Food and Agriculture Organization of the United Nations

FAO/WHO guidelines on microbials, botanicals and semiochemicals for plant protection and public health

Gu Boagen
Senior Agricultural Officer
baogen.gu@fao.org

Food and Agriculture Organization of the United Nations

Content

1. Background
2. Main Components of the Guidelines
3. Next Steps

Food and Agriculture Organization of the United Nations

International policy context: Integrated Pest Management

- Integrated Pest Management (IPM) is an ecosystem approach to crop production and protection that combines different management strategies and practices to grow healthy crops and minimize the use of pesticides.

- FAO promotes IPM as the preferred approach to crop protection.

- Biological control plays an important role in IPM.

Food and Agriculture Organization of the United Nations

1. Background

- 1.1 Importance of bio-pesticide
- 1.2 Problems

Food and Agriculture Organization of the United Nations

1.1 Importance of biopesticides

- Reduce risks to human health:
  - Majority of biopesticides have low toxicity with
    - LD_{50} >5000 mg/kg
    - No risk of chronic toxicity (except some may have toxic metabolites)
- Minimize environmental damage:
  - Minimal environmental damage
  - Contributing to agroecology and sustainable
- Improve food quality and safety
- Promote sustainable development of agriculture
- Evolve the pesticide industry

Food and Agriculture Organization of the United Nations

1.2 Problems encountered

Problems bringing them to the market:

- Production
- Registration
- Sale and use

Food and Agriculture Organization of the United Nations

Production

Difficulties of large scale production e.g.

- Insect viruses - in vivo
- Some fungi – solid state production
- Semiochemicals

Unstable quality

- Quality of botanicals influenced by source of materials, and extracting technology
- Quality of microbial affected by fermentation equipment and process

Lack of automatic production equipment and advanced technology

Contaminations during production

Food and Agriculture Organization of the United Nations

Registration

- Unsuitable data requirements
- No specialized criteria for data review and decision making for registration
- Lack of relevant expertise and experience of applicants and regulators

Food and Agriculture Organization of the United Nations

Registration: Chemical/physical data properties

- Chemical/physical data properties and specification of biopesticide are totally different from chemicals

By following chemical guidelines – there were technical problems :

Problems	Microbial	Botanical	Semi-chemicals
A.S. and analysis methods	Yes	Yes	Yes
Five batch analysis	Yes	Yes	Yes
Registration of technical	Yes	Yes	Yes
Formulation	Yes		Yes
Parameters for properties	Yes		Yes
Storage and shelf life	Yes		
Certified Labs.	Yes		

Food and Agriculture Organization of the United Nations

Registration: Efficacy

The chemical guidelines were not suitable for assessing efficacy e.g.

- Trial methods, size and number needed to be changed
- Reference products were not appropriate e.g. for microbials and semiochemicals
- Effectiveness assessment not suitable for microbials:
  - lower effectiveness
  - long term and short term effectiveness.
- Effectiveness assessment not suitable for semiochemicals:
  - how to assess on landscape scale?

Food and Agriculture Organization of the United Nations

Registration: Toxicity

- Acute toxicity: inhalation test for microbials?
- Sub chronic: microbial, if needed what tests?
- Chronic: botanicals and semiochemicals, what tests?
- Human pathogen test: microbials one or two methods?
- Additional tests:?
- Some may be toxic to specific animals

Food and Agriculture Organization of the United Nations

Registration: E-fate & non-target organisms

- Environmental fate: for botanicals and semiochemicals
  - What to do?
  - How to do it?

- Effects on non-target organisms:
  - How many organisms to be tested for microbials?
  - How many organisms to be tested for semi-chemicals?

Food and Agriculture Organization of the United Nations

Registration: Residues

- Microbial with metabolite:
  - Exemption?

- Botanicals:
  - Exemption?
  - If not how to do?

Food and Agriculture Organization of the United Nations

Sale and use

- Lower and slow efficacy?
- Higher costs for pest control?
- New techniques for application?
- Less competitive than chemicals?
- Less interest from farmers?

Food and Agriculture Organization of the United Nations

2. Main Components of the Guidelines

2.1 AIMs

2.2 Contents

2.3 How the guidelines address registration issues

Food and Agriculture Organization of the United Nations

2.1 Aims

Maintain a high level of protection of human health and the environment

…… **but ensure** there are no additional registration barriers for microorganism, botanical and semiochemicals.

