GSPP
Good seed and plant practices

Annex 14.6

Cmm infection handling, Root Cause Analysis (RCA) and Technical Investigation Procedure (TIP) in GSPP supply chain

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Annex 14.6 Cmm infection handling, Root Cause Analysis (RCA) and Technical Investigation Procedure (TIP) in GSPP supply chain

I. Scope

This procedure is part of the GSPP Standard and is mandatory for all GSPP Participants involved in a confirmed Cmm incident. This procedure concerns seeds and/or young plants originating from a GSPP product (seeds and/or young plants which are marketed and/or distributed under GSPP label or which have been part of the GSPP supply chain). Affected Companies who are not GSPP participants and who want to participate in a Root Cause Analysis (RCA) and/or Technical Investigation Procedure (TIP) must sign a Commitment Letter before they are allowed to participate in this procedure.
All definitions in this Annex 14.6 have the same meaning as in Annex 14.7; GSPP Definitions and explanation scopes.

II. Objectives

The objective of this procedure is to describe actions to be taken in a situation where a confirmed Cmm incident has occurred:

- To collect facts and draw technical conclusions based on these facts.
- To make recommendations to improve the GSPP system and reduce the risk of Cmm outbreaks in future.
- To adapt the GSPP Standard if needed.
- To Safeguard GSPP's reputation in the market.

III. Procedure

A. Reporting of suspected Cmm infections in tomato seeds or plants

The GSPP Participant who made the observation of, and/or who has received a 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 5 working/business days after the observation was made or after receipt of the written notification to the GSPP Participant(s) who supplied the seeds or young plants.

B. Confirmation and immediate emergency measures

The GSPP or non-GSPP Participant who made the observation is responsible for immediate action to get confirmation of suspected infection and contain the disease by taking at least the following precautionary measures:

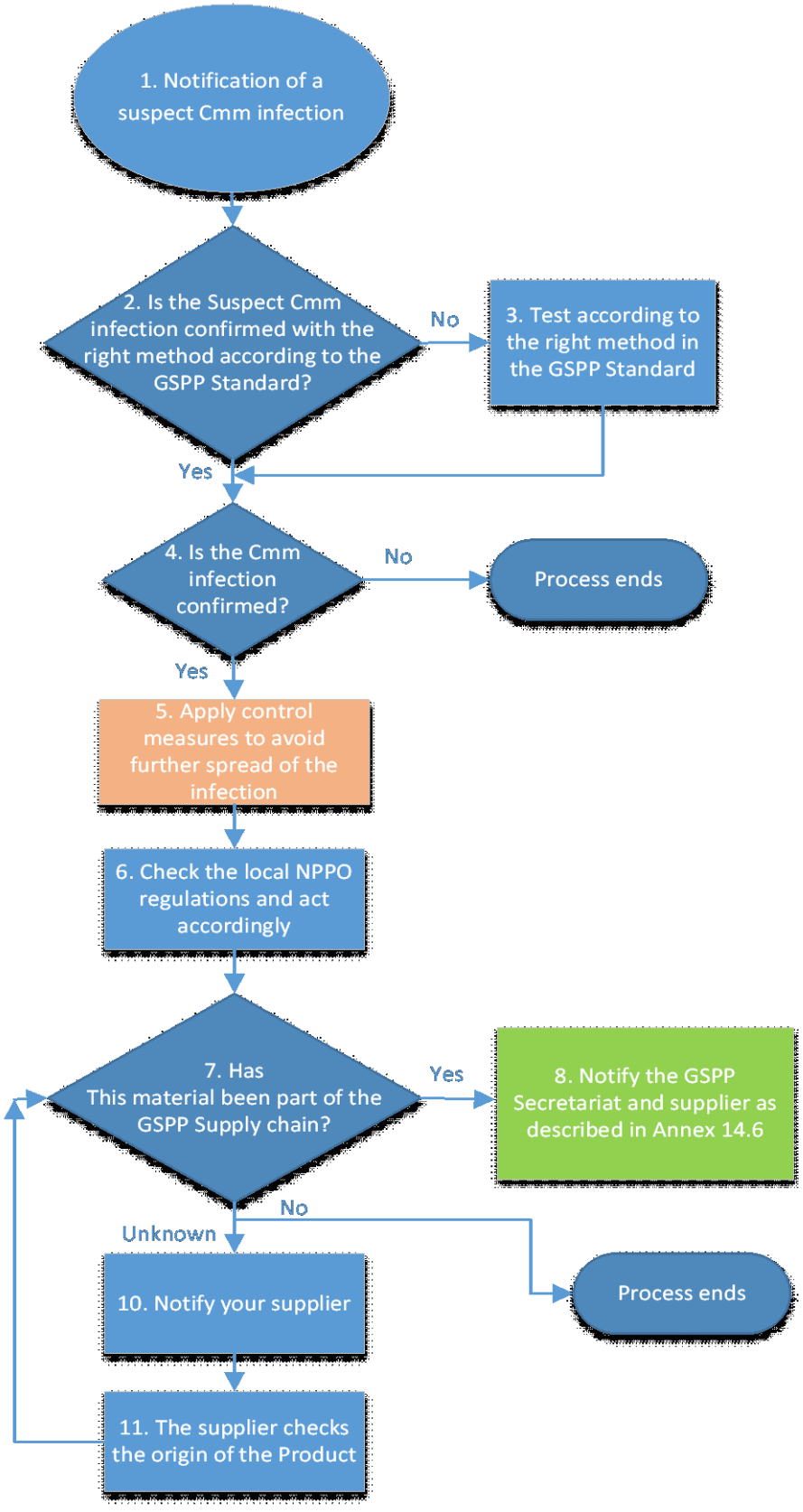
a. To sample suspected plants and obtain laboratory testing at laboratory using recognized testing methods (as defined in Annex 14.8);
b. To take hygiene measures and isolate the suspected entity;
c. To temporary suspend deliveries of seeds and/or young plants from this entity.
d. To document all the steps taken in writing.

