New EPPO Standard PP 1/296

Principles of efficacy evaluation for low-risk plant protection products

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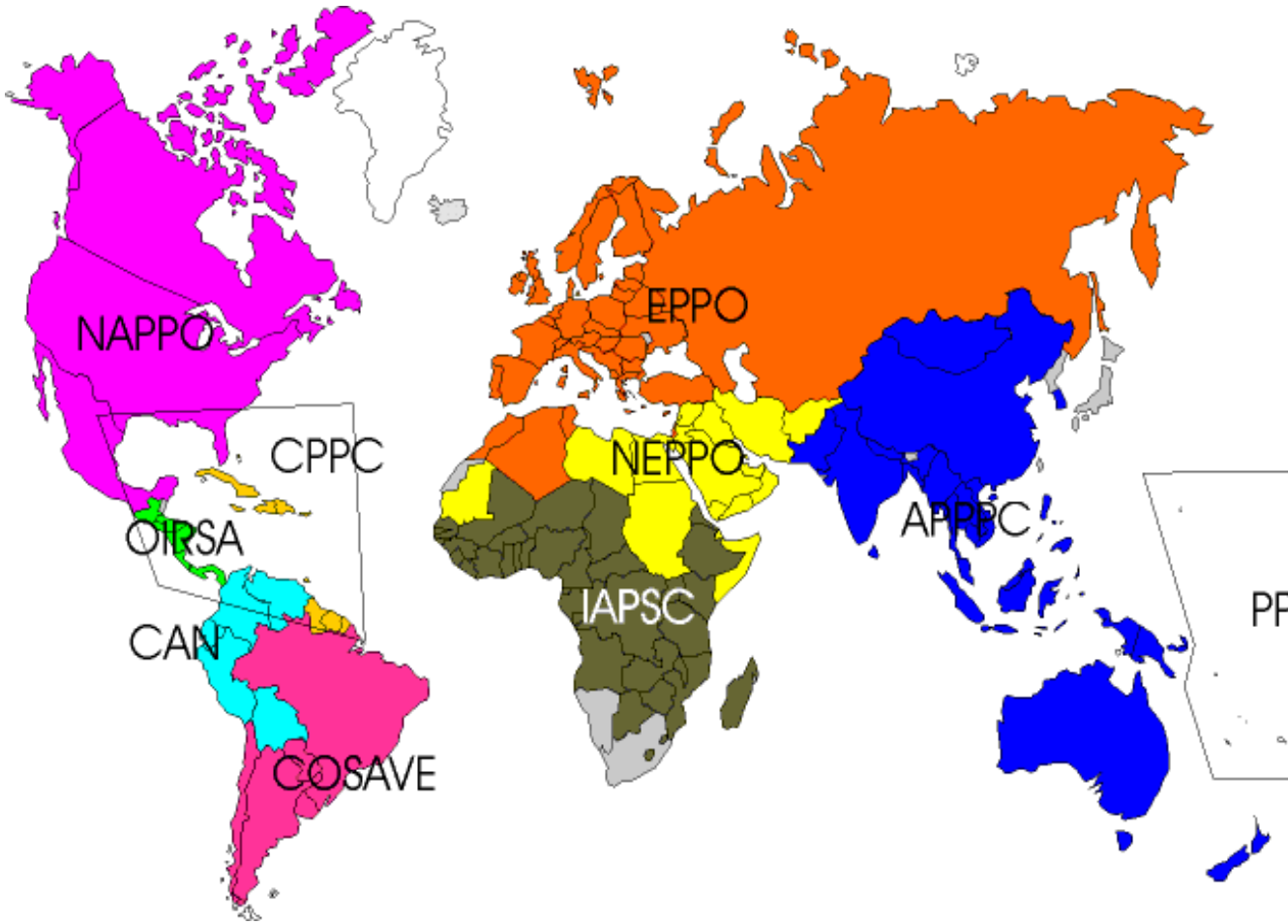
REGIONAL PLANT PROTECTION ORGANIZATIONS



International Plant Protection Convention
Protecting the world's plant resources from pests

