

GSPP Standard

for tomato seed and young plant production sites

Version 3.4

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CONTENTS

CONTENTS	2
HISTORY OF CHANGES	3
1 INTRODUCTION AND SCOPE OF THIS STANDARD	3
1.1 References	4
1.2 Schematic description of a GSPP site.....	5
2 IDENTITY.....	6
3 QUALITY MANAGEMENT SYSTEM (QMS)	6
3.1 Quality Policy	7
3.2 Scope.....	7
3.3 Organization.....	8
3.4 Staff	8
3.5 Quality Management Documents	9
3.6 Document Management	10
3.7 Audits	10
3.8 Management Review.....	11
4 RISK ANALYSIS	12
4.1 Risk Identification	12
4.2 Risk Analysis and Control Measures	13
5 CROP MONITORING FOR <i>Cmm</i>	13
6 CRISIS MANAGEMENT	14
6.1 Plants (minimum requirements)	14
6.2 Seeds (minimum requirements)	15
6.3 Facilities	15
6.4 Record the findings for both seeds and plants	16
6.5 Conditions that warrant a Root Cause Analysis or Technical Investigation Procedure.....	16
7 SALES AND SHIPMENT.....	16
8 TRACEABILITY	16
9 CUSTOMER RELATIONSHIP.....	17
10 DELIVERY DOCUMENTS & LABELS	17
10.1 Delivery documents	17
10.2 GSPP Product Seed	18
10.3 GSPP Product Plants.....	19
11 TECHNICAL REQUIREMENTS	19
12 REQUIREMENTS FOR LABORATORIES TESTING FOR THE GSPP SYSTEM	19

HISTORY OF CHANGES

Version	Chapter	Changes
3.0 & 3.0.1. (follows 2.1)	1.1	Other documents listed & wording
	1.2	Wording, new figure 1
	2	Added
	3.2.1	Wording
	3.2.2	Wording added
	3.2.4	New chapter
	3.3.3.	Chapter deleted, moved to 3.5.3
	3.5.2	Changes & wording added
	3.5.3	Changes & wording added
	3.7	Chapter changed
	3.8	Wording
	4.1.2	Wording added
	6.	Change
	6.1	Change
	6.2	Changes & wording added
	6.3	New chapter
	6.4	Was 6.3 in V2.1
	6.5	Was 6.4 in V2.1
	10.	Information included from Annex 14.5. 10.1, 10.2 and 10.3 new chapters, no changes in content.
	12.	New chapter
3.2	1.1	Alignment title Annex 14.7
	3.2.3	Wording changes
	6.	Chapter changed. Alignment with new version annex 14.6
	9.	Chapter changed
3.3	all	English text adapted
	3.5.1	Annexes to the standard is added
	3.7.1	Extraction is taken out, (not a vulnerable process)
3.4	3.2.3	Change

1 INTRODUCTION AND SCOPE OF THIS STANDARD

GSPP is an Certification system based on a process approach preventing the introduction and spread of seed- and plant-transmitted pathogens. GSPP is intended as a system for

certified companies to ensure that site(s), quality management systems, work methods and the way in which quality information is supplied comply with the defined standard and to check their performance, periodically.

The GSPP standard applies to the following crops:

- Tomato and tomato rootstock.

The GSPP standard applies to the following pathogens:

- *Clavibacter michiganensis subsp. michiganensis*(Cmm).

The GSPP standard is based on the following requirements:

- The Participant's quality management system.
- Risk assessment of defined threats in production facilities and processes.
- Technical requirements based on the listed crops and pathogen.

GSPP is a chain approach (see scope). When all applicable steps in this scope are carried out and checked, thereby providing evidence of compliance with all listed requirements, the Participant

- will receive GSPP recognition (certificate);
- is authorized to use the collective GSPP trademark.

GSPP Participants are operators in the business chain of producing tomato seeds and tomato young plants. The following GSPP Participants have been identified: Plant Raisers, Seed Companies, Seed Producers, Seed Technology Company, Sub-Contractors and independent seed Distributors. Though Commercial Growers and Service Suppliers are not included in the Standard, they play an important role in the success of the Standard.

All these aspects together form an integral framework:

GSPP-standard

For tomato seed and young plant
production sites

1.1 References

The following documents are available on the GSPP website (www.gspp.eu). They must be included in the Participant's quality management system:

- GSPP Standard for tomato seed and young plant production sites latest version.

