**Het huidige toetsingskader voor bijen**

Het Ctgb beoordeelt de risico's voor bijen op basis van het in de Rgb (Bijlage XV. Beoordelingsmethodieken uit richtsnoeren en andere beoordelingsmethodieken) aangereikte Guidance document on terrestrial ecotoxicology in the context of Directive 91/414/EEC. Sanco/10392/2002,rev 2 final (2002) (zie Bijlage, met het voor bijen relevant hoofdstuk 4).

In dit GD staat voor de toxiciteitsstudies verwezen naar EPPO 170, OECD 213 and OECD 214 guidelines. Dit is een dynamische verwijzing naar deze richtlijnen, aangezien er geen jaartallen zijn aangegeven.
EPPO 170 is in 2010 aangepast, waarbij specifieke guidance is gegeven voor het beoordelen van risico's van systemische stoffen. Dit is de meest actuele stand van de wetenschap die hiervoor beschikbaar is. Daarom is deze versie bij deze herbeoordeling gebruikt.

Volgens het Guidance Document moet ook gekeken worden naar residugegevens in pollen en nectar en indien nodig hogere tier studies moet uitvoeren met realistische blootstelling; deze gegevens zijn voor de vier herbeoordeelde stoffen aanwezig. In EPPO 2010 wordt ook gebruikt gemaakt moet worden van een chronische NOEC. De Europese stofbeoordeling van de vier stoffen heeft ook al een enigszins vergelijkbare aanpak gevolgd, ook al was EPPO 2010 toen uiteraard nog niet beschikbaar.

Aangezien bij de aanreiking van toetsingskader aan het Ctgb via Bijlage XV Rgb het Guidance Document specifiek is opgenomen en de genoemde EPPO richtlijn strookt met de insteek van de EU bij de herbeoordeling van deze stoffen voor Annex 1, is hier geen sprake van een beoordeling die vooruitloopt op de EU stand van de wetenschap.
Daarbij is duidelijk dat richtlijnen die genoemd worden in Guidance Documenten niet expliciet zelf worden aangereikt aan het Ctgb, maar via een dynamische verwijzing in het aangereikte Guidance document.

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
**E1 - Plant health**

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DRAFT

# Working Document

# Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC

This document has been conceived as a working document of the Commission Services which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Commission Directive 91/414/EEC, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

# Chapter 4 Bees

For general background information see the upcoming EPPO scheme (EPPO 2002b)

## 4.1 Data requirements and testing

### Acute toxicity to bees (Annex II 8.3.1.1, Annex III 10.4.1)

If honeybees are likely to be exposed to the active substance both acute oral and contact toxicity tests must be conducted as the toxicity by one route of exposure cannot be predicted from the other. Where there is only one relevant route of exposure (e.g. oral exposure in the case of soil application), testing can be restricted to this exposure route. The test result should be presented as µg a.s./bee or µg formulation/bee. If there are problems with solubility of the active substance, then the test should be conducted with a representative formulation.

Toxicity tests should be conducted according to EPPO 170, or OECD 213 and OECD 214 guidelines.

### Bee brood feeding test (Annex II 8.3.1.2)

The test method of Oomen et al. (1992), that is recommended in Annex II for insect growth regulators, is a worst case screening test. If no effects are found the conclusion is justified that no brood damage will occur when using the product. In the case of effects further cage/tent/tunnel or field studies are necessary to evaluate the risk under more realistic conditions. If toxicity to honeybee broods can already be predicted from the mode of action of the compound, testing may immediately start with cage/tent/tunnel or field trials.

### Residue test (Annex III 10.4.2)

Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop.

### Higher tier tests (Annex III 10.4.3, 10.4.4 and 10.4.5)

For higher tier testing (cage/tent/tunnel or field trials), the recommendations of EPPO guideline 170 should be taken into account.

### Testing of systemic plant protection products

For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed.

### Metabolite testing

Standard lab tests are normally not required for metabolites. Exceptions may be cases where for example the metabolite is the pesticidal active molecule. Before conducting studies the general guidance given in chapter 2.9 should be observed. If higher tier studies (cage/tent/tunnel or field) are conducted with the plant protection products under realistic exposure conditions, potential risks from metabolites should be covered.

## 4.2 Exposure assessment

For products applied as sprays where risk as assessed according to the HQ approach exposure should be established as the maximum single application rate of the product expressed as g/ha because the HQ was validated on this measure.

For systemic plant protection products, exposure considerations and calculations should be based on the a.s. (or metabolite) present in the respective plant parts (e.g. nectar, pollen) to which honeybees could be exposed. However, it should be noted that estimates of these concentrations are rarely available.

Exposure calculations in higher tier studies are already considered within the experimental design (e.g. honeybees foraging on treated field crops).

## 4.3 Risk assessment

### Hazard quotient for bees (Annex III 10.4)

The hazard quotient is stated to be application rate/oral LD50 or application rate/contact LD50, where the LD50 is expressed as µg a.s./bee and the application rate is in g a.s./ha. As stated above, the maximum single application rate should be used to calculate the oral and contact HQ-values. If the oral and contact HQ < 50, low risk to bees is concluded and no further testing is required. If the oral or contact HQ > 50, further higher tier testing is required to evaluate the risk to bees. The critical HQ of 50 was validated against incidents (EPPO 2002b); it is only applicable to spray products.

### Higher tier risk assessment for bees

There are no clearly defined endpoints for higher tier studies, therefore, a degree of expert judgement is required to interpret both semi-field and field study results. As regards semi-field trials, where there are replicated studies, there should be a statistical comparison between key parameters, e.g. foraging density, mortality, proportion of adults, larvae and pupae in the hive. It should be noted that the parameters considered should be relevant to the compound under consideration. For example if an insect growth regulator was being assessed then it would be more relevant to concentrate on developmental issues. As regards field trials, key parameters should be compared to either pretreatment levels or to control levels. It is important to consider any effects observed in relation to the overall survival and productivity of the hive. Key parameters which may be considered in a field trial include: mortality (assessed via the use of dead bee traps), behaviour (including foraging behaviour in the crop and around the hive), honey crop (assessed via weighing the hive at appropriate intervals) and state of colony (including an assessment of brood). Depending upon the concern highlighted in the initial risk assessment it may be appropriate to use pollen traps as well as appropriate analysis of dead bees. Analysis of honey and wax may be useful in determining exposure. The

use of a toxic standard in both semi-field and field trials along with an untreated control can aid interpretation of the results. For insect growth regulators and other active substances which may cause long-term adverse effects on hive health, evidence is required confirming a lack of effects on hive health over a long time period. It should be noted that further information is available in the EPPO guideline (EPPO 2001). The design of higher tier studies is dependant upon the risks highlighted and therefore it is recommended that applicants should consult the relevant authority.

## 4.4 Risk mitigation options

The risk mitigation measures outlined below are options only. These measures will require consideration at a national level and implementation will depend on local agronomic practice and conditions. If predicted effects to honeybees are considered as not acceptable, the following aspects of the use pattern may be considered for modification in order to mitigate the predicted risk:

- application rate
- timing of application (e.g. apply in the evening after honeybee flight, do not apply during honeybee flight)
- GAP adaptation (e.g. do not apply during crop flowering)

agronomic practice (e.g. mulch ground cover before application of the plant protection products)