DISPATCHES

# Summary of the EPPO Workshop on Flexible Scope

## Wageningen, the Netherlands, 26 to 28 June 2017

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## Background

Historically, the accreditation of laboratories was generally based on a fixed scope which should clearly and unambiguously define the tests covered by the laboratory's accreditation (*e.g.* immunofluorescence test for the detection of *Ralstonia solanacearum* on potato tubers). However, this does not readily allow new or modified tests to be added to a laboratory's scope, even when the competence of the laboratory in performing and validating related tests has already been evaluated by an accreditation body. Although applications for an extension to scope can be made at any time, the timescales involved may prevent rapid responses to client requests. Consequently, the concept of flexible scope has been developed. A flexible scope of accreditation allows a laboratory to undertake certain tests, and to report the results as accredited, even though these tests are not explicitly stated in the laboratory's scope.

Discussions between EA (European co-operation for Accreditation) and EPPO started in 2015 on the best way to implement flexible scope in plant pest diagnostic laboratories and to propose a regional harmonised approach. The main challenge faced by plant pest diagnostic laboratories when considering accreditation in the framework of official diagnostics is that there are over 300 pests (bacteria, fungi and chromista, insects and mites, nematodes, phytoplasmas, viruses and viroids, and invasive plants) recommended for regulation as quarantine pests by EPPO. Official plant pest diagnostic laboratories also perform analyses on exported plants and plant products for pests that are regulated by importing countries, in order to fulfil their international obligations under the International Plant Protection Convention (FAO, 1987). Laboratories in the EPPO region may then potentially need to test for hundreds of pests on thousands of pest/host matrices, under accreditation. The number of hosts affected by a pest may increase over time and, in particular, pests may increase their host range when they invade new areas and encounter potential new host plants. In addition, depending on their biology, they may be found in different parts of the plants or plant products, e.g. in the roots, leaves, fruits, and woody parts or packaging materials. Pests may also be present in substrates such as soil and water. For example, the stem nematode *Ditylenchus dipsaci sensu lato (s.l.)* attacks more than 1 200 species of wild and cultivated plants; it can attack

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aerial parts of plants but also bulbs, tubers and seeds and may be present in soil. As a consequence, the number of possible matrices to be tested and that would need to be validated for a single pest can be huge. In addition, different life stages of some of the pests (*e.g.* eggs, larvae, and adults for insects) may be present and require different tests to be used.

## The Workshop

An EPPO Workshop on flexible scope was organised and held in Wageningen, the Netherlands from 26 to 28 June 2017 with the collaboration of the Dutch National Reference Centre of the NPPO. The Workshop followed the series of Workshops on Quality Assurance and Accreditation. It was attended by 46 participants from 24 countries. Participants included laboratory managers, quality managers, and representatives from accreditation bodies.

The aim of the workshop was to share experiences at the different laboratories concerning flexible scope in order to improve harmonisation of approaches in the EPPO region. It was considered that this harmonisation process was urgently needed because requirements for laboratories to be accredited for all their activities in plant pest diagnostics are increasing. The workshop started with a plenary session, including presentations by the laboratories and the EA of their experience with flexible scope. Three small workshops, organised in parallel, followed the plenary session to discuss practical issues on validation, quality assurance and expertise as part of the diagnostic process, in the framework of flexible scope.

The initial output expected from the workshop was to identify the main components that should be included in an EPPO Standard on flexible scope. However, during the workshop, it became clear that a more suitable approach would be to revise the two existing Standards on Quality Assurance: PM *7/84 Basic requirements for quality management in plant pest diagnosis laboratories* and PM *7/98 Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* (see below).

A separate meeting of a small drafting group composed of experts from the EPPO Panel on Diagnostics and Quality Assurance followed. Revisions of PM 7/84 and PM 7/98 were prepared by the drafting group and the revised standards will be sent for country consultation by the end of October 2017.

A Scientific Officer from EPPO attended the meeting of the Laboratory Committee of EA in September 2017 and presented the outcomes of the workshop, which were very much welcomed.

The presentations and some details on the outcomes are available at http://archives.eppo.int/MEETINGS/2017_conferences/Workshop_flexible_scope.htm