BENAKI
PHYTOPATHOLOGICAL
INSTITUTE

EU & National Evaluation of Active Substances, Plant Protection Products and Biocidal Products on E-Fate, Chemical Composition, Physical Properties and Analytical Methods

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Laboratory of Chemical Control of Pesticides

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Historical Background

- ✓ Benaki Phytopathological Institute (BPI) has been involved in the Evaluation of active substances and formulations of pesticides according to the EU Directive 91/414 since 1995.
- ✓ After implementation of the European Regulation 1107/2009 with the Greek Law 4036/2012, BPI was set as the Competent National Authority for the Evaluation of the active substances and formulations of plant protection products.
- ✓ BPI is also involved in the Evaluation of active substances and formulations of biocidal products.

Scope

The Evaluation Purpose:

- Contributing to the sustainable use of pesticides
- Ensuring a high level of protection of both human and animal health and the environment

Areas of assessment

For:
- Efficacy
- **Identity, Physicochemical Properties and Methods of Analysis**
- Residues
- Toxicology
- Ecotoxicology
- **Fate and Behaviour in the Environment**

assessment is performed by the Evaluation Team of the Laboratory of Chemical Control of Pesticides at the Department of Pesticides' Control and Phytopharmacy

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Evaluation Team

Our team consists of 6 Regulatory Experts:

- 5 Chemists and 1 Environmental scientist

Starting from the oldest to the newest member of the team:

1. *Konstantina Dandika*, Chemist, 20 Years of experience
2. *Panagiotis Gatos*, Chemist, MSc, 11 years of experience
3. *Anna Angouridou*, Chemist, MSc, 8 years of experience
4. *Ioannis Kandris*, Chemist, MSc, 7 years of experience
5. *George Pavlidis*, Env. Scientist, MSc, 2 years of experience
6. *Niki Maragou*, Chemist, PhD, 1 year of experience

with Head of the Laboratory Dr Eleni Karasali.

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Main Activities

- ✓ Evaluation of studies and preparation of Assessment Reports (DARs and RARs) under **Regulation (EC) No 1107/2009** for the EU approval of **active substances** used in **Plant Protection Products** (PPPs).
- ✓ Reporting, evaluation, commenting tables
- ✓ Participation in technical meetings and teleconferences organized by **EFSA**.

Main Activities (2)

- ✓ Finalization of the reference specification for technical active substances after the ***EU peer review*** (GD SANCO/6075/2009 rev. 3) .

- ✓ Evaluation of studies for the Equivalence of technical materials from different sources than the EU approved (GD SANCO/10597/2003 rev. 10.1) and Preparation of Equivalence Reports.

Main Activities (4)

- ✓ Evaluation of studies and preparation of draft Registration Reports (dRRs) acting as **Southern Zonal** Rapporteur Member State in the context of zonal and inter-zonal authorizations of PPPs.
- ✓ Participation in pre-submission meetings.
- ✓ Commenting dRRs prepared by other MS.
- ✓ Evaluation of studies for the assessment of significant and non-significant changes in the chemical composition of authorized PPPs (GD SANCO/12638/2011 rev. 2).

Main Activities (3)

- ✓ Evaluation of studies and Preparation of Competent Authority Reports (CARs) under **Regulation 528/2012** for the EU approval of active substances used in **Biocidal** Products.

- ✓ Participation in technical meetings and teleconferences organized by **ECHA**.

