

Report of the meeting of the Technical Panel on Diagnostic Protocols, Central Science Laboratory, York, UK, 27 September – 1 October 2004 (final version 09/06/2005)

Present:

Robert Baayen,	The Netherlands
Gerard Clover	New Zealand
Lum Keng-Yeang	Malaysia
Maria Elena Manna	Argentina
Patrick Shiel	USA
Ana Lía Terra	Uruguay
Jens-Georg Unger	Germany (Steward)
Daphne Wright	UK
Vlasta Zloff	EPPO, France (Host)
Jane Chard	(Chair) (IPPC Secretariat)
Brent Larson	IPPC Secretariat

Introduction

The technical panel (TP) was welcomed to the UK by Stephen Hunter, Head of the UK Plant Protection Service and Mike Roberts, Chief Executive of the Central Science Laboratory. The panel members introduced themselves and elected Ms Chard as chair of the meeting. Ms Zloff (EPPO) described the EPPO process of producing nearly 60 diagnostic protocols and Ms Terra (UR) described the similar process used by COSAVE (approximately 100 protocols have been initiated and 30 are near publication). The panel also heard from other participants about the production of documentation for pest diagnosis in other parts of the world. The TP discussed the issues raised in the two discussion documents prepared for the meeting.

The TP reviewed the specification for the meeting and the draft format for diagnostic protocols produced by the email expert working group (EWG). The TP decided that in order to progress with the tasks outlined in the specification (primarily the tasks to develop diagnostic protocols for specific pests and to determine the mechanism for production of diagnostic protocols), there was a need to build on the work of the EWG and provide guidance on the scope and purpose of diagnostic protocols. The TP therefore worked on a draft standard to explain the scope, purpose and content of diagnostic protocols and recommended that specific protocols are added as annexes to the standard.

The TP considered that the two purposes of diagnostic protocols were:

- to share knowledge on methods for diagnosis of regulated pests
- to harmonize methods to facilitate international trade.

Key issues associated with diagnostic protocols

The TP identified a number of key issues associated with the drafting of diagnostic protocols.

1. Aim of diagnostic protocols. The TP recommended that diagnostic protocols should be written for diagnosticians and should contain sufficient information for the diagnosis of the pest. Sampling procedures for inspectors and inspectors' instructions on recognition of the pest from signs and symptoms should not be covered in diagnostic protocols. Where information on sampling or symptoms is included, this should be to aid the process of diagnosis by indicating on which part of the plant the pest may be found. In many cases diagnosticians may be involved in drafting such instructions for inspectors and such information may also help with this process.

2. Definitions. The process of diagnosis of pests involves using methods for both detection and identification of the pest. In order to clarify the parts of the process, the TP proposed the following draft definitions:

Pest diagnosis:	The process of pest detection and pest identification.
Pest detection:	The process of finding an organism either in symptomatic or asymptomatic material
Pest identification:	The process of ascertaining the taxonomic identity of an organism

The TP recognised that methods for detection may be interpreted differently depending on the type of pest being considered. For example, detection of an insect may relate to observation of individuals or signs of damage in consignments, whereas detection methods for bacteria may involve culturing extracts of plant material on semi-specific medium, which may also be used as an identification method.

3. Flexibility. Diagnostic protocols should contain methods that are appropriate for a range of circumstances, including the first finding of an organism in a country or laboratory and routine diagnosis of a (common) pest. Furthermore, diagnostic protocols should include several methods, where they are available, to take into account the different levels of expertise and facilities of different laboratories.

The TP recommended that diagnostic protocols should specify the minimum requirements for reliable diagnosis of the pest, with alternative or supplementary methods and procedures to provide flexibility. By indicating the sensitivity, specificity and reliability of the methods, NPPOs will be able to determine the level of confidence given by each method or combination of methods.

4. Validation of methods. The TP agreed that it was preferable to include methods that had been validated by multi-laboratory trials. However, it was acknowledged that this was not always possible. It was agreed, however, that for all methods there should be an indication of the sensitivity, specificity and reliability of the method.

The TP recommended that the experts drafting the protocol should consider all the appropriate methods for diagnosis of the pest to ensure flexibility. Where all the experts agreed that a method was suitable for inclusion, it should be included in the protocol.

