Group A: Low risk (bio)chemicals/botanicals /minerals

Main outcomes

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Number of trials: can be reduced

Need of harmonization

Extrapolation possibilities

Use of data from other zones

Need of **pre-pre-meeting** submission

1. Acceptable effectiveness levels and types of label claims

The dossier has to tell the story of the product

Justify the need for the market

Significant effect compared to untreated

Qualitative and Quantitative approach

Communication between farmers and applicant

It is what the farmer accepts

Control vs Suppression

2. Dose justification

No risk for environment and human, why do we need to prove minimum effective dose?

Could be a limited data set (Minimum requirements of EPPO guideline)

Provide information on MoA and lab trials

Make a reasonable combination of minimum effective dose and efficacy trials

3. Data requirement: what is the minimal amount of information to do a meaningful efficacy evaluation?

Minimum requirements in EPPO guidelines

GEP field trials are required

Data from non-EU countries: basically YES, depending on circumstances

Non-GEP trials (i.e. scientific publications): they are welcome but must be scientifically reliable

4. Extrapolation possibilities/ justification of extrapolation.

For low risk products extrapolation should be possible

To have more flexibility

5. Quality of dossiers/ role of applicant.

pre-pre-submission meeting could help

Write good summary

Be critical (be realistic) on your own data

No extra guidance is needed

6. Usefulness of Value assessment

Value assessment is usefull

7. other topics and issues that you would like to discuss

Workshop on LRs

Realistic examples (data requirements on LRs)

Rapid follow-up

Make a realistic time line on proposals generated during this workshop:

Make it happen & Yes you/we can!