



**The UK ESTA Standard  
European Seed Treatment Assurance (ESTA)  
Quality Assurance Scheme for Seed Treatment and Treated Seed**

**Effective from June 2020**

**ESTA Standard**  
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**Quality Assurance Scheme for Seed Treatment and Treated Seed**

**Foreword**

This document has been prepared under surveillance of ESA-STAT (European Seed Association – Seed Treatment and Technology). It is the standard on quality assurance for seed treatment and treated seed of ESA (European Seed Association), supported by the ESA membership and the agrichemical industry.

ESTA (European Seed Treatment Assurance) is a standard to support the industry. This standard provides a quality assurance system to assure that seed treatment and the resulting treated seed meet requirements defined by legislators and industry. The ESA standard can be found on the ESA website at <http://esta.euroseeds.eu/> and it is this which the UK ESTA standard is based on.

Companies certified to the ESTA standard reliably treat seed with plant protection products (PPP), resulting in quality products (treated seed) for the ultimate user: farmer, grower, plant raiser or contractor.

This standard can be used as an “umbrella” standard to which national and industry quality assurance schemes are benchmarked.

**ESTA Standard**

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## 0. Introduction

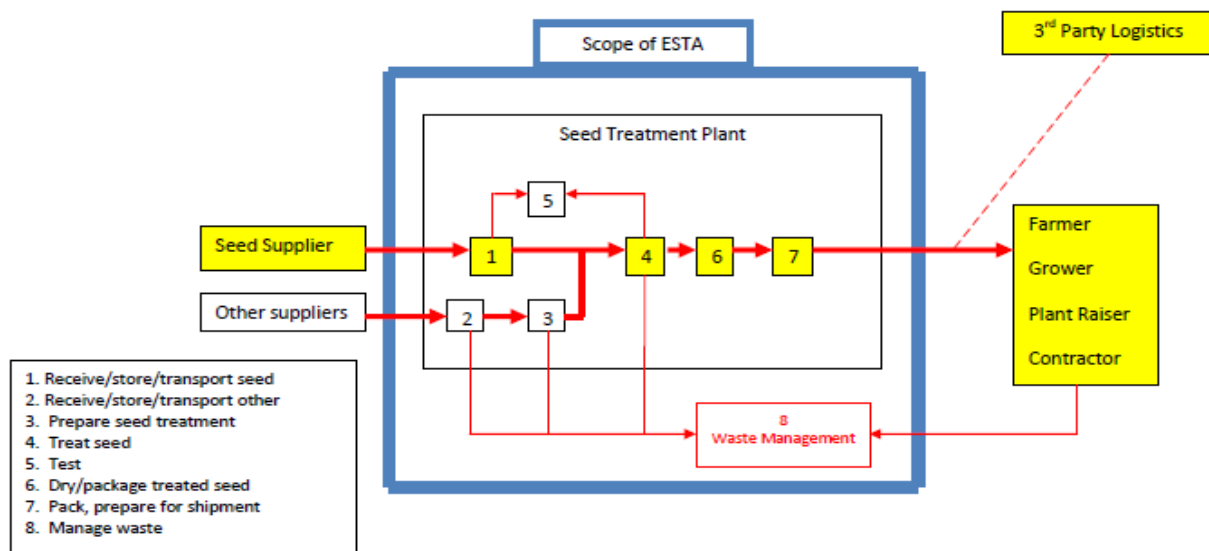
### 0.1 General

This standard on quality assurance for seed treatment and treated seed of Euroseeds is named ESTA (see also 0.2). It is meant to be a general basis for quality assurance in the application of all seed treatments including plant protection products.

ESTA has been designed to be compatible with ISO 9001 (general quality management system standard) and ISO 17065.

### 0.2 Scope

This standard regards the “seed treatment chain” as one system of interdependent processes, from seed suppliers through the seed treatment facilities and transport to the ultimate user of the treated seed. Achieving process control is a goal of ESTA. The schemes scope fall inside of the blue box, however, participants of ESTA will need to be aware that suppliers and end users, although out of direct control, will need to be the relevant guidance.



### 0.3 Management and use of ESTA

Euroseeds, as the owner of ESTA, will grant certification bodies the right to certify organisations to the ESTA standard (see annex 2 for details and requirements). Euroseeds will allow such certified organisations to use the ESTA logo (see annex 6).

### 0.4 ESTA: Main components

The Quality Assurance System consists of six main components:

1. General framework for the Quality Assurance System
2. Description of processes
3. Risk analyses as a basis for risk control
4. Key procedures
  - a. control of documents and records
  - b. control of nonconformities

- c. corrective and preventive measures
- d. recall of non-conforming product & complaint handling
- 5. Proven competence of personnel
- 6. Specific requirements for the seed/seed treatment companies

NOTE: An **(R)** in the text of this code indicates where there is a requirement to keep a record.

