitoring of seed production is state-of-the-art and associated reports will give reliable information, reflecting the true quality of the production. This will make a contribution towards ensuring seed contaminated with a non desired pathogen is prevented from being shipped.
2. It must become a system where Naktuinbouw can rely upon results concerning official inspection, therefore we will begin in the Netherlands. This fits with the philosophy of Naktuinbouw, whereby companies are competent in this matter.
3. It must become a system for market access, where also the Dutch National Plant Protection Organization (**NPPO**), the NVWA, can rely upon results (e.g. regarding issuing phytosanitary certificates).
4. We are aiming to make it global, making it possible to authorise foreign productions as well. Therefore it must become a secure system, with the appropriate checks and balances, in which it is demonstrated that it is justified to have confidence in it. When this is a fact, we will begin to gain acceptance of the standard (in the following order): Naktuinbouw, NVWA and other NPPOs.

For who is NAFI?

For the moment NAFI will be the exclusive domain of seed companies: companies with production and marketing of seeds from their varieties as core business. In the future it may become open for and extended to other branches (e.g. arboriculture, plant nurseries, etc.).

Companies can become authorized when they comply (according to authorization regulations) with the NAFI Conditions:2025:

- Naktuinbouw module quality management system requirements **and**
- Naktuinbouw module authorized field inspection

The NAFI Conditions:2025 are based upon for this purpose relevant requirements from:

- Algemene voorwaarden voor de teelt van in voorkoop gekochte zaaizaden (ATV):2002 (General conditions for seed production), Plantum NL
- The Netherlands Seeds and Planting Materials Act:2005 (covering all relevant EU-regulations, like 2000/29/EU, 2002/55/EU and 2004/117/EU)
- Voorschriften voor de verhandeling van teeltmateriaal van bloemisterij-, boomkwekerij- en groentegewassen:2008 (Regulations for negotiation of propagation material), Naktuinbouw NL
- Inspection Regulations:2018, Naktuinbouw NL
- NEN-EN-ISO 9001:2015
- OECD Seed schemes:2021
- Official Controls Regulation 2017/625/EU
- Plant Health Regulation 2016/2031/EU

The NAFI authorization of a company will be demonstrated through the NAFI-certificate, stating for which scope the authorization has been granted. This will be displayed on the website of Naktuinbouw.
The NAFI-authorized company can only bring crops under the scope that are under the supervision of Naktuinbouw inspections in the Netherlands[1]. For other crops, it is not allowed to make any reference to NAFI and / or authorization by Bureau Authorizations then.

Determined by the Board of Naktuinbouw
Roelofarendsveen, 13 December 2024

[1] See 'Regeling verhandeling teeltmateriaal'

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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 Not applicable for NAFI

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

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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 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

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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 assess non conformities
- 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 non-conformity established during internal and external audits, there must be drawn up a CAR (see 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 10)

10. Corrective (and / or Preventive) Action Requests (CARs)

10.1 The participant must deal with CARs adequately
10.2 This paragraph 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
11.7 The participant must present an overview of results / process performance / product conformity to the Bureau Authorizations on request

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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, means, devices and reference materials

13.1 The participant must be equipped with (or have access to) appropriate equipment, means, devices and reference materials, required / necessary where and when needed

13.2 The participant must identify and keep a log of all equipment, means, devices and reference materials 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, means, devices and / or reference material 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 10)

13.4 The participant must (where relevant) for this equipment, means, devices and / or reference materials (in relation to intended use) ensure / manage / make demonstrable:

- Acceptance / release, based on tests. Before the test can be started, criteria must be set, dealing with the allowed tolerance
- Appropriate use
- Maintenance and inspection
- 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
- Storage
- Appropriate disposal, to protect the participant's integrity / the environment

13.5 The participant must (where relevant) for these devices determine how and to ensure / manage / make demonstrable:

- Monitoring indicated values (in relation to critical control points)
- Calibration of the device:
  - At by the participant prescribed intervals
  - If the device is out of spec:
    - 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 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.

