



## ESTA governance

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

Version 2.2

#### Contents

On the scope and purpose of this Quality Assurance system.....	1
Legislation .....	1
Governance aspects covered in annexes to the standard .....	2
ESTA Standard Annex 2: ESTA: controlled use of name and logo; governance .....	2
ESTA Standard Annex 3: Requirements for certifying bodies.....	2
ESTA Standard Annex 4: Use and interpretation of the standard .....	2
ESTA Standard Annex 5: Complaints and appeals handling .....	2
ESTA Standard Annex 6: Suspension/ Withdrawal of certificate.....	2
ESTA Standard Paragraph 9: Technical standards for seed treatment and treated seed- Ring Test: Laboratory proficiency assessment .....	4
ESTA Board .....	5
ESTA Manager .....	6
ESTA governance (graphical).....	6
ESTA Review Committee (RC) .....	7
ESTA Stakeholder Meeting.....	7
On the link with national quality assurance schemes.....	7
Control of ESTA and certified companies .....	8
Audit check for treated seeds packed or re-packed at another treatment site.....	8
First use of the ESTA logo on packaged seed.....	8
Certifying bodies .....	9
Registers of certifying bodies and certified companies.....	9

This document is to summarize and clarify aspects of ESTA governance.

#### On the scope and purpose of this Quality Assurance system

ESTA provides a framework for good practices to prepare and apply seed treatments that *include crop protection agents*, till and including the intended use of the treated seed (drilling – sowing – planting). ESTA is restricted to those seed treatments that provide crop protection after drilling, sowing or planting through the crop protection agents on the seed.

It is the ambition of ESA that ESTA will be the general quality assurance system that supports unrestricted flow of (treated) seed within all EU Member countries.

#### Legislation

The EU Directive 2010/21/EU amends Annex I of the Directive 91/414/EEC with specific provisions on clothianidin, thiamethoxam, imidacloprid and fipronil.

Key statements are:



- The seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimized,
- Adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimization of spillage and minimization of dust emission.

Only this seed treatment specific EU Directive is cited here as it impacts the scope, purpose and use of the ESTA standard. Obviously more European legislation exists, especially on worker and environmental safety.

### **Governance aspects covered in annexes to the standard**

#### ***ESTA Standard Annex 2: ESTA: controlled use of name and logo; governance***

On controlled use, ownership and copyright of the name ESTA and the ESTA logo

On governance and use of ESTA

For the ESTA Board and all governance topics reference is made to this ESTA governance document.

#### ***ESTA Standard Annex 3: Requirements for certifying bodies***

Certifying bodies must meet the following requirements:

- be an accredited certifying body accredited or accepted by the competent national accreditation services of its registered offices
- be accredited to ISO/IEC 17065,
- have proven experience in the field of agriculture, forestry and fishing, group 01.01, 01.02, 01.61 as defined in NACE Rev. 2 – Statistical classification of economic activities in the European Community. 2008. European Commission.

If the accreditation of a certifying body is withdrawn the ESTA Board must promptly be informed; the right to certify to the ESTA standard will be suspended.

#### ***ESTA Standard Annex 4: Use and interpretation of the standard***

The certificate shall be valid for three (3) years after the day it will be issued. The day of issuance of the certificate is called the 'birthday of the certificate'. Within the period of the three years, at least three (3) audits shall take place (one initial plus 2 annual verification audits). The first annual verification audit can be scheduled six (6) months at the earliest and 18 months at the latest after the birthday of the certificate. The second annual verification audit can be scheduled as of 90 days prior to the expiration of the certificate.

In case the certificate is issued for the first time the first (1<sup>st</sup>) audit takes place before the certificate is issued

#### ***ESTA Standard Annex 5: Complaints and appeals handling***

Complaints from ESTA participants (auditees) on audit results or the certification scheme go to the certifying body. Escalation would be to the national accreditation authority or the Agent. In the last instance escalation is to the ESTA Board, which represents ESA, the owner of ESTA.

#### ***ESTA Standard Annex 6: Suspension/ Withdrawal of certificate***

The certificate shall be issued within four (4) weeks after the audit. Only exceptionally the issue of the certificate could be longer than four (4) weeks. The exceptions should be documented by the certifying body.

The suspension and withdrawal conditions depend on the fulfillment of the ESTA checklist criteria.