Food and Agriculture Organization of the United Nations

2.1 AIMs

(1) To raise awareness of importance for developing special registration policy for bio-pesticides.

(2) To facilitate development of proper data requirements.

(3) To provide technical guidance on data review, risk assessment and decision-making.

(4) To promote technical advice on fact track registration, labelling, and mixture etc.

Food and Agriculture Organization of the United Nations

2.2 Content of the guidelines

- **1. Introduction:** Scope, objectives, regulatory aspects to be considered
- **2. Microbial**

  Data requirements, Evaluation of the dossier
- **3. Botanicals**

  Data requirements, Evaluation of the dossier
- **4. Semiochemicals**

  Data requirements, Evaluation of the dossier
- **5.Specific issues:**

  Labelling, Mixtures, Fast-track registration

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Data requirements

To support a simplified approach:

No specialized data requirements for biopesticides:

The guidelines now provide:

- Data requirements for each group of substances (microbial, botanical and semiochemical) that are:
  - Proportional to the risks represented,
  - Indicate providing information that is directly relevant to each technology,

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Data requirements

To support a simplified approach:

Many biopesticide active substance are well known and well-studied so:

- A dossier may consist of information coming from published literature and in-house studies.
- Reasoned cases/justifications/waivers can be used to support the non-provision of certain data.
- Exchangeability of data is feasible: it is recognized that there may be common properties within groups of substances for example, some microorganisms.

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Data review

To support a simplified approach:

No specialized criteria for data review and decision making

The guidelines now provide:

- Evaluation criteria that:
  - Assesses only information relevant to the technology
  - Allows a good and appropriate risk assessment to be made,
  - Harmonize the evaluation with other regulatory authorities to allow reciprocation of dossiers and evaluations.

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Data Review

To support a simplified approach:

- Active substances are often formulated with materials that are of no toxicological concern, so the risk assessment can reasonably be based on information about the active substance only.

- There are often no suitable or validated testing methods available so in-house or external expert studies can be used. Non accredited or GLP labs.

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Special issues

To support a simplified approach:

Lack of relevant expertise and experience of applicants and regulators

The guidelines now provide:

- Regulatory tool to support applicants with biopesticides
- Guidance for regulators unfamiliar with biopesticides
- Mechanism to fast-track biopesticide risk assessments
- Mechanism for harmonized approach for biopesticides between countries – reciprocal approvals.

Together these support the improved availability of substance that can be used as part of IPM and support a sustainable agriculture policy

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Microbials

To support a simplified approach, some species of microorganisms can be considered for reduced data requirements with:

- Full and unequivocal taxonomic identification.
- Confirmation of the MPCA production process to demonstrate that the active substance contains target species cfu only.
- The formulation is only with inert (non-toxic) substances.
- Confirmation of cfu/potency in the final product following storage.
- Confirmation of product relevant physical and chemical properties.
- Confirmation human pathogen contaminants are below accepted levels in the product.
- Sufficient efficacy data to confirm label claims.

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Botanicals

To support a simplified approach the guidance considers that botanicals are mixtures:

'Botanical' covers substances that:

- Are an extremely heterogeneous group of substances,
- May be highly refined or a complex mixture,
- Have components which may or may not be biologically active.

For mixtures the critical regulatory aspects are:

- Quality control of source plant material,
- Correct identification of the source plant,
- Cultivation, harvest, storage, primary processing of plants,
- Manufacturing process of botanical material,
- Definition and variability in composition of the a.s.
- Residues
- Efficacy

Food and Agriculture Organization of the United Nations

2.3 How do the guidelines address registration---Semiochemicals

To support a simplified approach it is acknowledged that many semiochemicals:

- Have a non-toxic, target specific, mode of action,
- Are of natural occurrence, often at levels comparable to background levels,
- Generally effective at very low rates,
- Can dissipate and/or degrade rapidly in the environment,
- Pose low risk to human health and the environment,
- Often have no residues,
- Efficacy is difficult to assess on a landscape scale.

The guidance describes how to allow for these attributes and to assess the safety of semiochemicals for plant protection and public health.

Food and Agriculture Organization of the United Nations

3. Next Steps

(1) Publication of the Guidelines

(2) Pesticide regulatory authorities are the key players to implement the guidelines:

--Training

--Living document: for feedback from users

(3) Develop online toolkit.

Food and Agriculture Organization of the United Nations

Thank you