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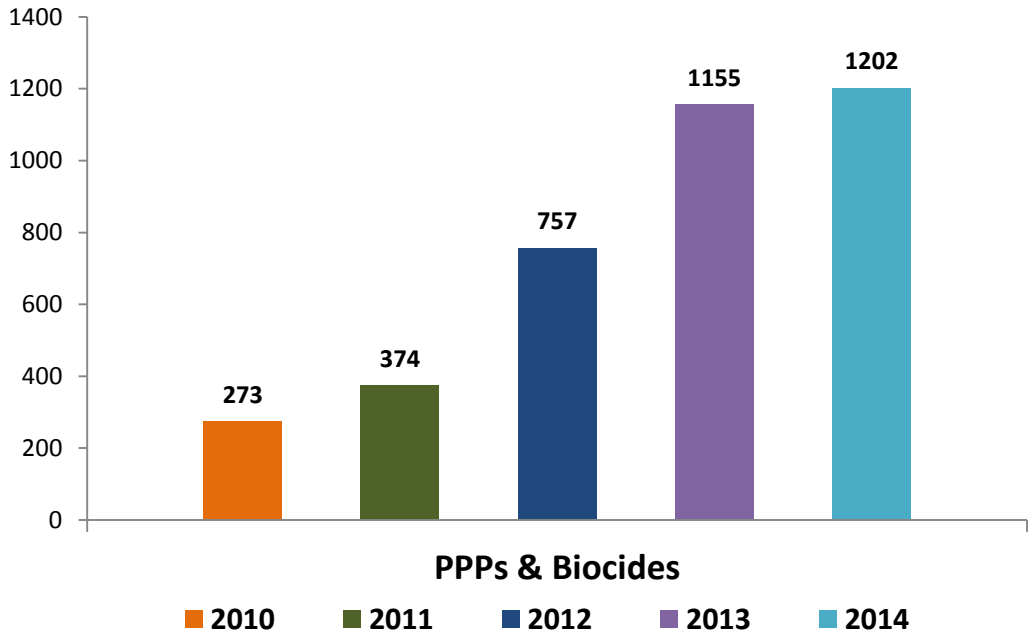
Indicative results of the scientific activity–evaluation of pesticides

DARs, CARs, dRRs & Reports of Control

Evaluation of Plant Protection Products & Biocides



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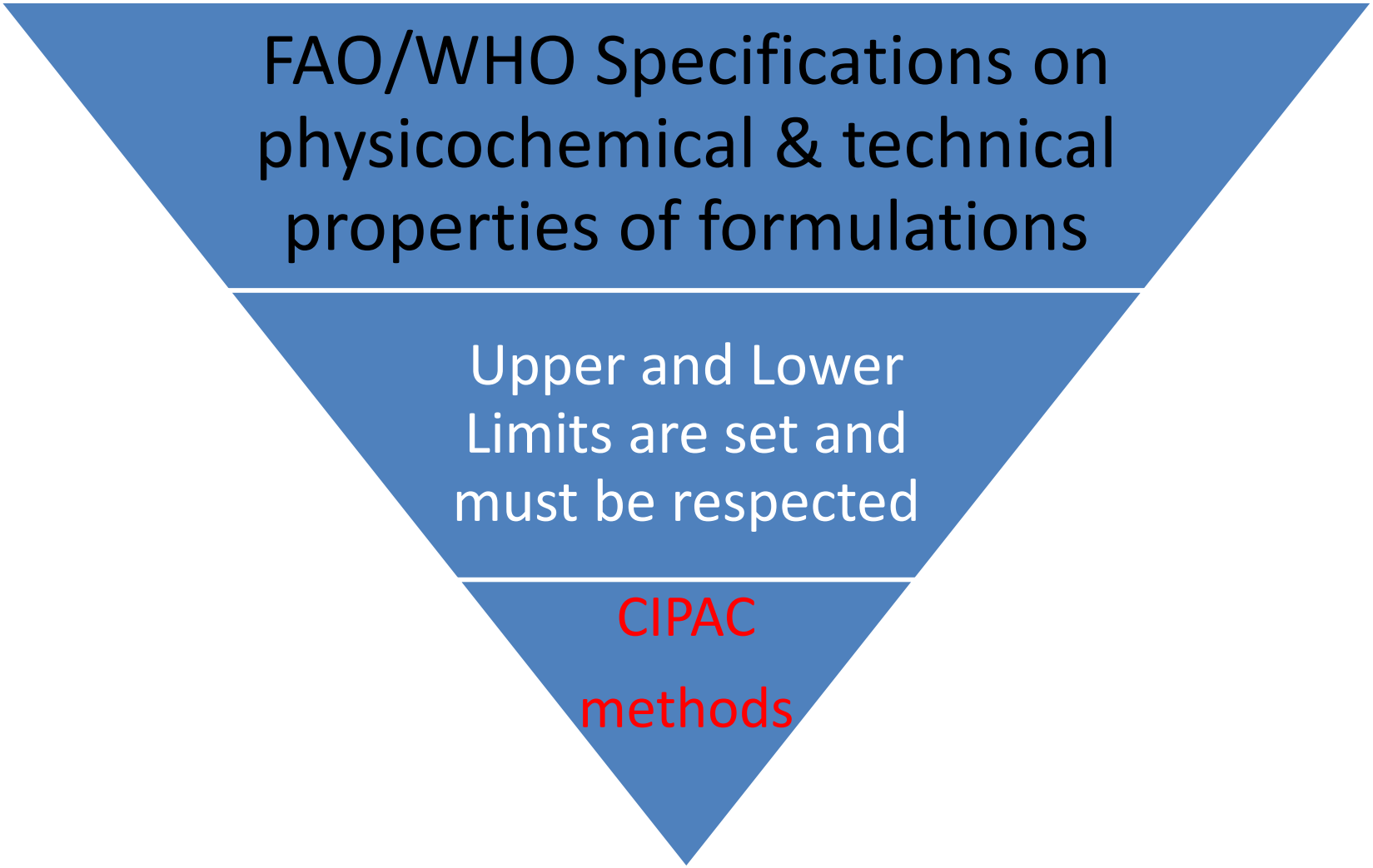
Evaluation and FAO/WHO specifications

