RESIDUE STUDIES FOR B&M RA: CONTROLLING THE UNCONTROLLABLE

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Residues studies for wild bird and mammal risk assessment (B&M RA) are performed to refine the residue level or decline rate on potential food items. Our experience in monitoring such studies has raised repeating or unusual issues with each new study. Often such residues refinements are changed or rejected during the EU pesticide review process, with little notice to the submitter. Newly revised EFSA B&M guidance (EFSA 2023[1]) provides clarification on performing these studies, but does it help to answer all issues? Will residue decline studies be as useful in future considering the new endpoint screening required to decide whether or not the time-weighted average approach can be used in the RA? This poster considers potential solutions to these issues, and references any useful information provided within the new draft guidance.

WEATHER

- Should this be representative of 'normal' patterns? Or 'worst case'?
- Rain can cause erratic results – increased degradation rate, or increased uptake by plants. Not realistic to avoid rain altogether.
- Application window often very small and with last minute changes due to rain or wind.
- With climate change, weather patterns are becoming more erratic – more droughts/floods. The 'new normal'? Historical weather data no longer useful?

B&M GUIDANCE DOCUMENT 2023 SAYS:

Appendix A: residues studies are a "trade-off between the ability to control the conditions of the experiment on one side and their environmental realism on the other." Field studies cover all processes, so not able to distinguish relative influences of processes.
It is recommended to perform multiple trials to cover environmental variability – implying that 'adverse' weather conditions in a single trial may not be a problem if it is accompanied by other trials. 4 trials are recommended. Regarding rain, the GD states: "The effect of the rainfall should be carefully evaluated when assessing the dissipation dynamics." But no specific guidance given for when rainfall would result in studies being rejected.

WE RECOMMEND:

For above-ground matrices, no rain for 24 hours after application unless quicker rainfastness has been proven. Thereafter, only light rain accepted before the DT50. Definition of (s)light/heavy rain according to WMO (world meteorological organization) 2018[2] guideline (intensity (i) < 2.5 mm/h = slight, 2.5 ≤ i < 10 mm/h = moderate, 10 ≤ i < 50 mm/h = heavy, ≥ 50 mm/h = violent/intense/extreme). Rainfall to be measured locally using a method suitable for determining hourly rates.

SITE REQUIREMENTS

- Practical implications with getting sufficient sites, e.g. finding willing farmers, previous treatments of fields, getting sufficient distance between sites, etc. Previous rule of thumb ~100km between sites. Particularly difficult for localised/permanent crop that requires a particular local climate.

B&M GUIDANCE DOCUMENT 2023 SAYS:

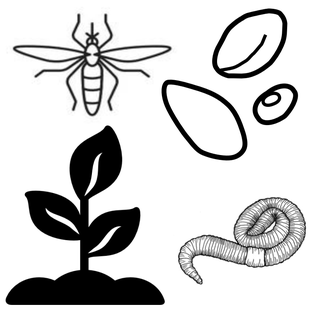
States ~100km, but 20-100km acceptable if sites proven to be sufficiently different (e.g. weather patterns). May still be impractical to get sufficient sites depending on the GAP. Emphasis is still given to spatial variability – though noting that temporal variability 'may also play an important role'.
Number of trials required: minimum 4 required for plants per category per zone, 2 per category per zone for invertebrates for residue decline studies; but if DT50 values are not all consistent, more trials may be needed (see Annex A, point 7.2).

WE RECOMMEND:

Follow the guidance (min 4/2 sites for decline studies) but consider logistics. Try to define ideal number of sites required initially, ideally in liaison with (z)RMS. GD now provides scheme for refining Residue per Unit Dose (RUD) values (e.g. matrix underrepresented in database, see ch. 6.4.1.) but note that database now larger in new GD. Pre-sample for soil type and consider climate to ensure differences between sites. Consider adding extra trial because things do go wrong. Avoid temporal variability (without spatial variability) if at all possible.