The above list is not exhaustive; circumstances may require more measures, depending on the nature of the incident.

In case the Suspected Cmm infection is not confirmed the RCA and the TIP will not apply.

C. Notification of a confirmed Cmm infection

The workflow in the schedule below describes when and how a notification of a confirmed Cmm infection in GSPP originating material must be made to the GSPP secretariat and/or the supplier of the GSPP product.


1. Notification of a suspect Cmm infection
2. Is the Suspect Cmm infection confirmed with the right method according to the GSPP Standard?
No
3. Test according to the right method in the GSPP Standard
Yes
4. Is the Cmm infection confirmed?
No
Process ends
Yes
5. Apply control measures to avoid further spread of the infection
6. Check the local NPPO regulations and act accordingly
7. Has This material been part of the GSPP Supply chain?
Yes
8. Notify the GSPP Secretariat and supplier as described in Annex 14.6
No
Unknown
10. Notify your supplier
Process ends
11. The supplier checks the origin of the Product

If the Cmm infection is confirmed, the Cmm isolate needs to be properly stored for strain identification and traceability research. The owner of the seeds and/or young plants in which the Cmm isolate was found, is responsible to store or have it stored properly at a laboratory using recognized testing methods (as defined in Annex 14.8).

The GSPP Participant sends a written notification to the GSPP Secretariat, ultimately within 5 working/business days after receipt of the written notification of the confirmed Cmm infection. The GSPP Secretariat reports the notification to the chairman of the GSPP Board within 5 working/business days.

Notification of the confirmed finding to the GSPP Secretariat has to be done according to the notification form that can be found on the GSPP website and that is publicly accessible.

The execution of the emergency measures and crisis management is the responsibility of the Affected company, where the Cmm infection is suspected/confirmed. These measures must comply to local NPPO's regulations.