Other documents that may be mentioned specifically are:

- Annex 14.1 Guidelines GSPP for sampling of seed lots for seed health testing, latest version.
- Annex 14.2 Protocol for *Cmm* diagnosis in plant material, latest version.
- Annex 14.3 ISHI protocol, latest version.
- Annex 14.5 Technical requirements GSPP Standard, latest version.
- Annex 14.6 *Cmm* infection handling, Root Cause Analysis (RCA) and Technical Investigation Procedure (TIP) in GSPP supply chain, latest version.
- Annex 14.7 GSPP Definitions & explanation scopes, latest version.
- Annex 14.8 Requirements for laboratories testing for the GSPP system.
- Annex 14.9 Overview GSPP accepted seed health test methods and validity of the results latest version.

Other documents used as references or forms in the GSPP Standard, for example the application and modification form, general audit regulations, Participation Letter etc.

1.2 Schematic description of a GSPP site

To fully understand the principle of the GSPP site, a schematic description of a GSPP site is given below. This model is applicable under different practical circumstances and colors are used to better illustrate the different areas (Figure 1).

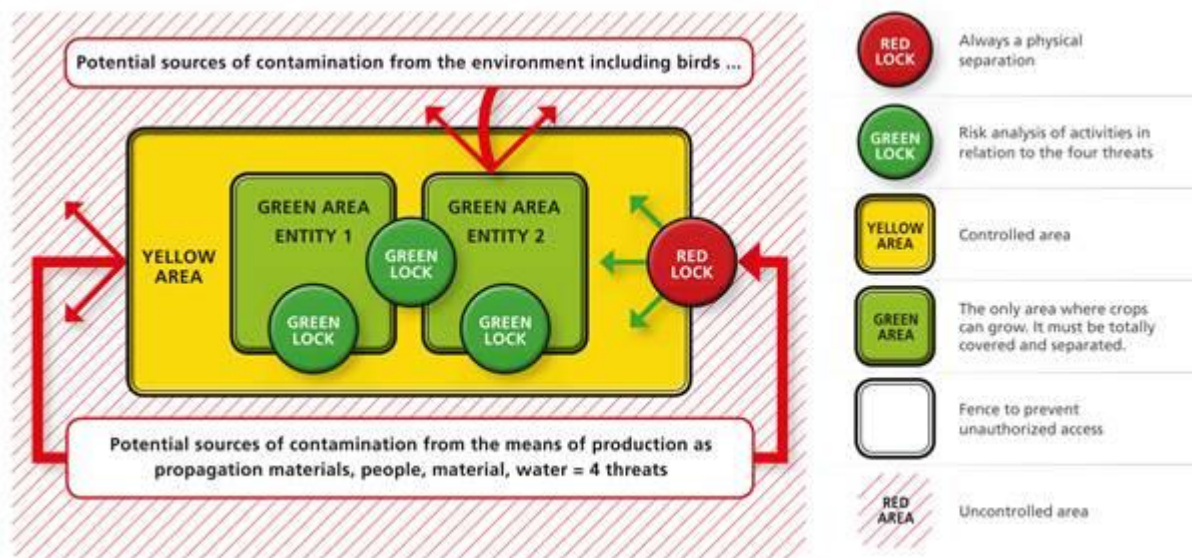


Figure 1 Schematic model of a GSPP site

A GSPP site is a physical location where plants and/or seeds are grown and/or processed, and the location may be separated into several production areas. A Site is specifically named on the certificate and/or certified list. Each site consists of so-called Red, Yellow, (optional), and Green areas.

The Red Area is an uncontrolled area that is separated from a Green or Yellow Area by means of a Red Lock. GSPP assumes that *Cmm* may be present in this area. A Red Lock is always physical. A Red Lock is designed to control the four Threats (propagation material, water, people and materials (including equipment)) with access to the Yellow or Green Areas after sufficient disinfection and/or a risk analysis that indicates that the potential for contamination with *Cmm* has been minimized. The risk of contamination between the Red and Green or Yellow Areas is minimized by a Red Lock. When entering the Yellow or Green area via the Red Lock, the boundaries (the start and end) of the Red Lock should be logical, identifiable/visible and controllable.

The Yellow Area is the section of the production site beyond the Red Lock, in which all important hygiene measures are followed. This area is separated from the Red Area (by a Red Lock) and from the Green Area (by a Green Lock).

The Green Area is the only area in which crops may grow. It must be completely covered and separated from Red Area. Additionally:

- In ventilation openings in Seed production (and its plant production for seed production) areas, netting is compulsory.
- In ventilation openings in Commercial Plant production areas, netting is not compulsory.