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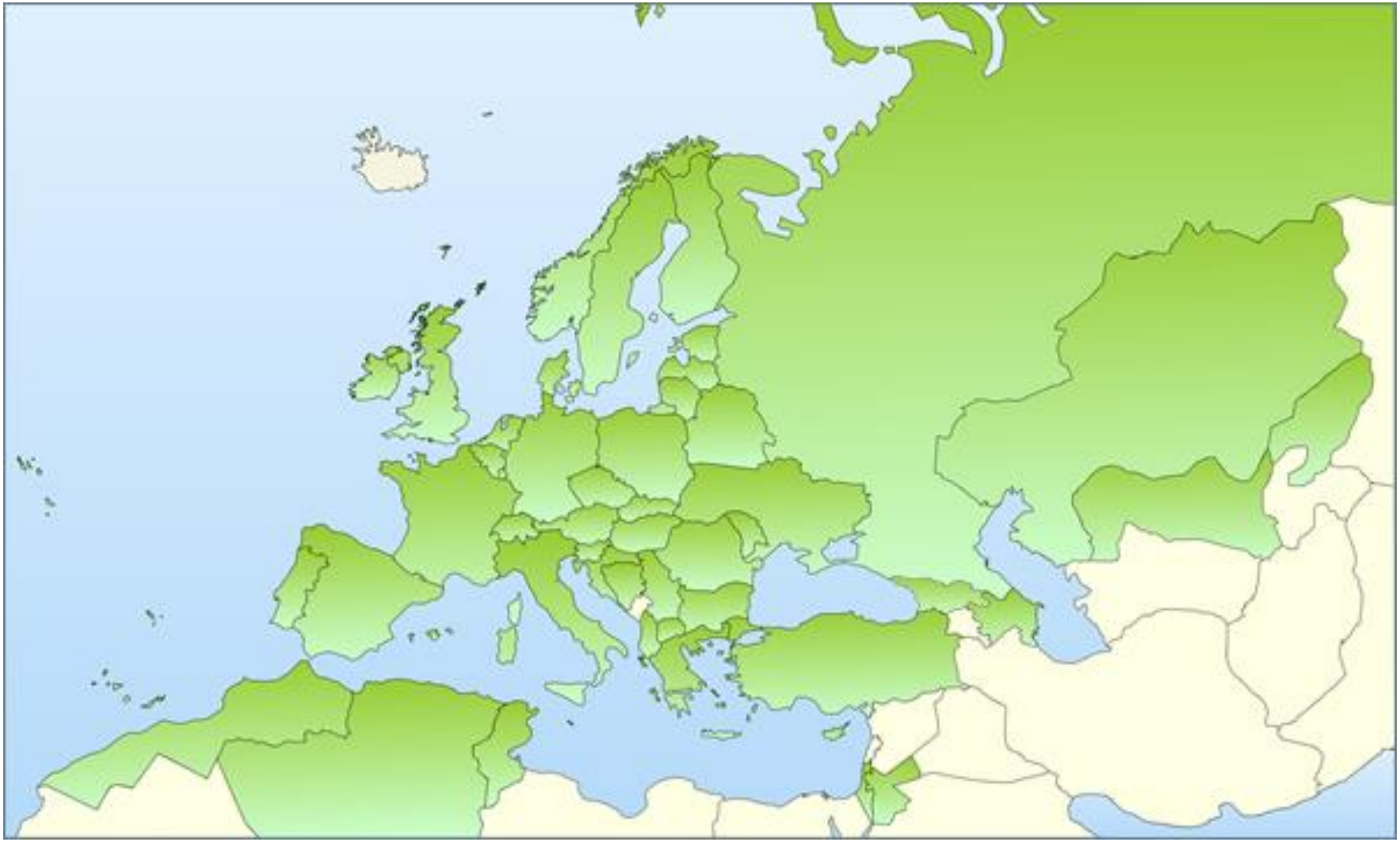
