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ESTA Standard

European Seed Treatment Assurance

Quality Assurance System for Seed Treatment and Treated Seed

Adopted by the ESA Board/ESA-STAT, March 23/May 3, 2012

Foreword

This document has been prepared under surveillance of ESA-STAT. It is the standard on quality assurance for seed treatment and treated seed of ESA, supported by the ESA membership and the agrichemical industry.

Note

To this standard several text boxes have been added that are clearly different from the text of the standard. They are all labeled "additional guidance" and serve for additional guidance and explanation.





ESTA Standard

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0 Changes to the previous version

The previous published version of this standard was version 1.0.

In the **standard** itself the following was changed:

1. in § 1.3, 2nd sentence: "*The first official version, published upon acceptance by ESA, was version 1.0.*" The word "*is*" has been replaced by "*was*".
2. in § 2 the expected publication of the replacement of ISO/EN 45011 has been deleted.
3. in § 2 the ESA reference table and 2010/21/EU have been added.
4. in the additional guidance to § 8 a sentence on machine cleaning has been added.
5. in § 9 reference to the FNPSMS laboratory has been added.

Annex 1

1. a definition of "must" has been added.



Annex 3

2. agricultural field now is further specified.
3. Certifying bodies are notified that in the future they have to take ESTA into the scope of their ISO/EN 45011 accreditation.
4. The sentence on audit reports is removed as this is already in ISO/EN45011.

Annex 4, 5 and 6 now have the text, based on the content agreed on in by ESA-STAT in its meeting of February 2, 2012.

1 Introduction

This standard on quality assurance for seed treatment and treated seed of ESA, the European Seed Association, is named ESTA (see also Annex 2). It is meant to be a general basis for quality assurance of seed treatments that include plant protection products.

ESTA 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.

This quality assurance system supports sustainable food, feed and fiber production by assuring the availability of crop protection through seed treatments. Seed treatments combine precision and minimal active ingredient amount with maximum efficacy and minimal environmental impact.

The adoption of this quality assurance system is a strategic decision of an organization. ESTA has been designed to be compatible with ISO 9001 (Quality management systems - Requirements) and ISO/IEC Guide 65 – ISO/EN 45011 (General requirements for bodies operating product certification systems).

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

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.

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

1.1 Scope of this Quality Assurance system

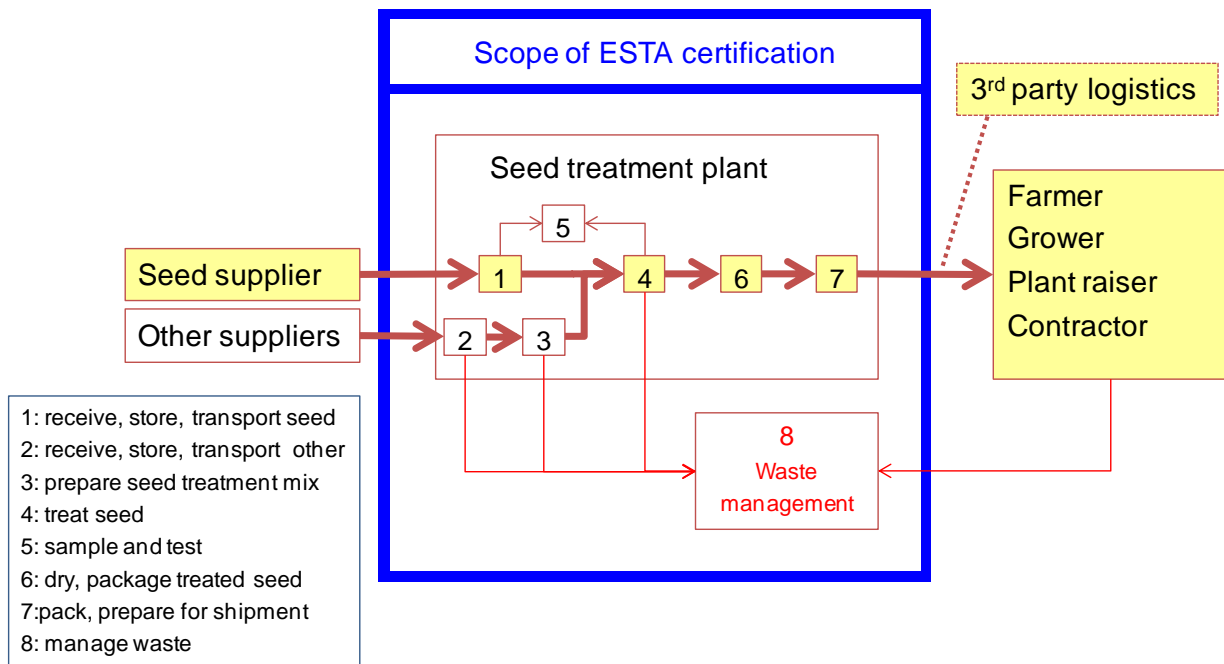
This Quality Assurance (QA) system provides a framework for good practices to prepare and apply seed treatments that include plant protection products. Certification will be granted per species and per seed treatment site.

