Health and Safety Executive

Efficacy requirements for the approval of new pesticides active substances

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What is efficacy? (I)

- Balance between positive effects of pesticide treatment e.g. pest/weed/disease control **and** negative effects e.g. direct crop damage.
- Net result = is the overall improvement in yield or quality of the crop, which must be sufficient to justify the use of the pesticide.

What is efficacy? (II)

- No pesticide is entirely free of risk and should only be used where there is a potential benefit at a dose which is the ‘minimum effective’.
- The assessment of efficacy is undertaken to establish if there is a real benefit from the application of a pesticide, thus avoiding any unnecessary exposure to the workers or to consumers.

Efficacy of new active substances under Council Directive 91/414/EEC

- There was no detailed consideration of the efficacy of new active substances under Council Directive 91/414/EEC.
- Assessments were conducted almost entirely at the Member State (MS) level within the Annex III ‘product’ package.
- Only at the product stage was dose justification and a realistic GAP considered - but was being conducted towards the end of an evaluation process.
  - Potential for 'worst case GAP' not actually being realistic of typical usage in most situations.
  - Risk of the GAP considered for Annex I listing not being worst case.

Why is a consideration of active substance efficacy important?

- Under 91/414 the principle of “one safe use” was established.
- For inclusion in Annex I of Directive 91/414/EEC it must be demonstrated that active substances have at least “one safe use.
- No assessment of whether the GAP was realistic or the ‘worst case’. So in some cases products might fail a risk assessment based on an unrealistic GAP, not typical of actual usage in field, or where GAP was not ‘worst case’ a new risk assessment might be needed at product level.
- Important therefore that risk assessments are based on realistic assumptions that particularly encompass the ‘worst case’ GAP (good agricultural practice) that may be subsequently encountered. Otherwise these other uses must be re-assessed at a later date by individual MS.

Efficacy of new active substances under Regulation (EC) 1107/2009 (I)

- Consideration of efficacy for active substance approval is therefore a new requirement under Regulation (EC) 1107/2009.
- Chapter II, Article 4(3) states that *'a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: a) it shall be sufficiently effective and c) it shall not have any unacceptable effects on plants or plant products*.'
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Efficacy of new active substances under Regulation (EC) 1107/2009 (II)

- Regulation (EC) No 1107/2009 Annex II point 3.2 also states that '*an active substance alone or associated with a safener or synergist shall only be approved where it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).'*
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How does this translate into data requirements? (I)

- Draft guidance document being considered by COM and MS that explores some of the principles and seeks to clarify new active substance data requirements. For example;
- What is ‘Sufficiently effective’?
  - Commission Regulation (EU) 546/2011;
  - EPPO guideline PP1/214 ‘Principles of acceptable efficacy’.
- What does no ‘unacceptable effects on plants or plant products’ mean?
  - Difficult to define in crop protection terms (see EPPO PP1/214 ‘Principles of acceptable efficacy’)
  - EPPO PP1/135 ‘Phytotoxicity assessment’ relevant

How does this translate into data requirements? (II)

- The principal objective of the efficacy evaluation of an active substance is to confirm that the doses are realistic for the GAP submitted for approval and representative for all subsequent authorisations.
- AND also to avoid a duplication of evaluation work for at least some of the individual GAP, which may otherwise result if efficacy is comprehensively considered for all uses both at approval of the active substance **and** at product authorisation.

How does this translate into data requirements? (III)

- General requirements;
  - At least one representative formulation.
  - At least one representative use on a widely grown crop in each zone, or a justification for presenting a use in only one zone.
  - The GAP with the maximum field rate for each principal crop type/application method (e.g. arable, top fruit, vine, seed treatment) should be identified.
  - Applicants should consider carefully when providing such evidence which uses will be representative of the ‘worst case’ GAP in different EU zones.

How does this translate into data requirements? (IV)

- A summary of effectiveness and crop safety for a representative pest/crop/situation of each should be presented.
- Some flexibility in how this is presented and could include;
  - Preliminary testing
  - Realistic field trials from at least one year in at least one crop, and on at least one of the target species using the representative formulation.

Future questions and challenges

- Active substances that have lower, delayed and/or more variable effects – EPPO guideline PP1/214 ‘Principles of acceptable efficacy’.
- Active substances for use *onl*y in co-formulation.
- Proposed GAP fails risk assessment and requires amendment – process for re-consideration of efficacy?
- Doses not representative for all subsequent authorisations.
- Draft guidance considers some of these issues but over time likely to be more so watch this space!

Thank you for your attention

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