Statement

Risk assessment of Imidacloprid for soil organisms for the use as seed treatment in sugar beet

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Content

1. Introduction

The effects and risks of Imidacloprid for soil organisms were intensively studied over the past decades. A comprehensive dataset is available assessing its effects on soil organisms under laboratory and realistic field conditions. Effect data and risk assessments for Imidacloprid were evaluated during the last EU review and a summary is provided in the EFSA Scientific Report from 2008 (EFSA Scientific Report, 2008). A detailed risk assessment for different soil organism groups is presented in the following.

2. Exposure of Imidacloprid in soil

Imidacloprid FS600 is used as a seed treatment in sugar beet at an application rate of 108 g a.s./ha (90 g a.s./unit at a recommended seeding density of 1.2 units/ha). The repeated application of 108 g Imidacloprid/ha leads to a maximum predicted environmental concentration (PEC) in soil of 0.170 mg a.s./kg in soil, which once reached will not increase even after continued long-term use. The PEC in soil is calculated following the principles which are described in agreed guidance documents (FOCUS 1997, EU Commission 2000).

3. Effects of Imidacloprid on soil organisms

A range of ecotoxicological studies are available for the active substance Imidacloprid and formulations used for treating the sugar beet seeds. Studies with different modes of application are given below, i.e. laboratory studies in which the substance was mixed into soil as well as laboratory and field studies in which the potential effects of treated seeds on soil organisms and organic matter degradation in a more realistic application regime were evaluated. Brief summaries of the studies are provided below.

Earthworms:

- In a chronic *Eisenia fetida* laboratory study with the active substance Imidacloprid ([redacted] 1999, M-032798-01-1, active substance mixed into soil) no adverse effects on earthworms were observed up to the highest tested concentration of 0.178 mg a.s./kg (EFSA Scientific Report, 2008).
- In a laboratory *E. fetida* reproduction study with Imidacloprid FS600 ([redacted] 2001, M-033067-01-1, according to the OECD 222 test design) treated sugar beet seeds were applied at an application rate of 585 g a.s./ha. Earthworms (i.e. *E. fetida*) show no adverse effects on survival, growth and reproduction (EFSA Scientific Report, 2008).
- In a long-term field trial ([redacted] 1998, M-007576-01-1) Imidacloprid FS 350 did not have adverse effects on natural earthworm populations after being repeatedly applied over 6 years as a seed treatment in cereals on two arable field sites in the UK (EFSA Scientific Report, 2008). Four species were found on the two field sites, i.e. the tanylobous *L. terrestris* and the epilobous *Aporrectodea caliginosa*, *Allolobophora chlorotica*, and *Aporrectodea longa*. The numbers fluctuated between test plots as usual for earthworm populations, without any indication of imidacloprid mediated effects on any species, neither in abundance nor in biomass on both test fields. Thus, the results of this study do not indicate any long-term effect of imidacloprid, repeatedly applied as treated seeds over multiple years at an application rate of 133 g a.s./ha, on earthworm populations in arable fields under practical agricultural conditions.

Soil micro-arthropods:

- A chronic earthworm laboratory study with the active substance Imidacloprid for the collembolan species *Folsomia candida* ([redacted] 1999, M-031094-01-1) showed no chronic effects up to concentrations of 1.25 mg a.s./kg (EFSA Scientific Report, 2008)
- A chronic *F. candida* laboratory study with the product Imidacloprid FS 600 ([redacted] and [redacted] 2002, M-060198-01-1) is available where the product was mixed homogeneously into artificial soil. No effects were observed a concentration of 0.2 mg a.s./kg (EFSA Scientific Report, 2008).
- A chronic *F. candida* laboratory test with Imidacloprid FS 600 ([redacted] 2003, M-083112-01-1) is available following application as a treated sugar beet seeds, which is a more realistic application pattern than mixing the substance into soil. No adverse effects were seen up to an application rate of 656 g a.s./ha (EFSA Scientific Report, 2008).
- The active substance Imidacloprid showed no effects on the predatory mite *Hypoaspis aculeifer* in a reproduction study up to the highest test concentration of 2.67 mg a.s./kg ([redacted] 1999, M-041284-01-1; EFSA Scientific Report, 2008).

Microorganisms – carbon and nitrogen transformation and fungi

- The effects of Imidacloprid on the process of microbial nitrification and carbon mineralization in soil was assessed in laboratory studies ([redacted] 1988, M-006964-01-2 and [redacted] 1988, M-006978-01-2) according to OECD 216 and 217 test protocol, respectively. No adverse effects were seen on nitrogen and carbon transformation up to the highest test concentration of 2.67 mg a.s./kg (EFSA Scientific Report, 2008).
- Different soil fungi were tested on potential effects of Imidacloprid on mycelium growth on artificial substrate (agar plates): *Phytophthora nicotianae, Suillus granulatus, Mucor circinelloides, Paecilomyces marquandii, and Agaricus bisporus*. No adverse effects were observed for these species up to a concentration of 30 mg/kg, except for *Agaricus bisporus* where a NOEC of 0.32 mg a.s./kg was determined (EFSA Scientific Report, 2008).

