European
Crop Protection

Exposure estimations before and after the new EFSA-Guidance

ECPA's perspective based on examples

Overview

- **Lack of clear guidance & room for interpretation**
  - Following the guidance document finalisation by EFSA, risk assessors and risk managers should conduct a testing phase of the guidance and its calculator before its implementation to check its validity and clarify possible divergent interpretation

- **Excessive conservatism and lack of transparency**
  - Risk assessments should reflect actual use patterns detailed in the relevant Good Agricultural Practices and default parameters should be consistent between guidance documents.
  - Data underlying the bystander and resident scheme should be made available or an alternative data source used.

- **Validation of the calculator and follow-up testing**
  - Once amended/corrected, the excel calculator should be thoroughly validated by an independent, accredited third party before its use in a regulatory environment.

- **Promoting hazard-based approaches**
  - In the guidance document, exposure via vapour should only be considered for volatile and semi-volatile substances as aligned with other guidance.

- **Implementation period**
  - After adoption of the guidance, implementation should only take place following a full growing season in case field studies need to be conducted.

Opportunities

- **Submissions**
  - Single model - potentially greater harmonisation in tier 1 approaches across MSs
- **Risk assessments and mitigation options**
  - Operator exposure models are more modern, therefore assessments are more relevant
  - Greater range of scenarios available (e.g. weed wipers, granules)
  - Inclusion of new working practices
    - drift reduction technology, buffer strips, re-entry restrictions
  - Acceptance of PPE for workers (although at MS discretion)
  - Acceptance of default DT50, inter-application decline and re-entry restrictions
- **Data sources and transparency**
  - Adoption of US ARTF data for TC values
  - Improving transparency of data
    - Some exceptions, e.g. US data
  - Visibility of key data gaps
    - Transfer coefficients, indoor data, amateur uses

Concerns (1)

- **Risk assessments and mitigation options**
  - Increased compound conservatism, moving away from ‘realistic worst case’
    - e.g. increased breathing rates, reduced body weights, ‘naked’ exposures, no clothing under coveralls, higher percentiles, conservative estimation of percentiles
  - No currently accepted options to mitigate vapour exposure risk assessment
  - Short-term position against acute risk assessment unclear
  - Opens opportunity for risk assessment of new areas in absence of guidance
    - e.g. metabolites, tank mixes

- **Calculator limitations and potential improvements**
  - Poor flexibility to refine outputs as calculator is locked
  - Not all data used in the calculator is fully transparent
  - Limitations of using single spreadsheet
    - Application types outside ground boom and air blast require multiple ‘runs’ of calculator

Concerns (2)

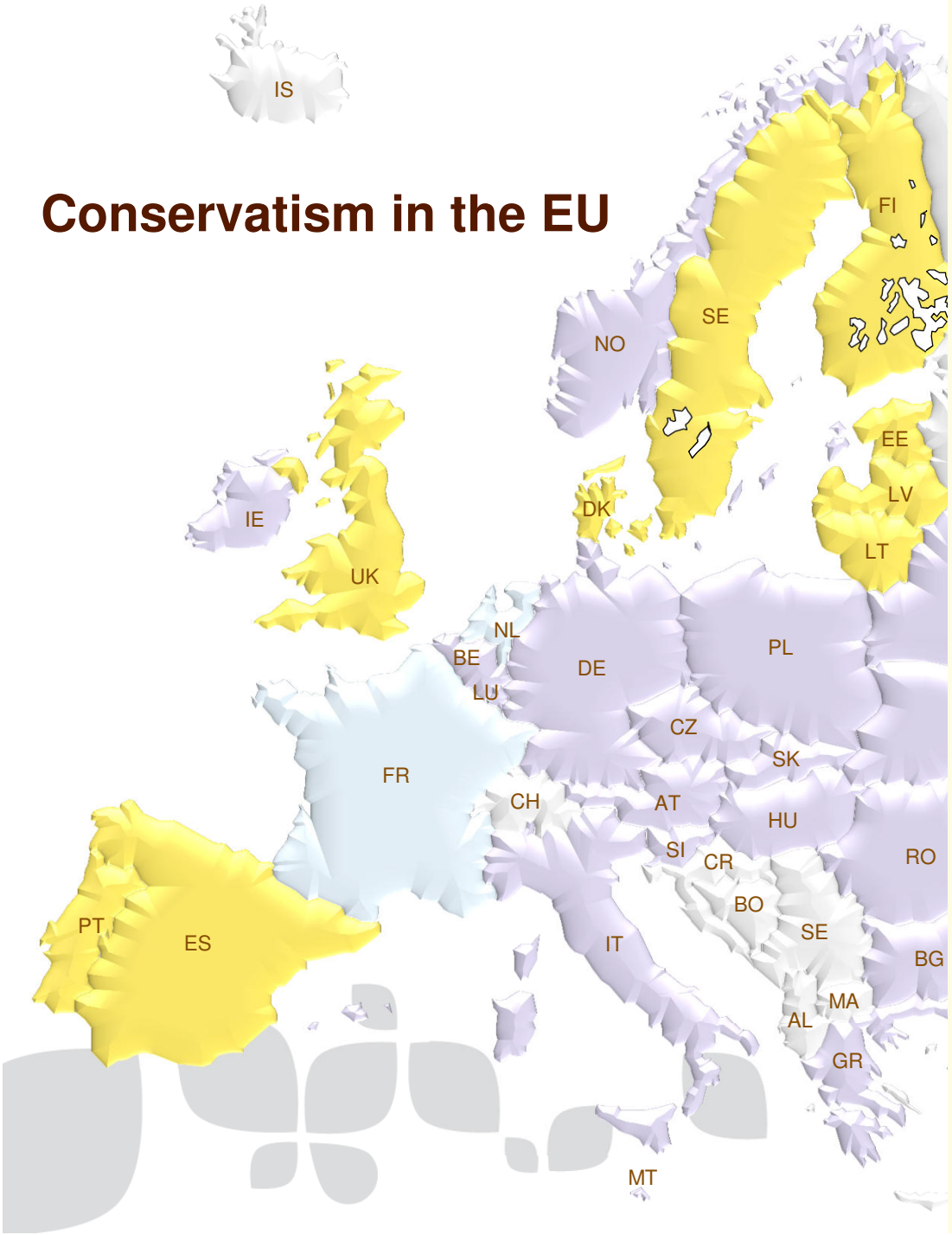
- **Submissions – potential local variance**
  - Guidance proposes new model(s) but does not specify which should be used
    - Decisions of appropriate levels of protection remain with MSs
  - Does not address combined risk assessment
    - Open to local variance at MS level in absence of guidance
  - No specific guidance is given for the use of tiered approaches