### 0.5 Relationship with other standards

Were appropriate seed quality tests required by users of this standard can be performed according to the International Rules for Seed Testing in ISTA accredited laboratories, but alternative tests can be used if customers or authorities agree.

### 0.6 Relevant Legislation

This list is not exhaustive but highlights the key legislation regarding the treatment of seed which must be understood and complied with.

The EC regulation 1107/2009

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF>

Directive 2009/128/EC Sustainable Use Directive on the use of pesticides

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:en:PDF>

Commission Directive 2010/21/EU of 12 March 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid (Text with EEA relevance) - Directive 2010/21/EU additional provisions to protect honey bees

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0021:EN:NOT>

### 0.7 Compatibility with other quality assurance/quality management systems

*EN-ISO 9001:2008. Quality management systems – Requirements.*

Internationally the most widely adopted quality management standard is EN-ISO 9001:2008. Core elements of this standard can also be recognized in this standard, which is targeted to the requirements of the “seed treatment chain”.

*ISO 14001:2004. Environmental management systems – Requirements with guidance for use.*

This standard specifies “requirements for an environmental management system to enable an organisation to develop and implement a policy and objectives which take into account legal requirements and information about significant environmental aspects”. The standard is compatible with ISO 9001:2008 and focuses on the Plan-Do-Check-Act cycle. (Establish objectives and processes/Implement/Monitor and measure/Take actions to continually improve performance of the environmental management system.)

*OHSAS 18001:2007. Occupational health and safety management systems – requirements.*

OHSAS 18001 has been developed to be compatible with ISO 9001 and ISO 14001 in order to facilitate the integration of occupational health and safety, quality, and environmental management systems.

REQUIREMENT	GUIDANCE
<p><b>1 Scope and purpose of this Quality Assurance system</b></p>	
<p>This Quality Assurance (QA) system provides a best practice framework for the preparation and application of treatments to seed that includes Plant Protection Products (PPP's).</p> <p>This assurance scheme covers static and mobile facilities.</p> <p>Seed suppliers to seed treatment applying companies can be regarded out of scope of this QA system.</p> <p>The scheme also covers the packing and re-packing of treated seed.</p>	<p>ESTA provides a best practice framework for good practices to prepare and apply seed treatments that include Plant Protection Products (PPP's), till and including the intended use of the treated seed. ESTA is restricted to those seed treatments that provide crop protection after drilling, sowing or planting through the Plant Protection Products (PPP's) on the seed.</p>
<p><b>2 Normative references</b></p>	
<p>Where appropriate:-</p> <ul style="list-style-type: none"> <li>• ISO Guide 65 / EN 45011. (Note: ISO 17065 will replace ISO Guide 65/EN 45011; expected publication date at the ISO website is Dec. 30, 2011.)</li> <li>• ISTA International Rules for Seed Testing</li> <li>• ESA reference method "Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds". Published at the ESA website; see <a href="http://esta.euroseeds.eu/Standard/TestMethod">http://esta.euroseeds.eu/Standard/TestMethod</a></li> <li>• ESA reference table 'Industry dust reference values'. Published at the ESA website; see <a href="http://esta.euroseeds.eu/Standard/Dust">http://esta.euroseeds.eu/Standard/Dust</a></li> </ul>	<p>Seed quality tests required by users of this standard can be performed according to the International Rules for Seed Testing. If samples are taken by ISTA accredited samplers and analysed in ISTA accredited laboratories the results can be reported on an ISTA Orange Certificate that acts as a passport in international movement of seed. It must be noted that within the EU the free trade regulations do guarantee that seed can pass borders. For export to countries outside the EU an ISTA Certificate (and a phytosanitary certificate) may be necessary. As dust tests are not available within the ISTA accreditation (today no ISTA Rule on testing for dust exists), such test results could, if needed on a certificate, only be reported in the field "other determinations".</p> <p>In general alternative sampling procedures and tests can be used if customers agree.</p>
<p><b>3 Terms and definitions</b></p>	
<p>A list of definitions and abbreviations (for reference purposes) is added to this standard as Annex 1.</p>	