Organic matter degradation – Litterbag study

- A field litterbag study (according to OECD guidance document No. 56) is available with Imidacloprid FS 600 ([redacted] 2004, M-032609-02-1), applied as treated seeds. The study demonstrated that the rate of 131 g a.s./ha applied as treated cereal seeds (together with a simulated plateau concentration for Imidacloprid) had no adverse impact on organic matter degradation under realistic field conditions (EFSA Scientific Report, 2008).

4. Risk assessment

The risk assessment for soil organisms is performed comparing the no-observed effect concentrations (NOEC) or no-observed effect rates (NOER) with the expected exposure in soil (PEC or application rate) following the recommended use pattern under field situation. The NOEC or NOER represents the highest concentration or rate in a toxicity study where no adverse effects were seen on the test organisms or parameters under investigation. If the concentration at which no effects on soil organisms were observed (NOEC or NOER) exceeds the expected exposure in soil (PEC or recommended application rate) at least by a factor of e.g. 5 (for laboratory studies with *E. fetida*, *F. candida*, or *H. aculeifer*) the margin of safety is considered high enough that no unacceptable risk can be concluded (as

laid down in the European Regulation 1107/2009 (2009) and the respective guidance document (SANCO/10329/2002 rev 2 final, 2002)). Hence, the toxicity-exposure ratio (TER), the ratio between the NOEC or NOER and the exposure in soil (PEC or application rate) should be above the critical TER trigger to conclude on an acceptable risk. For chronic laboratory studies with *E. fetida*, *F. candida*, and *H. aculeifer* the critical TER trigger is set to 5, for microbial studies and field studies a critical TER trigger of 1 is used (SANCO/10329/2002 rev 2 final, 2002).

In a first step (tier1) of the risk assessment the intrinsic toxicity of a substance is compared with the PEC in soil considering the studies in which the test substance was mixed homogenously into soil. This is done to assess the potential risk of a compound under unrealistic exposure assumptions in the laboratory test system (Table 1). In a second step, laboratory and field effect studies with more realistic application scenarios, i.e. application as treated seeds, are considered in the risk assessment as a refinement step (Table 2).

Table 1: Tier 1 risk assessment using studies in which the test substances were mixed into soil

	Test substance	NOEC [mg a.s./kg]	PEC [mg a.s./kg]	TER	Critical TER Trigger
E. fetida	Imidacloprid a.s.	≥0.178		≥1.0	
F. candida	Imidacloprid a.s.	1.25		7.4	
F. candida	Imidacloprid FS600	0.2	0.170	1.2	5
H. aculeifer	Imidacloprid a.s.	≥2.67		≥15.7	
Microbial nitrogen and carbon transformation	Imidacloprid a.s.	≥2.67	0.170	≥15.7	1
Soil fungi: *P. nicotianae*, *S. granulatus*, *M. circinelloides*, *P. marquandii*, *A. bisporus*	Imidacloprid a.s.	 ≥30 ≥30 ≥30 ≥30 0.32	0.170	 ≥176.5 ≥176.5 ≥176.5 ≥176.5 1.9	1

In the tier 1 risk assessment the toxicity-exposure ratios (TER) for *F. candida*, *H. aculeifer*, microbial nitrogen transformation, and soil fungi are above the critical trigger values for the active substance Imidacloprid, indicating no unacceptable risk for these organism groups (Table 1). For *E. fetida* (active substance) and *F. candida* (Imidacloprid FS600) the NOECs are above the expected field exposure following the recommended use pattern, however, do not exceed the critical trigger value of 5. In these laboratory tier 1 studies the test substance was mixed homogeneously into soil to assess the intrinsic toxicity potential of the substances in a first step.

However, laboratory and field studies are available with the recommended mode of application, i.e. application as treated seeds. A refined risk assessment for the treated seeds application is presented below in Table 2:

Table 2: Refined risk assessment for Earthworms and Collembola following the application of treated seeds in the toxicity studies

	Test substance	NOER [g a.s./ha]	Recommended application rate [g a.s./ha]	TER	Critical TER Trigger
Laboratory studies					
E. fetida	Imidacloprid FS 600	≥585	108	≥5.4	5
F. candida	Imidacloprid FS 600	≥656		≥6.1	
Field studies					
Natural earthworm community, 6-year monitoring study	Imidacloprid FS 350 (Zelmone)	≥133 (NOEAER*)	108	≥1.2	1
Litterbag study	Imidacloprid FS 600	≥131	108	≥1.2	1

*NOEAER: No-observed ecologically adverse effect rate

Considering the effect studies with treated seeds applications in the refined risk assessment demonstrates that no unacceptable risks to Collembola, earthworms, and the process of organic matter degradation can be expected if Imidacloprid is applied with an application rate of 108 g a.s./ha as treated sugar beet seeds. As all TER values exceed the relevant trigger values a sufficient margin of safety is demonstrated indicating no unacceptable risk to soil organisms (Table 2).

5. Conclusion

Imidacloprid FS 600 used as a seed treatment in sugar beets does not pose an unacceptable long-term risk for soil organisms and for the process of organic matter degradation and mineralization.

6. References

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