WORKSHOP ON GENERATING BMD10S FOR WILD MAMMALS UNDER EFSA'S 2023 BIRD AND MAMMALS GD

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The EFSA Guidance Document 2023 introduces BMD10 endpoints to replace NOAELs for bird and mammal risk assessment, with enforcement expected after October 2025. This transition presents significant technical and regulatory challenges requiring coordinated stakeholder action.

REGULATORY HURDLES

Current Implementation Status

- Varying adoption across EU Member States (full, partial, or none)
- Enforcement for active substance and product submissions after October 1, 2025
- Need for zonal harmonization to prevent conflicting endpoints

Key Challenges Identified

- Late confirmation of BMD10 requirements disrupts submission planning
- Limited technical pre-submission engagement with RMS
- Resource-intensive process requiring specialized expertise
- EFSA BMD tool lacks version control and user-friendliness
- Reproducibility and reliability concerns with current tool
- Lack of clarity on which endpoint is relevant for zonal submission

Proposed Solutions

- Early stakeholder engagement with clear timelines
- EU-level agreement on toxicological endpoints
- Reliable regulatory version of BMD tool with version control

BMD "COOKBOOK" APPROACH

Implementation Challenges

- Volume of data in toxicity packages
- Studies designed for NOAEL, not BMD10 derivation
- Many endpoints (especially from mammalian toxicology studies) are not considered to be ecologically relevant

Proposed Step-wise Filtering Process

- Exclude studies unlikely to drive the lowest BMD10
- Select studies with ecotoxicological relevance
- Identify relevant endpoints (focus on apical vs. interim effects)
- Run BMD calculations on filtered dataset

Stakeholder Response

- Need for justification when filtering out studies/effects
- Concerns about subjectivity in defining "relevant" endpoints
- Agreement that apical endpoints align with B&M guidance
- Interest in collaborative development of the approach

BMD STATISTICS

Technical Considerations

- Data formatting and dose-response evaluation requirements
- Setting appropriate parameters for BMD10 calculation
- Assessment criteria for BMD outputs
- Biological expertise needed to validate statistical outputs

Tool Development Needs

- Regulatory version with consistent version control
- Standard approach for cases where BMD cannot be calculated
- Improved user interface and guidance documentation
- Pre-testing with standardized datasets

FUTURE DIRECTIONS

Priority Actions

- Establish working group to refine "cookbook" approach
- Engage regulatory authorities in implementation discussions
- Develop version-controlled BMD tool
- Create training resources for stakeholders

Implementation Strategy

- Address version control issues (drawing lessons from FOCUS development)
- Define process for data quality assessment and filtering
- Establish timeline for harmonized implementation

CONCLUSIONS

The workshop established practical frameworks for implementing these changes while addressing the unique challenges of wild mammal assessment. Continued collaboration between stakeholders will be essential for successful adoption of the EFSA GD 2023 requirements.