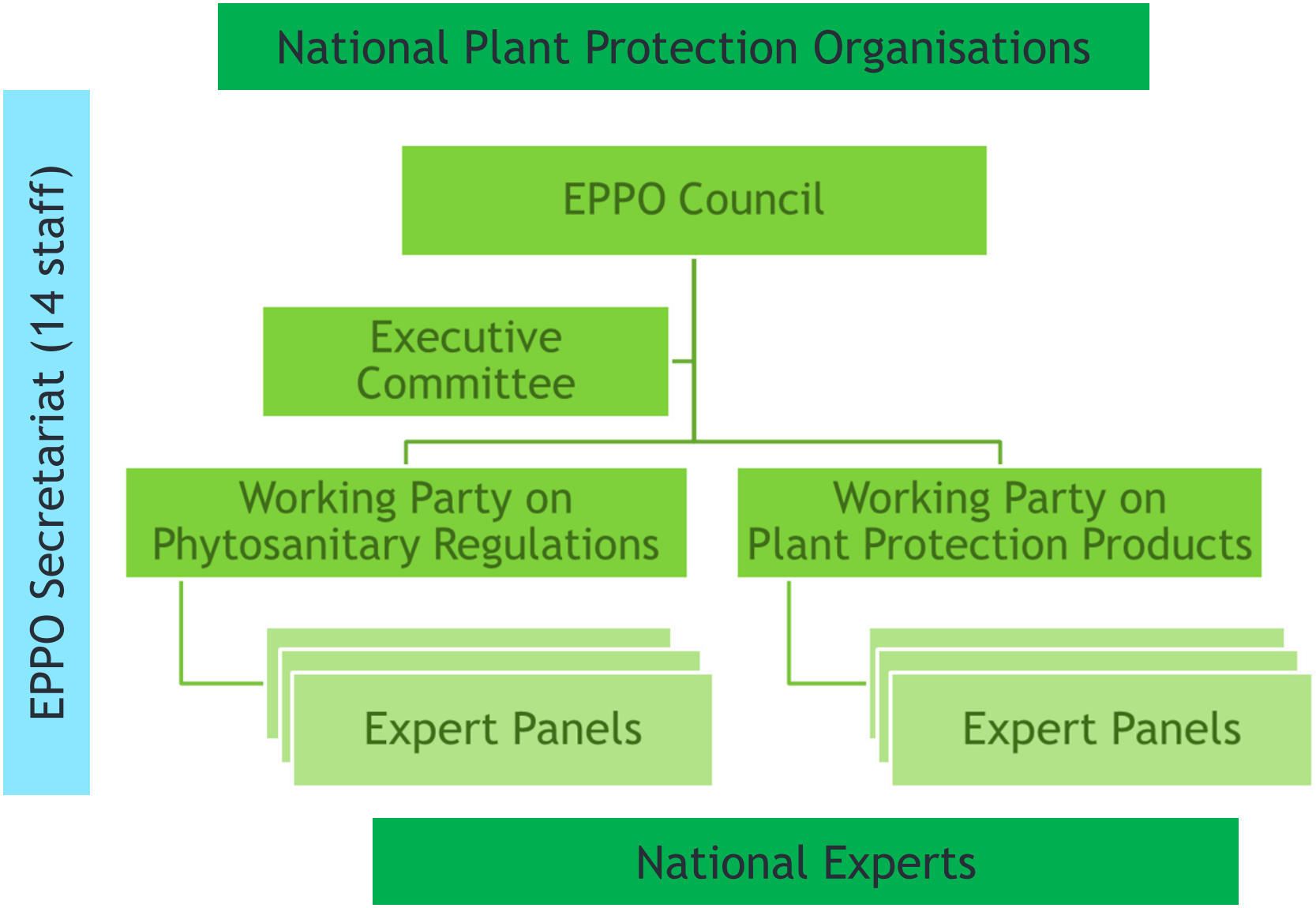
Founded in 1951, EPPO has grown from 15 original members to 51 member countries

