Health and Safety Executive

Comparative Assessment of Pesticide Products under Regulation 1107/2009

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Comparative assessment

- A new aspect of assessment introduced by Regulation 1107/2009
- Uses of **products** containing a Candidate for Substitution to be considered in a comparative assessment including non-chemical options
- A list of ‘Candidates for Substitution’ published by the European Commission came into force on 1 August 2015

Article 50 of 1107 – Summary (1)

CA performed by Member State:

- At application/evaluation stage
- Actives ‘approved’ as a candidate for substitution

Article 50 of 1107 – Summary (2)

- Products should not be authorised or should be restricted on specified crops where:

- significantly safer product exists
- non-chemical control exists
- does not present significant economic or practical disadvantages
- does not impact on minimising resistance.

Article 50 of 1107 – Summary (3)

- Allows for MSs to gain experience of using CA system (less than 5 years)
- Applies at latest from renewal or amendment of product authorisation
- MSs to decide to maintain, amend, or withdraw product authorisations

- must take effect 3 years after MS decision or at the end of the approval for the active substance, whichever is earlier.

Apparently simple principle

- Where there is a choice of methods of controlling a pest on a crop:

  Use the safer alternative

- Embodied in the regulatory decision rather than at the point of use

Substitution – What does this mean in practice?

- Applied if:
  - Alternatives (chemical or non-chemical) are significantly safer for human health or the environment
  - No significant economic or practical disadvantage to the user
  - Resistance risk in target organism is minimised
  - Where consequences for minor use are considered

EU guidance (1)

- An outline approach allowing flexibility for MSs
- Incorporates EPPO guidance
- Stepwise approach with options to start or finish the CA at any step

- Uses the criteria identifying the Candidate for Substitution as a possible focus for early stages of assessment

EU guidance (2)

- Clarifies when comparative assessment is and is not required
  - When considering applications for amendments only that **use** is subject to comparative assessment. All uses only considered at renewal.
  - Suggests some options when the derogation may be relevant to acquire practical experience.
- Confirms consideration of impact on minor uses rather than specific comparative assessment.

UK approach for comparative assessment

- Keep it as simple as possible
- Involve applicants
- Use readily available information to check potential for substitution
- Reach a conclusion at the earliest possible step
- UK guidance supplements EU guidance
- UK not taking optional approach, essential only

Development of UK approach

- CRD working group tasked to ‘sort out how to do it’
- Developed ideas and gained stakeholder comments
- Resulting UK guidance published following EU guidance being noted
- Updated to take account of the list of Candidates for Substitution which came into force on 1 August

CRD comparative assessment guidance

- Direct comparison of risks is difficult as it is unlikely that any two products will have been assessed in exactly the same way
- Easier to consider the appropriateness of substitution assuming there may be a significantly safer alternative.

e.g. are there sufficient alternative modes of action to manage resistance risk?

CRD expectation

- Applicants present their own case for the relevant uses of their product
- CRD guidance
  - stepwise
  - order most likely to reach early conclusions
  - possible to use in different order if applicant wishes

CRD working definitions (1)

- ‘Significantly different’ is understood as a very obvious difference
- The information on risk mitigation measures may be useful as a first step in considering this, e.g. no PPE required compared to full PPE including respirator
- Slight differences would not be sufficient to conclude a significantly safer option exists

CRD working definitions (2)

- Similar effect
  - Efficacy data determine the level of claim made on UK product labels
- Minor use
  - CRD website already provides a definition of minor use in the UK
- Significant economic or practical disadvantages
  - Suggest this should be at the level of **obvious**

Sources of information: UK Public domain data

- List of Candidate Actives (will be updated)
- Authorisation databases (including for minor uses)
- Agronomy databases/publications, including usage data
- Research (UK research on non-chemical alternatives)
- Resistance advisory groups
- Standardised efficacy requirements for specific claims
- Product labels

Sources of information: Company data

- Market sector intelligence to inform on eg impact if a major use were to be substituted
- Likely to need information from across the EU in some cases
- Applicant opportunity to draw any other information to regulators attention

CRD expectation on implementation

- Comparative assessment and substitution will be a matter for expert judgement rather than a purely scientific methodology
- Decisions are likely to vary between MSs
- Authorisation holders will have an opportunity to submit comments or further information if it is concluded the authorisation should be amended or withdrawn
- Other Central Zone MSs intend to follow a similar approach

Conclusions

- We will have a lot to learn and will need to share the lessons between us
- Expected that guidance will be updated in the light of experience
- Good luck to all

Any questions?

Further information:

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