Although certification is restricted to the seed treatment companies, this standard requires the seed companies to provide recommendations for handling and intended use of the treated seed.

Wherever legal requirements exist which cover or go beyond the ESTA Standard, those are controlled by authorities. These legal requirements prevail.



The scope of the ESTA certification can be visualized as follows:



This QA system addresses the entire 'chain' that starts with seed to be treated till the use of the treated seed, because each step must be properly managed to be able to ensure quality and safety of the treated seed. Safety is to be read as workers/human safety and environmental safety.

Seed companies and other seed providers carrying out seed treatments are under the scope of the certification. However, seed treating companies can also accept seed based on crop-specific quality criteria. In such cases the provider of the seed can be regarded out of scope for this QA system and the seed treatment company assumes the full responsibility that the ESTA requirements are fulfilled.

The scope explicitly excludes other seed treatments such as seed disinfection, priming, or pelleting if the pelleting process does not also apply plant protection products.

1.2 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. handle/rework of non-conforming product
5. Proven competence of personnel
6. Specific requirements for the seed/seed treatment companies.

1.3 Convention on coding/numbering

The ESTA standard has a date and version number. The first official version, published upon acceptance by ESA, was version 1.0. Minor revisions receive a number following the decimal



dot (1.1, 1.2, etc.) The standard, annexes and other relevant documents are published on the ESA website.

Text in this standard and associated documents preceded by "Note" is for guidance or clarification only.

2 Normative references

- ISO/IEC Guide 65 – ISO/EN 45011 (General requirements for bodies operating product certification systems). (**Note:** ISO 17065 will replace ISO Guide 65 – ISO/EN 45011)
- ISTA International Rules for Seed Testing (sampling only)
- 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 <http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance>
- ESA reference table '*Industry dust reference values*'. Published at the ESA website; see <http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance>
- 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; see <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:065:0027:0030:EN:PDF>

See also Annex 7.

3 Terms and definitions

A list of definitions and abbreviations (for reference purposes) is added to this standard as Annex 1.

4 General Framework

To gain acceptance of ESTA, the following aspects were listed and discussed as being important:

| | <i>Aspect to be addressed:</i> | <i>Conclusions:</i> |
|---|---|---|
| 1 | Independent | It was concluded that ESTA should be an industry standard owned and managed by ESA |
| 2 | Compatible with existing systems | Care has been taken to ensure that ESTA is compatible with the main international standards (ISO 9001, ISO 14001 and OHSAS 18001) |
| 3 | Easy to understand | The ESTA standard is rather compact (approx. 7 printed pages). (Interpretation/guidance is integrated in the standard.) |
| 4 | Limited 'extra' work for already certified companies | Especially ISO 9001 certification is rather common and ESTA has only two main components not by definition tackled in an ISO 9001 certified organization (linked to risk analysis and competence of staff); the extra work will be limited in such cases. |
| 5 | Fits with National quality assurance schemes | National quality assurance schemes on seed treatments are more restricted than ESTA: they are crop-specific and focus on control of dust. Such systems could easily be brought under the "umbrella" of ESTA |
| 6 | Sufficient attention for: i. environmental aspects ii. worker safety iii. safe food production | (agreed) |
| | | |



ESTA is a Quality Assurance system for all professional seed treaters and the resulting treated seed. As requirements do change over time, the QA system should be flexible. Therefore focus is on continual improvement.

The organization 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.

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

Organizations must have a system in place for continual improvement.

This continual improvement system may have the following inputs: (i) measurements of critical process parameters (ii) periodical customer satisfaction reviews; (iii) registration, analysis and mitigation of customer complaints; (iv) registration, analysis and mitigation of internal complaints, errors and non-conformities; (v) corrective and preventive measures insofar these are not dealt with in the points i to iv, and (vi) review of the risk analysis.

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.

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.

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

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

Responsibilities in the company have to be defined.