The Green Area is separated from the Yellow Area by a Green Lock. This may be a 'physical or non-physical separation', but remains a compulsory divide between the Yellow and Green Areas or between two entities. Entities must be recorded. A Green Lock is implemented and required if a risk analysis determines that there is a potential risk of contamination or cross-contamination. If this is the case, preventive measures must be documented and implemented. The risk of contamination between entities has to be minimized.

2 IDENTITY

The Participant must be a company that is organized and governed by the laws and regulations in force in its host country. The Participant is registered at the GSPP Secretariat by means of an application and/or modification form. The Participant's authorized representatives have signed the Participation letter and it has been accepted by GSPP Board.

3 QUALITY MANAGEMENT SYSTEM (QMS)

The Participant must have a quality management system in place that encompasses the items in this Standard.

3.1 Quality Policy

The Participant's management must formally express its wish to comply with the GSPP Standard in order to produce healthy plants/seeds, as required by this standard.

3.2 Scope

3.2.1 The Participant must clarify the scope of each site(s) in the Quality Manual (§ 3.5.3). Potential certification categories for Participants include:

SCOPE #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
PROCESS	Sampling and/or testing of starting material	Interface (shipment of starting material)	Production of plants for seed production	Interface (shipment of plants)	Production of seeds	Interface (shipment of fruits)	Extraction	Interface (shipment of seeds)	Seed processing	Interface (shipment of seeds)	Seed treatment / enhancement	Interface (shipment of seeds)	Sampling and/or testing of seeds	Interface (shipment of seeds)	Trading of seeds, issue the Collection Trademark	Interface (shipment of seeds with GSPP-Collective Trademark)	Production of plants for fruit production	Interface (shipment of plants with GSPP-Collective Trademark)

Figure 2 Reference table indicating which processes are part of the scope of a GSPP Participant

3.2.2 Steps 3, 5, and 17 are processes that are vulnerable to *Cmm* infection and must be conducted in the Green Area.

3.2.3 The Participant must be able to show evidence of sub-contracted processes. Subcontractor must follow same instructions as participant's employees unless stated otherwise. The quality requirements of the Participant for the service delivered by the Subcontractor must be clear. Supervision by Participant must lead to correct implementation of GSPP.

3.2.4 The explanation and boundaries of each Scope are explained in Annex 14.7.

3.3 Organization

3.3.1 The Participant must organize itself to be able to continuously comply with the requirements of this Standard.

3.3.2 The Participant must appoint:

- A technical manager (irrespective of title) who is directly responsible for the technical performance of the GSPP Production Site.
- A quality manager (irrespective of title) who is responsible for the Quality Management System and its implementation on site(s), including the reports related to this system.

3.4 Staff

3.4.1 The Participant must have a sufficient number of employees to be able to provide labor on the production site(s), with the qualifications and/or skills required for the completion of their tasks.

3.4.2 The Participant must define and maintain a recorded training procedure. This procedure must cover:

- The identification of training needs.
- The planning and provision of training.
- Evaluation of the training.
- A record of employee training and qualification.

3.4.3 Staff must be informed clearly of the tasks, competencies, and responsibilities assigned to them through:

- Procedures/working instructions.
- Adequate supervision.
- Qualifications/training/experience.

3.4.4 Task substitution must be arranged for key personnel.

3.4.5 Personnel shall not be under any financial, commercial, or other pressure that could have a negative influence on their work efficiency.

3.4.6 The Participant's management must ensure that appropriate communication processes are established within and between the departments or positions in question.

3.4.7 Communication must take place with regard to the efficiency and effectiveness of the Quality Management System.

3.5 Quality Management Documents

3.5.1 The QMS must be laid down in a quality manual that complies with the requirements of this Standard and annexes to the Standard.

3.5.2 The quality manual must be available in English, at least, with the provision that it and the procedures listed in the GSPP Standard may be written in French in France and in Dutch in The Netherlands. All other documents are allowed to be written in the local language. If the working instructions, forms, and other documents are written in the local language, the company should employ an independent translator during audits.

3.5.3 The quality manual must contain (at least):

- The name of the company.
- A general description of the company.
- GSPP Sites.
- Content page of the quality manual.
- Matrix: quality manual paragraphs/ GSPP Standard paragraphs.
- Quality policy and scope (per site, if applicable).
- Organization organigram.
- Flow chart of processes.

