

# **Annex 14.7**

## **GSPP definitions and explanation scopes**

**Version 1.7**

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## Annex 14.7 GSPP definitions & explanation scopes

### GSPP definitions

- Affected company:** the parties that are directly affected by a confirmed *Cmm* outbreak. Affected companies may consist of non-GSPP companies and GSPP Participants. These parties may be the producers and owners of seed or other starting materials in which *Cmm* has been confirmed, as well as the notifying companies.
- Applicant:** a company that has submitted the signed application form to become a Participant in the GSPP Certification system.
- Audit:** a systematic and independent examination to determine whether or not quality activities and related results are in compliance with planned arrangements/measures and whether or not these arrangements/measures have been implemented effectively and are appropriate in light of achieving the objectives set out.
- **Corrective Audit:** an extra Audit to verify corrective action in response to non-conformities. The AO can decide to handle non-conformities based on documentation or an Audit carried out on location.
  - **Documentation Audit:** an audit to check whether or not the Quality Management System itself is in line with the GSPP Standard and the site implementation and local documentation.
  - **Implementation Audit:** an audit to check whether or not daily practices are in line with the GSPP Standard and the Quality Management System of the Applicant/Participant (for both the general, as well as the Site-specific parts).
  - **Initial Audit:** the first Audit required to become Certified by GSPP by means of the GSPP Certification system: this is both a Documentation Audit, as well as an Implementation Audit.
  - **Periodical Audit:** an annual Audit required to maintain Certification by GSPP based on the GSPP Certification system. This is an Implementation Audit.
  - **Pre-Audit:** an audit to assess the preparedness of an Applicant to comply with the GSPP Standard based on the GSPP Certification system. The conclusions of the Pre-Audit are communicated to the Applicant only.

- **Re-entry Audit** an extra Audit to verify corrective action taken in response to emergencies (e.g. a pathogen outbreak).
- **Renewal Audit:** an audit to renew Certification by GSPP based on the GSPP Certification system for a three-year term: this is both a Documentation Audit, as well as an Implementation Audit.
- Unexpected Audit:** an unannounced Audit, which is optional. The Unexpected Audit is conducted based on a decision of the Board, but can be triggered in response to information received from an AO. GSPP bears the cost of an unexpected audit.
  
- Audit Organization (AO):** an organization appointed by the GSPP Foundation to conduct Audits on GSPP's behalf.
- **Sub-audit organization:** an audit organization with which the AO has signed an agreement to carry out Audits after consultation between GSPP and the other AO.
- Auditor:** a person who is qualified to perform quality assurance Audits, meeting the requirements as defined in the audit regulations; he/she is an employee of an Audit Organization.
- **Lead auditor:** the auditor in charge of an Audit and an employee of an Audit Organization.
- Basic seeds:** seeds used to plant parental lines for seed production.
- Board or GSPP Board:** the Board of the GSPP Foundation.
  
- Certification:** the process in which a company applies for Certification; this includes an Audit of the company and, where applicable, an audit of the production Sites involved. If the requirements of the GSPP Standard are met, the Audit Organization in charge of the audit process will send a recommendation to the GSPP Board. The GSPP Board decides on Certification on basis of this recommendation. In the event of a positive decision of the GSPP Board, the Applicant will sign the Participation Letter and the company will be incorporated into the GSPP Certification Register. Once all these steps have been completed, the company is Certified and is referred to as a Participant.

<b>Certification Date:</b>	the date of the initial Site audit or the recommended date of AO, as stated in the audit summary report. This date is the date upon which all criteria for Certification have been met by the Participant.
<b>Certification Register:</b>	the register in which all companies and Sites that have been audited and found to be in compliance with the GSPP Standard and that have signed the Participation Letter are listed; the register is published online at: <a href="http://www.gspp.eu">www.gspp.eu</a> .
<b>Certified List:</b>	the document linked to the Certificate of Certification that specifies the details and the Scope of the Certified Site(s).
<b>Certificate:</b>	a numbered Certificate of Certification issued per company that specifies Site details and the Scope(s) of the Certified Site(s) and the certification period.
<b><i>Cmm</i>:</b>	<i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> .
<b>Collective Trademark:</b>	the GSPP quality mark as registered with the relevant trademark authorities; it may only be used in accordance with the regulations on the use and supervision of the GSPP Collective Trademark.
<b>Commercial seeds:</b>	Hybrid or open-pollinated (OP) seeds for commercial use.
<b>Commitment Letter:</b>	a letter to be signed by a non-GSPP participant that is required to participate in a TIP.
<b>Confirmed <i>Cmm</i> infection:</b>	A <i>Cmm</i> infection is considered confirmed when the diagnosis is made using the method described in Annex 14.2 or Annex 14.3 of the Standard. For the method specified in Annex 14.3, the analysis needs to be carried out by a recognized laboratory.
<b>Control measure:</b>	any action or activity undertaken to prevent, reduce or eliminate a <i>Cmm</i> hazard.
<b>Corrective action:</b>	a documented action required of a GSPP applicant or Participant to correct and prevent a recurrence of a weakness in the system that fails to conform with the QMS and/or GSPP Standard.
<b>Corrective evidence:</b>	documented, objective proof of the implementation of corrective action. Objective evidence is data that shows or proves that something exists or is true. Objective evidence can be collected based on observations, measurements, tests or adapted procedures, working instructions, documents, photos, etc. and must be forwarded to the AO.