Companies must have a process to recall nonconforming product

Additional guidance to § 4

Two key aspects are central, although not always made explicit, for modern quality assurance systems: transparency and the promise "*say what you do and do what you say*". The central role of continual improvement leads to an extensive set of tools for improvement which' use is required. Focus on continual improvement also explains why ESTA avoids prescribing how to set up equipment and to treat seed, how to manage waste and care for the environment, or how to assure worker safety and quality of the treated product.

One specific improvement tool implemented in France for treated maize seed is that seed lots that exceed 3 g of dust per 100 kg of treated seed, but are below 4 g, can be sold, but that an improvement program has to be initiated immediately to ascertain that the dust level decreases again to below 3 g/100 kg. Government has to be informed within 48 hours if the 3 g/100 kg level has been exceeded.



5 Key procedures

As stated in § 4 (General Framework), organizations shall have a continual improvement system in place, control documents and records, and have a process to handle/rework nonconforming product. The importance of these aspects translates into the following key procedures to be in place:

- a. control of documents and records
- b. control of nonconformities
- c. corrective and preventive measures
- d. handle/rework of non-conforming product

Additional guidance to § 5

In this standard, procedures are high level documents that explain responsibilities; these are to be distinguished from work instructions or standard operating procedures.

6 Process description and risk analysis

To achieve reliable process control the processes and their relations should be described. The processes are a basis for the risk analyses. (Process) Measurements to assure process and product quality have to be defined.

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.

This standard does not prescribe use of a specific risk analysis tool; major tools are summarized in Annex 8.

Additional guidance to § 6

Having a clear picture of the processes and their relations serves two purposes. Firstly, this is the starting point for the risk analysis that typically lists all steps and associated risks per step for all processes. Secondly, process measurements to assess the functioning of the QA system can be optimally defined when processes, all inputs and outputs and the risks have been defined.

Full process control is a goal of the process approach. Process control is the opposite of output control; the latter would imply testing each treated seed batch for predefined specifications. Process control provides a higher level of assurance that the output of the process meets the defined product requirements.

Examples of process measurements in the seed treatment plant could be balances of the net weight of all incoming and outgoing products (including waste), volume or weight of seed treatment slurry applied per seed batch, measurements to determine deviations in seed treatment slurry composition, temperature and humidity measurements, and so forth. Measurements are company dependent and can change over time.

7 Proven competence of personnel

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

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).

All personnel, including temporary work staff, demonstrate general awareness of the identified risk factors related to general aspects of all seed treatment and seed handling operations performed at their place of work, and are aware about good practice behaviors mitigating such risks.

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 behavior in their work.

8 Specific requirements for seed/seed treatment companies

1. 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).
2. The seed treatment process, including the recipes used to prepare the seed treatment and the equipment used, must have a proven stability/reliability.
3. 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.
4. The seed treatment process has to be monitored, for instance by visual inspection of the seed lots before and after treatment.
5. An aspiration system should be used for the seed treatment process and following steps till packaging of the treated seed.
6. 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.
7. Samples shall be tested, at least on dust levels with the standard Heubach test, according to a defined scheme.
8. Records allowing for a plausibility check have to be kept on the used amounts of treatment materials per seed lot.
9. Adequate measures are to be in place for waste handling and disposal.
10. Treated seed has to be labeled according to legal labeling requirements and provisions of the registration of the plant protection product.
11. It is recommended to also label according to industry standards, see <http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance>
12. It is recommended that documentation be available that allows seed treatment companies to assess that the purchased seed treatment products meet purchase requirements.
13. 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.
14. Treated seed needs care till the crop has established itself. Farmers have to be made aware of the importance of proper handling.

Additional guidance to § 8

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 a defined scheme for testing samples: for instance in France for maize seed at least first five seed lots treated have to be tested and sales is to be postponed till the test results prove that the lots meet the requirements. During the treatment season at least 10% of the lots need to be tested, with a minimum of 1 test per week and five tests per treatment plant per crop per season.

Seeds not compliant with specific requirements (measured at time of bagging), such as dust levels and seed loading levels, are not to be put on the market. Such requirements are to be interpreted as meeting the most stringent requirement defined by:

- Legal requirements in the country of seed use and/or country of treatment
- Specific conditions of use/seed application in the registration of the seed treatment product
- ESTA industry reference values, as published on the ESTA web pages.

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.

9 Technical standards for seed treatment and treated seed

Best practices shall be used to minimize dust levels of treated seed. Scientific data, taking human and environmental risks into account, are to provide a basis for determining industry reference values. 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.

