## Working Group – Acceptability of effects in the field

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### Aims of the working group

The aim of this working group is to continue the work of field and semi-field group that had reported at the last Bee Protection Group meeting in Bucharest (2008). This had resulted in the latest revision of the EPPO 170 guidelines (2010)[1], with particular attention being paid to the higher tier (cage and field) studies. One of the primary considerations in the revision exercise had been to maintain a balance between providing sufficient information to enable suitable studies to be conducted but maintaining flexibility (not too prescriptive) to ensure that the specific requirements of all studies could be addressed.

During the revision of the EPPO 170 guidelines, a number of specific issues were identified that went beyond the scope of the current exercise but were considered to need further work. These could generally be characterised as the 'acceptability of effects in the field'.

### Specific issues identified

In the latest version of the EPPO 170 guidelines (2010)[1] it states that "Tests (cage and field) should be repeated where control mortality is excessively high or where effects in the toxic standard treatment are low". It was considered that more precise definitions of excessively high control or low toxic standard mortality would be appropriate. This issue formed the basis of another working group, led by Christine Vergnet ('Acceptable level of control and toxic reference mortality from in-cage and field tests'). Accordingly, to avoid duplication of effort, this aspect of cage and field testing was not addressed by the 'Acceptability of effects in the field' working group.

Another issue identified was the need for further guidance to be provided for the assessment of any effects seen in test colonies during cage or field tests i.e. as a result of the test item treatment.

The current requirements for cage and field testing identify the need to assess all factors e.g. mortality, behavior (including foraging activity) and colony assessments. In terms of the interpretation of the data collected, consideration is given to a statistical evaluation, particularly for cage studies (although the limitation on replication in field studies is recognised) but no specific guidance is provided. The main emphasis is given to an assessment of the biological significance of any effects seen, but again little specific guidance is given and reference is made to the need for 'expert judgement'.

These aspects therefore formed the basis of the work of this group.

### Current work

A key aspect identified for the approach of the working group is the need to avoid duplication of effort. Accordingly, it was considered important to identify existing guidance available as well as other ongoing initiatives that might be useful for its deliberations. A number of useful sources have been identified.

An assessment of field trial methodology has been undertaken by a working group in France to consider the use of field testing for national requirements. A comparison of the recommendations for the French field methodology with that provided by the EPPO 170 guideline[1] was presented at the meeting (see Hervé Giffard, this volume[2]). One specific aspect of the assessment of field effects relates to colony development and this is being addressed by the 'Bee brood' working group (see Becker *et al.*, this volume[3]). In addition, a number of papers were presented at the meeting that also provided useful information with regards to bee brood for the working group: 'Non-treatment related

variability of termination rates in honey bee brood studies and possibilities for further improvements of existing guidance (see Jens Pistorius *et al.*, this volume[4]); 'Improvement in the calculation of indices in brood tests' (see Hervé Giffard, this volume[5]).

In addition, a SETAC Pellston workshop, 'Pesticide risk assessment for pollinators' has been held in the US (15-21 January 2011)[6]. This identified key outputs from cage and field studies (largely based on the EPPO 170 guidelines) and then considered the interpretation of effects linked to identified protection goals e.g. pollination, honey production, etc. As a result of this a need was identified for additional statistical input into the existing study designs and appropriate statistical analyses of the results obtained. Accordingly, a steering committee has been set up to address advice and guidance on appropriate statistical approaches to analyses of study data. The field effects working group considered it appropriate to wait and see the output from this exercise and evaluate its use in developing the EPPO 170 guidance (proceedings from the SETAC Pellston workshop are due in spring 2012).

**Additional work identified**

In preliminary discussions, a number of issues had been identified for further consideration. An important first question is how much further guidance is needed or to put it another way, how much of the evaluation of cage and field testing should be left to 'expert judgement'? One concern about this is that appropriate expert judgement may not always be available, as the guidance has to be capable of being used throughout the EU for regulatory purposes. This involves consideration of the potential audience for the guidance, which may comprise a range of backgrounds e.g. experienced assessors, regulators (non-specialist), beekeepers, extension services etc.