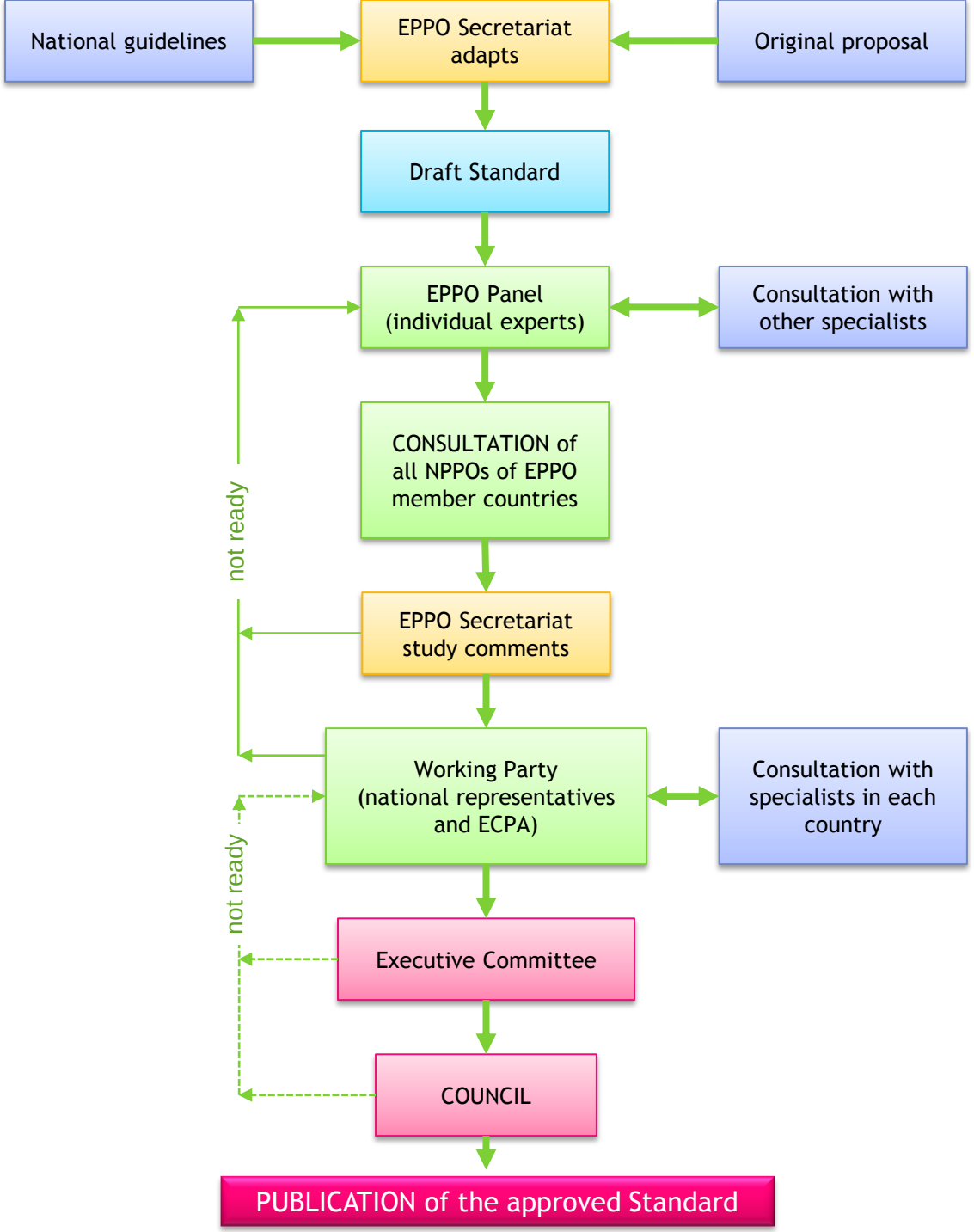


Organisation



EPPO technical activities

- are directed by two **Working Parties (WP)**: on Phytosanitary Regulations and **WP on Plant Protection Products**
- The results of EPPO's work are recommendations officially approved by EPPO's Council where all countries are represented. These recommendations are now considered at international level as 'regional standards'.
- The EPPO involvement in the field of PPPs is, however, very selective, since certain major aspects (toxicology, physiochemical characteristics, residues, labeling) are internationally covered by other bodies.
- EPPO Standards are intended to be used by National Plant Protection Organizations, in their capacity as authorities responsible for registration of PPPs, and by the agrochemical companies which apply for registration of their products.


National guidelines
EPPO Secretariat adapts
Original proposal
Draft Standard
EPPO Panel (individual experts)
Consultation with other specialists
CONSULTATION of all NPPOs of EPPO member countries
not ready
EPPO Secretariat study comments
Working Party (national representatives and ECPA)
Consultation with specialists in each country
not ready
Executive Committee
COUNCIL
PUBLICATION of the approved Standard

Workshop on Efficacy Requirements and Evaluation of Plant Protection Products based on Low-Risk Active Substances (Ede (NL), 2016-04-06/07)

- More than 100 participants; presentations , conclusions & recommendations at: http://archives.eppo.int/MEETINGS/2016_conferences/low_risk_substances.htm
- **one of the recommendations of the Workshop was to develop a new EPPO Standard on principles on efficacy requirements and evaluation of plant protection products based on low-risk active substances** and the Netherlands took a lead on drafting it.
- The EPPO WP on PPP, at its meeting in Malmö (SE) in May 2016, agreed on the idea of creating an *Ad hoc* group to support the development of this Standard.

Ad hoc Expert Working Group on low-risk substances:

David Cary (IBMA)

Pat Croft (CRD, GB)

Delphine Di-Bari (DGAL, FR)

Sara Furenhed (Swedish Board of Agriculture)

Benedicte Gautier (ANSES, FR) (& Laurent Thibault)

Udo Heimbach (JKI, DE)

Claudia Jilesen (NNVA, NL)

Per Kudsk (Aarhus University, DK)

Flora Limache (MUCF)

Willem Ravensberg (IBMA)

Johan Roman (NNVA, NL)

Jesús Jimenez Ruiz (INIA, ES)

Vlasta Zlof (EPPO)

