



AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

French Food Safety Agency Plants and Environment Department

T. Mercier - Mutual recognition an opportunity
for crop protection in the southern zone – 29-30/04/2010



Mutual recognition - zonal evaluation :

Authorization by member states

- Regulation (EC) n° 1107/2009
 - **Application for authorization or amendment of an authorization**

Articles 33 → 39

- **Mutual recognition of authorizations**

Articles 40, 41, 42



Experiences so far in zonal evaluation

▪ Existing experiences so far in zonal evaluation

- SMS projects : several ongoing dossiers
- New projects with industry
 - ✓ Pre-submission meetings with Afssa
- Guidance documents and Draft GDs on going :
 - ✓ 2 European workshops
 - ✓ Common procedures
- Experiences : Afssa, registration reports



Zonal evaluation

- Applicability : different dossiers
 - Registration of new PPP
 - ✓ No high complexity
 - Extension of uses major and/or minor
 - ✓ No experience, (No high complexity expected)
 - Re-registration of products
 - ✓ Complex to highly complex



Zonal evaluation : key elements

- Standardization of the evaluation
 - Common format : (draft) registration report
 - Common evaluation : hazard, risk and biological efficacy
 - Justifying specific MS evaluations (e.g. : ground water)
 - ✓ Specific data requirements :
 - Justified & data requirements available
 - ✓ Evaluation by the MS in addendum to registration report

- G.A.P. : different in MSs
 - rationalise G.A.P. as far as possible



Zonal evaluation - Areas for improvement

▪ **Action for Industry :**

- submission of draft registration reports
- submission of national addendum
- rationalisation of G.A.P.

▪ **Action for MSs :**

- further harmonisation in risk and biological efficacy assessments
- make available a well-documented registration report within the timelines
- major assessment not repeated, and recognised by other MSs



Conclusion : high priorities

- SMS Steering Group → Zonal steering committee
 - Coordination of the evaluation
 - Worksharing
 - Increasing zonal evaluation projects
 - Links with central zone projects
 - Minor uses dedicated procedures
- Simplification / harmonisation of the biological efficacy section between SMS – extrapolation rules