<p><b>4 Management System</b></p>	
<p>ESTA is a Quality Assurance system for all professional seed treatment applicators and the application of the treatment of seed. The participant 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 to the implementation and continual improvement of the QA system. <b>(R)</b></p> <p>A designated person 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.</p> <p>This continual improvement system must at least have the following inputs:</p> <ul style="list-style-type: none"> <li>(i) measurements of critical process parameters (e.g. control of goods in and out)</li> <li>(ii) registration, analysis and mitigation of customer complaints;</li> <li>(iii) registration, analysis and mitigation of internal complaints, errors and non-conformities;</li> <li>(iv) corrective and preventive measures to issues not dealt with in points i to iii;</li> <li>(v) review of the risk assessment.</li> </ul> <p>Companies must have a process to recall nonconforming product.</p> <p>A review shall be performed at least annually to evaluate functioning of the QA system.</p> <p>Documents required by this standard shall be controlled. This means that approved actual versions are accessible to users. <b>(R)</b></p>	<p>Records are documents stating results achieved or providing evidence of activities performed.</p> <p>Companies must keep records to allow for full tracking &amp; tracing of all incoming, stored and outgoing products.</p> <p>The participant must document the procedure for handling customer complaints. This procedure must include systems for the prompt recording and investigation of complaints, the prompt feedback to the complainant with findings and the recording of the internal actions required to prevent recurrence. Actions taken should aim to resolve the root cause of the complaint to prevent its recurrence.</p>
<p><b>Terms and conditions (T&amp;C'S)</b></p> <p>The company must have a system in place to ensure that customers'/ recipients' current terms and conditions are clear, unambiguous, recorded</p>	<p>The company must ensure that the contractual T&amp;C's from suppliers of crop protection products are made available.</p> <p>The company must ensure that its customers</p>

<p>and acted on. Terms and conditions must be communicated to, and understood by, all relevant staff and subcontractors. <b>R</b></p>	<p>(e.g. farmer end users) contractual T&amp;Cs are made available.</p>
<p><b>Specifications</b></p> <p>The company must send or receive a contract specification confirming details of the sale/purchase between the merchant and the customer/recipient, unless the customer/recipient elects not to receive such confirmations.</p>	
<p><b>Specification differences</b></p> <p>Where there is a known difference in specification this must be resolved and actions recorded. <b>R</b></p>	
<p><b>5 Process description</b></p>	
<p>To achieve reliable process control the processes and their relations should be described for the “chain” that links all components and companies involved from clean seed to drilling the treated seed (the “seed treatment chain”).</p> <p>The processes are a basis for the risk analyses.</p> <p>(Process) Measurements to assure process and product quality have to be defined. <b>(R)</b></p>	<p>“Determine the processes needed” is in the opening statements of the general requirements for ISO 9001:2008 (section 4.1 of ISO 9001:2008). Often this is interpreted as processes within the company. To allow for a full risk analysis, the processes have to be considered for the entire seed treatment chain as (especially) interfaces between the various parts of the chain are associated with hazards.</p>
<p><b>6 HACCP (Hazard Analysis Critical Control Point)</b></p>	
<p>A formal food/feed safety HACCP must be carried out with the aim of identifying and controlling any hazards that might adversely affect the integrity of food/feed. HACCPs must be carried out in accordance with recognised HACCP principles as summarised below <b>(R)</b>:</p> <ul style="list-style-type: none"> <li>• establish a HACCP team</li> <li>• define process steps</li> <li>• carry out hazard analysis</li> <li>• establish prerequisites</li> <li>• establish critical limits</li> </ul>	



<ul style="list-style-type: none"> <li>• identify Critical Control Points</li> <li>• implement control measures</li> <li>• establish corrective actions</li> <li>• establish documentation required</li> </ul> <p>The HACCP must include a procedure for product recall and carry out a mock recall at least once per year to prove the traceability system. <b>(R)</b></p>	
<p><b>7 Staff training</b></p>	
<p>Staff must receive training for all work that they are expected to undertake. Training and competence must be reviewed annually. Training records must be maintained for all staff (permanent and temporary). Training records must be dated and include certificates (where held) obtained from external training organisations <b>(R)</b></p>	
<p>Training must include the following as a minimum:</p> <ul style="list-style-type: none"> <li>• An understanding of the purpose this standard</li> <li>• Any in-house procedures implementing the detailed requirements of this standard</li> <li>• The requirements of relevant seed legislation.</li> </ul> <p><b>(R)</b></p>	<p>Examples of training could be BASIS and certificated of competence for handling PPPs.</p>
<p>Training must be:</p> <ul style="list-style-type: none"> <li>• Regular</li> <li>• Updated</li> <li>• Documented</li> <li>• Signed and dated by the trainer and trainee <b>(R)</b></li> </ul>	
<p>The participant must demonstrate how the business maintains a knowledge of current legislation. <b>(R)</b></p>	
<p>A designated person must have authority and</p>	