<b>Disinfection:</b>	the act or process of cleaning or purifying a room, wound, item of clothing etc, from pests that cause disease. The disinfection should be able to take away the potential presence of <i>Clavibacter</i> bacteria.
<b>Emergency Team (ET):</b>	a team consisting of representatives of (minimally) the Affected companies, with or without the inclusion of a GSPP Expert, to investigate in the event of a <i>Cmm</i> outbreak and reach technical conclusions.
<b>Entity:</b>	<ul style="list-style-type: none"> <li>- a group of plants that are separate from other groups of plants;</li> <li>- this separation relates to the four threats;</li> <li>- this separation must be achieved using a Green Lock;</li> <li>- an Entity can be sub-divided into other Entities;</li> <li>- when sub-dividing an Entity, a plant's Entity must remain clear at all times (tracking and tracing), both downstream and upstream in the process.</li> </ul>
<b>Fruit sampling:</b>	a sampling method in which fruits are sampled to generate a composed seed lot from which test and reference samples are generated.
<b>Green Area:</b>	<p>the only area in which crops may grow. This area must be completely covered and separated.</p> <p>Additionally:</p> <ul style="list-style-type: none"> <li>- with regard to ventilation openings in seed production (and the subsequent plant production): the use of netting is compulsory.</li> <li>- with regard to ventilation openings in commercial plant production: the use of netting is not compulsory.</li> </ul>
<b>Green Lock:</b>	a 'physical or not-physical separation' that is required to be present between Yellow and Green Areas and/or between two entities. A Green Lock may also be implemented if a risk analysis reveals a potential risk of contamination or cross-contamination. If it does, preventive measures taken must be documented and implemented. The presence of a Green Lock minimizes the risk of contamination between Entities.
<b>Grower:</b>	a commercial fruit grower.
<b>GSPP Expert:</b>	an independent expert selected by the Emergency Team or the GSPP Board and appointed by the GSPP Foundation to perform an investigation and root cause analysis of the circumstances surrounding and origins of a confirmed <i>Cmm</i> infection in the GSPP supply chain.

<b>GSPP Foundation or Foundation:</b>	The Foundation for Good Seed and Plant Practices; the holder of the Collective Trademark.
<b>GSPP Product (-s):</b>	seeds and plants produced in accordance with the GSPP Standard.
<b>GSPP Secretariat or Secretariat:</b>	a professional secretary appointed by the GSPP board and referred to as the GSPP Manager. He/she performs the tasks mandated by the Board and is assisted by support staff.
<b>GSPP Standard or Standard:</b>	the requirements and conditions laid down for the production of seeds and plants in an effort to keep contamination by seed-transmitted pathogens to a minimum. The GSPP standard is subject to continuous development and, as such, the relevant Version of the Standard should always be referred to. Participants should keep themselves informed of the applicable version by consulting the GSPP website ( <a href="http://www.gspp.eu">www.gspp.eu</a> ).
<b>GSPP supply chain:</b>	the network of GSPP-certified companies involved in the production and distribution of GSPP seeds and plants. It represents the processes as defined in Scopes 1 to 18.
<b>In Progress:</b>	refers to the status of a company whose application is complete up until the company's certification is approved by the Board, subject to the following criteria: For seed production, a positive audit must be conducted during the production cycle sown after application. Seeds from that production cycle may be sold as GSPP seeds, but only after the certification of the company. For plant raisers, an audit may only be conducted on production cycles sown after application.
<b>Involved company:</b>	all parties involved within an Entity in which a confirmed <i>Cmm</i> infection is found and that are not the Affected companies.
<b>ITC:</b>	International Technical Committee.
<b>Non-conformity (NC):</b>	daily practices that are not in compliance with the QMS of the participant and/or daily practices that are not in compliance with the GSPP Standard and/or when the QMS does not comply with the GSPP Standard.