MATRICES

- Needs to be relevant to diet we want to refine
- Finding naturally occurring matrices can be a challenge: weeds might not be present in the seed bank. Earthworms found in low numbers in arable fields, particularly in SEU. May be questioned for proof of exposure of earthworms, especially if there is foliage cover.
- Can be reliant on weather – persistent dry weather can result in earthworms dying or going into 'aestivation' or plants not germinating.
- How best to measure residues in seeds? If spread in the field they will eventually germinate (therefore not a seed any more). Heat-treating acceptable? How seeds swell/germinate is also highly dependent on the weather (rain/moisture content of the soil). Should rain cover be used? For 'weeds seeds' – what are acceptable surrogates? How to find/collect very small seeds in field?
- Desiccating herbicides: investigating residues in plant matrices can be a challenge. Consideration has to be made of the moisture content of the plant, as this could impact residue dynamics. The B&M guidance uses wet weight as the default for dietary calculations – is this appropriate for these herbicides? Can it be accepted that desiccated plants are less attractive to NTOs (Non-Target Organisms)?
- What BBCH for "weeds"?



B&M GUIDANCE DOCUMENT 2023 SAYS:

More advice is given on sampling for invertebrates, but little on the other matrices. Does clarify that monocots and dicots can be extrapolated between at higher growth stages, and maize shouldn't be used for non-grass weeds. Sampling methods only mentioned for arthropods and pollen/nectar. BBCH doesn't need to match GAP for inverts and seeds. But timing of apps in GAP should be followed for all items (summer, autumn, etc.).

WE RECOMMEND:

Pre-sampling of arthropods/Earthworms and irrigating prior to treatment if needed to ensure sufficient sampling matter. Irrigation according to standard agricultural practice if dryness threatens plants' survival (absolute minimum 24hr before app). Using a UV-permeable rain cover for seed residue trials, using a surrogate 'weed' seed that can be easily found on the soil surface. Can use crop seeds of suitable size – but be wary of germination times (can be rapid). Decide on a sampling strategy e.g. only sample non-germinated seeds, and when to cease sampling due to germination (x% germinated seeds). Surrogate crops used as well/instead of weed plants where not available.

OTHER THINGS TO NOTE IN EFSA 2023

- New 'Critical Assessment Tool' will be used to assess all studies - an Excel file.
- Chapter 6.1.4: Criteria to assess whether you can use an fTWA <1. If the criteria are not met, then even the tier 1 default assumption of a half-life of 10 days cannot be used. For more info see CEA poster "Time-weighted average factor (ftwa) assessments for birds and mammals under the new bird and mammal guidance: experiences to date" (Brooks *et al.* 2023).
- The generic species scenarios/diets may be different compared to the previous GD, so relevant matrices may be different (e.g. generic model species granivore). But insectivorous bird and herbivorous mammals still most critical.

GUIDANCE

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Risk assessment for Birds and Mammals

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WE RECOMMEND:

Best to consider critical assessment tool when designing studies (not tested yet). Should carefully check the fTWA criteria before performing studies to avoid wasting time and resource (DT50 may be irrelevant if fTWA not allowed). Best to also consider a worst-case assessment without fTWA and prepare alternative refinement options should regulator disagree with your check. Check the relevant diet and which part of it is most critical (under current GD and future when the new GD is in force). May need to consider if residue studies are best use of your resource.

References:
[1] EFSA (European Food Safety Authority), Aagaard A, Berny P, Chaton PF, AntiaAL, McVey E, Arena M, Fait G, Ippolito A, Linguadoca A, Sharp R, Theobald A and Brock T, 2023.Guidance on the risk assessment for Birds and Mammals. EFSA Journal 2023;21(2):7790, 300 pp.
[2] WMO (2018). WMO-No. 8: Guide to Instruments and Methods of Observation, Volume I – Measurement of Meteorological Variables. World Meteorological Organization (a specialized agency of the United Nations), ISBN 978-92-63-10008-5.