responsibility for the implementation of the requirements of this standard. <b>(R)</b>	
The designated person must ensure that all staff covered by the scope of the standard are provided with written instructions that confirm their duties and the procedures. <b>(R)</b>	
The interrelation of staff and job functions within the participants operation shall be defined in an organisation chart. <b>(R)</b>	
<b>8 Specific requirements for companies in various parts of the seed treatment chain</b>	
The companies in the various parts of the seed treatment chain deal with different processes which have specific requirements. In general, participants must take measures to ensure all processes conform to ESTA and that records are kept. <b>(R)</b>	For certified seed production, the requirements of this section are met through the official seed certification system and are therefore not audited under ESTA.
<i>8.1 Seed treating companies/seed providers</i>	
Seed shall meet crop-specific criteria on moisture and cleanliness agreed with the seed treating company. <b>(R)</b>	<p>Seed treating companies shall assure that seed lots submitted for seed treatment meet requirements agreed with the seed treating company (or in-house seed treating facility) on moisture and dust levels, presence of broken/damaged seeds and other materials (like chaff, other seeds, sclerotia, inert material).</p> <p>Moisture level of the seed has a direct impact on shelf life of the treated seed if a certain level is exceeded. Extremely dry seed may be sensitive to damage during transport and treatment. All materials in the seed batch that are not pure seed can impact the quality of the seed treatment; especially small particles, chaff, soil and the like can become treated and result in coarse dust with active ingredient(s). Besides the dust issue this also has a negative impact on loading (defined as the percentage of the active ingredient(s) on the seed related to the target value).</p>

<p><i>8.2 Seed treating companies (and in-house facilities) – <b>statics and mobiles</b></i></p>	
<p>The seed treatment process, including the recipes used to prepare the seed treatment and the equipment used, must have a proven stability/reliability <b>and be monitored</b>. Ensure treated seed meets reference standards where they apply and ensure that all dust checks and machinery calibration are carried out. <b>(R)</b></p> <p><b>Based on the HACCP, samples shall be tested on dust levels with the standard Heubach test, according to a defined scheme. Treated seeds that exceed the industry dust reference values or any legal requirements if lower shall not be put on the market (For further information see Annex 4). (R)</b></p> <p><b>A summary of Heubach test results must be issued to AIC annually so they are compiled and sent to Euroseeds anonymously as a requirement of the scheme. (R)</b></p> <p>Worker safety must be assured.</p> <p>Treated seed shall be labelled according to national requirements.</p> <p>Adequate measures are to be in place for waste handling and disposal. <b>(R)</b></p>	<p>Safety measures at seed treatment companies are to address worker and environmental safety. Specific risks may be identified; for instance linked to the preparation of seed treatment recipes, <b>the use of aspiration systems when handling dust and dust exposure</b> (safety of the installations including potential explosion risks, safety issues during cleaning and maintenance), or in general linked to waste handling and disposal.</p> <p>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.</p>
<p><i>8.3 Transport &amp; logistics</i></p>	
<p>Seed is sensitive to environmental influences. Great care should be taken to avoid temperature extremes, moisture and rough handling. Guidance on seed handling must be provided to the transport company. <b>(R)</b></p>	<p>If seeds are to have special conditions of carriage, then these must be recorded. The records must cover loading and unloading to ensure the product has arrived in good condition.</p>
<p><i>8.4 Farmers, growers, plant raisers and contractors drilling/planting the treated seed</i></p>	
<p>The ESTA participant must make available to the farmer, grower etc. information on the correct use of the seed. <b>(R)</b></p>	<p>Farmers must handle treated seed in ways which ensure worker safety and protection of the environment. The ESTA participant must provide growers and other users with information about</p>

Treated seed returned from distributors or farmers cannot be re-shipped without assuring that the seed still meets requirements.	the safe use of treated seed. This includes appropriate labelling and any legally required product safety information. Farm operators should be encouraged to train in the use of handling treated seed.
<i>8.5 Suppliers of crop protection products and other seed treatment components</i>	
Suppliers shall provide material safety data sheets (MSDSs) (or COSHH data sheets) and further documentation relevant for correct and safe use (and disposal if relevant) of their products. <b>(R)</b>	The documentation shall allow seed treatment companies to assess that the products meet the purchase requirements.

### Annex 1: List of definitions and abbreviations

CEN	European Commission for Standardization
CENELEC	European Committee for Electrotechnical Standardization
Plant Protection Product	Plant protection products (PPP) registered for use according to Council Directive (EC) 1107/2009.
EN	European Standard: a document that has been adopted by one of the three recognized European Standardization Organisations: CEN, CENELEC or ETSI. An EN is available, in principle, in the three official languages of CEN (English, French and German).
ESA	European Seed Association
ESA-STAT	Seed Treatment And Technologies working group of ESA, dealing with all issues in the area of seed treatment and treated seed, related technologies and practices and the relevant regulatory issues of general importance for the seed industry. ESA-STAT reports to the Board of ESA.
ESTA	European Seed Treatment Assurance
ETSI	European Telecommunications Standards Institute
HACCP	Hazard Analysis and Critical Control Points. A system for identifying specific hazards and preventive measures for their control that can be applied throughout the food chain from the primary producer to the final consumer.
Heubach	(1) manufacturer for dust test equipment: Heubach GmbH, Langelsheim, Germany; (2) standard dust test as described in the ESA reference method "Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds".
IEC	International Electrotechnical Commission
ISF	International Seed Federation
ISO	International Organisation for Standardization
ISTA	International Seed Testing Association
Lot (seed)	quantity of seed that is physically and uniquely identifiable