- ✓ Under Regulation 1107/2009, formulations must comply with FAO/WHO specifications.
- ✓ FAO/WHO specifications are very important for the evaluation in terms of the active substance and the relevant impurities content in both TC and formulations.
- ✓ Upper limits for relevant impurities and Lower Limits for active substance are set and must be respected.

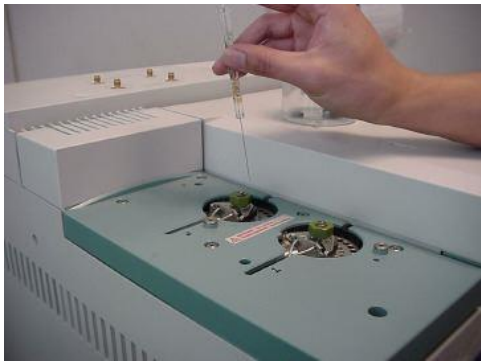
Evaluation and CIPAC methods

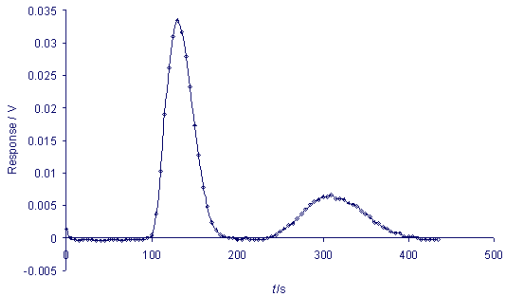


Evaluation and CIPAC methods (2)

- ✓ **CIPAC analytical** methods are often used by the applicants in order to address the requirement for determination of pure active substance in a TC or a formulation.

- ✓ **CIPAC analytical** methods are helpful to the evaluation as they are already fully validated and only example chromatograms must be submitted by the applicants.





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Additional Activities of the Evaluation Team

- ✓ Training of Polish Colleagues in the Evaluation of existing active substances and registration and surveillance of biocidal products.

- ✓ Training of colleagues from Kosovo in the context of TAIEX Event “Study Visit on experiences in packaging, classification and labelling of plant protection products”.

- ✓ Training of colleagues from Bosnia in the context of TAIEX Seminar/Workshop on “Evaluation of identity and physiochemical properties of plant protection products”.

On behalf of the Evaluation Team

THANK YOU FOR YOUR ATTENTION!