Note: Reference test methods

To assess dust levels of treated seed the ESA method (standard protocol or work instruction) '*Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds*' is the reference method.

See: <http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance/> for the ESA method and for ESTA industry reference values.

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.

Use of the dust test by industry laboratories as described in the abovementioned ESA reference method '*Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds*' asks for monitoring of the performance of the laboratory. This can be done through participation in a comparative test program.

Note: SGS does provide a voluntary certification for test laboratories for testing seed 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*'. A comparative test program managed by SGS is part of this certification scheme. The FNPSMS laboratory (France), accredited by COFRAC for the Heubach dust analysis 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*', organizes voluntary annual "proficiency tests" for laboratories in order to evaluate and monitor their performance.





Annex 1: List of definitions and abbreviations

| | |
|-----------------------------------|--|
| CEN | European Commission for Standardization |
| CENELEC | European Committee for Electrotechnical Standardization |
| EN | European Standard: a document that has been adopted by one of the three recognized European Standardization Organizations: 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 |
| FMEA | Failure Mode and Effect Analysis. A systematic method of identifying and preventing product and process problems before they occur |
| 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 Organization for Standardization |
| ISTA | International Seed Testing Association |
| Lot (seed lot) | quantity of seed that is physically and uniquely identifiable |
| Must | A synonym of <u>shall</u> as defined in the public ISO list ' <i>Guidance on some of the frequently used words found in the ISO 9000 family of standards</i> ': <i>is to, is required to, it is required that, has to, only ... is permitted, it is necessary</i> |
| OHSAS | Occupational Health & Safety Advisory Services |
| Plant protection product | Plant protection product registered for use according to Council Directive 91/414/EEC |
| 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 |
| QA | Quality Assurance |
| Record | Document stating results achieved or providing evidence of activities performed |
| STAT | See ESA-STAT |
| (Accepted national) System holder | Organization governing a seed treatment quality assurance scheme in one of the member states that meets the requirements of the ESTA standard |
| 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.) |
| ZHA | Zürich Hazard analysis. A method for systematically identifying and managing risks owned by the Zürich Insurance Company |



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

General

Use of the name ESTA and the ESTA logo is controlled. Only ESTA certified organizations 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 organization will enter into an agreement with ESA that grants a non-exclusive license for use and specifies the conditions for use.

European Seed Treatment Assurance: ESTA. Name, logo and use

To emphasize the relation between ESTA and the European Seed Association ESA a logo has been designed that uses a plantlet as known from the ESA logo as the 'T' in ESTA. The arrow-and-seed (or pellet) part of the logo can also be used separately, if appropriate.

Also a grey-scale (monochrome) version is available.



Ownership and copyright

The ESTA documentation, name and logo are owned by ESA, a non-profit international association according to Belgian Law. ESA obtained Community trademark protection for the ESTA name and logo in color and in grey-scale (monochrome).

Governance and use of ESTA

The ESTA Board is appointed by the Board of ESA and represents ESA as the owner of ESTA. Its structure, membership, competences, relations with ESA bodies, acceptance of national system holders, relations with accepted national system holders, use of ESTA in member states with accepted national system holders, financial aspects and all other relevant governance issues are in a separate document (ESTA governance), approved by the ESA Board.

Annex 3: Requirements for certifying bodies

The ESTA Board will grant certifying bodies (either independently or via national system holders) the right to audit organizations on compliance to the ESTA standard and to grant the ESTA certification.

A public register of the accepted certifying bodies will be maintained on the ESTA web site.

A certifying body must be accredited to ISO/IEC Guide 65 – ISO/EN 45011 (General requirements for bodies operating product certification systems) and must 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 organizations to the ESTA standard will be suspended till the accreditation is re-installed.

It is foreseen that the ESTA standard will be required in the scope of the ISO/EN 45011 accreditation of the certifying body when sufficient experience with ESTA has been obtained. A decision to initiate this process could be taken by the ESTA Board in 2013.

Certifying bodies shall report to the ESTA Board annually (directly or via national system holders) on the following:

1. Full name, address, legal structure, ESTA certification with scope and expiry dates of each ESTA certified organization
2. Annual report on audit findings; granted and rejected certificates.

Upon certification of an organization the certifying body reports (directly or via national system holders) the following to the ESTA Board:

3. Full name, address, legal structure and date the certification was granted
4. Scope of the ESTA certification (species).

