

CEUREG Forum XVI

October 15th-16th, 2012



*Challenges of Efficacy Evaluation
under Regulation (EC)
1107/2009*

- AT Impressions

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1. Regulations / Guidelines

- Basics/Requirements for „Efficacy“
- What is really new?

2. Challenges / obstacles

- Information gaps
- Harmonization needs
- dRR quality
- New GAP template
- Assessment points to be addressed

3. Refinements

- Harmonization
- Communication



A plant protection product,
*consequent on application consistent with good plant protection
practice and having regard to realistic conditions of use, shall meet
the following requirements:*

(a) it shall be sufficiently effective;

(b), (c), (d), ...

(valid for active substances and PPPs)

REGULATION (EC) No 1107/2009
concerning the placing of plant protection products on the market and repealing Council Directives
79/117/EEC and 91/414/EEC

(CHAPTER II / Section 1 / Article 4; CHAPTER III / Section 1/ Article 29)

Regulation (EC) of the European Parliament and of the Council

No 1107/2009

of 21 Oct. 2009; (entry into force: 14 June 2011); concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC

- assessment of plant protection products **on a zonal level**;
- zonal Rapporteur Member State (zRMS)
- core assessment/national addenda
- - „Uniform Principles“

Commission Regulation (EU)

No 545/2011 & No 546/2011

of 10 June 2011

- data requirements
- “Uniform Principles”
- - “EPPO standards”



„Uniform Principles“

*Minimum
Requirements*







“EPPO standards”

Framework




Evaluation points (eg.):

- Preliminary **range-finding** tests
- Minimum effective dose** tests
- Efficacy** tests
- Effects on **yield and quality**
- Impact on the quality of plants and plant products
- Effects on the processing procedure
- Effects on the yield of treated plants and plant products
- Phytotoxicity** to host crop
- Adverse effects** on beneficial organisms
- Adverse effects on parts of plants used for propagating purposes
- Impact on succeeding crops
- Impact on other plants including adjacent crops
- Information on the possible occurrence of the development of **resistance**...

General Standards (eg.):

-  pp1-135-e- Phytotoxicity Assessment
-  pp1-152-e- Design and analysis of efficacy evaluation trials
-  pp1-213-e- Resistance risk analysis
-  pp1-214-e- Principles of acceptable efficacy
-  pp1-242-e- Taint tests
-  pp1-243-e- Effects of plant protection products on transformation process

Specific Standards (eg.):

-  pp1-004-e- Uncinula necator
-  pp1-026-e- Foliar diseases on cereals
-  pp1-195-e- Fungi on flower bulbs and tubers

New Standard:

„Principles of zonal data production and evaluation“

SANCO/6895/2009 rev 1; 2 Oct. 2009

- on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) **Registration Report**

SANCO/6896/2009 rev 1; 2 Oct. 2009

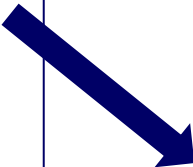
- on a process for intra & inter-zonal work-sharing to facilitate the registration and re-registration of plant protection products following inclusion of an active substance in annex I of Council Directive 91/414/EEC

SANCO/13169/2010 rev 5; 11 March 2011

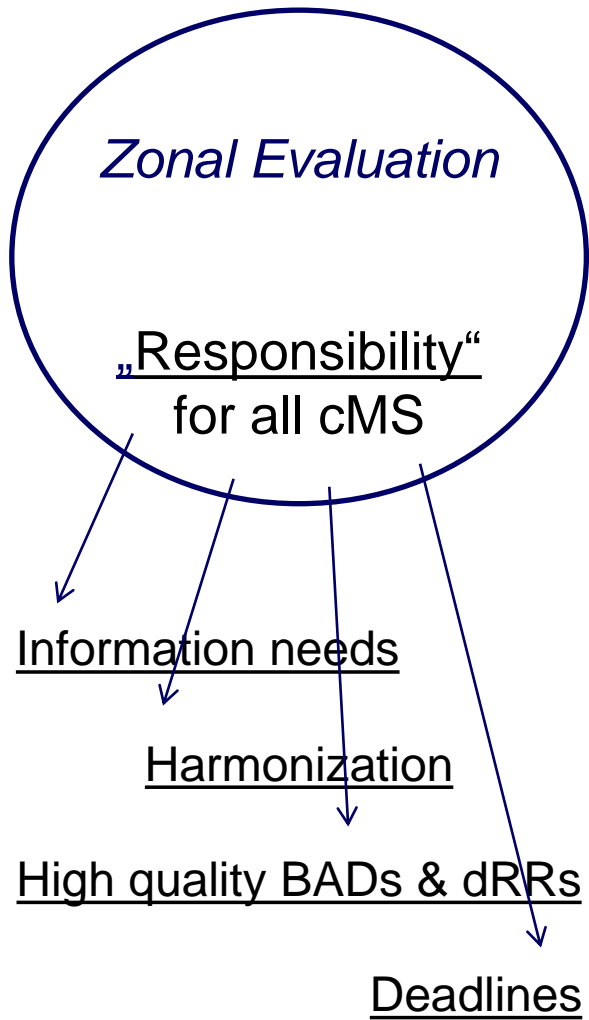
- on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009

