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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http://en.bpi.gr
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.
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 Behavior 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
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.
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.
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).
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.
Indicative results of the scientific activity—evaluation of pesticides

DARs, CARs, dRRs & Reports of Control
Evaluation of Plant Protection Products & Biocides

![Graph showing PPPs & Biocides evaluation from 2010 to 2014]

- 2010: 273
- 2011: 374
- 2012: 757
- 2013: 1155
- 2014: 1202

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.
FAO/WHO Specifications on physicochemical & technical properties of formulations

Upper and Lower Limits are set and must be respected

CIPAC methods
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.
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!