Annex 4: Use and interpretation of the standard

ESTA certification can only be granted upon an evaluation, as meant in ISO/EN 45011, which includes an on-site audit. After this initial evaluation at least annual verification audits are required.

Terminology as used by ISO is followed; see especially: *Guidance on some of the frequently used words found in the ISO 9000 family of standards*¹. See also Annex 1 for additional definitions and abbreviations used in this standard and the *terms and definitions* chapter in EN-ISO 9000: 2005.

A word not in the ISO list is must. Must is to be read as a synonym of shall as defined in the ISO list mentioned above: *is to, is required to, it is required that, has to, only ... is permitted, it is necessary*.

Annex 5: Dispute and complaint handling

Disputes and complaints are in first instance handled by the certifying body. Having a '*policy and procedure for dealing with appeals, complaints and disputes*' is a requirement for ISO/EN 45011-accredited certifying bodies (ISO/EN 45011, § 4.5.3m).

Escalation is in first instance to the national Accrediting Authority.

National systems may put a system in place to handle disputes and complaints. National systems handle escalations before these are brought to the ESTA Board.

Escalation to the ESTA Board is foreseen only if at national level no satisfactory solution has been found.

¹ See: <http://isotc.iso.org/livelink/livelink/open/tc176SC2public>



Annex 6: Sanctions

If non-conformances are not solved in time, as agreed with the certifying body, the certificate will be withdrawn.

Withdrawn participants (i.e. companies that were certified to ESTA) will remain in the register for 18 months. After this period a company would have to apply as a new participant.

Annex 7: Relationship with other standards (informative)

- **ISTA International Rules for Seed Testing**
The International Seed Testing Association (ISTA) accredits seed test laboratories to its 'International Rules for Seed Testing', which are updated annually. The sampling module of this standard (Chapter 2 of the Rules) provides internationally recognized rules for sampling seed lots. Sampling according to the ISTA Rules ensures that all requirements are met for international movement of seed, treated or untreated. The ISTA Rules do allow for lot sampling as well as for automatic or manual sampling from a seed stream. 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.
- **EN-ISO 17025: 2005. General requirements for the competence of testing and calibration laboratories.**
Reference methods should be rigorously validated; EN-ISO 17025 provides requirements for selection and validation of methods, equipment, calibration and reference materials.
- **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 organization 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.

Additional guidance to the Annex

On sampling procedures

As incorrect sampling can lead to major inconsistencies in test results based on such samples care must be taken that samples duly represent the seed lot from which they were taken.

The sampling module of the standard of the International Seed Testing Association (ISTA) (Chapter 2 of the Rules) provides internationally recognized rules for sampling seed batches. Sampling according to the ISTA Rules ensures that all requirements are met for international movement of seed, treated or untreated.

In general alternative sampling procedures can be used if customers agree.



On seed testing in general

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 analyzed 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'.

In general alternative sampling procedures and tests can be used if customers agree.

Annex 8: Risk analyses; major toolboxes (informative)

Risk analyses are a valuable tool for continual improvement in general and to address hazards including those linked to interfaces between the various parts of the 'seed treatment chain'.

Risk analyses have become an accepted tool in modern quality assurance schemes. Major risk analysis tools are Failure Mode and Effect Analysis (FMEA²), Hazard Analysis and Critical Control Points (HACCP³), Fine & Kinney and the Zürich Hazard Analysis (ZHA⁴). Zürich defines a hazard as "a process step with a potential risk". Basically a risk can be defined as hazard times probability of occurrence (RISK = HAZARD x OCCURRENCE).

Of these four main toolboxes, FMEA is the more flexible with a limited learning curve. Both HACCP and the proprietary ZHA methodology require a significant training effort before the toolbox can be effectively applied, whereas Fine & Kinney often is preferred for safety assessments. For FMEA it is claimed that teams can be immediately productive if team members know the basics of working on a team, like consensus-building, idea generation (such as brainstorming) and maintaining project documentation.

The FMEA tool can result in tabulating the risks associated with all process steps into a table like the example below.

| Process step | Requirement | potential failure mode | potential effect(s) of failure | severity | potential cause of failure | current controls, preventive | occurrence | current controls, detection | detection | RPN |
|--------------|-------------|------------------------|--------------------------------|----------|----------------------------|------------------------------|------------|-----------------------------|-----------|-----|
| | | | | | | | | | | |

The product of the three factors severity, occurrence and detection assist to prioritize the risks to be addressed first. It is called RPN, Risk Priority Number.