lot)	
OHSAS	Occupational Health & Safety Advisory Services
Procedure	Description of a process or activity in a logical order with for each step listed the roles/functions that are responsible, accountable, provide support, need to be consulted or informed.
Participant	The Seed treating company being audited
QA	Quality Assurance
Validation	Confirmation, through objective evidence, that specified requirements for a specific intended use or application have been met.
Work instruction	Detailed description showing how to carry out a process or activity (also known as standard operating procedure (SOP). (For SOP different definitions exist.)

## Annex 2: Requirements for certification bodies

ESA, as the owner of ESTA, will grant certification bodies the right to certify organisations to the ESTA standard and to allow such certified organisations to use the ESTA logo. A public register of the accepted certification bodies will be maintained on the ESTA web site.

Certification bodies must be annually audited by the national accreditation body (UKAS).

A certification body must be accredited to ISO/17065 (General requirements for bodies operating product certification systems). If the accreditation of a certification body is withdrawn ESA must promptly be informed. The right to certify organisations to the ESTA standard will be suspended by ESA till the accreditation is re-installed.

A certification body also must have proven experience in the field of agricultural, 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.*

Certification bodies shall report to ESA annually on the following:

- Name, address, legal structure, ESTA certification and expiry dates of each ESTA certified organisation

For each ESTA certified organisation:

- Scope of the ESTA certification
- Audit findings (a copy of the audit report(s) including conclusions on functioning of the continual improvement cycle)
- Measurements/performance indicators on the following:
  - Number of seed lots not passing relevant tests such the dust test according to the ESA reference method “Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds” for those crop/active ingredient combinations for which legal requirements are defined, plus measures taken

### **Annex 3: Audit dispute and complaint handling**

#### *Audit Complaints*

Complaints about either a participant or the scheme certification body should be directed to the scheme certification body where they will be acknowledged, reviewed and actions taken to resolve the cause of any problems.

The scheme certification body is accredited by the UK Accreditation Service (UKAS) and works to strict codes of conduct. If participants are not satisfied with the way in which the scheme certification body handles the complaint, they should refer the matter to AIC. Please refer to the UK ESTA Scheme Rules for further information.

#### *Audit Disputes*

A participant has the right of appeal against decisions made by the scheme certification body. Appeals shall be made in writing to the scheme certification body within 14 days of being advised of a decision that is the subject of appeal.

The scheme certification body acknowledges appeals and an initial investigation is made by the certification body's scheme manager. If the scheme manager does not support the decision against which the appeal is based then the scheme certification body will correct the erroneous decision. If the scheme manager supports the decision on which the appeal is based then an independent panel, which will include an AIC representative, is convened to handle the appeal. The scheme certification body, AIC and the participant are entitled to attend the appeals panel and present information to the panel.

The independent appeals panel makes a ruling based on information supplied during the hearing. The ruling of the appeals panel is binding and final on the scheme certification body and participant. The appeals panel will be convened within 30 days of receipt of the appeal.

### **Annex 4: Maximum allowable dust levels in seed treated with neonicotinoids (informative)**

On cleanliness: all materials in the seed batch that are not pure seed can impact the quality of the seed treatment; especially small particles, chaff, soil and the like can become treated and result in coarse dust with active ingredient(s). Besides the dust issue this also has a negative impact on loading (defined as the percentage of the active ingredient(s) on the seed related to the target value).

On material safety data sheets (MSDSs): to allow for prompt action if an incident would occur, the active ingredients being used must always be known/visible.

Processes for handling of treated seed are defined such as to minimize the creation of dust through abrasion, e.g., assuring methods for gentle handling and minimizing amount of internal seed movements.

Good practice must be applied in machine cleaning to avoid mixing with plant protection products not intended for the next treatment.

Processes for transport preparations to be defined such as to minimize the creation of dust through abrasion during delivery logistics, e.g., by assuring tight stretch wrapping of pallets with treated seed bags, and verification of proper stowing of delivery trucks.

Elements of the information that has to reach farmers can a.o. be the following. Care must be taken to avoid ingestion of treated seed by birds or farm animals. Measures must be taken to limit dust during drilling/planting. Worker safety has to be assured before, during and after drilling. Disposal of leftover seed and packing materials needs specific measures.

Dust levels of treated seed shall be as low as technically and economically feasible, taking human and environmental risks into account. Scientific data are to provide a basis for determining thresholds. Hazards linked to dust are associated with the active ingredient(s), the type of seed, the sowing window (period of the year), climatic conditions during and after sowing, and the equipment used.

