EFSA workshop on the development of a fit-for purpose methodology for the assessment of actives substances of low-concern (LCAS)

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Ireland experience in assessing LCAS

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LCAS evaluated by Ireland

Plant extracts

Garlic extract

Uses: insecticide, nematicide, vertebrate repellent

Co-RMS: Denmark

Other uses: food additive, health supplement

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Naturally occurring minerals

Aluminium ammonium sulfate

Uses: vertebrate repellent

Co-RMS: Portugal

Other uses: additive in baking powder, food additive, water purification, cosmetic industry

LCAS evaluated by Ireland

Naturally occurring sugars

Maltrodextrin

Uses: insecticide and acaricide, physical mode of action

Co-RMS: France

Other uses: food additive, pharmaceutical industry

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LCAS evaluated by Ireland

Pheromones

3-Methyl-6-isopropenyl-9-decenyl acetate (Rescalure)

Uses: insecticide, mating disruptor

Co-RMS: Portugal

Other uses: pest control

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Occurring issues regarding available data

- Inadequacy of data requirements – what to expect in a dossier? rely on expert judgement? Availability of data is limited
- Waivers: rely on expert judgement to decide regarding the robustness of a waiver
- Bridging principles/ read-across
- Issues with studies quality (aquatic studies – issues with the analytical verification of test item), Relevant and reliable?
- Inadequate study design that doesn't consider the Mode of Action of the Active Substance (e.g. Maltodextrin& NTAs glass plate studies);

Other occurring issues

- High application rate and high frequency of application (e.g. Maltodextrin)
- Determination of background level – challenging to determine and sometimes not reliable;
- Presence of co-formulants that are possible substances of concern (leading to possible data gaps for the formulation)
- ED assessment (no ED scenario is applicable , rely on waivers)

Possible suggestion to improve the evaluation of Low Concern Active Substances

- Harmonization/ Clarification of Data Requirements (Standardized approach)
- Minimum data requirements that are based on the Mode of Action of the Active Substance (more emphasis of the quality of the studies)
- Study design – that reflects the Mode of Action and application scenarios (adequate discussion on exposure);
- Discussion of risk mitigation proposed by the applicant (mainly for co-formulants)
- ED assessment (more details regarding the approach when an ED waiver is satisfactory e.g when no ED scenario is applicable)
- Applicant side: increased awareness of what is required when it comes to authorization of LCAS

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Thank you for your attention!

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