Where methods were proposed but there was insufficient information on their performance, these methods should be referred back to the diagnostic community to provide further evidence of the validation of the methods. In some cases there may be a requirement for multi-laboratory testing of the proposed methods to ensure that they were suitable for inclusion in the protocol.

5. Molecular methods. The TP acknowledged that in many cases traditional methods, such as morphological characterisation of insects or fungi, may be the methods of choice for many laboratories. However, where molecular methods are available and are suitable for inclusion as a method in the diagnostic protocol (either as an alternative minimum recommended method or to provide flexibility for diagnosis), these should also be included.

6. Generic diagnostic protocols. The TP considered that there may be cases where a diagnostic protocol was produced for a pest genus, for example where several species within a genus are regulated pests. In these cases it could be possible to produce a generic diagnostic protocol in the first instance, followed by more detailed protocols for individual species if necessary.

7. Quality assurance/laboratory accreditation schemes. The TP acknowledged the value of quality assurance and laboratory accreditation schemes in providing confidence in diagnosis. The TP recommended inclusion of critical elements, such as the requirement for positive and negative controls, rather than all the elements of these schemes. It was also suggested that the methods should not be drafted as standard operating procedures or working instructions, but that there should be sufficient information for NPPOs to be able to create such documents for their own purposes.

The TP suggested that there may be a need for a future standard on quality assurance schemes and/or laboratory accreditation for diagnosis of pests.

Procedure for production of diagnostic protocols

The TP proposed working procedures for the production of diagnostic protocols (Annex 1).

Work programme

The TP identified the priority organisms for production of diagnostic protocols. The TP first agreed a “long list” of potential pests for protocol production. The criteria for listing in this initial included:

- pests listed in the call for "topics and priorities for standards" in 2003
- pests covered by an existing RPPO protocol or draft protocol
- additional pests considered by panel members to be important (e.g. quarantine pest in their country/region, significant pests of international concern)

Pests in the long list were selected for the production of specific protocols and were divided into first priority and second priority organisms. The criteria for the further selection of pests were:

- non-contentious protocols (important pests for which protocols should be non-contentious to draft)
- protocols that were important, but difficult to draft (for example important pests for which agreement is required amongst experts before a protocol was likely to be produced) This category was selected in the knowledge that it may take several years to complete the protocol.

For most pest types, one pest for each category was selected at each priority level (Annex 2).

The TP proposed a work programme for 2004-5 (Annex 3), which involved submission of the draft standard on diagnostic protocols to the Standards Committee in May 2005 and (hopefully) country consultation in summer 2005. It also involved initiation of the process of standard (diagnostic protocol) production, based on the draft format for diagnostic protocols contained in the draft standard.

Authorship of diagnostic protocols

The TP heard from EPPO, and members of the TP, of problems encountered by scientists that have been asked to draft diagnostic protocols because they are not considered by management in some institutes to have the same status as refereed publications in scientific journals. The TP tried to address this in the draft standard by including a form of words that would indicate the importance of diagnostic protocols and the fact that they would have been through the most thorough scrutiny possible during the country consultation stage.

The TP agreed that the criteria selection of experts for producing protocols should include:

- fair representation
- broad coverage of expertise
- technical and scientific knowledge of the organism
- the political importance of the organism for a region
- experience with producing protocols

The TP also agreed that authors who had already produced diagnostic protocols should be asked to participate or lead in the production of new or updated protocols.

Interaction with other Technical Panels

The TP agreed that they would consult the TP on pest free areas and systems approaches for fruit flies and the TP on forest quarantine, if required, for relevant experts to draft diagnostic protocols in their areas.

Composition of the TP

The TP acknowledged that in considering priorities for protocols, they had not been able fully to consider forestry, weed or tropical pests. The proposed procedure for production of protocols and links with the other TPs should address this.

The TP considered that it should contain a core group comprising the following disciplines: bacteriology, virology, nematology, mycology, entomology, botany/weeds.

The TP should also invite specialists in acarology, malacology and from ISTA as required.

The following specializations should be covered by the representatives of the above core disciplines if possible: molecular biologist with application experience; laboratory systems / accreditation; regulatory background; previous experience in developing diagnostic protocols.

Specification for the TP

Based on the work done during the first meeting, the TP proposed amendments to the specification (Annex 4).

