



DRAFT Checklist ESTA Standard

Quality Assurance System for Seed Treatment and Treated Seed

This guideline is designed for auditors to help them while auditing seed plants to the ESTA standard. The goal of this standard is to provide a quality assurance system to assure that seed treatments and the resulting treated seed meet requirements defined by legislators and industry.

This audit guide is designed to provide guidance and themes for each step of the process to be audited as well as key points to check.

Effective standard

Audits shall be conducted under
ESTA STANDARD version 1.2, published May 4, 2012 by European Seed Association

European Seed Treatment Assurance
Quality Assurance System for Seed Treatment and Treated Seed

Auditor

☐ **Name of auditor :**

☐ **Name of second auditor (if applicable) :**
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Company

☐ **Name of the company :**

☐ **Name of the person of the company in charge of ESTA standard implementation :**
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☐ **Name of the audited seed treatment plant :**
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☐ **Address of the audited seed treatment plant :**
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Scope of certification :

Species under the scope (tick one or more boxes):

- | | |
|---|---|
| <input type="checkbox"/> Maize (<i>Zea mays</i> L.) | <input type="checkbox"/> Carrot (<i>Daucus carota</i>) |
| <input type="checkbox"/> Sunflower (<i>Helianthus annuus</i>) | <input type="checkbox"/> Pea (<i>Pisum sativum</i>) |
| <input type="checkbox"/> Allium spp. (<i>Allium Cepa</i>, <i>Allium porrum</i>) | <input type="checkbox"/> Others: |
| <input type="checkbox"/> Bean (<i>Phaseolus vulgaris</i>) | |
| <input type="checkbox"/> Brassica spp. (<i>Brassica napus</i>, <i>Brassica rapa</i>,
<i>Brassica oleacea</i>, <i>Brassica nigra</i>) | |
| <input type="checkbox"/> Grain cereals | |
| <input type="checkbox"/> Chicory (<i>Cichorium intybus</i>) | |



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- ☐ Beet (Beta vulgaris)

Date of audit:

- ☐ Date of current audit:
- ☐ Date of previous audit (if relevant):

ISSUES FOR DISCUSSION BY PROCESS STEP AND KEY POINTS TO CHECK

General Guidance

When the term "legal requirements" is written, it should be understood as legal requirements in the country of production.

General Framework :

Section 4 of ESTA Standard

1. Management representative

Compliance criterion:

A management representative shall be responsible for the activities necessary to fulfil the requirements of this standard and for reporting to top management on performance of the quality assurance system and on possible improvements.

Guidance for this criterion

A quality manager on the seed treatment plant (on site or within the company) is considered as a management representative.

N.B.: This point may be covered by a certification ISO 9001: 2008, (point 5.5.2)

Auditor judgement:

- ☐ CONFORM ☐ NON CONFORM

Auditor remarks :

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2. Continual improvement

2.1 Continual improvement system:



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Compliance criterion:

Organizations must have a system in place for continual improvement.

🔗 Guidance for this criterion

The standard (§ 4) requires that organizations “shall establish and continually improve a QA system that meets the requirements of this standard and requirements imposed by legislators and industry. Top management has to commit itself to implementation and continual improvement of the QA system.” Individual components of the continual improvement toolbox can be non-conform or absent, *but the continual improvement as a whole must be functioning*. The annual review to evaluate functioning of the QA system plus actions to improve the system is mandatory. Active involvement of management in the review is required.

Four key procedures linked to continual improvement (standard § 5) must be present and their proper use can be audited. Also the risk analysis and an actual or updated action plan is mandatory (standard § 6).

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.2 measurements of critical process parameters:

Compliance criterion:

*This continual improvement system may have the following inputs:
(i) measurements of critical process parameters;*

🔗 Guidance for this criterion

Regarding to the use of the auxiliary “may”, if the criterion is not fulfilled, the auditor judgement on the conformity will not challenge certification but will only lead to a remark.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.3 periodical customer satisfaction reviews:

Compliance criterion:

*This continual improvement system may have the following inputs:
(ii) periodical customer satisfaction reviews;*



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🔗 Guidance for this criterion

Regarding to the use of the auxiliary “may”, if the criterion is not fulfilled, the auditor judgement on the conformity will not challenge certification but will only lead to a remark.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.4 registration, analysis and mitigation of customer complaints:

Compliance criterion:

This continual improvement system may have the following inputs:

(iii) registration, analysis and mitigation of customer complaints;

