

Low risk can do with less efficacy

We need clear guidance on requirements and what can be included in the efficacy evaluations

The data package should show any benefit of the product

Sufficiently effective

- This means any benefit over doing nothing demonstrated for the low risk product

Differentiated labels for low risk

- Variable efficacy claims (can be scales of efficacy and/or descriptive usage statements)
- Main objective is to manage expectations for the growers
- Some member states already use this (DE, DK, LI, AU) it should be adopted across the EU
- Low risk label claims is controversial issue, requires further discussion.

Value Assessment as applied by some MS, need to be harmonised and applied at zonal level

There was consensus about:

- Formulate new EPPO guidance for low risk, based on existing EPPO guidelines
- Detailing which other types of information can be used to support the claim (product performance, benefits, scientifically sound efficacy trials, lab trials, historic use, growers' needs)
- **Keep it simple** and make use of existing flexibility

120 day zonal approval, how can efficacy assessment contribute ?

- Improved dossiers for efficacy
- We need special expertise to evaluate low risk products
- Countries should install green TEAMS if they have the capacity
- Zonal co-operations/worksharing ??
- Early PSM helps to have good quality dossiers
- Limit efficacy requirements (any benefit)

We can have one EU-zone for low risk

The way forward

- COM and EPPO receive the outcomes of this workshop
- Working group needs to start
- Who will participate ??
- We can use the flexibility from the existing EPPO guidances NOW
- Promote exchange on efficacy between MS on Low Risk