- **Impact of acute risk assessments is currently uncertain**
  - specifically states that no acute assessments should be conducted in the absence of a relevant acute endpoint, which should not be set until there is appropriate guidance and only at Annex 1 inclusion / renewal

…BUT…

  - Potential risk of variance in practice of acute risk assessment at MS level

Conservatism in the EU



- Areas of conservatism
  - Northern zone
  - UK
  - Iberian peninsula
- Local models
  - NL
  - France
- Drivers of conservatism
  - Economics
  - Socio-political environment
  - Competition

Examples - Operator

Application method	Formulation type	EFSA without PPE	German BBA no PPE	UK POEM no PPE
Spray boom	Liquid	802	609	6245
	WG	342	583	6425
	WP	7732	886	8212
Knapsack	Liquid	1174	-	13135
(low crop)	WG	1174	-	13485
	WP	1174	-	13510
Air assisted	Liquid	1690	1056	9614
	WG	1553	1046	9668
	WP	3904	1167	10204
Knapsack	Liquid	849	1170	-
(high crop)	WG	849	512	-
	WP	849	627	-

- **Summary**
  - Outputs of new model typically represent an increase in conservatism against German BBA
    - Expect to see greater requirement for mitigation/PPE across majority of EU MS
  - Effect of PPE considered to be more reflective of in-field scenario
- Tank / lance and weedwiper do not have specific comparator in existing models

Examples – bystander/resident

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- **Summary**
  - Bystander/resident assessments will be more conservative
  - Proposed approach with multiple exposure routes puts significant emphasis on contribution of inhalation
  - Vapour exposure for child resident alone could be fatal negative
    - **Any AI with an AOEL of <0.001 mg/kg/day will fail**
    - **Any AI classified as volatile with an AOEL of <0.025 mg**
  - Hazard cut-off, not risk assessment
  - No currently accepted refinements
    - ECPA OBEEG are proposing to generate new field data

    on bystander/resident exposure in 2015

Examples – re-entry worker

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- **Summary**
  - Worker assessments will be more conservative
  - Greatest impact on key crops (e.g. grapes)
    - **>100% increase** in exposure estimate
    - ECPA OBEEG are looking to conduct a new TC study on vine maintenance and harvesting in 2015
  - Will drive greater data generation to enable mitigation arguments
    - DFR / decline / exposure
  - Inclusion of potential exposure TC's encourages MS to consider naked workers, not t-shirt and shorts

Regulatory perspectives

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efsa
European Food Safety Authority

REPORT OF THE JOINT WORKING GROUP ON BYSTANDER RISK ASSESSMENT

1.6 The working group considers it appropriate that estimates of potential exposure through each pathway and route should be aggregated (combined). However, some pathways and routes of exposure may make only a very minor contribution to total potential exposure in comparison with others and can therefore be ignored as they will have no material impact on the risk assessment. Simple addition of individual (conservative) estimates is not appropriate as this will yield an unrealistic exposure estimate that is overly conservative. Rather the group recommends that, if possible, probabilistic modelling is the most appropriate approach to aggregation.

EFS

SCIENTIFIC OPINION

Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

Council Directive 91/414/EEC requires that the residues of plant protection products (PPPs) applied in accordance with good plant protection practice must not have "any harmful effects on human or animal health". Currently, risk assessment for operators, workers, bystanders and residents uses a deterministic method, in which a check is made that reasonable upper estimates for daily systemic exposure are below a relevant toxicological reference value, the Acceptable Operator Exposure level (AOEL). Available data do not indicate any major flaws in the current methods of risk assessment for operators, workers, bystanders and residents.

PPR panel has aimed for a level of precaution similar or slightly higher than currently applied

Summary

- Better links with stewardship would help to inform exposure scenarios
- Lack of clear guidance, therefore leaving **room for interpretation** at MS level and loss of harmonisation
- **Creeping conservatism** and incomplete data transparency
- Promoting hazard-based approaches (volatiles)
- **External validation** of the calculator and follow-up testing should be mandated
- Implementation period should include a **full growing season**
- Process for submitting new data and issuance of updated guidance should be made available