SANCO/2010/13170 rev 7; 11 March 2011

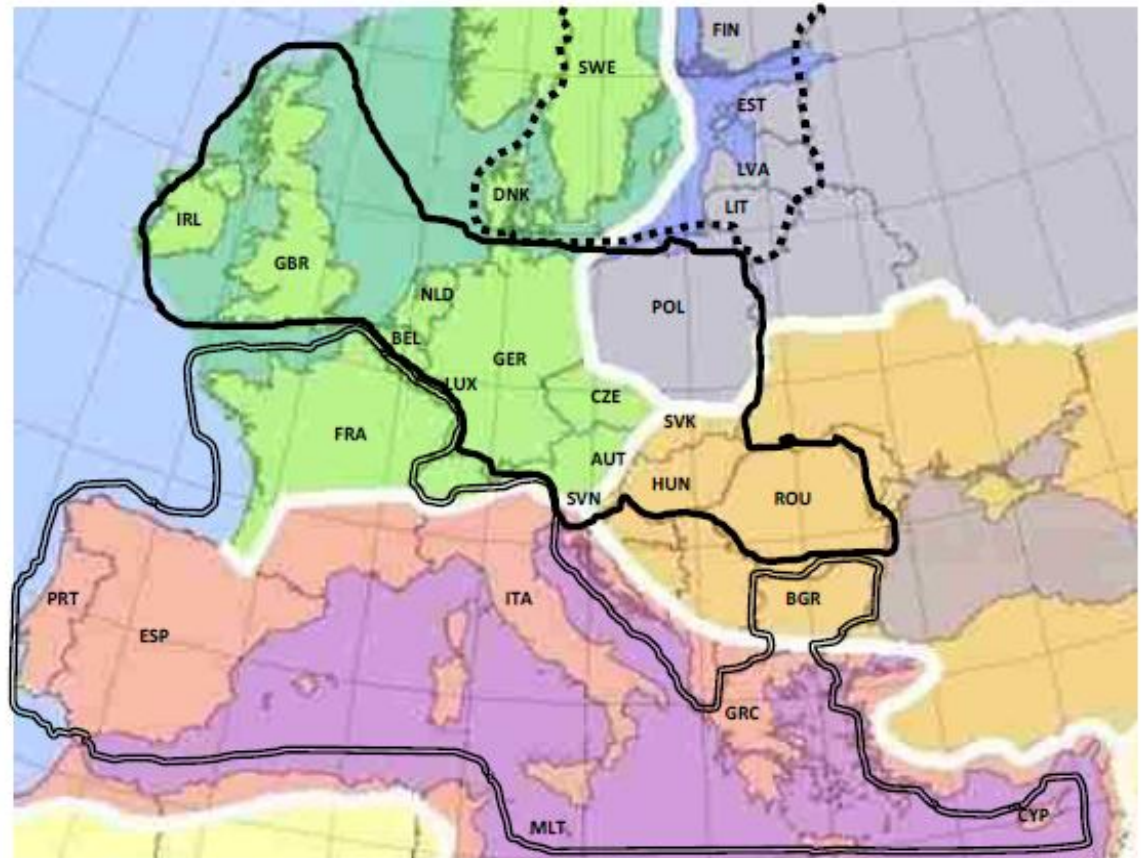
- on renewal, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009

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- layout and practicalities
 - core assessment vs. national addendum
 - dRR