ESA is to agree on standards that can be linked to ESTA to create uniformity on technical aspects of seed treatments. Assuring that reliable methods are available to measure such characteristics is a responsibility of ESA and ECPA, the European Crop Protection Association. Such reliable methods preferably are validated thoroughly as to allow using the term “reference method”.

Other aspects of treated seed and agriculturally or environmentally relevant aspects linked to the use of such seed may lead to technical standards based on similar rationales: non-intended impact as low as technically and economically feasible and based on scientific data.

To assess dust levels of treated seed the ESA method “Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds” is the reference method. A standard protocol (work instruction) on how to perform this test is available; see ESA reference method “Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds”.

The accuracy, reproducibility, precision, robustness and general reliability of reference methods must be beyond doubt. Therefore extensive validation procedures have been developed for reference methods. EN-ISO 17025 provides requirements for selection and validation of methods, equipment, calibration and reference materials.

If a reference method exists, alternative methods can be used if sufficient evidence is available to show that an alternative method yields comparable results. In case of a dispute on test results, the reference method should be used.

The dust reference values that were developed by Euroseeds are listed below:

- Corn: 0.75g of dust/ 100 000 seeds
- Oilseed rape: 0.50g of dust/ 700 000 seeds
- Sugar beet: 0.25g of dust/ 100 000 seed pellets
- Sunflower: 0.40g of dust/ 75 000 seeds
- Cereals: 4 g of dust/100 kg
- Carrots, endives: 0.1 g of dust/100 000 seeds
- Onions: 0.2 g of dust/100 000 seeds
- Sweet corn: 0.75 g of dust/100 000 seeds

The dust reference values for the following crops are advisory as of July 1, 2019 and for one year. As of July 1, 2020 they will become normative.

- Green and seeded beans: 0.4 g of dust/ 100 000 seeds
- Vegetable peas: 0.2 g of dust/100 000 seeds

Further information can be found on the following link - <https://www.euroseeds.eu/esta-the-european-seed-treatment-assurance-industry-scheme/dust-reference-values-heubach-test-method/>

### Annex 5: Equipment requirements and approval

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

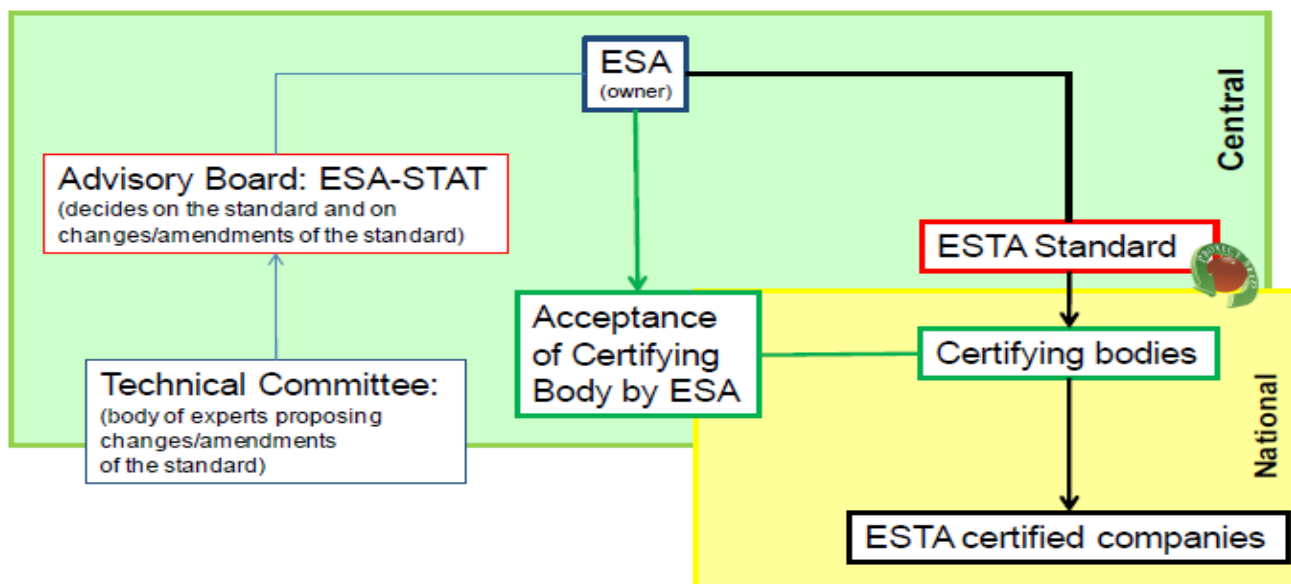
### Annex 6: Legal structure, management, ownership and use of ESTA

ESA, a non-profit international association according to Belgian Law, is the owner of ESTA.

