Acceptable levels of control and toxic reference mortality from semi-field and field tests - working group 2011 report summary

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Abstract

The EPPO guideline 170 (2010) recommends that semi-field or field tests should be repeated where control mortality is excessively high or where effects in the toxic standard treatment (if included) are low. Therefore, the working group was in charge of giving a better definition of:

- what is an excessively high control mortality, and:
- what are low effects in the toxic standard, focusing on mortality?

Preliminary outputs were presented:

- Control mortality needs to be considered in the context that natural (background) mortality in colonies can be highly variable.
- Also, if mortality in individual colonies is excessive, e.g. due to diseases or other non-treatment related factors, these may be excluded from the analysis rather than compromising a particular test group, where this can be justified.
- While there should be a statistically significant increase in effects with the toxic standard compared with the untreated control (as appropriate to the mode of action of the compound), the actual level will depend on the trial conditions (e.g. the attractiveness of the test crop) and so it is not always appropriate to set a required level.

The actual remit of the working group was questioned ('Formulate sharp cut-off criteria for mortality, or more broadly define validity criteria'). It was wondered whether there is a need for a formal quantitative approach (statistician) or whether qualitative criteria could suffice.

Several issues were identified (data collection: how to handle confidentiality issues, membership, geographical bias, overlap with field effects group).

The main outputs at Wageningen symposium are:

- Sharp cut-off criteria are neither desirable nor feasible. Mortality should be regarded in a broader context of factors affecting study validity.
- At the same time, clear guidance is needed to help regulators to objectively distinguish between biologically significant and deviant effects.

Given the overlap of issues addressed, the working group asks to liaise with the other field effects working group on 'acceptability of effects in field studies'.