

Data collection for the estimation of ecological data and residues on food items to be used in pesticide risk assessment for birds and mammals

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Background

To enable consistent and harmonised implementation of the requirements of Regulation (EC) No. 1107/2009 and its related regulations concerning the placing of plant protection products (PPPs) on the market, Guidance Documents (GD) are developed by the EU Commission and the European Food Safety Authority (EFSA).

The current EFSA Guidance Document (GD) for the risk assessment for birds and mammals (2009) follows a tiered approach. For the first tier assessment a range of scenarios have been developed. The scenarios are combinations of ecological characteristics of 'generic focal species' and other factors relevant to exposure, e.g. the type and structure of crop, and the type of formulation of the pesticide product (spray, granular, etc.).

In addition, the GD provides a range of options for higher tier risk assessment, in cases where a low risk cannot be identified with the first tier risk assessment. The refinement steps may include:

- the identification of specific focal species (FS, Figure 1 & Figure 2),
- the use of measured residues and residue decline in FS food items,
- field information on the composition of diet obtained from treated area (PD factor), and
- field information on the proportion of an animal's daily diet obtained in a real habitat treated with pesticide (PT factor).

Objective

Since the GD came into force, a considerable amount of new data has been produced, which can potentially add valuable information to the birds and mammals risk assessment. In consideration of this, in 2016 we began to compile ecological (FS, PT, PD) and residues data in order to enable a proper and consistent use of these data in the future.

Once the project is finalised, the new databases may be used by EU regulatory authorities and may also be useful for the revision of the EFSA GD (2009) on risk assessment for birds and mammals.



Figure 1. The insectivorous Yellow wagtail (*Motacilla flava*), a potential avian focal species.



Figure 2. The herbivorous Common vole (*Microtus arvalis*), a potential mammalian focal species.

Approach

The public literature was screened for relevant publications by searching various bibliographies with relevant sets of key words. Other data sources (Table 1) include EFSA outputs for substances approval purposes, EU Member State reports for product authorisation purposes and original study reports provided by industry.

Table 1. Data sources.

| Type of document | Type of assessment | Source |
|---|-----------------------------|---|
| Peer-reviewed scientific and grey literature | NA | Bibliographic databases (via WUR library) |
| Draft Assessment reports, addenda, EFSA conclusions | EU substance | EFSA Extranet CIRCABC |
| Zonal evaluations | Product (zonal or national) | CIRCABC |
| Study reports (mostly confidential) | Various | Industry |

NA = Not applicable

Progress

Since the project began, a large number of scientific papers and reports has been collected. The searches in bibliographies for potentially relevant public literature yielded c. 15,000 'hits' for birds, c. 12,000 hits for mammals and c. 14,000 hits for residue levels and residue decline. These papers are first screened using general exclusion criteria. Publications which are not considered relevant according to these criteria are discarded, e.g., studies conducted outside the EU, conducted in other crops than mentioned in the GD, non-field studies and publications that do not deal with agricultural habitats. The number of relevant public papers is much less than the number of hits from the searches, around one thousand.

The retrieval of study reports from industry dossiers is still underway but the number may add up to several hundred.

Relevant studies are thoroughly screened and divided into three categories according to their quality. The lowest score determines the overall quality score. The quality criteria used are specific for ecological and residue studies, and are based on the study methods recommended in the GD and its annexes. Finally, the data are organised and summarised in unified databases with various numeric and non-numeric fields.

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