The Board of ESA delegated all activities related to ESTA to its working group STAT. In STAT representatives of the European seed and agricultural industry are participating.

STAT decides on the ESTA standard and all associated documents. STAT can seek advice from a technical committee: a permanent or ad-hoc expert body installed by STAT that proposes changes or amendments to the standard.

#### ESTA structure



ESA appoints an “ESTA certification manager” to guide candidate certification bodies towards acceptance, to monitor compliance of all certification bodies and certified companies, to answer questions on ESTA, to collect and collate requests for changes and amendments of the standard and probably to organize meetings (user group(s), stakeholders, technical committee).

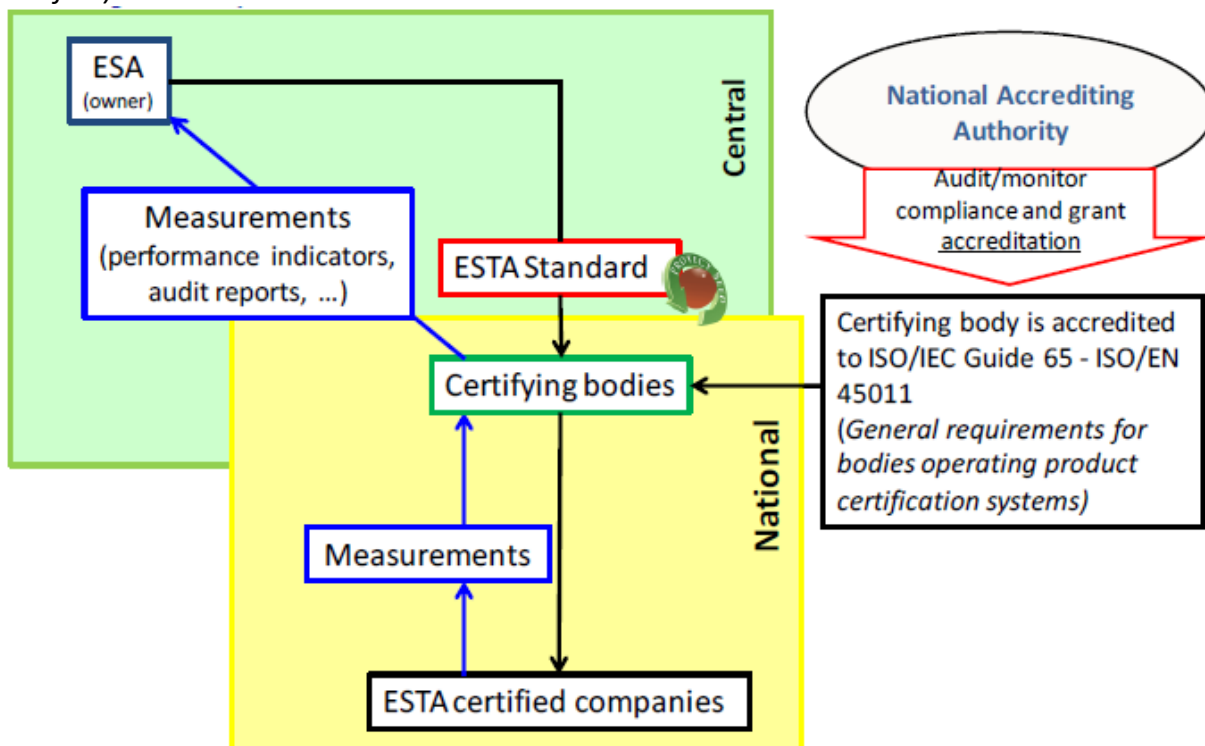
Certification bodies, accepted by ESA to certify organisations to the ESTA standard and to allow such certified organisations to use the ESTA logo, do provide the data ESA demands to monitor compliance.