### ***ESTA Checklist: classification of criteria***

The ESTA criteria are classified as follows:

**Critical criterion:** a critical criterion is a criterion that is significant within the ESTA scheme. A non-conformity for this criterion would be critical for scheme compliance

**Major criterion:** a major criterion is a criterion that, in case not fulfilled, it will not jeopardize the system and the compliance against the ESTA Standard

**Minor criterion:** a minor criterion can be understood as recommendations for product and process improvement

The non-fulfillment of a critical/ major/ minor criterion leads to a critical/ major/ minor non-fulfillment.

The certifying bodies may comment which elements of the criterion need continuous improvement and they will be checked at the next audit.

The certifying bodies have the right to stop the certification if they consider that the treatment site abuses the principles of the scheme.

### ***Time slots for the closure of the corrective action requests (CARs)/ Certificate suspension-withdrawal conditions***

In case of non-conformity of a:

- **critical criterion:** In case of non-conformity of a critical criterion the certificate is suspended after the finding until corrective actions will be put in place. The treatment site has 30 days at maximum to put in place corrective actions. If no corrective actions have been put in place within 30 days, the certificate is withdrawn or not delivered.

Special derogation for the non-conformity of critical criteria: additional time may be given to solve the non-conformity of a critical criterion. In this case the certifying bodies will justify the reasons to the Agent/ ESA. The decision for the additional time to solve the non-conformity will be given with the consent of the Agent/ ESA.

- **major criterion**

- the site has 30 days to inform the certifying body which measure it will put in place to solve the non-conformity of a major criterion, otherwise the consequences are the same as for the non-fulfillment of a critical criterion. In this case apply the conditions described above.
- the site needs to clarify when they will put in place corrective actions to solve the non-conformity. The time for the non-conformity to be solved cannot be longer than 30 days after the site informs the certifying body
- following the above mentioned the site has 60 calendar days to inform and put in place the measures to solve the non-conformity
- Even without a certifying body notification the major criterion becomes critical. This means that the ESTA certified site has 60 days between the first notification and the suspension of the certificate.



- **minor criterion:** A minor non-conformity has to be solved by documents or at least on site by the next audit. If the non-conformity of a minor criterion will not be solved by the next audit then the criterion will become major.

Certificate **withdrawal:** the treatment site has to put in place corrective measures within the agreed and above described timelines after the certificate suspension. If not, the certification is withdrawn.

***ESTA Standard Paragraph 9: Technical standards for seed treatment and treated seed- Ring Test: Laboratory proficiency assessment***

In order for a laboratory to be a successful participant in a ring test, each individual result  $x_i$  shall have  $z_i$  score between  $\pm 2$  (z score used for proficiency assessment according to NF EN ISO 17043 and NF ISO 13528).

The full results of the laboratory should be compatible with a normal distribution. The number of  $z_i$  scores  $< \pm 2$  should exceed  $\left( 0.95 - 2.58 \sqrt{\frac{0.95(1-0.95)}{n}} \right) * n$  where  $n$  is the number of samples used in the ring test ( $n > 12$ ). This limit is defined for a confidence level of 99%.

Only the laboratories that are accredited by their national accreditation body for the Heubach dust analysis according to the ESA reference method can provide each participating laboratory with a report. The latter will include the participant's personal code and the anonymous results of all other participants.

The accredited laboratory will send each participant a yearly conformity certificate based on the rules mentioned above.

A laboratory is stated non-conform if the number of results observed is  $<$  critical threshold. (For example, the FNPSMS/GERM-Services ring-test includes 20 samples. It is stated non-conform if more than 4 (Z-Scores) are  $< -3$  or  $> 3$ ).

A laboratory can be disqualified even if it passed the previous ring test and during the participating of the current ring test the number of outlier values is higher than the number of values allowed  $< -3$  or  $> 3$  for the whole ring test, to conclude indeed that it will be non-conform.

If a laboratory starts participating on an ongoing ring test, it can be stated as conform only if it obtains at least 16/20 values between  $-3$  to  $3$ .

When a laboratory is declared non-conform, it receives a red card. In the event of a **red card**:

- The authorization for the concerning laboratory will be withdrawn temporarily
- The laboratory will not be allowed to perform Heubach analysis until it will get back to the system
- The laboratory shall inform the seed treatment company about the above mentioned immediately. Therefore, ESTA will provide a proposal for a draft 'order' concerning Heubach testing which can be used by a treatment site to assure that a lab informs as soon as possible the treatment site about a red card
- All results prior to the issue of the red card are considered valid



- Implementing immediately corrective actions, with the support of accredited laboratory, to return as quickly as possible to compliance and in the meantime subcontract analyses

The reference laboratory can issue a **yellow card** in case it considers it to be necessary to warn the laboratory that it is not performing adequately. In the event of a yellow card:

- The laboratory is still allowed to perform the Heubach analysis
- The laboratory is not obliged to inform the treatment company about the issue of the yellow card
- The laboratory could contact the accredited laboratory to implement preventive actions

Only the list of the laboratories that have participated in the ring-test will be indicated on the ESTA website. No further information on whether they failed the ring-test will be disclosed.