Procedure

- 1st draft by Claudia Jilesen, Johan Roman NNVA (NL), Henk Brouwer (Ctgb, NL) and Willem Ravensberg (IBMA) ► then to *Ad hoc* EWG (3 teleconf.)
- Discussed by all EPPO Efficacy Evaluation Panels (General Standards, Fungicides-Insecticides, Herbicides-PGRs)
- Country consultation (sent to all 51 EPPO member countries)
- Comments addressed by the EWG and those late ones by the WP ► recommended for approval at the WP (May 2017)
- Adopted by the EPPO Council on 27 September 2017
- Now available as an 'early view' online version on Wiley's on-line library (page numbering does not correspond to the final one in the paper version of the EPPO Bulletin)
  http://onlinelibrary.wiley.com/doi/10.1111/epp.12396/abstract?campaign=wolearlyview
- **Bulletin OEPP/EPPO Bulletin Vol. 47/3 December 2017,** after publication it will be included into EPPO PP 1 database

EPPO database on PP 1 standards on Efficacy Evaluation of PPPs

http://pp1.eppo.int

- Today, **305** Standards have been approved by EPPO and are included in this database:
- **277 Specific Standards:** describing the conduct of trials to assess efficacy of PPPs against a particular pest in a particular crop, but many Standards cover groups of pests and/or groups of crops if these share common characteristics relevant to efficacy testing.
- **28 General Standards:** covering all aspects of efficacy to help countries in understanding and fulfilling their obligations in the registration of PPPs. All general standards are freely available.

EPPO Standard PP 1/296 *Principles of efficacy evaluation for low-risk plant protection product*

- describes the principles for determining the requirements for an efficacy evaluation of low-risk plant protection products in a registration procedure.
- it refers to the EC Regulation 1107/2009 (EC, 2009) and to Commission Regulation (EU) 2017/1432 and to relevant EPPO Standards.
- objective to accelerate the introduction of low-risk PPPs to the market

"Important reasons to assess efficacy are to ensure that growers use only sufficiently effective products to secure yield quantity and/or quality benefits, and that they use only minimum amounts of plant protection products to reduce environmental and human risks."

The Standard PP 1/296…some of the general principles:

- The efficacy evaluation may be flexible regarding the variability or level of effectiveness and less supporting efficacy data may be needed
- Lower effectiveness of low-risk product compared to the eff. of conventional product is acceptable
- Product should show results that are significantly superior to those in the untreated control (i.e. the use of the product is better than no use)
- The net result of the positive and negative effects should be sufficient overall benefit in order to justify the use
- The contribution of the proposed use to agricultural sustainability is considered in the evaluation of low-risk products (benefit: compatibility within an IPM system)

Some of the general principles: Con't

- GEP should be followed, however, non-GEP trial data may be acceptable if it is scientifically sound and in line with other applicable EPPO Standards (a clear justification should be given and valid data from other sources may be used to supplement this data)
- The applicant should provide a comprehensive and detailed description of the MoA of the a.s. in the product (and applicants should be critical (realistic) about their own data)
- Applicants are advised to liaise with relevant registration authorities as early as possible in the registration process
- Two-years' data should normally be provided, but where justified , with additional information to ensure robust field performance including distribution of trials across relevant EPPO zones, one year trial data may be considered sufficient

Some of the general principles: Con't

Minimum number of direct efficacy trials in an area of similar conditions required for low-risk PPP

	Fully supportive results required
Major pest (group*) on major field crop (group*)	6
Major pest; protected conditions	4
Other uses	3

It may be possible to use data generated from field trials on crops and pests other than those for which registration is proposed, or from small-scale trials, to reduce the number of trials conducted on a specific crop against a specific pest (Section 9 Extrapolation).

Extrapolation possibilities for effectiveness

- Based on the principle that certain groups of pests or groups of crops are similar in relation to the efficacy of the low-risk products
- Depending on the MoA of the product possibilities to extrapolate between different crops and pests, resulting in a smaller efficacy data set
- Good quality data and science are essential, clear justification and information to support the proposed extrapolation should be provided
- Extrapolations are possible within the same agro-climatic zone; between zones if conditions are comparable

Some of the general principles: Con't

- Where the data indicate that there are significant inconsistencies in the performance of a product the reasons for these inconsistencies should be explained.
- The instructions for use should enable the user to identify the conditions under which the product will provide optimal performance, and any factors that may have an impact on effectiveness.
- In Section 8 aspects that label recommendations may address are given

Thank you!

From Dr. Ravensberg's e-mail

"This has been quite an achievement and a good example of collaboration between stakeholders. Let us hope it will help bringing more low risk products faster to the market and help moving harmonization further. Altogether this project is a good example that if there is a will, a result can be quickly achieved."

EPPO Secretariat thanks all experts for their commitment and efforts to get this Standard finalized so quickly.

I wish you happy reading of the Standard.