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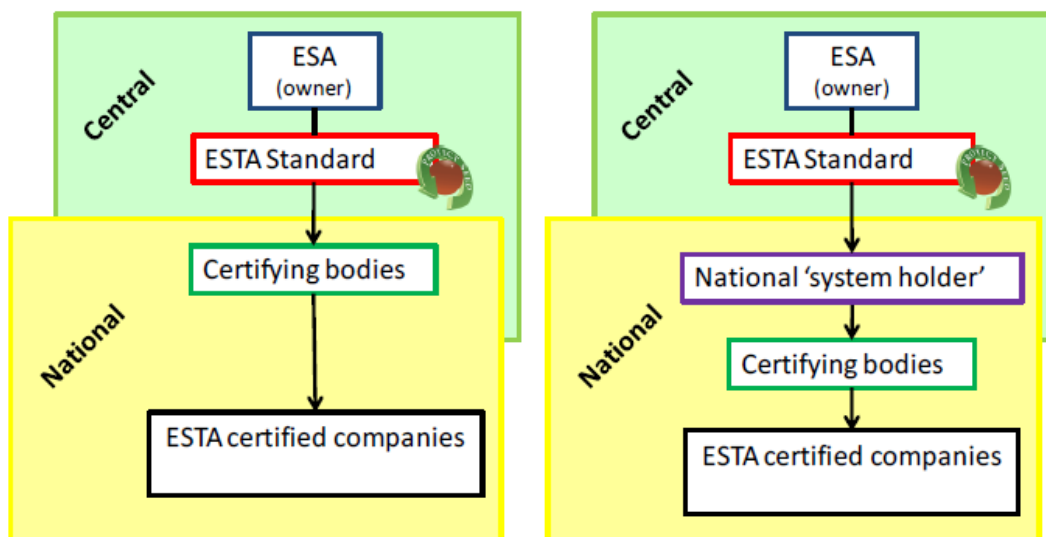


ESTA can be embedded in existing (national) certification systems; national seed/trade associations can drive the process within the individual member states.

*ESTA seen from the point of view of a certified company (or a company interested in becoming certified)*



If ESTA is to be embedded in a national system the central part of the graph above would change as follows (left: without national “system holder”, right with “national system holder”):



**ESTA: controlled use of name and logo**

Use of the name ESTA and the ESTA logo is controlled. Only ESTA certified organisations can use name and logo as specified:

- in their communication

- on packaged seed treated in an ESTA certified seed treatment plant if the treatment is within the scope of the ESTA certification.

Before use of the name ESTA and the logo is allowed the ESTA certified organisation will enter into an agreement with ESA that grants a non-exclusive license for use and specifies the conditions for use.



## Annex 7: HACCP

### References:

HACCP information from the AIC web site

### 1) HACCP team

In order to establish a HACCP system, the applicant must appoint a team to conduct the HACCP study that comprises personnel from all of the relevant operations and functions within the company and at least one member with formal HACCP training. The members of the team must be recorded within the HACCP study.

It is acceptable for individual members of staff to fulfil multiple roles in the HACCP team or to utilise resources from outside of the company, provided that the role of the HACCP team remains demonstrably effective.

### 2) Defining process steps

The HACCP team must identify and record all of the process steps involved in the storage operations from receipt of goods to outloading and must be in the form of a flow diagram of the operation/process.

### 3) Hazard analysis

The HACCP team must identify and record any possible chemical, physical or microbiological hazards that could occur at each process step and adversely affect the stored materials, recognising the nature of their products and their intended use.

#### a) Pre-requisites

For practical purposes, participants may wish to recognise 'prerequisites' for the HACCP scheme they implement. These are specified, formal procedures that control potential hazards on a site-wide basis, such as pest control, glass policies, training, etc and help to prevent repetition of hazards and control measures at multiple process steps. Such prerequisites must be defined as part of the HACCP plan and included in any auditing schedule established as a result of the HACCP plan.

### 4) Identify critical control points

Where it is essential that a hazard is controlled at a particular process step (ie the hazard can not be controlled or eliminated at a later process step), this step must be identified as a Critical Control Point (CCP).

### **5) Establish critical limits**

The HACCP team must identify the critical limits for all of the critical control points and pre-requisites that have been identified and be able to show the basis on which the suitability of these limits is based. Critical limits must be set at levels such that the safety and integrity of the stored materials is assured.

### **6) Control measures**

For each process step at which a hazard is identified, the participant must implement and record a system or procedure to control the operation. These are known as control measures and must be sufficiently robust to control hazards and ensure that critical limits are not exceeded. The operation of the control measures must be monitored and recorded to allow the participant to demonstrate the hazard is controlled and to allow action to be taken if critical limits are exceeded.

### **7) Actions when hazards are not under control**

The participant must take suitable, prompt and effective remedial action when monitoring shows that hazards are not within critical limits. The participant must record the action taken and make sure that actions are designed to deal with the cause of the problem as well as the problem itself.

### **8) HACCP Reviews**

The participant's HACCP team must carry out regular reviews of the HACCP system. The aim of these reviews is twofold:

**(1)** To check whether the requirements of the system are being met (i.e. are the procedures being followed);

**(2)** To check that the system effectively and consistently ensures the safety and integrity of materials (i.e. are the procedures effectively controlling the hazards). At least one complete review must be carried out each year, but more frequent reviews may be necessary due to other changes in the business. Examples of changes which may require an additional HACCP review are:

- A new piece of equipment;
- When critical limits are exceeded;
- Changes in personnel/ procedures.

A record must be kept of HACCP review showing the HACCP team findings and actions required. For practical reasons, many participants will carry out the HACCP review in conjunction with their internal audits.