To legally bind the laboratory to comply with the above-mentioned a legal order will have to be signed between the laboratory and the treatment company. The order will be drafted by ESA and it will contain the following elements:

- The laboratory shall inform immediately the treatment company in case of a red card
- The laboratory will have to inform and prove annually the treatment company about its successful participation to the ring-test
- The laboratory is not obliged to inform the treatment company in case of a yellow card

The treatment site is responsible for using only accepted and registered Heubach labs.

### **ESTA Board**

- ▶ ESA installed the ESTA Board. The ESTA Board is appointed by the Board of ESA and represents ESA as the owner of ESTA. The ESTA Board assumes governance of ESTA; STAT will maintain an advisory role towards the ESA Board.
- ▶ The ESTA Board consists of the Executive Committee of ESA, the Chair of STAT and the ESTA Manager in an advisory role.

Tasks and responsibilities of the ESTA Board:

- manages the ESTA documentation (standard and accompanying documents) and publishes the adopted standard and relevant accompanying documents on the ESTA web pages;
- decides on adaptations of the ESTA standard and relevant accompanying documents and on acceptance of (national) Agents;
- grants certifying bodies the right to audit organizations on compliance to the ESTA standard and maintains a public register of the accepted certifying bodies at the ESTA website;
- enters into non-exclusive license agreements with the ESTA certified organizations on the use of the logo;
- publishes certifications on the ESTA website;
- maintains adequate communication with all stakeholders.

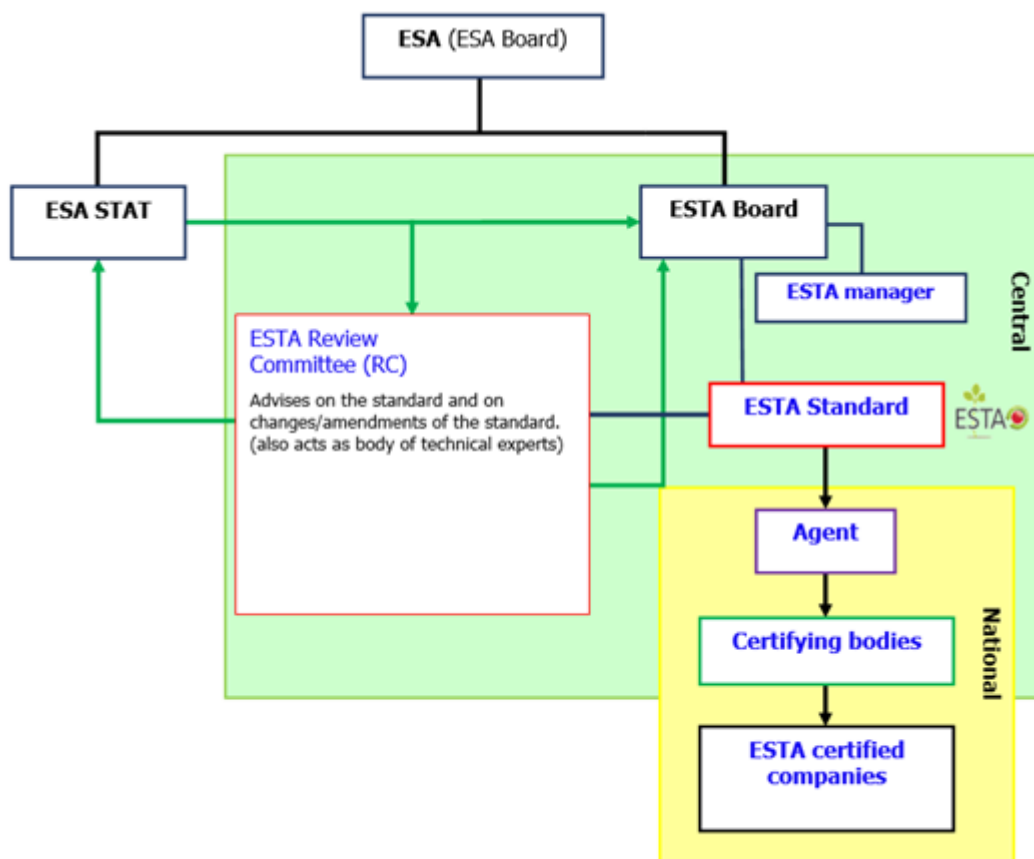
## ESTA Manager

- ▶ ESA appoints an ESTA Manager to support the ESTA Board.