🔗 Guidance for this criterion

Regarding to the use of the auxiliary “may”, if the criterion is not fulfilled, the auditor judgement on the conformity will not challenge certification but will only lead to a remark.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.5 registration, analysis and mitigation of internal complaints, errors and non conformities:

Compliance criterion:

This continual improvement system may have the following inputs:

(iv) registration, analysis and mitigation of internal complaints, errors and non conformities

🔗 Guidance for this criterion

As this criterion is also stated in Chapter 5 of the ESTA standard, and even if the auxiliary “may” is used, the criterion has to be fulfilled.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:



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☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.6 registration, analysis and mitigation of internal complaints, errors and non conformities:

Compliance criterion:

This continual improvement system may have the following inputs:

(v) corrective and preventive measures insofar these are not dealt with in the points i to iv

🔗 Guidance for this criterion

Regarding to the use of the auxiliary “may”, if the criterion is not fulfilled, the auditor judgement on the conformity will not challenge certification but will only lead to a remark.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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2.7 review of the risk:

Compliance criterion:

This continual improvement system may have the following inputs:

(vi) review of the risk analysis

🔗 Guidance for this criterion

As this criterion is also stated in Chapter 5 of the ESTA standard, and even if the auxiliary “may” is used, the criterion has to be fulfilled.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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3. Review of Quality Assurance system



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Compliance criterion:

A review shall be performed at least annually to evaluate functioning of the QA system. Actions to improve the system shall be formulated and carried out. This review is part of the continual improvement system. Active involvement of management is required.

🔗 Guidance for this criterion

This can be an internal review.

NB. This point may be covered by a certification ISO 9001: 2008, (point 5.6)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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4. Process for waste disposal

Compliance criterion:

Companies must have a process for waste disposal that meets legal requirements, is in line with Good Agricultural Practices (GAP), and meets expectations on sustainability / sustainable business conduct.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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5. Control of documents

Compliance criterion:

Documents required by this standard shall be controlled. This means that approved versions are accessible to users.

🔗 Guidance for this criterion

NB. This point may be covered by a certification ISO 9001: 2008, (points 4.2.3 and 4.2.4)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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6. Records for tracking and tracing

Compliance criterion:

Companies must keep records to allow for full tracking and tracing of all incoming, stored and outgoing products.

Guidance for this criterion

“Products” are seed treatment chemicals, seeds and treated seeds.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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7. Definition of responsibilities

Compliance criterion:

Responsibilities in the company have to be defined.

Guidance for this criterion

Responsibilities have to be defined at least for the seed treatment facility and its management.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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8. Process to recall nonconforming products

Compliance criterion:

Companies must have a process to recall nonconforming products.

Guidance for this criterion

A non conforming product is a product (chemical, seed and treated seed) that doesn't meet legal or customer requirements (including, for treated seed, the requirement for dust levels below the industry reference values as set in the table industry dust reference values.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.3)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM



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Auditor remarks :

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9. Process to handle/rework nonconforming products

Compliance criterion:

Organizations shall have a process to handle/rework nonconforming products.

🔗 Guidance for this criterion

A non conforming product is a product (chemical, seed and treated seed) that doesn't meet legal or customer requirements (including, for treated seed, the requirement for dust levels below the industry reference values as set in the table industry dust reference values.

NB. This point may be covered by a certification ISO 9001: 2008, (point 8.3)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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Process description and risk analysis :

Section 6 of ESTA Standard

10. Process description

Compliance criterion:

To achieve reliable process control the processes and their relations should be described.

🔗 Guidance for this criterion

NB. This point may be covered by a certification ISO 9001: 2008, (point 4.1)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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11. Definition of measurements



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Compliance criterion:

(Process) Measurements to assure process and product quality have to be defined.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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12. Risk analysis

Compliance criterion:

Companies must maintain a risk analysis of their primary process. Risks that would potentially lead to non-conforming product, incidents and/or environmental damage caused by the primary process in the treatment plant should be adequately addressed. The interfaces with other parts of the seed treatment chain must be addressed. The risk analysis shall be periodically reviewed as part of the continual improvement system; an actual or updated action plan is mandatory.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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Proven competence of personnel :

Section 7 of ESTA Standard

13. Competence of personnel

13.1 Training of employees

Compliance criterion:

Employees shall be properly trained to perform their tasks, recognize deviations and work safely.

➤ Guidance for this criterion

Training can consist of combinations of formal education (school/college), technical courses (in house or external), on the job training and refresher courses. For specific tasks legal requirements may exist and must be met (for instance for driving forklifts or handling hazardous chemicals).

NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2)

Auditor judgement:



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☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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13.2 Records of competence

Compliance criterion:

The organization must keep records to prove that individual employees (including temporary staff) have and maintain the required level of competence. The organization should monitor that employees timely attend refresher courses and take action to avoid that necessary diplomas or certificates expire.

Guidance for this criterion

To assure that individual employees do have and maintain the required level of competence it is strongly advised that relevant training and retraining is performed periodically for all personnel (including temporary staff).

The lack of monitoring can only lead to a remark on certification and not a non conformity challenging certification.

NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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13.3 Adequate knowledge of the identified risk factors

Compliance criterion:

All personnel, including temporary work staff, demonstrate adequate knowledge of the identified risk factors related to their specific area of responsibilities and actively and consistently implement good practice behaviour in their work.

Guidance for this criterion

NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2)

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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Specific requirements for seed / seed treatment companies :

Section 8 of ESTA Standard

14. Crop-specific criterion

Compliance criterion:

Seed to be treated shall meet crop-specific criteria on moisture and cleanliness (dust levels, presence of broken/damaged seeds and other materials like chaff, other seeds, sclerotia, inert material).

Guidance for this criterion

Crop-specific criteria are defined by the company. Control of the quality of input products is a vital element of process control.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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15. Proven stability/reliability of the seed treatment process

Compliance criterion:

The seed treatment process, including the recipes used to prepare the seed treatment and the equipment used, must have a proven stability/reliability.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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16. Availability of documentation on seed treatment products

Compliance criterion:

Material safety data sheets (MSDSs) and further documentation relevant for correct and safe use (and disposal if relevant) of the seed treatment products must be available on site.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM



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Auditor remarks :

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17. Monitoring of the seed treatment process

Compliance criterion:

The seed treatment process has to be monitored, for instance by visual inspection of the seed lots before and after treatment.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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18. Aspiration system

Compliance criterion:

An aspiration system should be used for the seed treatment process and following steps till packaging of the treated seed.

Guidance for this criterion

The lack of an aspiration system can only lead to a remark on certification and not a non conformity challenging certification (use of the term “should be” in the standard), unless worker safety is compromised.

In § 1.1 of the standard it is stated that the QA system is to ensure safety and that safety comprises workers/human safety and environmental safety. In the guidance to § 4 it is mentioned that the standard does not prescribe in detail how to assure (worker) safety - but it needs to be OK. Therefore, if the lack of a functioning aspiration system would lead to worker safety concerns a non-conformity has to lead to a corrective action.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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19. Reference samples

Compliance criterion:

Reference samples of each treated seed lot shall be taken and safely stored. Sample sizes, storage conditions and minimum periods of storage have to be defined.



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Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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20. Control plan

Compliance criterion:

Samples shall be tested, at least on dust levels with the standard Heubach test, according to a defined scheme.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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21. Records on the used amounts of treatment materials

Compliance criterion:

Records allowing for a plausibility check have to be kept on the used amounts of treatments materials per seed lot.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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22. Waste handling and disposal

Compliance criterion:

Adequate measures are to be in place for waste handling and disposal.

Guidance for this criterion

It has to meet at least legal requirements, must be in line with Good Agricultural Practices (GAP) and meets expectations on sustainability / sustainable business conduct (§ 4 of the standard).



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Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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23. Labelling of the treated seed

Compliance criterion:

Treated seed has to be labelled according to legal labelling requirements and provisions of the registration of the plant protection product.

Guidance for this criterion

It is recommended to also label according to industry standards, see <http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance>.

Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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24. Information on handling of treated seeds

Compliance criterion:

Treated seed is sensitive to environmental influences. Therefore, the transport companies have to be made aware that great care must be taken to avoid any extreme handling. Treated seed needs care till the crop has established itself. Farmers have to be made aware of the importance of proper handling.

Guidance for this criterion

It can be covered by a label or on a separate leaflet.


Auditor judgement:

☐ CONFORM

☐ NON CONFORM

Auditor remarks :

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Technical Standards for seed treatment and treated seed :

Section 9 of ESTA Standard

25. Reference test method in laboratory

Compliance criterion:
The accuracy, reproducibility, precision, robustness, and general reliability of reference methods must be beyond doubt. Use of the dust test by industry laboratories asks for monitoring of the performance of the laboratory. This can be done through participation in a comparative test program.

Auditor judgement:

☐ CONFORM ☐ NON CONFORM

Auditor remarks :

SYNTHESIS

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AUDITOR GENERAL JUDGEMENT

☐ CONFORM ☐ NON CONFORM



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Date:

Signature: