ESTA Checklist

Title	ESTA Checklist
Version	11
Euroseeds nr	24.0012
Date	February 27, 2024

Quality assurance system for seed treatment and treated seed

The goal of ESTA standard is to provide a quality assurance system to assure that seed treatments and the resulting treated seed meet requirements defined by legislators and industry.
This checklist, developed by Euroseeds, is a benchmark checklist designed for auditors to provide guidance while auditing seed plants in reference of ESTA standard. Certifying Bodies must assure that all points covered by the ESTA checklist are taken into account appropriately.

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Effective standard

Audits shall be conducted under
ESTA STANDARD version 2.8, published February 27, 2024 by Euroseeds

Certifying body and auditors

- Name of certifying body : .....
- Name of auditor : .....
- Name of second auditor (if relevant) : .....

Company

- Name of the company : .....
- Name of the person of the company in charge of ESTA standard implementation : .....
- Name of the audited seed treatment plant : .....
- Address of the audited seed treatment plant : .....

Scope of certification:

- Species under the scope must be listed here using either their common name (example: "bean" or "sunflower") or the scientific name (example: "Brassica spp.")
- Is the site audited for packing and/ or repacking of already treated seeds? If yes, the seeds that will be packed and/ or re-packed shall come from an ESTA certified site for the same crop.

Date/duration of audit:

- Date of ongoing audit: .....
- Date of previous audit (if relevant): .....
- Starting/ending time of ongoing audit: .....

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CRITERIA			REFERENCE TO ESTA STANDARD	COMPLIANCE WITH THE CRITERIA / INDICATOR	SPECIFICATIONS	ASSESSMENT			REMARKS
						CONFORM	NON CONFORM	NOT CHECKED	
Process description and risk analysis									
1	Critical	Process description	Section 6	To achieve reliable process control, the processes and their relations shall be described.	NB. This point may be covered by a certification ISO 9001: 2008, (point 4.1) / ISO 9001:2015 (point 4.4)				
2	Critical	Risk analysis & review of the risk analysis	Section 6	Companies must maintain a risk analysis of their ESTA scope related process. Risks that would potentially lead to non-conforming product, incidents and/or environmental damage caused by the ESTA scope related 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 should be available.	At least the following points have to be checked on potential risk factors : - traceability - cleanliness of seeds - aspiration - stable and approved recipes - accuracy of measurements (seeds and phytopharmaceutical products) - accuracy of dosage (seeds and phytopharmaceutical products) - appropriate sampling methods - appropriate analyses methods - workers safety (e.g. contact with phytopharmaceutical products or whole dressing) - safety of environment (spillage, leakage, disposal) - workers training/ proven competence - interfaces with other parts of the seed treatment chain - carryover seed (seed not sold in former season or returned by customer)				
3	Critical	Definition of measurements	Section 6	(Process) Measurements to assure process and product quality have to be defined.	Specific points for measurement must be defined including the definition of reference values. The defined measurements must reflect the process defined in criteria no.11 as well as criteria no. 15, 18, 19, 20, 21 & 27. Measurements must cover at least critical process parameters (also see criteria no. 7). Measurements can be related to mixing the seed treatment suspension (amounts of various components); needed to be able to calculate the amounts of phytopharmaceutical products and active ingredients applied on the seed. Other process parameters can also be relevant and used as measurements, like drying temperature and drying time (if the seed is dried), or temperature and relative humidity of storage. The risk analysis can assist in determining what should be measured.				

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General requirements									
4	Major	Definition of responsibilities	Section 4	Responsibilities in the company have to be defined.	Responsibilities have to be defined at least for the seed treatment plant and its management.				
5	Major	Management representative	Section 4	A management representative shall be responsible for the activities necessary to fulfil the requirements of this standard and for reporting to top management on performance of the quality assurance system and on possible improvements.	A quality manager on the seed treatment plant (on site or within the company) is considered as a management representative. N.B.: This point may be covered by a certification ISO 9001: 2008, (point 5.5.2) / ISO 9001:2015 (point 5.3)				
6	Minor	Review of Quality Assurance system	Section 4	A review shall be performed at least annually to evaluate functioning of the Quality Assurance 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.	The annual review to evaluate functioning of the Quality Assurance system and actions to improve the system is mandatory. NB. This point may be covered by a certification ISO 9001: 2008, (point 5.6) / ISO 9001:2015 (point 9.3)				
7	Minor	Continual improvement system	Section 4	Organizations must have a system in place for continual improvement. This system may include: (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	Organizations shall establish and continually improve a Quality Assurance 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 Quality Assurance system. Individual components of the continual improvement toolbox (points I to V, except IV) can be non-conform or absent, but the continual improvement as a whole must be functioning. Four key procedures linked to continual improvement (control of documents and records, control of nonconformities, corrective and preventive measures, handle/rework of non-conforming product) must be present and used. Customers could be internal or external clients. Internal complaints, errors and non conformites may be synonyms. NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1) / ISO 9001:2015 9point 10.3; 10.3)				

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General requirements									
8	Critical	Registration, analysis and mitigation of internal complaints, errors and non conformities	Section 4	This continual improvement system may have the following inputs: (iv) registration, analysis and mitigation of internal complaints, errors and non conformities	Internal complaints, errors and non-conformities do not need to lead to customer complaints, but have to be registered and used for continual improvement. For instance, if the dust level is too high and the seed lot would be rejected before sending it to a customer this is a non-conformity and measures have to be taken to avoid re-occurrence. But errors can be many, also linked to wrongly mixing chemicals, spilling materials, labeling errors and so forth. Even if the auxiliary “may” is used, the criterion has to be fulfilled. NB. This point may be covered by a certification ISO 9001: 2008, (point 8.5.1) / ISO 9001: 2015 (point 10.1; 10.3)				
9	Critical	Control of documents	Section 4	Documents required by this standard shall be controlled. This means that approved versions are accessible to users.	NB. This point may be covered by a certification ISO 9001: 2008, (points 4.2.3 and 4.2.4) / ISO 9001:2015 (point 7.5; 8.5.6)				
10	Critical	Records for tracking and tracing	Section 4	Companies must keep records to allow for full tracking and tracing of all incoming, stored and outgoing products.	“Products” are seed treatment chemicals, seeds and treated seeds.				
11	Critical	Process to recall, handle or rework nonconforming products	Section 4	Companies must have a process to recall nonconforming products. Organizations shall have a process to handle/rework nonconforming products.	A non conforming product is a product (chemical, seed and treated seed) that doesn’t meet legal or customer requirements, including, for treated seed, requirements for dust levels (dust reference values table). Companies should produce documents to prove the conformity of products including from suppliers. NB. This point may be covered by a certification ISO 9001: 2008, (point 8.3) / ISO 9001:2015 (point 8.7, 10.1, 10.2)				

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Proven competence of personnel									
12	Critical	Training of employees	Section 7	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). NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2) / ISO 9001:2015 (point 7.1.2, 7.2, 7.3)				
13	Critical	Records of competence	Section 7	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). The lack of monitoring is not a non conformity NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2) / ISO 9001:2015 (point 7.1.2, 7.2, 7.3)				
14	Critical	Adequate knowledge of the identified risk factors	Section 7	All personnel, including temporary work staff, demonstrate adequate knowledge of the identified risk factors related to their specific area of responsibilities and actively and consistently implement good practice behaviour in their work.	Personnel need to understand how to handle plant protection products, know how to use personal protection, know how to handle when exposed to a phytopharmaceutical product and how to deal with spillages. NB. This point may be covered by a certification ISO 9001: 2008, (point 6.2.2) / ISO 9001:2015 (point 7.1.2, 7.2, 7.3)				

