Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

JKI
Julius Kühn-Institut
Bundesforschungsinstitut für Kulturpflanzen

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

CA-Procedure in Germany

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*)

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

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BVL — Management, decision

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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?
- PPP legitimate for organic farming (active substances in Ann. II Reg. (EC) 834/2007)
- 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)

List of alternatives

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)

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Experiences

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

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Thank you for your attention!

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