Next steps:

In case the Cmm infection is confirmed one of the procedures below must be carried out:

- to start a Root Cause Analysis procedure (RCA).

  or

- to start a Technical Investigation Procedure (TIP).

D. Possibilities and borders for a RCA and/or TIP

When a Cmm confirmed infection involves a rootstock and a scion, both GSSP labeled or having been part of the GSPP supply chain, the later sowing date of the material involved (the scion) will be used as starting date of the time line.

If batches of the rootstock and scion are of different origin (GSPP labeled or have been part of the GSPP supply chain and the other of non GSPP origin) the following is applicable. If one batch (scion or rootstock) is of GSPP origin than for that batch the systems of borders applies and if both (rootstock and scion) are not of GSPP origin than the TIP/RCA is not applicable.

E. Conditions to start a Root Cause Analysis (RCA) procedure.

1. In case a confirmed Cmm infection is found by a GSPP Participant at its own GSPP Accredited Site(s) and no other companies are involved, the GSPP Participant must initiate a RCA and provide the RCA report to the GSPP secretariat. When the GSPP Participant is informed of the date of the next audit, the GSPP Participant needs to inform the Audit Organization (AO) in writing about the RCA and/or TIP that has been carried out.

2. In case a Cmm infection is confirmed by a GSPP Participant at its own GSPP Accredited Site(s) and/or at any point in the GSPP Supply Chain, and other Affected Company(ies) are involved (within the timeline described under above chapter D), the GSPP Participant must start an Emergency Team (ET). The ET must initiate an RCA and provide the report to the GSPP secretariat.

The ET only contains representatives of Affected Companies and can only be chaired by a GSPP Participant. The ET decides on the appointment of a chairman. The chairman is appointed either by the GSPP Participant who made the observation, or who has received a written notification. Affected companies which are non-GSPP participant(s) can only be part of the ET after signing a Commitment Letter and the GSPP Secretariat received the advanced payment from them.

ET participants can not start legal procedure(s) during the RCA and/or TIP. If they do, they will be excluded from the RCA and/or TIP and will have no further access to all related documents and confidential information developed during the TIP and/or RCA.

The Involved Companies (14.7 GSPP definitions) will be informed by the ET about the confirmed Cmm outbreak immediately after formation of the ET; at the latest 10 working/business days after notification to the GSPP Secretariat.

An involved company could become an affected company and be part of the ET. A non-GSPP Participant can only be part of the ET after signing a Commitment Letter.

F. Conditions to start a TIP:

Affected Companies, both GSPP and non-GSPP Participants, can propose to the ET to start a TIP. The decision to start a TIP must be taken by ET members unanimously. Alternatively, the chairman of the GSPP Board can decide to start a TIP when any of the following occurs:

- the RCA report results give reason to initiate a TIP, e.g. when the Affected Company is not able to put the red lock in place or the Affected Company is not able to contain the contamination as per GSPP standard;
- multiple GSPP Participants are involved;
- the Affected company or companies have difficulties to finalize and agree on a RCA report;
- the RCA report cannot be delivered on time (within two months from the Cmm confirmation date);
- conflicts/disagreements arise within the ET.

The timeline for a possible request for a TIP should be respected (see chapter D).

The main difference between an RCA and TIP is that an external expert will be appointed for a TIP by the chairman of the GSPP Board. No external expert will be appointed for an RCA. A specific expert can be proposed for the TIP either by:

- the ET, however the members of the ET have to agree unanimously to the proposed expert;
- if the ET is not able to agree unanimously, the chairman of the GSPP Board will appoint the expert.

The GSPP Expert has to sign a consultancy/confidentiality agreement with the GSPP Foundation before the start of his/her assignment. Furthermore, the GSPP expert has to sign a confidentiality agreement with each of the Affected Companies separately. Only template agreement approved by the GSPP Board can be used for signing.

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

The GSPP expert collaborates with the ET and will be the chairman of the ET during the TIP. He must be independent in concluding and reporting. He has to present the ET with his preliminary conclusions and has to reply to all different opinions/facts and findings of all members of the ET.
Affected companies must provide all necessary information and must cooperate with any further inspection, test or simulation that is necessary to get clarity on the root cause of the Cmm incident.

