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Implementation of the EC Roadmap on phasing out animal testing in Pesticides & Biocides Human Health Risk Assessment: Strong points, Opportunities, Challenges

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Q.1 Which elements of the EC Roadmap provide the strongest basis for **accelerating** the replacement, reduction and refinement of animal testing in pesticide and biocide assessments, and why?

Harmonised EU strategy
Common policy direction for 15 EU Legislative Domains including pesticides and biocides.

- ✓ Opportunity to **reduce regulatory fragmentation** and improve consistency between pesticide and biocide assessments.

Recognition that the transition requires a paradigm shift to a new scientific framework
For complex endpoints it may not be possible to simply replace an animal test with one alternative test.

- ✓ **Regulatory space** to integrate information from multiple approaches and rely more strongly on mechanistic understanding of toxicity, use of IATA/Defined Approaches, mechanistic WoE, AOP-informed assessment, exposure-led approaches.

Clear recommendations for the transition to non-animal approaches
Actions are organized based on time-frame as short-term, medium-term and long-term

- ✓ Opportunities on how to achieve the 3Rs are planned are **short-/med-term actions**.
- ✓ **Prioritisation** based on severity (acute tox) and complexity of toxicity endpoints: genotoxicity, carcinogenicity, DNT, developmental toxicity, ED.

Regulatory needs drive method development
Regulatory needs guide priorities for method development, validation, qualification, standardisation.

- ✓ Opportunity to move towards **regulatory question-driven NAM** development; problem formulation is the 1st step in pesticide & biocide risk assessments.



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Safe spaces

Discussion between applicants and regulators on new approaches before formal submission.

Strong link between Research and Regulatory implementation

The Roadmap connects regulatory needs with EU research programmes (PARC, ASPIS, NAMWISE, Horizon Europe) and European Innovation Council.

- ✓ Opportunity for exploratory dialogue and scientific advice on alternative approaches and their regulatory applicability without regulatory consequence *via* existing regulatory processes, e.g. **"early WG meetings" in biocides** (ECHA/MS/Applicant).
- ✓ The BPR has the mechanism to take into account the availability of alternatives to animal testing when deciding on a testing proposal through regular updates of the **BPR Guidance** on Information Requirements and Assessment and Evaluation.
- ✓ Opportunity to consider research from Industry or EU research programmes in regulatory risk assessments (e.g through dedicated joint EFSA/ECHA workshops).

Recognition that method validation may be a bottleneck in the process

The Roadmap proposes additional measures including revision of OECD GD34, optimisation of EU-NETVAL/PARERE, and development of readiness criteria for non-animal methods and defined approaches.



- ✓ Opportunity to make the 3R process more efficient as validation is not necessarily the rate-limiting step in the use on NAMs.
- ✓ Possibility for updates in regulatory use of NAMs through expert discussions in EFSA (e.g. **PREV biannual Plenary meetings**) & ECHA (e.g. **Technical Agreements for Biocides, TABs**).

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Q.2 What are the main scientific, regulatory or practical barriers that could **prevent** promising non-animal approaches from being routinely accepted and used in pesticide and biocide dossiers?



Definition of "adequate level of protection"

Considers acceptable or at least tolerable residual **risk** from a societal risk-benefit perspective. The quantitative bencharks for "acceptable" or "tolerable" are not clearly defined.



Implementation of 'cut-off' criteria

Pesticide and biocide legislation includes hazard-based cut-offs for CMR and ED substances, whose CLP classification relies largely on animal data



Current data requirements for pesticides and biocides

NAMs are used for selected toxicological endpoints, while complex endpoints still require animal studies for pesticide and biocide approval. Additional support on reduction through study design optimization is needed.



Availability of acceptable NAMs, levels of NAM readiness, Guidance

The acceptable level of NAM readiness for regulatory use in pesticide and biocide assessments is not clearly defined; lack of regulatory-relevant inventories of NAMs & updated guidance



Skills and training gaps

Regulators and assessors will increasingly need expertise in mechanistic toxicology, computational modelling, *in vitro* methods, omics, AI and integrated evidence assessment.

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Thank you for your attention

Questions & discussion

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