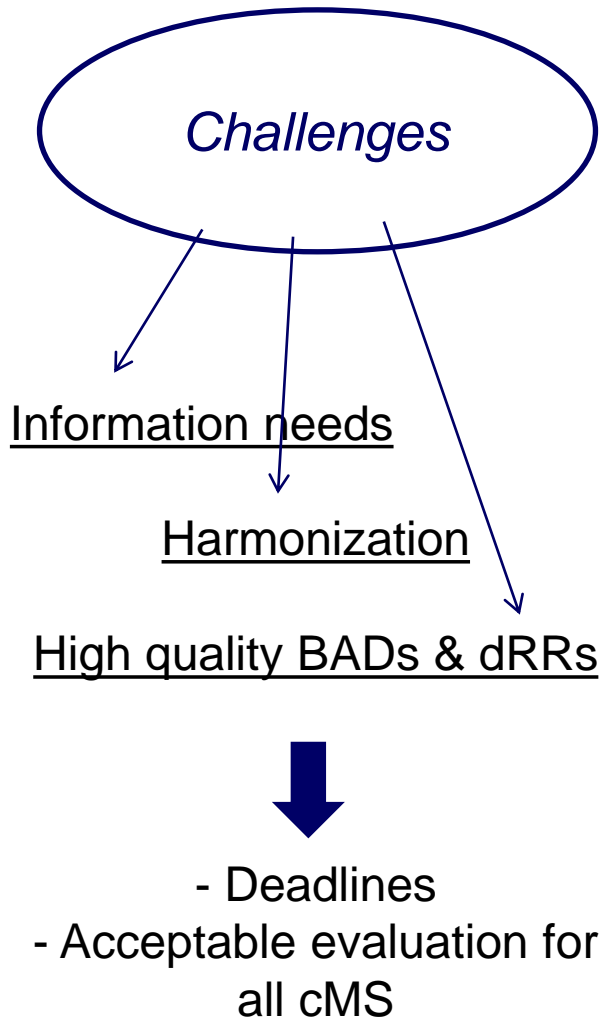
What is new?



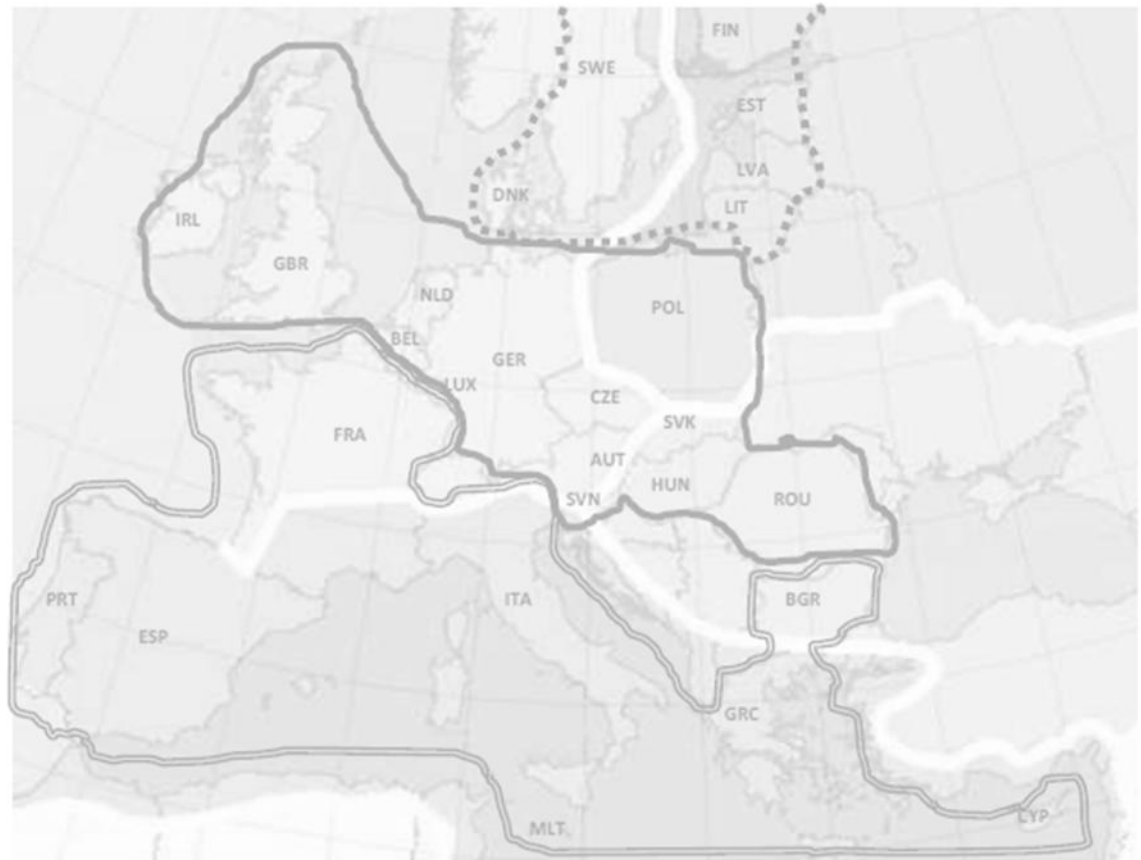
Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).



