European Food Safety Authority

Calibration

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Why calibration?

- Initial stakeholder survey responses:
  - Some suggest existing guidance is over-conservative
  - Some say too many substances fail first tier

- **Revised guidance document should apply an appropriate degree of conservatism**

How to achieve this?

1. **<u>Calibrate</u> the proposed assessment procedure using information on actual impacts in the field**

2. Estimate the proportion of substances that would fail at tier 1 (*in case Comm./MS wish to take this into account*)

3. Adjust the proposed assessment procedure to provide an appropriate degree of conservatism

Proportion failing at tier 1

- Part of Regulatory Impact Assessment

- Representative selection of substances
- Typical first tier datasets
- Apply proposed assessment procedure
- Determine proportion failing first tier

Calibration using field data

- **Can only be done for endpoints and substances for which appropriate field data exist**
- Best example: acute risk to birds
  - Field studies with OPs and carbamates previously collated by Mineau (2000)
  - Additional field studies from industry (if available)
  - Endpoint is visible mortality: implications for population level will be considered
- More details in “Modelling group” presentation, day 3

What will results look like?

FIR/bw, PD	RUD, PT	Calibration factor (CF)	% visible mortality at TER=10	% substances fail at tier 1
Mean*	90th %ile*	?	?	?

- Initial result may not give desired level of conservatism at TER = 10
- Introduce a **CALIBRATION FACTOR** to adjust level of conservatism

* Choice of value not yet decided, e.g. mean, 90%ile, 95%ile

Who decides?

- Set calibration factor to achieve appropriate level of conservatism
- This is a risk management decision
- EFSA can advise on science, e.g. implications for populations

Key messages

- First tier assessment procedure will be revised to take account of best available science
  - Some inputs may decrease, e.g. PT
  - Some inputs may increase, e.g. some RUDs
- A range of calibration factors will be provided together with regulatory impact assessment
- Choice of calibration factor & level of conservatism will be left to the relevant authorities