

UK Implementation of Comparative risk assessment

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The principles and approach

- Based on the principle of using the 'safest alternative' when controlling a 'pest'
- Applied if there are significantly safer (for human health or environment) alternatives (chemical or non chemical)
- No significant economic or practical disadvantage to the user
- Resistance risk in the target organism is minimised
- Consequences for minor use are considered





- EU draft guidance document SANCO/11507/2013 REV 12 (10 October 2014)
- Decisions on this aspect are made at Member State level
- Clarifies when a comparative assessment is and is not needed
 - For applications for amendments only that use is subject to comparative assessment
 - ALL uses on major crops are considered at renewal
 - Provides some options when the derogation may be relevant to acquire practical experience

CRD approach



- Detailed guidance is available at: <u>http://www.hse.gov.uk/pesticides/resources/U/UK-Comp-Assess-Guidancev2.pdf</u>
- Clear stepwise approach
- Definitions:
- Significant difference; very obvious difference
- Information on risk mitigation measures may be useful as a first step e.g. types of PPE
- Slight differences are insufficient to conclude a significantly safer option exists
- Similar effect: efficacy data determine the UK claim level
- Minor use: a working definition of what is considered to be a minor use is provided within the CRD guidance
- Significant economic or practical disadvantage; this should be obvious





- We use the principles in EPPO PP1/271(1)
- We use a stepwise approach but the steps are not in the same order as in the EPPO standard
- Our approach enables us to effectively filter those which are acceptable and those which need more detailed examination and work
- This is important as a lot of products need to be examined
- We are not currently doing the 'optional' assessments for products not containing candidate for substitution as detailed under Article 50(2)

Sources of information we have used: Public domain data



- List of Candidates for Substitution
- Authorisation databases (including for minor uses)
- Agronomy databases/publications; usage data
- Research (UK research on non-chemical alternatives)
- Resistance advisory groups
- Standardised efficacy requirements for specific claims
- Product labels



CRD experience

- We believe the UK guidance has been working well
- The guidance has enabled effective filtering, so we can focus the more detailed assessment on a 'lower' number of products which require more detailed scrutiny
- The vast majority so far they have only gone up to step 8 of the UK guidance
- We have identified some products where is was concluded that the product could be substituted and UK authorisation was refused

Candidates for substitution: useful links that the UK uses



- EU list of actives which are candidates for substitution:
 - https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides ppp app-proc cfs draft-list.pdf
- UK comparative assessment guidance:
 - http://www.hse.gov.uk/pesticides/resources/U/UK-Comp-Assess-Guidancev2.pdf
- UK question and answer briefing on CA:
 - http://www.hse.gov.uk/pesticides/topics/pesticideapprovals/pesticides-registration/applicantguide/candidates-for-subsitution.htm



What have been the challenges?

- A large number of products need to be considered
- The EU list of candidates for substitution needs to be kept up to date
- The detailed efficacy assessment can be time consuming and we need to use multiple sources of information
- It is time consuming to validate the product lists of available modes of action for a specific pest
- Also these are a function of the date of the CRA assessment



What is on our UK 'wish list'?

- The EU list to be kept completely up to date
- To find some more streamline ways of doing the detailed efficacy assessment on the available products, MOA, levels of control etc. to see if we can justify substitution of the product
- To understand more about what other Member States do to see if we pick up some tips to help us further improve our approach

Now for something different: cutest dog?





