Data requirements for the EU approval of active substances and their plant protection products regarding the identity, the physicochemical properties and methods of analysis under Regulation EC 1107/2009

BENAKI PHYTOPATHOLOGICAL INSTITUTE

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INTRODUCTION:

Authorities worldwide establish regulations and guidelines regarding the authorization and use of pesticides in order to protect the environment and human safety. In the European Union, pesticides are authorized according to Regulation EC No 1107/2009, concerning the placing of plant protection products on the market. According to this regulation, substances should only be included in plant protection products if they present a clear benefit for plant production and harmful effect on human or animal health or any unacceptable effects on the environment are not expected.

The evaluation involves the following areas:

- **Identity**
- **Physicochemical and technical properties**
- **Analytical Methods**
- Efficacy
- Toxicology and metabolism
- Residues in crops
- Environmental fate
- Ecotoxicology

IDENTITY

ACTIVE SUBSTANCE

- Information on the active substance (ISO-name, CAS No, structural formula, etc.) and its producer.
- Information on the method of manufacture.
- Specification on minimum purity of active substance and maximum content of relevant and significant impurities in the technical, supported by 5-batch analysis data for each manufacturing plant.
- If the active substance originates from a different/new producer, the equivalence with the EU approved source must be established.

PLANT PROTECTION PRODUCT

- Information on the composition of the plant protection product (content of active substance and its variant, safeners, co-formulants, and maximum content of relevant impurities) and its producer. Technical should be originated from an EU approved source.
- Compliance with existing **FAO** limits on the active substance content in the formulation.
- Type and code of the plant protection product according to 'Manual on development and use of **FAO** and **WHO** specifications for pesticides'.

PHYS/CHEM PROPERTIES

ACTIVE SUBSTANCE

- Evaluation of physicochemical properties of active substance (appearance, melting/boiling point, vapour pressure, solubility in water/organic solvents, partition co-efficient, dissociation constant, spectra and surface tension).
- Evaluation of safety properties (flash point, flammability, self-heating, explosive and oxidising properties)
- Classification and labelling (under Regulation 1272/2008).

PLANT PROTECTION PRODUCT

- Evaluation of physicochemical properties of plant protection product (appearance, pH/acidity/alkalinity, viscosity, surface tension, density, storage stability at high/low/ambient temperature, physicochemical compatibility with other products and adherence/distribution to seeds).
- Evaluation of technical properties of plant protection product (depending on the type of the formulation) according to **CIPAC** methods and compliance with the relevant **FAO/WHO** specifications for pesticides.
- Evaluation of safety properties (flash point, flammability, self-heating, explosive and oxidising properties)
- Classification and labelling (under Regulation 1272/2008).

METHODS OF ANALYSIS

ACTIVE SUBSTANCE

Analytical methods for the determination of:

- **active substance** in the technical (the applicability of existing **CIPAC** method must be assessed, in case of **CIPAC** method further validation shall not be required except for example chromatograms).
- **relevant and significant impurities and additives** in the technical.

PLANT PROTECTION PRODUCT

Analytical methods for the determination of:

- **active substance and/or variant** in the plant protection product (the applicability of existing **CIPAC** method must be assessed, in case of **CIPAC** method further validation shall not be required except for example chromatograms).
- **relevant impurities** in the plant protection product.

RESIDUE ANALYTICAL METHODS

Enforcement methods (post-registration) and **Data generation methods** (pre-registration) for the determination of active substance residues in:

- Food/feed of plant origin
- Food/feed of animal origin
- Soil,
- Water (surface and drinking water)
- Air
- Body fluids and tissues

✓ The analytical methods should be **validated** as regards specificity, linearity, accuracy, precision and LOQ.

✓ Validated **confirmatory methods** and **Independent Laboratory Validation (ILV)** shall be submitted if appropriate.