Current Challenges of Evaluation



Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).



Current Challenges of „Efficacy“ Evaluation

Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).

Information gaps

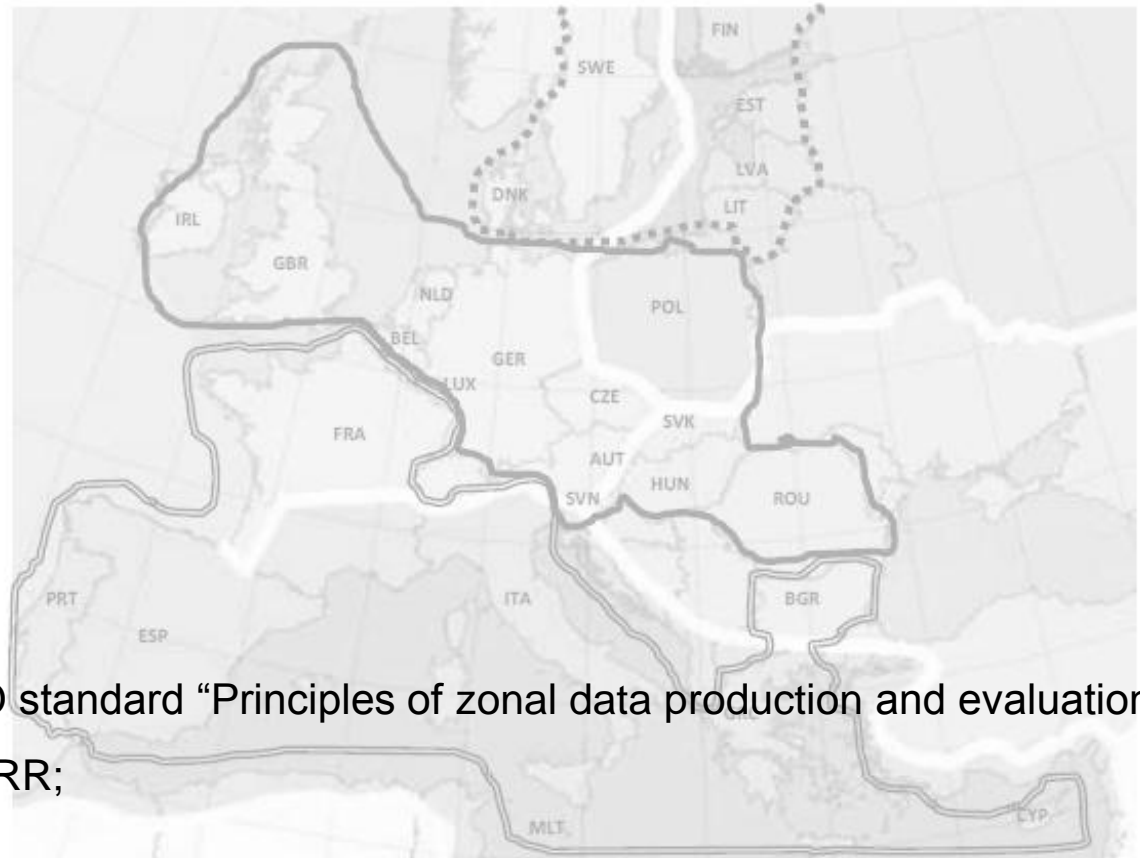
Pest

Crop

Agricultural practice

Climate

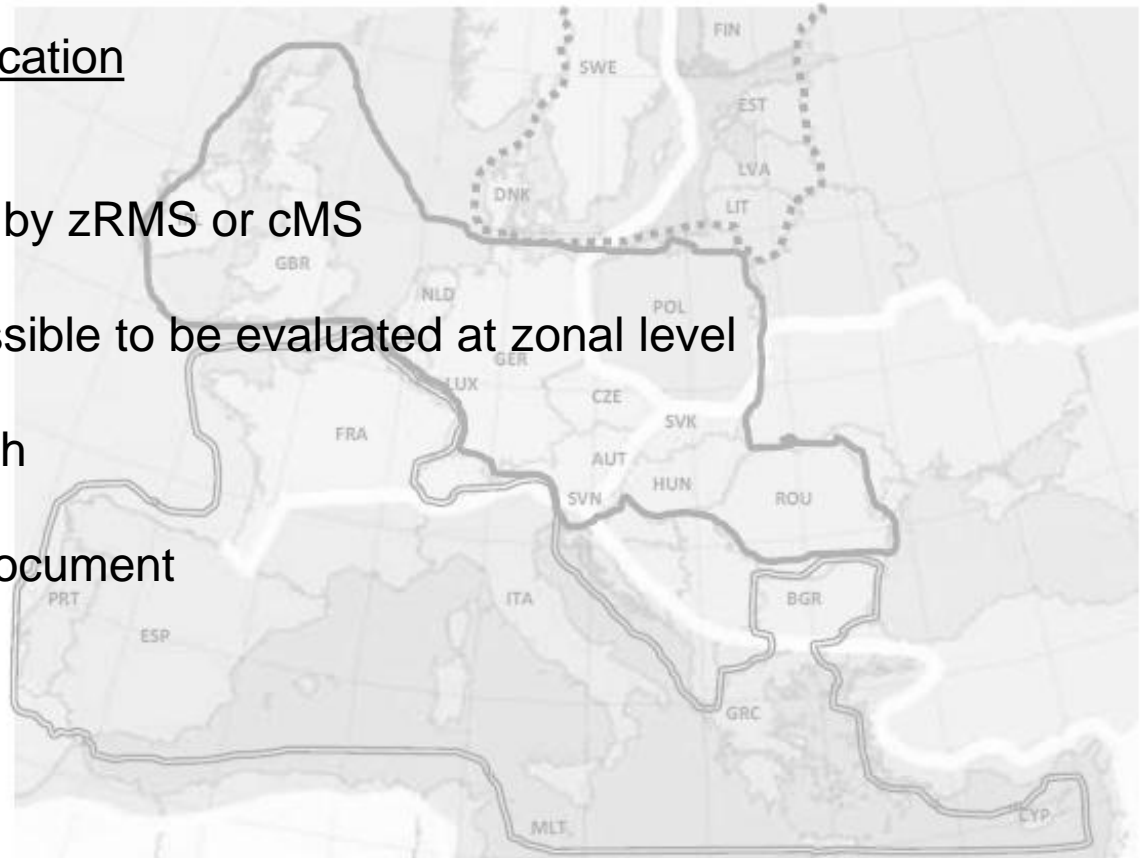
- following the draft EPPO standard “Principles of zonal data production and evaluation”;
- to be presented in the dRR;



Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).

