Comparative Assessment acc. to Art. 50 Reg. (EC) Nr. 1107/2009 - countries‘ experiences – -Germany-
Parties involved

... in the CA in Germany

- BVL (decision making and authorisation)
- JKI (efficacy)
- BfR (residue + toxicology)
- UBA (ecotox + fate)
- External expertise of the extension services of the German federal states
- Statements of the applicant
CA-Procedure in Germany

Principles

- **CA is done during the authorisation process**
- **To keep the workload low the decision of the necessity of the PPP takes place at the very beginning of the authorisation process with the help of some easy criteria**
- **No optional CA for PPP without CfS acc. to Art. 50 (2) of the Reg. 1107/2009**
- **Step-wise approach considering EPPO Standard PP 1/271 (2) Guidance on CA, but in a different order**
Step-wise approach

BVL  Identifying products where substitution is not appropriate by criteria on active-, ppp- (and use) level

JKI  Finding alternative control measures by following the EPPO Standard PP 1/271 on use level (*alternative list*)

UBA, BfR  Conducting comparative risk assessment, comparing risk between candidate and substitutes

BVL  Management, decision
Criteria for an early stop of the CA

First step of CA at BVL (EPPO points acc. to standard 1/271(2))

- Art. 50 (3): e. g. is the CfS new in the applied use or is it used in a innovative new formulation?
- Applications acc. to Art. 51 of the Reg. (EC) Nr. 1107/2009 (point 12)
- PPP only for non-professional users in homegarden (more strict criteria in regular assessment) where the exposure to operators and bystanders is very low (e. g. sticks)
- PPP that are necessary to avoid authorisations acc. to Art. 53 Reg. (EC) Nr. 1107/2009 (points 11, 15)
- PPP of importance for minor uses (at least 50 % or at least 5 minor uses of public interest) (point 13)
Second step: preparing a list of alternatives by JKI acc. to the following criteria and the EPPO standard:

• Only authorised ppp
• A ppp with another (also a CfS) or the same active can be a substitute
• Minor uses will not be substituted
• Crop/object
• Target
• Area of use, timing of application, technique, … (all information in the GAP table)
• Check for non-chemical control measures (Defra-Project on Non-chemical control methods)
• + expert judgement (including external expertise)

Substitutes from the efficacy point of view underly the next step of the CA (comparative risk assessment)
For **36 applications** a CA were conducted; in

- **2 cases**: CA were done till the end of the procedure (alternatives available), however, the ppp were authorised because alternatives are not significant safer,

- **7 cases**: CA were stopped at an very early stage (BVL),

- **4 cases**: derogation acc. to Art. 50(3) was granted because the CfS is foreseen to be used in new uses -> 5 years authorisation,

- **23 cases**: mutual recognition of candidates, **18** ppp were refused, **5** ppp authorised because of importance (emergency use(s)) for the German agriculture.

→ **Result**: no ppp was refused because of CA when mutual recognition applications were not considered!
Main reasons of stopping CA

- Derogations acc. to Art. 50 (3) mainly because of new use(s) with the candidate product (CfS is new in the use applied for)
- 60 % of CA were stopped at an early stage in the BVL mainly because of minor uses involved (without mutual recognition)
- 78 % of mutual recognition applications with a CfS were not accepted because the ppp is not necessary (emergency use(s)) for the German agriculture
Open questions

- Impact on IPM measures
- Impact of economy in practice
- Exact target spectrum of the candidate product
- Comparing a candidate as single product with substitutes having 2 or more actives (flexible use of actives, resistance risk, …)
- Wider consequences for maintaining effective crop protection
- Considering financial impact for companies in the final decision (approving selected single uses or all uses applied for?)

normally only few information available
Thank you for your attention!

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