In terms of specific issues, it was considered important to provide a clear definition of the protection goals that are being addressed when assessing the significance of any effects seen in field testing. These could comprise a number of factors including biodiversity, honey production, pollination as well as other aspects. It was also important to define the relative role of statistical and biological significance in any overall assessment i.e. when would an effect be considered biologically important and when would statistical significance be considered necessary. It might be possible to identify stable background levels that provide a reference point for treatment effects under trial conditions (taking into account between-colony variability). This can provide the basis for an assessment of effects on the basis of percentage increases/decreases or ratios (comparing pre- and post-treatment levels). However, it was also recognised that it is necessary to define limitations for these approaches as if background levels are low the outcome can be very misleading (e.g. high relative changes but low in absolute terms). This could also involve considering a difference between cage and field studies. Should cage studies just be a trigger for field studies (above a certain threshold level of effects) or can they also be used for direct assessment of the significance of effects, taking into account the increased severity of exposure and differences in assessment?

**Approaches to assessment**

Preliminary consideration has been given as to whether it might be possible to identify specific thresholds of concern for different assessment parameters. For example, mortality: is there a level that is considered to have a significant impact on colony viability e.g. >50 bees/day (above background levels) for >2 days? Foraging activity: can we consider an acceptable level of effects on colony viability and pollination efficiency e.g. >50% reduction for >3 days. It is important to realise that these kinds of proposals are designed to provide a starting point for discussion to assess the feasibility of this approach. In reality the situation is more complicated and we also have to consider other factors e.g. crop, seasonal effects, size of hives and so on.

In the case of other sub-lethal effects (e.g. behavioural), we need to ask how do we determine the impact on colony viability. Firstly, we need to identify which sub-lethal effects might be important in this context e.g. disorientation, repellency and so on. However, this list can become extensive and we need to consider what *can* be assessed under field conditions (i.e. what is possible from a practical point of view). We then need to consider what *should* be assessed i.e. for the purposes of regulatory

risk assessment (significance in relation to protection goals). It is important that we provide information that is of value in relation to the assessment and not simply because it might be of interest or is being addressed by what we are already doing.

**Additional considerations**

In the first instance, consideration of colony development is to be addressed by the 'Bee brood' working group, as previously explained. A number of additional questions were also identified in preliminary discussions. It was felt that the over-wintering survival of colonies need only be included in specific circumstances e.g. late season application (according to GAP) or where there is the potential for residue carry-over. With regards to the assessment of interactive effects e.g. effects of treatment together with disease, climate etc, it was considered that this was beyond the scope of the regulatory risk assessment scheme but would be useful when considering other factors in post-registration evaluations. Finally, it was felt that the incorporation of risk management practices into the test guidance would be useful (to indicate what might be possible) although it was recognised that this would ultimately be addressed at a national level.

**Future work**

At the Bee Protection Group meeting in Wageningen, it was decided that the two working groups 'Acceptable level of control and toxic reference mortality from in-cage and field tests' and 'Acceptability of effects in the field' should be combined into a single 'Semi-field and field testing' working group, under the joint co-ordination of Christine Vergnet and Gavin Lewis. A call was made for any additional participants and following the meeting a number of people expressed an interest so that the working group now comprises 21 members from academia, regulatory authorities and industry (in order to maintain the viability of the group membership is now closed). An initial meeting of the working group has been held in January 2012 (at ANSES, France). In order to facilitate the work of the group, three subgroups have been identified: Acceptability criteria for the control and the toxic reference results (Chair: Jens Pistorius, JKI, Germany); Study design factors (Chair: Franck Marolleau, ANSES, France); Treatment effects (Chair: Gavin Lewis, JSC, UK). It was agreed to hold annual meetings (2013 at the Norwegian Food Safety Authority and 2014 at JSC, UK) until the next full meeting of the Bee Protection Group in Ghent, 2014. The sub-groups will carry out their specific work in the intervening periods with full discussion of all issues at the annual meetings of the working group.

**References**

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