

BOG D on Semiochemicals

Acceptable effectiveness levels and types of label claims

- **Not a fixed level** % of pest control should be the aim, but the result should be an improvement of harvestable product (economically viable)
- Dossier should contain **history of trial plot** wherever possible to appreciate initial pest levels to better appreciate results
- Contribute to reduce pest pressure: either as **stand-alone or with complementary measures**
- Number of applications of pheromones that **reduce the number of chemical treatments**/other measures
- **Observable effects** on plant (e.g. stem) and harvestable product (e.g. fruit)
- **Alternative testing** could be part of the dossier and reduce the number of field trials. Example: Cage trials but they require rearing of the insects.
- Only one year trial instead of two years trials
- **Not grading terminology**, but clear explanation for the farmer how to use the PPP, conditions and limits. *Moderate* not useful for farmer.
- **Phytotoxicity** not necessary when released by dispensers; otherwise (e.g. sprayable formulations) do observations in efficacy trials
- **Change of dispenser**: If same release rate and number → no field trial necessary. If change of number → bridging or trials

Dose justification

- Not necessary to define Minimum Effective Dose.
- EPPO standard microbials: Not applicable
- OECD guidance microbials: Not applicable

Data requirement: minimal information?

- EU data requirements can be addressed by data/trials, justification, review of public literature
- If field trials in EU, then according to GEP (otherwise will not be acceptable by all 28 MS).
- Optional: information about pest development after application (long term observation)
- Invasive species: no full data package necessary, but reduced with information from country of origin
→ details eg on pest, crop, weather and field conditions, justification.

Extrapolation possibilities/justification of extrapolation

- Extrapolation from 1 pest and 1 crop to same pest in other crops
- For one pest to another: bridging always necessary
- **Worst case** should be tested and extrapolated
 - Outdoors/indoors, warm climate, high humidity
- **1 EU zone for low risk products**
 - ➔ create efficacy envelope with zonal labels
- Good quality data and science are key

Minor crops and minor uses

- Revise definition of minor use
 - ⇒ harmonised list of minor uses
- Single assessment of 'minor use' throughout EU
- Harmonised crop grouping system/
extrapolation from 'major' to 'minor'.
- Get rid of national specific requirements

Quality of dossiers

- MAO: Semiochemicals ⇒ modified behaviour
- To have a **good example dossier**; good quality trials, data and presentation of the data including statistics, justifications
- Agree between MS regulatory authorities how trials should be reported/presented (tabular format, charts etc.) ⇒ **Guidance needed** with example for insecticide, fungicide, and herbicide.
- **Pre-submission meeting** granted on request

Usefulness of value assessment

- Benefits should be included and considered!
Examples: Fits IPM, organic farming, no residues, no effect on NTO, reduce conventional treatments, management of resistance
- More feedback on Canadian experience needed.
- Develop a holistic approach to assessment