Responsibility for preparing risk assessment GDs “transferred” from DG SANCO to EFSA

Priorities identified by PSC:
- Birds & mammals
- Soil persistence
- Operator-worker-bystander-resident exposure
- Terrestrial and aquatic ecotoxicology

PPR Panel can also self task
- e.g. Emissions from protected crops
Status on EFSA preparation of new GDs:

- 1 finalised and published
  - Birds & mammals risk assessment

- 1 close to finalisation
  - Operator, worker, bystander & residential exposure assessment

- 8 still in preparation
ECPA experience with current process [1]

- Increased scientific complexity in risk assessments
- Increased conservatism, with no indication that the current risk assessment is not protective
- Lack of pragmatism for regulatory implementation
  - Encourage MS specific approaches
- Result:
  - Uncertain and unpredictable for applicants
  - More inconsistency between MS evaluations
**ECPA experience with current process [2]**

Guidance usually developed by those who use them…

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<tr>
<th>Sector</th>
<th>GD developed by:</th>
<th>GDs used by:</th>
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<td>GMOs</td>
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ECPA experience with current process [3]

- Lack of validation of new approach before implementation
  - e.g. reproductive risk assessment birds & mammals

- 2 stage process (risk assessment and risk management) does not help produce a coherent GD

- Lack of involvement of those who will use the GD

- No impact assessment of new requirements

- Setting new data requirements…?
Guidance documents should be to harmonise the risk assessment and risk management processes

Drafting of GD should be by those who use them

Role of PPR Panel should be to scientifically peer review
  - Not write them (same process as new data requirements)
**A 4 step process:**

1. **Initiation**
   - Justification and project plan (*inc. terms of reference*)
   - Protection goals
   - *Panel opinion on “state of the art” (if necessary)*

2. **Drafting**
   - By experts who use the guidance (*inc. industry & academia*)
   - Include phase for consultation of stakeholders

3. **Scientific peer review**
   - PPR Panel provides independent opinion

4. **Implementation**
   - Final decision by Standing Committee
   - Including process and entry-into-force dates
ECPA proposal [3]

1. INITIATION
   - SCFCAH & PSC
   - Regulators, industry & academia

2. DRAFTING
   - SCFCAH
   - Decision: SCFCAH

3. SCIENTIFIC PEER REVIEW
   - Application: Industry, MSs & PRAPeR
   - Industry, MSs
   - EFSA & MSs

4. IMPLEMENTATION
   - Industry, MSs & PRAPeR
   - Application: Industry, MSs & PRAPeR
   - Decision: SCFCAH
Guidance document for guidance documents

- Draft prepared in 2010
- ECPA supports the concept
  - A transparent process for development of GDs
- Allows GDs to be developed by most appropriate experts
- ECPA looks forward to finalisation
  - Progress to be made in 2012…?
Conclusions

- Guidance documents should be developed by those who use them
  - PPPs process is unlike other EFSA sectors
    - *Panel will not be using the GD*
  - PPR Panel has key role
    - To provide a scientific peer review of draft guidance
    - Ensuring consideration of latest science
- “Guidance on the guidance” to set out a clear process
  - *Essential to support the zonal system*
THANK YOU