**Non-conformity Major:**

a non-conformity that forms a direct threat to the quality of the product itself and/or when a complete criteria or paragraph of the standard has not been implemented / carried out.

**Non-conformity Minor:**

a non-conformity that does not form a direct threat to the quality of the product itself, but does need to be solved in order to comply with the GSPP Standard.

**Notification:**

warning alert of a suspected *Cmm* infection to the supplier of seeds and/or young plants or a confirmed *Cmm* infection communicated to the GSPP secretariat.

**Participant:**

a company that has met all the requirements for Certification.

**Participation Letter:**

a letter that an Applicant must sign to complete the Certification process.

**Plan of approach:**

a plan that the auditee must send to the AO within the agreed upon time frame that includes a root cause analysis and corrective evidence regarding a NC. A plan of approach is only accepted in exceptional cases in which an auditee and auditor both agree (on the day of the audit) that it is desirable and possible to release the auditee from the constraints of this time frame because there is no risk / harm to the QMS and/or contamination of a production and that sending in a plan of approach is sufficient. The features of a plan of approach are as follows:

1. It must describe who will do what and within what timeframe in response to the NC.
2. This description must be specific, measurable, acceptable, realistic and time bound.
3. After receiving the plan of approach, the auditor will determine whether or not the plan is sufficient.
4. If it is sufficient, the AO will inform the auditee and will await further corrective evidence accompanying this plan of approach and proceed accordingly. Otherwise, a request for a revised plan of approach will be made within a specified period.

**Plant Raiser:**

responsible for QMS with or without a production Site:

- registered as a Plant Raiser Participant with the GSPP Foundation;
- has its own QMS;
- has its own production Site or has an established contract with a Seed Producer, Sub-Contractor or Service Supplier defining activities and responsibility;
- responsible for Traceability of used GSPP Seed;
- responsible for GSPP labelling;

- differentiates between Plant Raiser of plants for seed production and plants for fruit production;

- audited by an AO.

**Preventive action:**

actions determined by the organization to eliminate causes of potential non-conformities in order to prevent their occurrence, i.e. conducting a risk assessment.

**Quality Management System**

**(QMS):**

the organizational structure and provisions required to be able to adequately execute the quality policy, in order to comply with the requirements of the GSPP Standard.

• **Internal Audit:**

an independent, objective, quality-assurance activity designed to add value and improve an organization's operations. It brings a systematic, disciplined approach to the evaluation and improvement of the effectiveness of risk management, control and governance processes. Professionals referred to as internal auditors are employed by the Participant to perform the internal auditing activity.

• **Quality Manual:**

a set of documents (may be either hardcopy or digital) that together represent the QMS, in compliance with the requirements of the GSPP Standard. The quality manual must be available in English, at least, with the proviso that the Quality Manual in France may be in French and that in the Netherlands in Dutch. The quality manual must contain, at a minimum: the name of the company, a general description of the company, GSPP Sites, contents, matrix: quality manual paragraphs/GSPP standard paragraphs, quality policy and scope (if applicable: per site), organization organigram and flow chart of processes.



- Red Area:** an uncontrolled area. Management must assume that *Cmm* may be present in this area.
- Red Lock:** a Red Lock is always physical. A Red Lock is designed to provide access for the 'four threats' (propagation material, water, people and materials (including equipment)) to Yellow and/or Green Areas after sufficient disinfection and/or a risk analysis is conducted that indicates that contamination with *Cmm* has been minimized. The risk of contamination between 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 beginning and end) of the Red Lock should be logical, identifiable/visible and controllable.
- Reference sample:** a seed sample, that has at least the GSPP-required sample size, in the same phytosanitary state as the *Cmm* test sample, (used to confirm absence of *Cmm*), stored for investigation in the event of complaints.
- Root-cause analysis (RCA):** An objective, thorough and disciplined process used to define, evaluate and systematically analyze 'a confirmed *Cmm* infection in the GSPP supply chain' to determine the underlying factor(s) leading to or reason(s) for the infection; annex to the GSPP Standard.
- Scope:** (a) scope(s) is/are the processes, as identified in Annex 14.7, in the production cycle of GSPP Products at a GSPP Participant location for which Certification is given.
- Seed Company:** responsible for QMS with or without a production Site:
- registered as a Seed Company with the GSPP Foundation;
  - has its own QMS;
  - has its own production Site or has established a contract with a Seed Producer, Sub-Contractor or Service Supplier defining the Scope of its activities and responsibility;
  - responsible for checking that all the steps in the chain (from basic seeds to labelling of the final package) are managed according to GSPP requirements;
  - responsible for GSPP labelling on the final packaging;
  - audited by an AO.