The scales used for the three factors are arbitrary, starting with 1 and ranking for instance to 10, or (regularly used in the horticultural field) to 4, or 5.

G.F. Kinney and A.D. Wiruth, building upon work of W. Fine, developed a risk assessment system based on the likelihood of a hazard (ranging from 'might well be expected' to 'virtually impossible'), the likelihood of people being exposed to the hazard (ranging from continuous to

² FMEA originated in the aerospace industry in the 1960s and was developed especially in the automotive industry as a quality improvement tool. A vast body of literature on FMEA is available. Starting point could be: 'The basics of FMEA'. 2nd Edition, 2009. R.E. McDermott *et al.* CRC Press/Taylor & Francis Group, New York.

³ <http://www.fao.org/docrep/v9723t/v9723t0e.htm>

⁴ http://www.zurich.com/riskengineering/global/services/strategic_risk_management/zha_services



very rare) and the consequences if the hazard would give rise to an unwanted event (ranging from catastrophe to noticeable)⁵.

A parallel with the three FMEA parameters is visible. A difference is that in the Fine & Kinney model the scales are not linear; the highest value can be a factor 100 over the lowest one. However, several scales, including scales that put a dollar value on each category, are in use.

Annex 9: Comparison table ESTA/ISO/OHSAS (informative)

Correspondence between ESTA, ISO 9001: 2008, ISO 14001: 2004 and OHSAS 18001: 2007

| Comparison Table | ESTA | ISO 9001:2008 | ISO 14001:2004 | OHSAS 18001:2007 |
|---|--------------|--------------------------|----------------|------------------|
| General framework | | | | |
| ♦ Management commitment | 4 | 5.1 | 4.2 | 4.2, 4.4.1 |
| ♦ Management representative | 4 | 5.5.2 | 4.4.1 | |
| ♦ Continual improvement | 4 | 8.5.1 | 4.2 | 8.4 |
| → process measurements | 4 | 8.2.3, 8.2.4, 8.4, 8.5.1 | 4.5.1 | 4.5.1 |
| → customer satisfaction | 4 | 8.2.1 | | |
| → customer complaints | 4 | 8.2.1 | | |
| → non-conformity follow-up | 4, 5 | 8.3 | 4.5.3 | 4.5.3.2 |
| → corrective and preventive measures | 4,5 | 8.5.2, 8.5.3 | 4.5.3 | 4.5.3.2 |
| ♦ Periodical internal review of the QA system | 4 | 5.6 | 4.6 | 4.6 |
| ♦ Waste disposal process | 4 | | | |
| ♦ Traceability of products | 4 | 4.2.4 | 4.5.4 | |
| Key procedures | | | | |
| ♦ Control of documents and records | 4, 5 | 4.2.3, 4.2.4 | 4.4.5, 4.5.4 | 4.4.5, 4.5.4 |
| ♦ Control of nonconformities | 4, 5 | 8.3 | 4.5.3 | 4.5.3.2 |
| ♦ Corrective and preventive measures | 4, 5 | 8.5.2, 8.5.3 | 4.5.3 | 4.5.3.2 |
| ♦ handle/rework of nonconforming product | 5 | 8.3 | 4.5.3 | |
| Process description | 6 | 4.1 | | |
| Risk analysis | 4, 6 | | | 4.3.1 |
| Proven competence of personnel | 7 | 6.2.2 | 4.4.2 | 4.4.2 |
| Specific requirements | 8 | 7.5.5 | | |
| Technical standards | 9 | | | |
| audits by certifying bodies | 1.1, annex 3 | (implicit) | (implicit) | |

Note: on relations between the ESTA and the ISO 9001 standard

Design & development aspects (ISO 9001; 7.3) are in the ESTA standard covered through the requirement that the seed treatment process, including the recipes used to prepare the seed treatment and the equipment used, must have a proven stability/reliability (§ 8.2). Basically this takes development out of the ESTA standard, but requires proof that the total process is stable and reliable.

Requirements on reliable purchasing (ISO 9001; 7.4) are covered by the ESTA standard as a recommendation (§ 8.12).

Complaint handling (ISO 9001; 7.2.3) is not in the ESTA standard.

⁵ Kinney, G.F. and Wiruth, A.D. (1976). Practical Risk Analysis and Safety Management. AD/A-027189 Washington, US Dept. of Commerce National Technical Information Service. See also: Geoff Taylor, Kellie Easter and Roy Hegney (2004). Enhancing Occupational Safety and Health. Elsevier Butterworth-Heinemann, Oxford