Instructions for authors

The TP recommended that instructions for authors be drafted and added to the administrative guidelines produced by the Secretariat. These instructions should provide guidance on preparing a diagnostic protocol. This was added to the work programme.

Conclusions:

1. A draft standard was produced outlining the scope, purpose and content of diagnostic protocols.
2. A procedure for initiation and production of diagnostic protocols was produced, together with a list of priority organisms and a work programme.
3. Amendments to the specification were proposed and the TP made recommendations on the expertise required for the panel.
4. The TP identified that there may be a need for standard on quality assurance schemes and laboratory accreditation in the future.
5. The TP also identified that there may be a requirement for multi-laboratory testing of certain methods before they are accepted for inclusion in diagnostic protocols. These may require funding.

Technical Panel on Diagnostic Protocols (TPDP), York, 1-10-2004**WORKING PROCEDURES****Annual work programme**

- The TPDP annually identifies priorities for the development of a diagnostic protocols (DP) (taking into account guidance from the Standards Committee (SC) and any requests for reviews and amendments to a DP that have been received by TPDP members) and submits them in the form of a work programme to the SC.
- The TPDP reports annually through the Steward to the SC. This report includes achievements and the proposed work programme.

Commissioning of new diagnostic protocols

- A suitable expert for each DP is commissioned to lead the development of a DP by adapting a regional DP if it exists or develop a new DP as needed. The expert uses the instructions to authors for guidance and additional instructions are given by the TPDP if needed.
- The DP is reviewed by a small group of experts from the particular discipline related to the DP. The small group of experts is selected by the lead expert in consultation with the TPDP member(s) from that discipline.
- The DP is then submitted to the TPDP for assessment.
- The DP is submitted to the SC or returned for further work.

Review

- On an annual basis, the TPDP members oversee the review of existing DP in their discipline.
- If a change is required, the TPDP either modifies the DP using expertise within the panel and proposes a new draft or recommends inclusion of the DP in the annual work programme.
- The revised draft is submitted to the SC.

Review of country comments

- Country comments are compiled by the Secretariat and forwarded to the TPDP member from the respective discipline.
- The comments are reviewed by the TPDP member from the respective discipline who produces an amended draft of the DP (with track changes and reasons documented) and circulates it to all TPDP members.
- If substantial comments are received, they are dealt with by the TPDP coordinated by the TPDP member from the respective discipline in consultation with the small group of experts who drafted the DP. Proposed changes may be incorporated, not incorporated or there may be a recommendation for further study, with the reasons documented.
- The amended DP(s) are then submitted to the SC.

Nominations of Experts

- The Secretariat calls for nominations of experts for DP identified as priorities.
- The CVs of nominated experts are reviewed and summarized by the Secretariat and recommendations are submitted to the TPDP.
- TPDP comments are considered and the chosen experts are invited to participate in drafting of the DP.
- [Use the same procedure as the EWG nominations]

Expertise required for experts to draft DPs

- The expert group should have appropriate global coverage.
- Authors of existing protocols should be included in the expert group.

Core expertise required:

- technical and scientific expertise with the pest, especially diagnostic expertise

Additional expertise that would be helpful:

- taxonomy and molecular diagnostics
- practical experience related to the pest (detection, identification, isolations etc.)
- [quarantine DP expertise]
- drafting diagnostic protocols (such as regional diagnostic protocols)
- development of novel diagnostic methods

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**LIST OF PESTS CONSIDERED AS PRIORITY FOR DIAGNOSTIC
PROTOCOLS**

Pest	Priority
Bacteria	
<i>Erwinia amylovora</i>	1
<i>Xyllela fastidiosa</i>	1
<i>Xanthomonas axonopodis</i> pv. <i>citri</i>	1
<i>Liberibacter</i> spp / <i>Liberobacter</i> spp	2
<i>Xanthomonas fragariae</i>	2
Fungi and fungus-like organisms	
<i>Phytophthora ramorum</i>	1
<i>Tilletia indica</i> / <i>T. controversa</i>	1
<i>Guignardia citricarpa</i>	2
<i>Gymnosporangium</i> spp	2
Insects and mites	
<i>Anastrepha</i> spp	1
<i>Thrips palmi</i>	1
<i>Anoplophora</i> spp	2
<i>Trogoderma granarium</i>	2
Nematodes	
<i>Bursaphelenchus xylophilus</i>	1
<i>Ditylenchus destructor</i> / <i>D. dipsaci</i>	1
<i>Xiphinema americanum</i>	2
Viruses and phytoplasmas	
<i>Plum pox virus</i>	1
Tospoviruses (TSWV, INSV, WSMV)	1
<i>Citrus tristeza virus</i>	2
Phytoplasmas (general)	2

