Summary of break-out groups

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1. Quality of Studies

Solutions

Quality assessment of study reports is essential and should be practiced in Ethiopia.

- Short term action for Regulation: Adopt some of the existing relevant protocols (OECD, EU, JMPR) to check the quality of the data in the dossier / Setting quality assessment parameters

- Check if studies are performed under GLP

- Develop Regulations, Directives and guidelines by adapting international protocols

- Man power capacity building on quality assessment

- Awareness creation of stakeholders

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2.Evaluation of dossier by authority

<u>Advantage</u>:
- Check that pesticide is safe to all protection goals
- Confidence development on the data provided
- Checking compliance with the legislation
- Building the capacity of technical staff and the decision makers
- Helps to identify gaps in rules and regulations
- Identify and encourage providing quality dossier (reliable dealers)

<u>Disadvantage</u>
- Needs to build up human and financial capacity
- Needs more time for evaluation
- Unable to get complete study report
- Lack of reference sources
- Discourages potential registrants due to low market demand

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3.Setting Reference Values

Which is the best option at the moment?

A. Based on dossier evaluation by Ethiopian authority

B. Use only available reference values (EU, JMPR, EPA etc)

C. Use only available reference values & check dossier for more series effects

Option D was invented and preferred:

D. Use C + national situation to adjust reference values

-> It creates flexibility to consider local situation.

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4.Protection Goals

Which groups of people should be considered? In decreasing order:

1st.Operators
     a. Small scale /Field
     b. Large scale /Field
     c. green house/ Covered
     d. Aircraft /Field
2nd.Workers
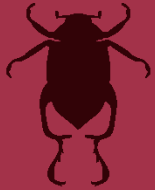3rd.Bystanders / Flag man
4th.Residents

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5. Models

Should we use available models as such? Or do we need to consider better defaults first?

- Adopt user friendly models from other countries because of the non-existence or low experience on using the models

- Consider local default (based on local data/Base line studies) to adjust to the real local conditions

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6. Dermal Absorption

Proposal: Use the data provided by applicant as such, without further evaluation

Advantage

- It saves time

Disadvantage

-May provide unreliable or poor quality data. Needs capacity

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7. Personal Protective Equipment

Proposal: Do not use PPE as a refinement in risk assessment or only on experts' judgment

Advantage

- It allows flexibility in decision making. Expert judgment allows us to determine the risk in situations where farmers are hardly using PPEs

Disadvantage

- Decision depends on the competence of the expert. Expert judgment may not always be correct.

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