Involved companies can be requested to take part in the ET as an Affected Company when the investigation results indicate so.

G. Collection of facts in RCA and/or TIP

Steps: duration 2 calendar weeks

- The Cmm infection, related risks and facts presented by the ET are carefully assessed.
- The ET determines who will participate in the RCA and what the scope of the analysis is. The scope (e.g. involvement of parties in multiple countries) determines if additional experts are needed besides the already appointed GSPP Expert. This scope will be the basis for the formulation of the assignment for the GSPP Expert. The chairman of the GSPP Board will decide if such additional experts will be appointed. The ET starts a RCA.
- The ET chairman sends a brief report of the initial survey which has been agreed by all members of the ET to the GSPP Secretariat within 2 weeks. The ET includes in this report of the initial survey a first assessment of the situation.
- The GSPP Secretariat, in consultation with the chairman of the GSPP Board:
    - decides about next steps and communicates these to the ET;
    - evaluates if the reported results lead to the proposal to the GSPP board

to suspend the accreditation of the concerned Site(-s) of GSPP Participant(-s).

H. Preliminary RCA/TIP-technical-Report

The ET, through the ET chairman, has to prepare a preliminary technical RCA/TIP report. This has to contain conclusions (and an executive summary) about the root cause(s) of the contamination and continued risk of non-compliance to the GSPP Standard:

a. all facts about the direct/indirect consequences of the outbreak are quantified (e.g. number of plants destroyed, yield loss, etc.);
b. all findings about the investigation and RCA except for any confidential information and/or trade secrets of any company participating to the RCA/TIP that would not be relevant to the RCA/TIP;
c. technical conclusions.

The preliminary ET RCA/TIP technical report is written by the ET chairman. It must be sent to the GSPP Secretariat within 2 months after the start of the investigation. In case more time is needed to complete the final preliminary ET RCA/TIP technical report, the GSPP Secretariat must be informed 5 days before the deadline of 2 months. Once the preliminary RCA/TIP report is completed, it is shared with all ET members for comments. It is not sent to the GSPP Secretariat until it is finalized. The ET will use the guidelines for a technical format of the RCA/TIP report (see annex 2).

I. Preliminary RCA/TIP technical Report Verification

Members of the ET have three calendar weeks to comment on the preliminary ET RCA/TIP technical report. In case they do not agree with the technical findings and/or conclusions they can forward additional facts, own findings and their conclusions to the chairman of the ET. The chairman of the ET and/or the GSPP Expert (in case of a TIP) will consider the additional facts and findings, comment to all facts, comments and findings made by ET members and prepare(s) the final report. An approval from all the ET members is needed to reach the final version of the preliminary RCA/TIP report. The report shall reflect the opinion of each of the parties, and therefore may include different opinions.

J. Final RCA/TIP technical report

The final ET RCA/TIP technical report is sent to the GSPP Secretariat and chairman of the GSPP Board within 2 weeks after receiving feedback from the ET members. Members of the ET will receive a copy. The report must contain a conclusion, and if applicable, an action plan to prevent future incidents. The GSPP Secretariat receives an anonymous executive summary of the final ET RCA/TIP technical report, prepared by the chairman of the ET and approved by all the ET members. Anonymous in this context means that the executive summary should not contain any data that would make it possible to identify the company and/or site. Information on corrective actions taken, will be part of the executive summary of the final ET RCA/TIP technical

report.

K. The procedure planning for both RCA/TIP

In the schedule underneath an overview is given of the planning of activities for the procedure.