Technical Panel on Diagnostic Protocols, York, 1-10-2004**WORK PROGRAMME 2004-5**

2004	
Oct	8 Oct - final draft of standard sent to TPDP by Secretariat 5-15 Oct - TPDP members contact Steward of EWG to consult on the draft standard with regard to formatting of DPs 30 Oct - comments on format from EWG due back to steward of EWG and steward of TPDP
Nov	15 Nov - Steward reports to SC on TPDP activities (submits priorities, work programme and interpretation of scope and purpose of TPDP specification) 30 Nov - Call for nominations of experts to RPPOs by Secretariat
Dec	1 Dec – Comments on draft standard from TPDP due to Secretariat 15 Dec - Comments compiled by Secretariat and submitted to Steward 15 Dec - Instructions to experts draft by R Baayen and circulated to TPDP for comments 30 Dec - Steward incorporates comments into draft and circulates 30 Dec - Nominations of experts due to Secretariat
2005	
Jan	15 Jan - Final draft of Standard submitted to Secretariat 15 Jan - Compiled nominations circulated to TPDP 30 Jan - TPDP determine experts
Feb	1 Feb - Comments on Instructions to experts due to R Baayen 15 Feb - Instructions to experts submitted to Secretariat 28 Feb - Experts invited to work on DP by Secretariat
Mar	
April	25-29 April - Draft standard on DP considered by SC
May	
June	
July	
Aug	
Sept	
Oct	1 Oct - Decision on whether to hold a TPDP meeting 15 Oct - DP drafts due to TPDP member of the relevant discipline, who circulates them to the TPDP for consideration at the Dec meeting
Nov	15 Nov - Other documents for the TPDP meeting circulated
Dec	5-9 Dec, Penang, Malaysia - TPDP meeting, TPDP reviews draft DPs

SPECIFICATION FOR TECHNICAL PANELS NO. 1 (REVISED)
(revised by TPDP York, UK, 1-10-2004)

Title: Technical Panel to develop diagnostic protocols for specific pests.

Reason for the Technical Panel: ICPM-6 identified the need for diagnostic protocols for specific pests to be recommended to the Standards Committee. To do this, a Technical Panel on diagnostics was proposed.

Scope and purpose: The Technical Panel will produce diagnostic protocols for specific pests utilizing the format for diagnostic protocols established by the Expert Working Group.

Tasks:

- Identify priorities for specific protocols to be developed and submitted to the SC. Aspects to consider include:
 - availability of existing regional standards and/or protocols used by individual countries
 - suggestions for new protocols (i.e. those put forward by NPPOs, RPPOs, EWGs or other Technical Panels).
- Identify specialists.
- Produce or supervise the production of diagnostic protocols for specific pests as future annexes of ISPM ... Diagnostic Protocols for Pests.
- Submit to the SC draft diagnostic protocols for specific pests and where necessary revision of previously adopted protocols.

Provision of resources: Funding for meetings is provided from the regular programme of the IPPC Secretariat (FAO) except where expert participation is voluntarily funded by the expert's government.

Proposed work programme: To be determined.

Steward: Jens Unger.

Collaborator: To be determined.

Expertise: At least 5-7 participants comprised primarily of diagnostic (taxonomic) experts with at least one representing each discipline: entomology, acarology, nematology, mycology, plant bacteriology, virology (including viroids and phytoplasma) and botany. Between them participants should have practical expertise in the use of morphological and molecular/biochemical diagnostic techniques, and in phytosanitary procedures.

Participants: To be determined.

Approval: Introduced into the work programme by the ICPM at its Sixth Session in 2004, specification approved by the Standards Committee, April 2004.

References: Regional standards; NPPO protocols; diagnostic manuals; EPPO protocols; ISTA; other relevant information.

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York, UK, 27 September –1 October 2004**

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