3.5.4 The Participant must also provide a specification of:

- Procedures.
- Working instructions.
- Physical layout of the site(s).
- All forms.

3.5.5 The quality documents must be maintained and kept up to date.

3.6 Document Management

3.6.1 Document control

The Participant must define a system:

- To manage all documents and data pertaining to the requirements of the GSPP Standard;
- Including, and where applicable, documents from external sources.
- This management system must:
 - Process document versions.
 - Approve documents.
 - Implement changes to documents (including removal of obsolete documents).
 - Ensure documents related to the function/task/process are available on site.

3.6.2 Records control (including electronic quality data).

The Participant must be able to justify its decisions regarding:

- Which quality records are kept.
- By whom and where.
- For how long.
- And how they are removed/destroyed after this period.

It must be demonstrated that the reliability and stability of any electronic data processing systems is such that it does not influence the accuracy of results. Data security must be ensured, including prevention of unauthorized access and unauthorized modification of computer data.

3.7 Audits

3.7.1 Internal audits:

- The Participant must define and maintain a procedure for planning and implementing Internal Audits pertaining to quality.
- The Internal Audit must be performed by the Applicant/Participant and must be in line with the QMS requirements, and the flow of activities. The Applicant/Participant plans Internal Audits as follows:
 - At least once every three years for non-vulnerable processes (processes that do not entail a risk or have a low risk on *Cmm* contamination), e.g. quality manual review, document control, etc.
 - At least once a year for vulnerable processes (processes that entail a high degree of risk of contamination with *Cmm*: Scopes 3, 5, and 17), e.g. crop monitoring, sowing, grafting, harvesting, etc.

- All processes are audited according to an internal audit plan. Based on the outcome of Internal and Implementation/Documentation (external) Audits, a logical Audit plan has to be made considering the processes and their importance of appraising. The logical audit plan must:
 - Include an assessment of the status and the significance of the audited process;
 - Include internal auditors being independent regarding the audited process;
- Internal auditors who have attended an auditor training course and/or are skilled.
- During an Internal Audit, the internal auditor checks whether or not daily practices are carried out in accordance with:
 - The GSPP Standard
 - And the Participant's QMS.

3.7.2 The Participant must do the following after an Internal and External (Implementation/Documentation) Audit:

- Record the results of both the Internal and External Audit and bring these results to the attention of those employees responsible for the audited process.
- Carry out a root-cause analysis and take adequate corrective action for any non-conformity revealed during an audit.
- Verify and record the effectiveness of any corrective measures.

3.8 Management Review

The Participant's management must review its processes annually to determine the effectiveness of its QMS. The management review objectives/outcome must be SMART: Specific, Measurable, Acceptable, Realistic and Time bound.

The management review must include, at least (as evidenced by minutes):

- Minutes from the previous management review.
- Results of audits (e.g. non-conformities).
- Feedback from customers.
- Control measures.
- Process indicators related to the functioning of the site.
- Possible contamination.
- Status of preventive and corrective actions.
- Possible changes (e.g. in GSPP Standard, lay out, staff, etc.) with consequences for the Participant in relation to GSPP.
- The conclusions may suggest a need to improve the QMS. If this is the case, it must be set out in new objectives (specific, measurable, acceptable, realistic and time bound) for the coming year(s), in addition to a:
 - Plan of approach.
 - Possible constraints.
 - Implementation/communication with employees.

4 RISK ANALYSIS

4.1 Risk Identification

4.1.1 A procedure describes how risks are identified (method, responsibility, frequency, etc.). The risk analysis must be updated regularly and in the event of changes related to:

- All processes.
- New insights into risks.
- Organization.

4.1.2 The possible risks from the four threats must be identified prior to any risk analysis for:

- Each process.
- On each site (including Red and Green Locks).
- For the whole production and processing cycle.

4.1.3 This must be carried out by a risk-identification team that is competent, multi-disciplinary and expert related to the requirements of the Standard and *Cmm* Hygiene.

This team, which includes representatives from both management and operators/employees, must be familiar with the interfaces between relevant processes.

4.1.4 Identifying risks means considering each process at the working-instruction level by:

- Observing the process(es) applied on a daily basis to address specific risks related to the four threats.
- Noting findings (process step–risk/cause).

4.1.5 Records must be kept.

4.2 Risk Analysis and Control Measures

All identified risks must be analysed individually. This must be done by a competent and multi-disciplinary team.

