

Annex 14.6 Technical Investigation Procedure (TIP) in GSPP chain

The scope of the TIP

The TIP is a technical investigation procedure which needs to be followed and adhered to by all GSPP Participants, as agreed in the Participation Letter, in case an incident has been reported to a GSPP Participant with regard to *Clavibacter michiganensis* subsp. *michiganensis* (*Cmm*) infections on seeds and/or young plants which are marketed and/or distributed under GSPP label.

In case a *Cmm* confirmed infection is found by a GSPP Participant at its GSPP Accredited Site(s) and no other companies are involved, the respective GSPP Participant does not have the obligation to initiate a TIP provided it will inform the Auditing Organization before the next audit. At the presentation of the audit plan the GSPP Participant needs to brief the AO regarding the procedure it followed to solve this incident.

All *Cmm* confirmed infections in which a GSPP Participant is involved, must be reported to the GSPP Secretariat. The Secretariat sends the report to the chairman of the GSPP Board. The affected GSPP Participant(s) or the chairman of the GSPP Board can decide to start a TIP, based on the report.

The objective of the TIP

The objective of this procedure is to achieve technical conclusions in situations where a *Cmm* incident has occurred.

The TIP describes the necessary steps and information needs in order to:

- Limit the damage,
- Reveal all the technical facts,
- Reach a sound technical conclusion,
- Recommend adaptations of the GSPP Standard.

Emergency Team participants are expected not to start legal procedure(s) during the TIP. If they do, they will be excluded from the TIP and will have no access to related documents and confidential information.

The TIP is part of the GSPP Standard and must be followed mandatorily by all GSPP Participants involved in a *Cmm* outbreak in material originating from a GSPP Product. Affected Companies that are non-GSPP participant(s) and want to participate in an ET will have to sign a Commitment Letter prior to participating to a TIP.

Procedure to be followed during the TIP

1. Reporting of Suspected *Cmm* Infections of tomato seeds or plants

The GSPP Participant who made the observation, and/or who has received a written notification by a third party of a Suspected *Cmm* Infection reports to the GSPP Participants who supplied the seeds or young plants of the crop where *Cmm* infection is suspected, ultimately within 5 days of the observation or written notification by a third party.

2. Confirmation and initial emergency measures

If the *Cmm* infection is confirmed, the GSPP Participant sends a copy of the written report of the confirmed *Cmm* infection to the GSPP Secretariat.

The GSPP Participant to whom the observation was made is responsible to immediately take measures to get confirmation (or not) of suspected infection and following confirmation, to contain and limit the damage by the possible consequences of an infection by taking all reasonable precautionary measures as below.

Confirmation and initial emergency measures may thus comprise the following activities. This list is not exhaustive but is the minimum; circumstances may require more activities.

- a. Pictures of suspected plants
- b. Sampling of suspected plants for independent laboratory testing
- c. Storage of suspected material (deep-freezing) for possible future independent retesting
- d. Increased isolation and hygiene measures for the suspected entity
- e. Temporary suspension of deliveries of seeds and/or young plants from this entity

In case there is no confirmation the procedure will be finished. In all other situations an Emergency Team will be formed. The execution of the emergency plan and crisis management is the responsibility of the affected party where the *Cmm* infection is confirmed. 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 have to be in line with local NPPO's regulations.

N.B. Steps 3 and 4 of this procedure may partly run in parallel.

3. Formation of the Emergency Team (ET)

Upon confirmation of the *Cmm* infection, the GSPP Participant, where the observation was made or who was notified first by a Grower or Plant Raiser, immediately takes the initiative to form the Emergency Team (ET). The ET consists of Affected Companies and non-GSPP participant(s) who signed a Commitment Letter.

The Involved Companies will be informed by the ET of the confirmed *Cmm* outbreak.

The ET may agree unanimously on an expert and propose a GSPP expert to the GSPP Secretariat in order to be appointed, if they deem such an expert necessary. If no agreement can be reached on whether or not to appoint a GSPP Expert and/or on the person to be appointed, the GSPP Expert will be appointed by the GSPP Chairman. The GSPP Expert has to sign a consultancy/confidentiality agreement with the GSPP Foundation, before the start of his/her assignment.

The ET appoints a person to keep good and clear records of all actions, findings and decisions and to make these available to the GSPP Expert, if appointed.

4. Investigation and root cause analysis

The GSPP Expert collaborates with the ET and is the chairman of this group. He must be independent in concluding and reporting, but has to present the ET with his preliminary conclusions and has to reply to different opinions/facts and findings of all members of the ET. If no GSPP Expert is appointed, the ET has to appoint a chairman.