PHASE 1	TIME LIMIT	PHASE 2	TIME LIMIT	PHASE 3	TIME LIMIT
DAY 0	**5 working/business days**	DAY 0	**5 working/business days**		
Suspected Cmm observed or notified	Notify GSPP participants (supplier of seeds or plants)	Confimed Cmm	Inform GSPP secretariat		
			10 working/ business days		
			inform all involved companies behind the same red lock		
			2 calendar weeks		
			Provide report of the initial survey of the Cmm incident to the GSPP secretariat		
			2 calendar months	DAY 0	**2 calendar weeks**
			Provide Preliminary RCA and/or TIP report to the GSPP secretariat	Preliminary report sent to ET	Send the final report to the GSPP secretariat

IV. Procedure Consequences

No information collected about the RCA/TIP will be made public by any party.

A. GSPP participants: Accreditation status

The anonymous executive summary of the final ET RCA/TIP technical report is shared with the GSPP Board. Based on the anonymous executive summary of the final ET RCA/TIP technical report, the GSPP Board decides about continuation or suspension of GSPP Accreditation of the affected Site(-s) of the GSPP Participant(-s). The GSPP Board will decide and motivate its decision within 2 calendar weeks after receipt of the executive summary of the final ET RCA/TIP technical report. In case of suspension, affected GSPP Participant (-s) and AOs are informed in writing and prior to the removal from the website. Suspension of the accreditation in a TIP or RCA won't be possible in the following situations:

(1) the RCA doesn't clearly identify company or its material coming from the affected Site (s) as the unique source of the Cmm contamination;

or

(2) the set of measures and checks implemented by the GSPP Participant has demonstrated to work well and the transfer of the risks to the next GSPP Participant or to the non GSPP Participant was properly and timely detected.

Appeal against a decision of suspension of Accreditation by the GSPP Board is not possible. 5 working/business days after the above notice of 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 by an AO. The GSPP Board may decide to lift the suspension based on the Re-entry Audit results. The GSPP Board will decide within 5 working/business days from the date of receipt of the recommendation report from the AO. If there is positive recommendation, the GSPP Board will add the name of the Affected GSPP Participant or Site(-s) on the GSPP website within 5 working/business days from the date of the decision by the GSPP Board.

B. Implications for AOs

The AOs are not involved in the whole RCA/TIP procedure. Their involvement is only required in case of suspension and or before the next audit. Next audit is either a regular

audit or an audit initiated by the GSPP Board. Before the next audit the Affected GSPP Participants must inform the AO in writing that they have been involved in a RCA/TIP.

C. Corrective actions

Affected GSPP Participants must check whether the conclusions of the RCA/TIP report require a change of procedures, methods or controls on their sites. Required changes must be implemented as soon as possible. Efficiency of these measures will be audited by the AO during the next audit.

D. Impacts on GSPP standard

The GSPP Board can decide to send the anonymous executive summary of the final ET RCA/TIP technical report, on a confidential basis, to the International Technical Committee ("ITC") for consultation about the impact it might have on the present GSPP Standard.

E. Role of the GSPP Secretariat

The GSPP secretariat has the following roles in this procedure:

- To inform the ET via the ET chair on the GSPP Standard and the annexes in case of a Cmm incident.
- To inform the GSPP Chairman on a Cmm incident.
- To facilitate the execution and progress of the RCA / TIP and in case of a TIP the process of identifying and finalizing the contract with an external expert as well as of the Commitment letter.
- To facilitate the exchange of information at the end of the procedure with GSPP Chairman and GSPP Board

V. Costs of the TIP

The costs of the TIP are determined by the GSPP Foundation to ensure that the procedure accomplishes its primary objectives of sound technical conclusions and a transparent system to the GSPP Participants. These costs include i.a. all reasonable costs of the GSPP Expert regarding the particular TIP. The Expert will present the GSPP Foundation with a quotation up front, to be approved in writing before the start of the TIP. The costs will be borne by the GSPP Foundation.

VI. Annexes:

1. Commitment Letter

See website: https://www.gspp.eu/documents
Document: "Commitment letter Third Party" most recent version

2. Guidelines for a technical format of the RCA/TIP technical report

See website: https://www.gspp.eu/documents
Document: "Guidelines for a template for the RCA TIP technical report" most recent version