DRAFT DIAGNOSTIC PROTOCOL FOR PHYTOPLASMAS (2004-018): RESPONSE TO FORMAL OBJECTION RECEIVED

(DP NOTIFICATION PERIOD: 01 JULY – 15 AUGUST 2015)

BACKGROUND

[1] According to the stage 4 of the Standard Setting process, adoption and publication, all draft ISPMs presented to the CPM are subject to a formal objection. If a contracting party (CP) has a formal objection, the CP submits the formal objection along with the technical justification and suggestions for improvement of the draft ISPM to the Secretariat.

[2] For Diagnostic Protocols (DPs), the CPM has delegated its authority to adopt DPs on its behalf to the Standards Committee (SC). This reflects the decision number 8 on the new Standard Setting process by CPM-7 (2012). Once the SC approves the DP, the Secretariat makes it available and Contracting Parties are notified.

[3] The notification period for approved DPs is twice a year on the following defined dates: From 01 July to 15 August and from 15 December to 30 January.

[4] CPs have 45 days to review the approved DP and submit a formal objection, if any. A formal objection should be a technically supported objection to the adoption of the approved diagnostic protocol in its current form, sent through the official IPPC contact point. If no formal objection is received, the SC, on behalf of the CPM, adopts the DP. DPs adopted through this process are noted by the CPM and attached to the report of the CPM meeting.

[5] The draft DP for Phytoplasmas (2004-018) was submitted to the DP notification period[1], which closed on 15 August 2015. This draft DP received one formal objection from the European Union (E.U.)[2] and it was sent back to the Technical Panel on Diagnostic Protocols (TPDP) for analysis.

[6] The TPDP sent the formal objection to the DP drafting group[3] for their consideration. On October 2015 a response to the formal objection received was provided to the panel.

[7] The TPDP analyzed and revised the response to the formal objection via e-decision (2015_eTPDP_Oct_03). The TPDP response to the formal objection was presented to the SC for approval along with the revised draft DP.

SC RESPONSE TO THE FORMAL OBJECTION

[8] The TPDP and the SC acknowledge the formal objection from the European Union (E.U.) relating to the controls recommended for use in the DP for Phytoplasmas (2004-018).

[9] This draft DP was submitted to the member consultation period in 2014[4]. Specifically relating to paragraph 63 (comment 60) of the draft DP, the negative extraction control section, the E.U. recommended that the minimum controls should include a control to monitor contamination during nucleic acid extraction. The comment was considered by the authors and the by the TPDP but not incorporated. However, wording was included in paragraph 70 on negative extraction controls

[1] DP notification period page: https://www.ippc.int/en/core-activities/standards-setting/draft-ispms/notification-period-dps/

[2] https://www.ippc.int/en/publications/81394/

[3] IPPC Diagnostic Protocols (DPs) drafting groups: https://www.ippc.int/en/publications/2582/

[4] 2014 Compiled comments with SC Responses: Draft Annex to ISPM 27 - Phytoplasmas (2004-018): https://www.ippc.int/en/publications/81245/

pointing out that "*Multiple controls are recommended to be included when large numbers of positive samples are expected*".

[10] The draft DP was submitted for the DP Notification Period from 01 July – 15 August 2015. The E.U. was still concerned with the wording and lodged the formal objection. The E.U. was still concerned that a negative extraction control should be required in addition to the positive nucleic acid control, the internal control and the negative amplification control. In particular, there is concern that a country should not challenge a positive laboratory result obtained based on a test performed with no negative extraction control.

[11] The original proposal during member consultation was for paragraph 63, and this would still be the preferred place for additional wording. However, the E.U. recognizes that risks of cross contamination are higher when handling many positive samples and has therefore put forward a compromise suggestion for strengthening the wording in paragraph 70. The EU also proposes that it should also be added that the negative extraction control can be a buffer control and does not need to be healthy host tissue. The E.U. proposed the following wording for Paragraph 70:

[12] "**Negative extraction control.** This control is used to monitor contamination during nucleic acid extraction and/or cross-reaction with the host tissue. The control is buffer or comprises nucleic acid that is extracted from uninfected host tissue and subsequently amplified. ~~Multiple controls are recommended to be included when large numbers of positive samples are expected.~~ In cases where large numbers of positive samples are expected, it is recommended that negative extraction controls are included between the samples for test. "

[13] The DP drafting group and the TPDP considered and accepted [5] the proposed wording and acknowledge that the negative extraction control can be a buffer or nucleic acid extracted from uninfected host tissue. The following wording for the negative extraction control section is proposed and agreed by the SC[6]:

[14] "**Negative extraction control.** This control is used to monitor contamination during nucleic acid extraction and/or cross-reaction with the host tissue. The control may be the extraction buffer or may comprise a nucleic acid extraction from uninfected host tissue and subsequently amplified. In cases where large numbers of positive samples are expected, it is recommended that negative extraction controls are included between the samples for testing. "

[5] 2015_eTPDP_Oct_03

[6] 2015_eSC_Nov_10