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Specific requirements for seed / seed treatment companies									
15	Critical	Proven stability/reliability of the recipes used to prepare the seed treatment	Section 8	The recipes used to prepare the seed treatment must have a proven stability/reliability.	The treatment process must contain approval of the recipe by a competent responsible person. The release parameters for the recipe must consider the following criteria : Adaptation of the formulation regarding the quantity of additives and changing work conditions (variable thousand grain weight, etc.).				
16	Critical	Availability of documentation on seed treatment products	Section 8	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.	Material safety data sheets must be available on site at the workplace and must be updated. In the case additives or auxiliaries are used, the use of such substances requires complete documentation. Shelf life and storage conditions also need to be available. Important information may be also on how to handle spillage and how to handle when a person has come in contact with a phytoparmaceutical product.				
17	Critical	Records on the used amounts of treatment materials	Section 8	Records allowing for a plausibility check have to be kept on the used amounts of treatments materials per seed lot.	The requirement means that the weight or volume of seed treatment material applied on a specified amount of seed must be known for each treated seed lot as that allows for calculating that the correct amount has been applied. See criteria no. 3				
18	Critical	Proven stability/reliability of the seed treatment process	Section 8	The seed treatment process must have a proven stability/reliability	To prove the stability of the treatment recipe and treatment process, documentation on test treatment and commercial treatment must be available. A work order must be available for every treatment. This work order must contain or must be linked to the following information: species, variety, lot number and thousand grain weight, treating recipe including application rate, commercial name and active ingredient of phytopharmaceutical products The release parameters are assessed while considering the maximum quantity of active ingredient homologated for the respective indication. The dust value is defined as a release criterion. Release parameters are also valid for carryover seed.				
19	Critical	Monitoring of the seed treatment process	Section 8	The seed treatment process has to be monitored, for instance by visual inspection of the seed lots before and after treatment.	The monitoring must consider the control plan as defined under criteria no. 27 and the records on the used amounts (see criteria no. 3) The whole treatment process has to be monitored via treating protocol.				
20	Critical	Crop-specific criterion	Section 8	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).	Crop-specific criteria are defined by the company. Control of the quality of input products is a major issue of process control.				

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21	Critical	Proven stability/reliability of the seed treatment equipment	Section 8	The seed treatment equipment must have a proven stability/reliability	All used equipment must be appropriate for the intended use. The equipment must be calibrated and maintained regularly.				
22	Critical	Aspiration system	Section 8	An aspiration system shall be used for the seed treatment process and following steps till packaging of the treated seed.	Cleaning of seeds is the most important initial step to produce high quality seeds. To reduce dust as much as possible aspiration is necessary and needs to be installed before and after the treating unit. This is necessary to produce seeds with low dust values.				
23	Critical	Process for waste disposal/ Waste handling and disposal	Section 8	Companies must have a process and must implement adequate measures for waste handling & disposal that meets legal requirements. This must be in line with Good Agricultural Practices (GAP), meet expectations on sustainability & sustainable business conduct.	Documents shall be at hand for verification of appropriate disposal.				
24	Critical	Labelling of the treated seed	Section 8	Treated seed has to be labelled according to legal labelling requirements and provisions of the registration of the phytopharmaceutical product.	It is recommended to also label according to industry standards, see http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance.				
25	Major	Information on handling of treated seeds	Section 8	Treated seed is sensitive to environmental influences. Therefore, the transport companies have to be made aware that great care must be taken to avoid any extreme handling. Treated seed needs care till the crop has established itself. Farmers have to be made aware of the importance of proper handling.	It can be covered by a label or on a separate leaflet.				
26	Critical	Reference samples	Section 8	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.	The samples taken shall be divided up appropriately if relevant (reference samples, samples for official certification, samples for clients). The different samples shall be adequately sized (0.5 kg or more for Heubach Testing). The samples should be stored at least 12 months.				
27	Critical	Control plan	Section 8	Samples shall be tested, at least on dust levels with the standard Heubach test, according to a defined scheme.	A control plan must list measurement points containing defined frequencies, methods, reference values and thresholds (if relevant). Also see criteria No. 11. The control plan shall enable appropriate monitoring (see criteria no. 19). It is recommended that visual inspections of the seedlots (raw material as well as treated seed) are also listed in the control plan. Additional loading tests are recommended. Pelleted seeds shall be tested for dust levels at least once every two weeks, while the rest of the seeds shall be tested at least once per week. For onion and carrot seeds apply the following: -In case the seeds were treated more than one year ago, Heubach test is performed on the seed to be (re)packed, provided that the batches are more than 5 kg. In case of batches less than 5 kg, no Heubach test is performed. -In case the seeds were treated less than one year ago, no Heubach testing is performed on the seed to be (re)packed.				

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Technical Standards for seed treatment and treated seed									
28	Critical	Reference test method in laboratory	Section 9	The accuracy, reproducibility, precision, robustness, and general reliability of reference methods must be beyond doubt. Use of the dust test by industry laboratories asks for monitoring of the performance of the laboratory. This shall be done either by successfully participating in corresponding ring tests organized by a laboratory which is accredited by its national accreditation body for the Heubach dust analysis according to the Euroseeds reference method or by a Heubach certification delivered by an independent certifying body.					

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Total of criteria conform, non conform or not checked							
Synthesis and proposal on ESTA certification:							