High quality (dRR) application

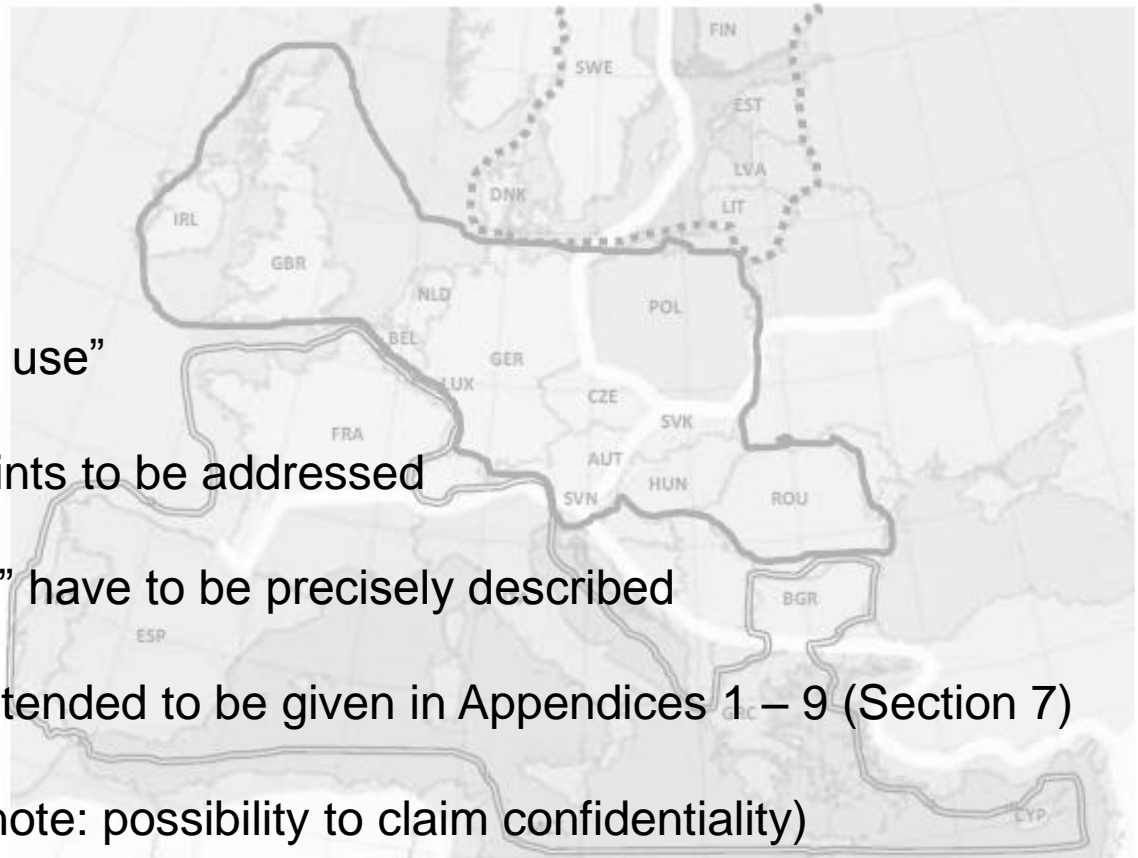
- uses to be assessed by zRMS or cMS
- as many uses as possible to be evaluated at zonal level
- no envelope approach
- dRR = stand alone document



Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).

High quality dRR