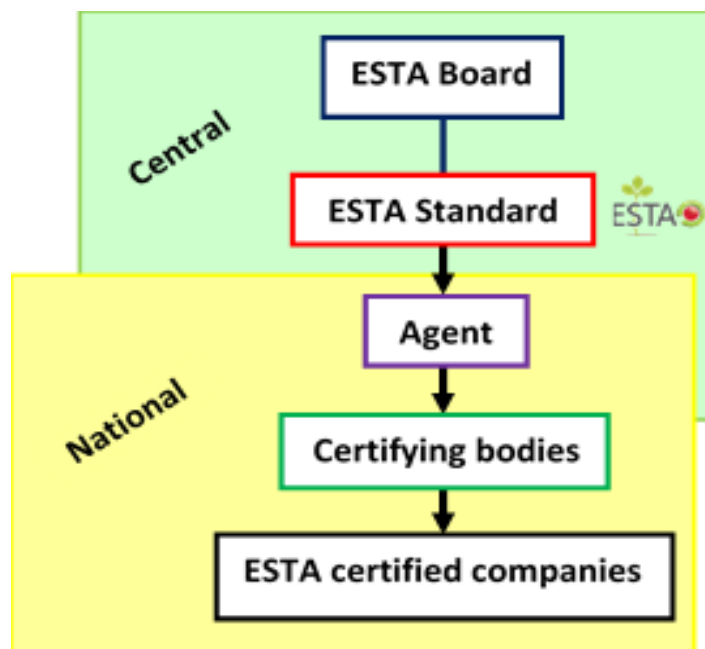
Tasks and responsibilities of the ESTA manager:

- Lead responsibility for implementation, maintenance and further development of ESTA, including relations with certifying bodies and Agents
- Manage relevant ESA Working Groups, including meeting preparation, minutes and follow-up, in close cooperation with the ESA membership
- Liaise closely with colleagues in national seed associations and company offices
- Develop processes to ensure successful and effective coordinated management of ESTA by ESA and relevant national bodies, including a regular review of ESTA and its operation
- Develop and maximize relations with key opinion formers and relevant decision-makers
- Ascertain documentation and data management via the ESA and ESTA website (information on accepted certifying bodies, certified treatment facilities etc.)

## ESTA governance (graphical)



ESTA is operated by Agents. All seed treatment sites that want to get ESTA certified shall contact one of the ESTA Agents and arrange with it all the administrative details of the scheme.



### ESTA Review Committee (RC)

The ESTA Board appoints a delegation of experts; these can be members of ESA-STAT, but this is not a prerequisite.

Tasks and responsibilities of the ESTA RC:

- discuss proposals to amend the ESTA standard and remarks to the standard or other aspects of ESTA and formulate proposals for modification of the standard
- propose additional guidance
- Review the 'regular review of ESTA and its operation' and conclude on relevant amendments of the ESTA standard and other aspects of ESTA

Proposals of the ESTA RC are sent to the ESTA Board and to ESA-STAT; ESA-STAT is invited to advise the ESTA Board. The ESTA Board will not decide on proposals before ESA-STAT has had time to react.

### ESTA Stakeholder Meeting

An annual conference on ESTA may be a relevant platform to discuss ESTA, developments, issues and opportunities. Such a conference may provide a platform to all stakeholders, including farmers, growers, legislators and NGOs.

### On the link with national quality assurance schemes

In principle no conflicts can develop if a national QA scheme adds additional components or restrictions to ESTA.



Conflicts would develop if a national QA scheme would either allow things not acceptable for ESTA, or if conflicting requirements would be mandatory.

On purpose the ESTA standard makes no reference to national QA schemes. ESTA is to provide a framework that can act as the 'umbrella' over national schemes that typically are more focused (specific for crop, active ingredient, or a key aspect like dust emission).

In the Steering Group meeting (March 23, 2011) this was worded as: ESTA should be the benchmark; it sets the standard. There is flexibility how national bodies implement it. However, it is not compulsory to have national systems; if no such system is in place, an organization still could seek ESTA certification.

### Control of ESTA and certified companies

► ESA wants to monitor performance of the certified companies and the certifying bodies. If a (national) Agent is in place control can be simplified and streamlined through the Agent, but ESA does not completely step out and leave it entirely to the Agent. This aspect will be covered in the agreements (i) between ESA and the certifying bodies and (ii) between ESA and the Agents.