**Seed Distributor:**

responsible for QMS without a production Site:

- registered as a Seed Distributor with the GSPP Foundation;
- has its own QMS;
- has established a contract with a Seed Company defining the scope of its activities and responsibility;
- responsible for Traceability;
- responsible for GSPP labelling on final packaging;
- audited by an AO.

**Seed Producer:**

responsible for QMS with or without a production Site:

- registered as a Seed Producer with the GSPP Foundation;
- has a direct contract with the Seed Company/Companies defining the Scope of its activities and responsibility;
- has its own QMS;
- responsible for Traceability;
- has its own production Site or has established a contract with a Sub-Contractor, Seed Technology Company or Service Supplier;
- audited by an AO.

**Seed sampling:**

sampling method in which seeds are collected from one or more separate seed lots to generate a single or composed sample to create test and reference samples.

**Seed Technology Company:**

responsible for sub-processing (e.g. coating, pelleting, seed enhancement, priming):

- registered in the Certification Register;
- has a direct contract with the Seed Company/Companies defining the Scope of its activities and responsibility;
- has its own production Site or has established a contract with a Sub-Contractor or Service Supplier
- has its own QMS;
- audited by an AO.

**Seeds in stock:**

seeds that are dried and in storage, e.g. produced and tested, packed etc., before a change comes into effect after a decision of the GSPP Board.

**(GSPP) Site:**

a physical location where plants and/or seeds are grown and/or processed. Within the same site, location(s) can be separated in several production areas. The Site is named on the certificate and/or certified list.

**Starting material:**

All material used to initiate production of basic or commercial seeds. These include (among other things) seeds, cuttings and tissue cultures. Pollen is not considered starting material.

**Sub-Contractor:**

an individual or a company that provides services or conducts activities related to a Scope of a GSPP participant.

These services and activities can be separated as follows:

- Vulnerable services and activities (based on the 'four threats') that must be carried out at a GSPP-certified site and fall under the GSPP certification of a company. These activities are audited by the AO, as indicated in the Audit Regulations.
  - Non-vulnerable services and activities (based on the 'four threats') that must be covered in a risk analysis and, if needed, audited by the Company. An audit by the AO is not performed if the Risk Assessment and the results of the Internal Audit are sufficient.
  - Laboratory services and activities must be carried out/provided by one of the GSPP-recognized, accredited laboratories.
- vulnerable activities are specified in Scopes 3,5 and 17.

- auditing takes place based on the Risk Analysis by the GSPP participant. The AO determines whether or not the risk analysis sufficiently addresses the relevant risks. The risks and preventative measures need to be clearly addressed. The AO may request permission to perform an audit of the Sub-Contractor, when in doubt.

- the GSPP Participant has to carry out a sufficiently clear risk analysis in order to comply with the GSPP Standard.

**Sub lot:**

a collection of seeds within a production cycle. These can be separate or combined harvests, seed extractions or received seed lots, separate or mixed.

**Suspected *Cmm* infection:**

the presence of disease symptoms on tomato plants most likely caused by *Cmm*, according to a plant pathologist or other internal expert involved with GSPP Participants. Infection must still be confirmed by testing using a GSPP-approved testing protocol.

<b>Sustained complaint:</b>	a complaint of Confirmed <i>Cmm</i> infection in tomato seeds/plants that has been traced back to having originated from the seeds supplied and/or plants supplied. Testing of suspected plant material and testing of a seed sample of the lot used to produce the contaminated plants (both in accordance with the latest version of the GSPP norm) and systematic root-cause analysis are tools that can be used to demonstrate that the complaint is 'sustained'.
<b>Technical Investigation Procedure (TIP):</b>	Root-Cause Analysis (RCA) led by an external expert, appointed by GSPP; annex to the GSPP Standard.
<b>Test sample:</b>	the seed sample used for a <i>Cmm</i> -test.
<b>(GSPP) Threats:</b>	the risk factors identified by GSPP as needing to be managed and controlled by Participants to minimize the risk of a <i>Cmm</i> infection. The four threats identified are water, people, propagation material and materials.
<b>Traceability:</b>	an auditee must be able to demonstrate for each GSPP-product (plants and/or seeds, depending on the Scope) the links, one step backward (to the Site/GSPP Participant where it originated from) and one step forward (to the next site/GSPP Participant) in the GSPP chain.
<b>Trilateral Agreement:</b>	agreement between the GSPP Foundation, Naktuinbouw and SOC.
<b>Vulnerable processes:</b>	Within GSPP, Scopes 3, 5 and 17 are considered vulnerable processes. These are processes in which <i>Cmm</i> can infect seeds and plants leading to an increased risk of disease outbreak in subsequent steps of plant production.
<b>Yellow Area:</b>	the optional section of the production Site, beyond the Red Lock, where all important hygiene measures are followed. This part is separated from the Red Area (by a Red Lock) and the Green Area (by a Green Lock).