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- 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)
  - The requirement above is not applicable for the following devices:
    - The pH-meter, in case the device is calibrated by using calibration fluid, 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)
    - (Real-Time) PCR instruments, in case the apparatus is calibrated through an appropriate calibration service (like CYCLERtest or instrument performance verification), which enables laboratories to assure its thermocyclers to perform according to specifications
  - Good practices mus 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 the products and / or service meet the requirements. Before the test can be started, criteria must be set, dealing with the allowed tolerance
- Define the type and degree of inspection of the product; 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

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15. Risk assessment seed production process

15.1 The participant must define the seed production process in a process flow

15.2 The participant must ensure that the seed production process (alterations must follow the same process) is reviewed and controlled by a multidisciplinary team (only relating to the scope, e.g.: QA function / seed production experience / pathologist / breeder):

15.2.1 Identify possible hazards in relation to the scope

15.2.2 Analyze all identified hazards (for cause + probability + possible impact), in order to determine if a hazard poses a risk.

15.2.3 If a hazard poses a risk, it must be determined if control measures are necessary. It can be that control measures are not necessary, because a process step later in the process does eliminate or mitigate the risk well enough. When control measures are necessary (to eliminate or mitigate the risk), the participant must determine:

- If present control measures are sufficient
- If present control measures need to be adapted
- If new control measures need to be developed

15.3 The participant must determine whether a control measure needs to be monitored (and how)

16. Field inspector

16.1 The field inspector must be competent and familiar with general principles of biology, plant and seed physiology, genetics and propagation / seed production

16.2 The field inspector must:

16.2.1 Have been trained at an approved institute:

16.2.1.1 Naktuinbouw

16.2.1.2 Other institutes / companies that are demonstrably approved by Bureau Authorizations

16.2.2 And have obtained knowledge of and access to information(-systems) regarding:

16.2.2.1 Relevant procedures / instructions

16.2.2.2 Monitoring techniques

16.2.2.3 Hygiene aspects

16.2.2.4 Reporting

16.2.2.5 And concerning the scope:

- Varietal identity / true to type

16.3 The field inspector must be trained / have knowledge of / access to information (systems) regarding issues as (only relating to the scope):

16.3.1 Varietal identity / true to type:

- UPOV test guidelines (http://www.upov.int/test_guidelines/en/)
- Descriptions of varieties / parental lines (and which mother line A + father line B will produce hybrid C)

16.3.2 Varietal purity:

- Company standards
- Degeneration / off-types

16.3.3 Physical purity:

- Company standards
- Weeds (features, noxious or not, whether it is hard to clean out or not)

16.3.4 Plant health:

- Company standards
- Appearance of diseases / pathogens / pests
- Diagnosis / deduction methods

16.4 The field inspector must have practical experience in field inspection

16.5 The field inspector must have been appointed as field inspector (and it must be indicated for which crops)

16.6 The field inspector must maintain expertise and attend an internal harmonization meeting or refresher course annually

16.7 The field inspector must be witnessed by a colleague field inspector at least one day biennially; as an equivalent an internal ringtest is possible (where several inspectors inspect the same plot and draw conclusions, where these / results are compared and discussed afterwards

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16.8 The field inspector must participate in a proficiency test, when organized by Bureau Authorizations and where appropriate (appointment / crop)

16.9 The field inspector can be assisted by a trainee, as long as the trainee is working under his / her supervision on the job

17. Field inspection

17.1 The participant must determine method / frequency / stage(s) of inspection:

17.1.1 E.g. based upon the outcome of 15.2)

17.1.2 At least an inspection at the end of production, which will cover the entire production as much as possible

17.1.3 Which option is chosen for plant health:

1. Production healthy, except for what is perceived/observed or
2. Production healthy, except for what is excluded on beforehand or
3. Production healthy, regarding a predetermined selection.