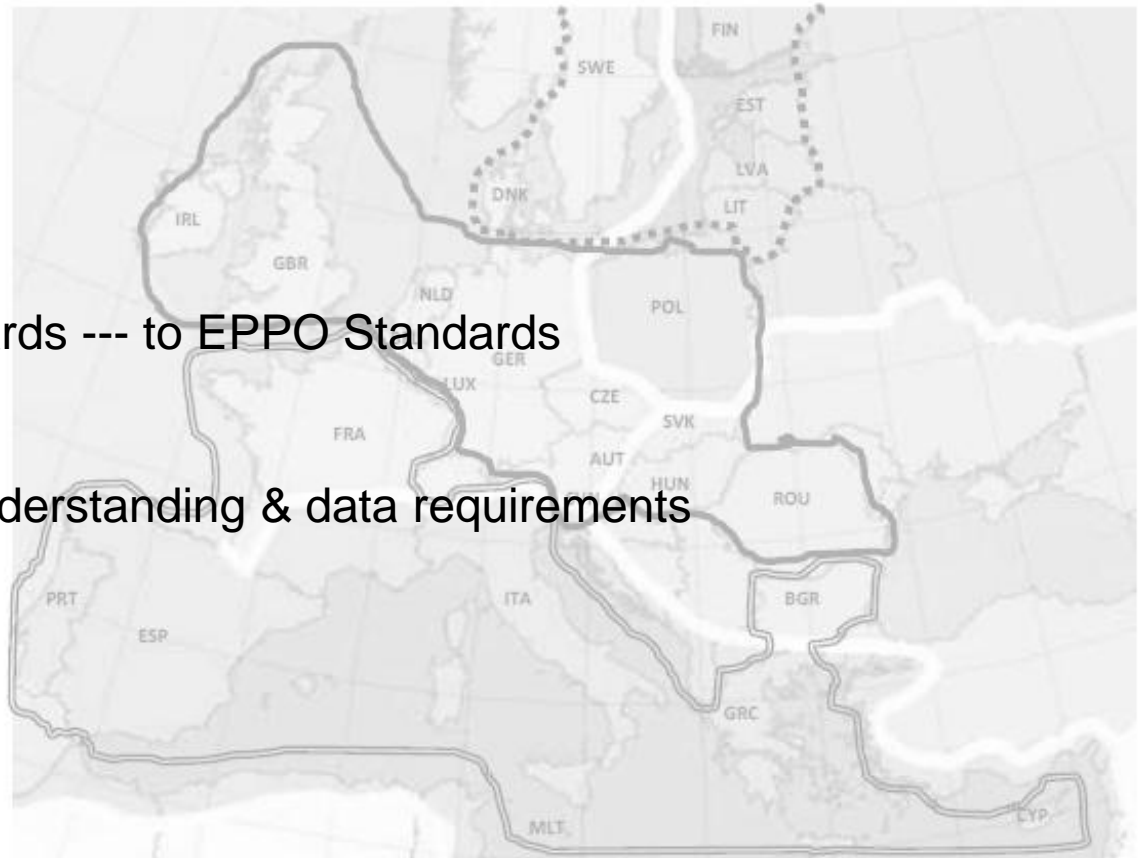
- New GAP format
- “Master directions for use”
- Each assessment points to be addressed
- “Protected conditions” have to be precisely described
- Information usually intended to be given in Appendices 1 – 9 (Section 7) should be provided (note: possibility to claim confidentiality)