The team must:

- Consider each risk and its possible cause(s).
- Determine the possible impact.
- Decide whether or not a control measure is required.
- Develop a new control measure or,
- Adapt an existing control measure.
- Enact/manage control measures as necessary (the control measures have to be visibly managed/monitored in an appropriate way to reduce/minimize the risk of contamination by *Cmm*).
- Note the conclusions (process step – risk/cause/impact – conclusion/motivation. For example, no control measure required or reference to a control measure with a link to a procedure or instruction).
- Make clear which records have to be kept to monitor the control measures (to demonstrate whether or not an aspect is under control).

5 CROP MONITORING FOR *CMM*

The production site must have a crop monitoring procedure that indicates:

- Responsibilities,
- Competencies,
- Frequency,
- Method,
- Forms.

The results of inspections must be recorded.

6 CRISIS MANAGEMENT

The Participant must have a Crisis Management Procedure (this procedure must be applied immediately in the event of detection of suspicious plants or seeds).

The GSPP Participant that observes, and/or has received written notification of a Suspected *Cmm* Infection (either from a GSPP or non-GSPP participant) reports this notification to the GSPP Participant(s) who supplied the seeds or young plants. This must be done within five days of the initial observation or of the receipt of written notification from the GSPP Participant(s) who supplied the seeds or young plants.

Confirmation and initial emergency measures may thus comprise the activities listed in 6.1 and 6.2. The list of activities is not exhaustive – it includes the minimum required actions. Circumstances may require additional activities.

In the event of no confirmation, the RCA and TIP do not apply.

If *Cmm* infection is confirmed, Annex 14.6 is applicable and its enactment mandatory for all GSPP Participants involved in a confirmed *Cmm* incident. This annex concerns seeds and/or young plants originating from a GSPP product (seeds and/or young plants that are marketed and/or distributed under the GSPP label or that have been part of the GSPP supply chain).

The execution of the emergency plan and crisis management is the responsibility of the affected party (i.e. where the *Cmm* infection was confirmed). Temporary suspension of deliveries of seeds and/or young plants from this entity is required. The emergency plan consists of the crisis measures to be taken by a Suspected *Cmm* and/or Confirmed *Cmm* company to prevent the spread of the disease. These measures must be in line with local NPPO regulations.

The minimum requirements for plants and seeds are listed below.

6.1 Plants (minimum requirements)

- Mark and isolate the suspected plant.
- Inform management.
- Restrict access to the suspected area and adapt the working method.
- Sample and investigate the suspected plants by means of laboratory testing (see Annex 14.2).

Negative outcome: carry on with the normal working procedure.

Positive outcome:

- Carry out root cause analysis to identify the entities that are affected (downstream and upstream) in the process.
- Start cleaning and sanitation.
- The management must inform GSPP Participants that produce beyond the same red lock in the relevant production cycle.
- Decide whether a recall is necessary.

6.2 Seeds (minimum requirements)

- Inform the management.
- Block the lot and lots in the same Green Entity.
- Confirm the suspicion.
- Make decisions based on the results of analysis.

Negative outcome: carry on with the normal working procedure.

Positive outcome:

- Carry out Root Cause Analysis to identify the entities that are affected (downstream and upstream) in the process and define action plan.
- Start cleaning and sanitation.
- Under no circumstances may seeds from the same Green Entity be used in the GSPP system, production or delivery.
- Decide whether a recall is necessary.
- If *Cmm* has been found behind a Red Lock and there was starting material present for GSPP Production, the seed company must notify all seed producers that have received starting material from that entity and production cycle.
- If *Cmm* has been found behind a Red Lock, the Seed Producer must inform all GSPP Participants that produce seeds behind this Red Lock in this production cycle.

6.3 Facilities

In the event of the red lock being broken or failing and there is a high risk of *Cmm* entering the yellow and/or green area:

- The incident be registered and risk assessment must be executed on the situation.
- If necessary a root cause analysis must be done and corrective measures related to the four threats must be taken and registered.
- Registration, risk assessment and corrective evidence need to be audited afterwards in internal audits and by the AO during an external audit (periodical, renewal or re-entry audit).

6.4 Record the findings for both seeds and plants

All relevant findings must be recorded and registered.

6.5 Conditions that warrant a Root Cause Analysis or Technical Investigation Procedure

The handling of *Cmm* infection, Root Cause Analysis (RCA) and Technical Investigation Procedure (TIP) in the GSPP supply chain are described in Annex 14.6.