### Audit check for treated seeds packed or re-packed at another treatment site

In the case of an ESTA certified treatment site makes use of another site for packaging or re-packaging the treated seed, that other site must be ESTA certified for the same crop to maintain the status of ESTA certified treated seed. Any type of re-treatment of the seeds is similar to the initial treatment so it can be considered as seed treatment.

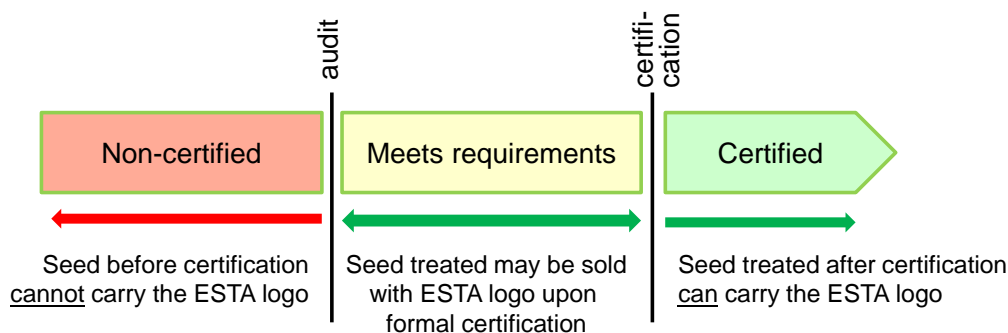
During the audit, the receiving site shall declare from which site the seeds came. The auditor should check the ESA on-line registration whether the site where the seeds came from is ESTA certified.

### First use of the ESTA logo on packaged seed

Use of the name ESTA and the ESTA logo is controlled as described in Annex 2 of the standard. A newly ESTA certified seed treatment plant will enter into an agreement on use of the logo.

Seed treated before the first ESTA certification cannot be labeled with the ESTA name or logo. However, seed treated after the site passed the audit with the conclusion of the auditor(s) that certification will be recommended, is eligible for carrying the ESTA logo when the formal certification and the agreement on use of ESTA are in place.

Graphically, on a time-scale, this may be represented like below:







If the auditor(s) did not recommend certification, the Corrective Action Requirement(s) ('CAR's) must be closed and/or the site may have to pass a re-audit before certification will be recommended. Seed treated during this period cannot carry the ESTA logo. (In the graph: the site did not yet meet the requirements, so the left (red) side of the graph applies.

Non-ESTA certified treated seeds that are returned to certified sites cannot be mixed with ESTA certified seeds and labelled with the ESTA logo.

### **Certifying bodies**

▶ A certifying body has to be accepted by the ESTA Agents for auditing the ESTA standard and certifying the audited organizations.

▶ The ESTA Agent will be in contact with the certifying body. The certifying body grants the ESTA certification.

After the certification a certain data set will be sent to the ESTA Manager who makes certain that the company appears in the public register of ESTA certified companies. The ESTA Agent will be the only point of contact for ESTA in such a case. The contract for use of the ESTA logo will be arranged through the ESTA Agent.

The ESTA Agents have to monitor the performance of the certifying bodies and certified companies. ESA basically only needs to be informed periodically (for instance once a year) on the monitoring results.

Exceptions would be newly certified companies (where ESA needs to make additions to the public register) and certificates withdrawn (where ESA also needs to withdraw and remove the company from the public register).

Costs could be different too. The fees per unit is standard and it will be paid to ESA, while the management fee will be defined by the different Agents.

A company can directly approach a certifying body to check conformity of its business to the ESTA standard with the aim that the certifying body (directly) will grant the ESTA certification. If specific legal requirements are in place nationally such an approach may be irrelevant because the national requirements would probably formally not be met in such a case.

### **Registers of certifying bodies and certified companies**

For each accepted **certifying body**, the following information will be published in the public ESTA Register of accepted certifying bodies:

- Name, address and accreditation number of the certifying body
- Date of acceptance of the certifying body by the legal entity managing ESTA
- ESTA certifying body registration number
- Scope of the ESTA certifications that the accepted certifying body can issue
- Remarks



For each **ESTA certified company** the following information will be published in the public ESTA Register of ESTA certified companies:

- Name, address, first certification date, expiration date and reissue date of the certificate of the certified company
- Name and ESTA certifying body registration number of the certifying body
- Scope of the ESTA certification. Species that belong to vegetables and cereals will be registered as such. All the other crops will be registered individually
- Remarks