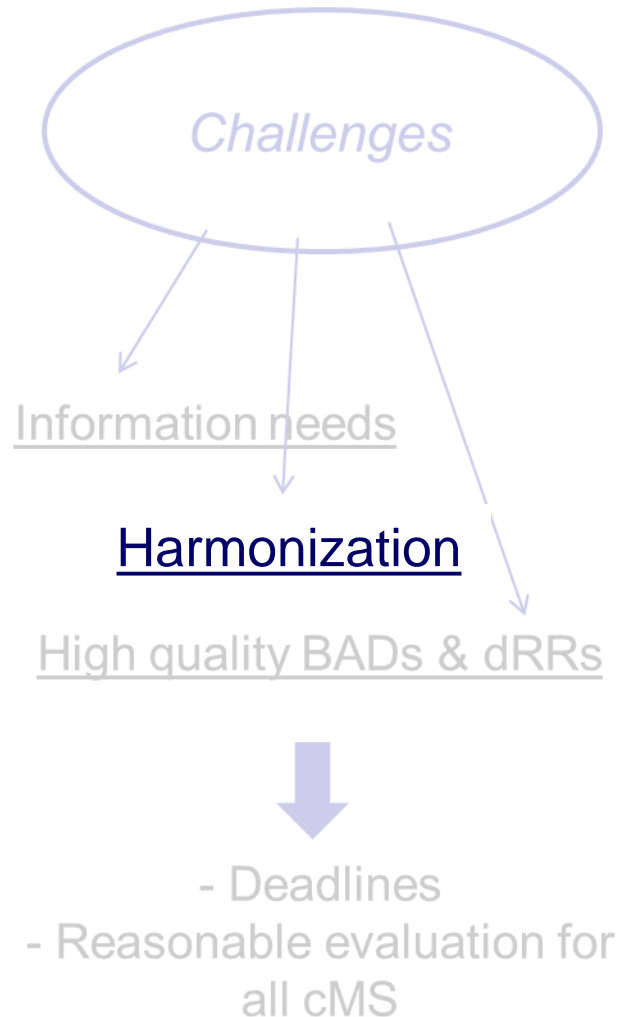


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Harmonization

- ❑ From national standards --- to EPPO Standards
- ❑ --- to harmonized understanding & data requirements





SANCO guidance documents (drafts)

- ✓ Core/national assessment
- ✓ New dRR Format

EPPO guidelines

- ✓ “Principles of zonal data production and evaluation”
- ✓ Drafting of new standards:
eg. Uses under protected conditions;
Septoria tritici requirements;
- ✓ Amendment of existing standards



- Deadlines
- Reasonable evaluation for all cMS

Authority level

- ✓ Workshops, Panels, Working Parties (EPPO...)
- ✓ Informal meetings
- ✓ Peer review

Dialogue Authorities ↔ Applicants

- ✓ Pre-submission meetings

Challenges of Efficacy Evaluation

Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, *Guidance on comparable climates*) superimposed with the three European zones (EC Regulation 1107/2009).

Let's stay in contact!