17.2 A control measure as result of a field inspection (cleaning or mitigation) must always be followed by a field inspection to check the result of this

17.3 The inspector must check / compare the assignment with what he observes in the field

17.4 The participant must have an appropriate administration, indicating or making a reference to the following information:

17.4.1 The assignment and identification (e.g. plot code, crop, variety) of the production

17.4.2 The address or co-ordinates of the production location

17.4.3 The plot size (it must be indicated which metric system is applied)

17.4.4 The observations of the inspector must be recorded, e.g. (only relating to the scope + general):

17.4.4.1 General

- Expected yield in relation to the forecast
- Whether the necessary control measures have been carried out
- The name or initials of the field inspector
- The date(s) of field inspection and stage(s) of the crop (e.g. started flowering, around harvest 31st cluster, etc.)
- Possible irregularities / remarks; these must be brought to the attention of a function which is appointed to manage / correct such irregularities; it must be demonstrable who is informed about these, when and what the follow up is on these

17.4.4.2 Varietal identity / true to type

- Whether the production (or parental lines) can be regarded to be true to type (because it meets the descriptions) or not

17.4.4.3 Varietal purity

- Uniformity of the production / parental lines (indicated in percentage or description)
- Whether the company standard is met or not
- For hybrids: ratio female / male parent lines and whether female flowering is sufficiently overlapped by male flowering or not
- Whether the distance / separation to neighboring productions / relevant crops / weeds (e.g. in verge) is sufficient, in order to avoid undesired cross pollination or mixture (harvest!)

17.4.4.4 Physical purity

- Occurrence of weeds (percentage, degree, center, etc.) and whether (according pest management plan):
  - It is possible to clean or not
  - There is a need to clean
  - It is possible to separate a contaminated / deviating part from the healthy rest (to be clearly defined in the field, plus drawing or picture)
  - There was a need to bring the occurrence to the attention of the NPPO
- Whether the company standard has been met or not
- Whether samples have been taken for verification at a (diagnostic) lab or that an expert visit has taken place (and the result of that)

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17.4.4.5 Plant health

- Occurrence of diseases / pathogens / pests (percentage, degree, center, etc.) and whether (according pest management plan):
  - It is possible to clean or not
  - It is possible to separate a contaminated / deviating part from the healthy rest (to be clearly defined in the field, plus drawing or picture)
  - The whole production must be regarded as lost
  - The occurrence is brought to the attention of the NPPO
- Whether the company standard has been met or not
- Whether samples have been taken for verification at a (diagnostic) lab or that an expert visit has taken place (and the result of that)

17.5 Final conclusion regarding inspection

17.5.1 The participant must determine the final conclusion, considering:

- The (various) inspection result(s)
- Whether control measures as cleaning or mitigation were sufficient, as determined in a field inspection afterwards (note: not meant here are control measures that are taken afterwards, e.g. by means of processing, treatment or laboratory testing)
- Whether or not the final result can be determined, even in cases where not every inspection (as intended) has taken place

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MISCELLANEOUS

18. Revision history (NAFI Conditions 2025 compared to NAFI Conditions 2024)

We made the following changes through the document:

Introduction
Reference to Appendix I deleted. Added ‘regeling verhandeling teeltmateriaal’

2.1
Added: where

4.3 split in 4.3.1 and 4.3.2
4.4 split in 4.4.1 and 4.4.2

7.2
For at least 7 years changed in: 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

10.3
Added: and the impact

13.4, 13.5 and 13.6
Deleted, added and replaced some text. Most important elements:
- Added to Acceptance / release: …based on tests. Before the test can be started, criteria must be set, dealing with the allowed tolerance
- Added to draw up a CAR: …in the period until the previous calibration
- Added to calibration by an accredited subcontractor: In case a very high accuracy of the device is needed, the participant should ensure itself that the subcontractor uses sufficiently accurate calibration instruments.
- Deviation of the calibration instrument must be max 10% of the tolerances as determined for the device that needs to be calibrated: only for non-accredited subcontractors or internal checks

14.2 and 14.3
Replaced some text from 14.2 to 14.3 and vice versa.
14.2 bullet 2 added ‘Before the test can be started, criteria must be set, dealing with the allowed tolerance

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