Affected companies have to provide all necessary information during the investigation and root cause analysis and have to cooperate with any further inspection, test or simulation which needs to be done in order to get clarity on the root cause of the problem. It is

possible that during the investigation process Involved companies are requested to take part in the ET as an Affected company, as the investigation results indicate so.

a. Investigation phase

- The ET performs an initial survey,
- The initial survey is limited in to maximum 3 working days ,
- The *Cmm* infection, related risks and the facts presented by the ET are carefully weighed,
- The ET assesses whether a full scale root cause analysis is required and if so what would be the scope of the analysis. The scope (e.g. involvement of parties in multiple countries) determines if additional experts are needed. The chairman of the GSPP Board will decide if such additional experts will be appointed or not.
The ET chairman sends a brief report to the GSPP Secretariat and ET (within 2 weeks) with a first assessment of the situation and a proposal for root cause analysis (if needed),
- The GSPP Secretariat, in consultation with the chairman of the GSPP Board, decides and communicates next steps towards root cause analysis to the ET,
- The GSPP Secretariat and the chairman of the GSPP Board will also evaluate if the report leads to a proposal that concerned Site(-s) of GSPP Participant(-s) needs to be (temporarily) suspended of its Accreditation.

The GSPP Board decides on proposals for suspension on the basis of anonymous reports prepared by the GSPP Secretariat. Affected Companies which are represented in the GSPP Board are excluded from voting in the GSPP Board on this matter.

b. Root cause analysis phase

Root cause analysis may comprise of the following activities.

1. Check source of seeds/young plants; origin, inspection and test results;
2. Check deliveries of seeds of same lot and origin to other Plant Raisers/Seed Producers/Growers;
3. Check deliveries of plants from same Plant Raiser and same production period;
4. Secure all relevant information (copies, pictures, interviews, etc.);
5. Identification of the isolates, e.g. with molecular techniques.

This list is not exhaustive; circumstances may require more/less activities.

- Retesting of samples may be necessary to reach a final technical conclusion,
- The reference sample stored by the Seed Company should be retested by an independent GSPP recognized laboratory using the latest version of the ISHI protocol for *Cmm*.

5. Preliminary Technical Report

The ET, through the ET chairman (in case of expertise it is the GSPP Expert who is the chairman), has to prepare a preliminary technical report with conclusions on the root cause(s) of the contamination if possible and, if relevant, on continued risk of non-compliance with the GSPP Standard:

- a. All facts on the direct/indirect consequences of the outbreak are quantified (e.g. number of plants destroyed, yield loss, etc.);
- b. All findings of the investigation and root cause analysis if any;

c. **Technical conclusions.**

The preliminary report is made by the ET chairman. It has to be sent to the GSPP Secretariat within 2 months from the start of the investigation. In case more time is needed for the issuance of the final preliminary technical report, the GSPP Secretariat will be informed timely. Once the preliminary technical report is completed, it is shared with all ET members. It is not sent to the GSPP Secretariat until it is finalized.

6. Verification

Members of the ET have two weeks to comment on the preliminary technical report in case they do not agree with the technical findings and/or conclusions in the draft preliminary technical report. They can forward additional facts, own findings and conclusions, etc. to the chairman of the ET and to the GSPP Secretariat. The chairman of the ET and/or the GSPP Expert considers the additional facts and findings, address/reply to all facts, comments and findings made by Affected Parties and prepares the final report.

7. Final technical report

The final technical report is sent to the GSPP Secretariat within 2 weeks of receiving feedback from the ET. Members of the ET receive a copy. The report should contain a conclusion, and if applicable, an action plan to prevent future incidents. Involved GSPP companies and the GSPP Board should receive an anonymous executive summary of the final technical report, prepared by the GSPP Secretariat.

Costs of the TIP

The costs of the TIP should be borne by the GSPP Foundation to ensure that the procedure accomplishes its primary objectives of sound technical conclusions and system transparency to the GSPP Participants. These costs include: all reasonable costs of the GSPP Expert and costs concerning the root cause analysis.

Follow-up on TIP procedure

No publications will be made by any party.

a. GSPP Board

Based on the anonymous executive summary of the final technical report, the GSPP Board decides on continuation or suspension of GSPP Accreditation of affected Site(-s) of the GSPP Participant(-s).

The GSPP Board will decide within 2 weeks of receipt of the report by the GSPP Secretariat. In case the GSPP Board decides on suspension, affected GSPP Participant(-s) and AO's are informed.

Appeal against a suspension by decision of the Board is not possible. Upon suspension the name of the affected GSPP Participant or Site(-s) is/are removed from the Accreditation Register on the GSPP website.

Suspended Site(s) of the GSPP Participants may request for a Re-Entry Audit following implementation of eradication and corrective measures and verification of effectiveness of these measures. Following a Re-entry Audit, the GSPP Board may decide to lift the suspension on basis of the Audit results. The GSPP Board will decide within 2 weeks of receiving the recommendation report from the AO.

b. Involved GSPP Participants

Involved GSPP Participants must check whether the conclusions of the report necessitate a change of procedures, methods or controls on their Sites and if so, must implement these

measures as soon as possible. Efficacy of these measures will be audited by the AO during the next audit.

c. International Technical Committee

The ITC must check whether the conclusions of the anonymous summary have impact on the GSPP Standard. The GSPP Secretariat provides an anonymous summary of the report to the ITC, for the purpose of GSPP Standard review.

Annex:

1. Commitment Letter