## **Explanation scopes**

The Scopes and boundaries of each Scope are explained as follows:

### **1 Sampling and/or testing of starting material:**

Sampling and/or testing of parent lines intended for multiplication or hybrid seed production, as well as mother material of vegetative/tissue culture productions. Sampling must be performed according to the rules defined in Annexes 14.1 and 14.4. Testing must be performed using an approved test protocol by a laboratory recognized by the GSPP Foundation.

### **2 Interface (shipment of starting material):**

Transport of GSPP starting material subject to GSPP control. No use of GSPP Collective Trademark.

### **3 Production of plants for seed production:**

Production of young tomato plants intended for seed multiplication or hybrid seed production. Production of plants occurs in a protected Green Area.

### **4 Interface (shipment of plants):**

Transport of plants grown under GSPP conditions subject to GSPP control. No use of GSPP Collective Trademark.

### **5 Production of seeds:**

Production of fruits containing seeds on plants that have been grown in a Green Area.

### **6 Interface (shipment of fruits):**

Transport of harvested fruits grown under GSPP conditions subject to GSPP control. No use of GSPP Collective Trademark.

### **7 Extraction:**

Extraction of seeds from harvested fruits and possible subsequent processes including fermentation and acid treatment and/or seed disinfection. Extraction ends with dry seeds.

### **8 Interface (shipment of seeds):**

Transport of seeds extracted under GSPP conditions subject to GSPP control. No use of GSPP Collective Trademark.

### **9 Seed Processing:**

Processing of seeds (performed on dried seeds) consisting of cleaning of seeds, sizing, etc...

It may be carried out by the Seed Company, the Seed Producer, a sub-contractor or by a seed technology company.

### **10 Interface (shipment of seeds):**

Transport of seeds processed under GSPP conditions subject to GSPP control. No use of GSPP Collective Trademark.

### **11 Seed treatment/Enhancement:**

Seed treatment and/or enhancement may consist of (one of) the processes of seed disinfection, priming, pelleting and/or coating.

It may be carried out by the Seed Company, the Seed Producer or a Seed Technology company.

### **12 Interface (shipment of seeds):**

Transport under GSPP controlled measures of seeds treated and/or enhanced under GSPP conditions. No use of GSPP Collective Trademark.

### **13 Sampling and/or testing of seeds:**

Sampling and/or testing of seeds is compulsory in order to assess the efficacy of the measures taken to address previous vulnerable processes and must be carried out before shipment of any seeds carrying the GSPP logo. Sampling must be performed according to the rules defined in Annex 14.1. Testing must be carried out using an approved test protocol by a laboratory recognized by the GSPP Foundation.

### **14 Interface (shipment of seeds):**

Transport of seeds sampled and/or tested under GSPP conditions subject to GSPP control. No use of GSPP Collective Trademark.

### **15 Trading of seeds, issue the Collective Trademark:**

Trading of seeds includes the packing of seeds to be delivered that carry the GSPP logo, together with associated documentation. It is performed by the Seed Company or Seed Distributor. The trading of seeds comply with the 'Regulation of the use and supervision of the GSPP collective trademark'. The regulations are available to GSPP Participants or upon request by the applicant.

**16 Interface (shipment of seeds with GSPP logo):**

Transport of seeds marketed under GSPP conditions with the application of GSPP Collective Trademark subject to GSPP control.

**17 Production of plants for fruit production:**

Production of young tomato plants for commercial tomato production purposes. Plants are raised from GSPP seeds or in-vitro propagated material and are grown under GSPP-certified conditions. Young plants are grown/raised in protected Green Areas.

**18 Interface (shipment of plants with GSPP Collective Trademark):**

Transport of plants grown under GSPP conditions to commercial growers subject to GSPP control.