The objective here is to describe actions that must be taken in a situation in which a confirmed *Cmm* incident has occurred:

- The collection of facts and drawing technical conclusions based on these facts.
- Making recommendations to improve the GSPP System and reduce the risk of *Cmm* outbreaks in the future.
- Adaptation of the GSPP Standard, if needed.
- Safeguarding the GSPP's reputation in the market.

7 SALES AND SHIPMENT

Plants and seeds are packed and handled in such a way during the sales and shipment phase that risks are negligible.

8 TRACEABILITY

The Participant must have a system to:

- Track and trace the entire history of a lot (seeds, plants, pollen or plant parts) throughout the entire GSPP process chain and across possible Entities (in terms of participant responsibility).

9 CUSTOMER RELATIONSHIP

The Participant must have:

- A complaint handling procedure, to which Annex 14.6 is applicable and mandatory for all GSPP Participants involved in a confirmed *Cmm* incident. This annex concerns seeds and/or young plants originating from a GSPP product (seeds and/or young plants that are marketed and/or distributed under GSPP label or that have been part of the GSPP supply chain).
- A logical recall procedure that complies with local phytosanitary regulations.

10 DELIVERY DOCUMENTS & LABELS

10.1 Delivery documents

Delivery documents must be clear and unambiguous.

All rights and obligations concerning the Collective Trademark are laid down in "REGULATIONS ON THE USE AND SUPERVISION OF THE GSPP COLLECTIVE TRADEMARK". In the event of a contradiction between the interpretation document and the Regulations, the Regulations shall prevail.

Use of the Collective Trademark is only permitted by GSPP Participants:

- Provided it is not included in another logo or mark to form a new combination;
- Provided the size allows for clear and easy reading of the letters "GSPP" in the Collective Trademark;
- Provided the Collective Trademark does not surpass the attention value of the Product, trademark and/or trade name. The Collective Trademark must always be communicated and presented as a Collective Trademark. It may not be used as a brand name or presented in such a way that suggests this is the case.

Use of the Logo is only permitted:

- In the mock-up and typographical design, as specified and available for GSPP Participants on the website www.gspp.eu;
- In black/white or in the registered color combination, as specified below:



The Participant must prove that GSPP certification was in place during the production period and sales of the GSPP products.

10.2 GSPP Product Seed

The participant must ensure:

- GSPP certification for all Scopes 1-16.
- Identification of batches of seed production plants produced according to the GSPP Standard (method: track and trace system, not labelling).
- Identification of batches of seed produced according to the GSPP Standard (method: track and trace system, not labelling).
- Commercialization of GSPP seed (method: track and trace system, invoices and/or waybill (shipping documents) of GSPP seed, where the invoices and/or waybill display the GSPP logo and/or a reference to GSPP is made that is linked with the seed product description).
- Demonstration of the seed packaging material with affixed GSPP logo.

Or for a seed distributor:

- GSPP certification for all Scopes 15-16.
- Identification of batches of seed produced according to the GSPP Standard (method: track and trace system, not labelling).
- Commercialization of GSPP seed (method: track and trace system, invoices and/or waybill (shipping documents) of GSPP seed, where the invoices and/or waybill display the GSPP logo and/or a reference to GSPP is made that is linked with the seed product description).
- Demonstration of the seed packaging material with affixed GSPP logo.

Seed producers should demonstrate (through their track and trace system) the production of seeds according to the GSPP Standard. The seed, produced by a seed producer, must be identifiable for the seed company as GSPP seed. No visible GSPP logo is allowed on the seed packaging. In their contracts with seed producers, seed companies should specify that any disruption of GSPP certification must be communicated to them.

10.3 GSPP Product Plants

The participant must ensure:

- GSPP certification for Scope 17 and 18.
- Identification of batches of plants produced according to the GSPP Standard (method: track and trace system, not labelling).
- Commercialization of GSPP plants (method: track and trace system, invoices and/or waybill (shipping document) of plants, where, on these documents, a reference sentence, such as, "Produced according to the GSPP Standard" is added; the GSPP logo may also be printed on the documents).

11 TECHNICAL REQUIREMENTS

The technical requirements for the GSPP Standard are specified in Annex 14.5.

12 REQUIREMENTS FOR LABORATORIES TESTING FOR THE GSPP SYSTEM

The requirements for laboratories that conduct both seed testing and testing of suspected plants according GSPP requirements are specified in Annex 14.8. An overview of GSPP-accepted seed health test methods and validity of the results are mentioned in Annex 14.9.