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1.2.P Evaluation of honey bee larvae data: sensitivity to PPPs and impact analysis of EFSA Bee GD

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Abstract

In addition to other assessments, the EFSA bee guidance document (2013) requires the risk assessment of plant protection products on honey bee larvae. At the time the EFSA GD was finalized, no data on honey bee larvae were available due to absence of suitable methods. That is why in 2013 the European Crop Protection Association (ECPA) perfomed an impact analysis of the new EFSA risk assessment, using extrapolated endpoints derived from acute oral honey bee endpoints. Today, a number of honey bee larvae toxicity studies (138 active substances or formulated products) have been conducted according to the newly developed testing methods for single exposure (OECD TG 237) repeated exposure studies until the end of the larval development (D7/D8) and repeated exposure testing (OECD GD 239) until adult hatch (D22). These experimental data have been used to determine the 'pass rates' for 215 worst case uses (72 fungicide spray and solid uses, 91 herbicide spray uses, incl. 8 PGR uses and in total 52 insecticide spray and solid uses, incl. 2 nematicide and 3 IGR uses) according to the EFSA Bee GD and to compare with the original ECPA impact analysis. As standardized test methods for non-*Apis* bees larvae were not available, risk assessment according to EFSA for bumblebees and solitary bees based on the honey bee endpoint as surrogate corrected by a safety factor of 10. Morevoer, the sensitivity of the NOEDs at D8 and D22 in repeated exposure (D 22) studies were analysed.

Overall, the toxicity of fungicides and herbicides to honey bee larvae (expressed as means and medians of NOED and LD_{50} values) was moderate to low, while insecticides as expected displayed stronger toxicity. Moreover, the endpoints for herbicides were on average a factor of 2 higher than fungicides which ranges within the normal biological variability (factor of 3). In addition, it is unclear, if the difference is related to a slightly higher toxicity or other factors like different physical chemical properties (e.g. lower solubility). For insecticides, toxicity was about 125 (based on medians) and 6 to 8 (based on means) times higher than herbicides. In the screening risk assessment according to EFSA Bee GD the majority of fungicide (83.3%) and herbicide (95.6%) uses passed the risk assessment for larvae; whereas, for all insecticide uses thr pass rate was about 29%. In the Tier 1 risk assessment, these pass rates slightly increased and were even higher in the 'treated crop' and 'weed in the field' scenarios for fungicide and herbicide uses, almost being 100%. Pass rates for insecticide uses did not improve very much and amounted to be about 42% for both scenarios. When basing the risk assessment of bumblebee and solitary bee larvae on $1/10^{th}$ of the honey bee larval endpoint, the majority of active substances and their respective products will fail the screening (overall about 96%) and Tier 1 risk assessment (overall about 90%).

Alternative risk assessment approaches proposed by ECPA (*e.g*. following the EPPO approach; ECPA Option 1 using refinement options and more representative assumptions) or comparing an assummed exposure concentration to the NOEC (ECPA Option 2) led to a slight increase (Option 1) or even no differences in the pass rates (Option 2a) compared to EFSA Tier 1 risk assessment. Thus both, the standard risk assessment according to the EFSA Bee GD as well as the alternative ECPA Option 1 and 2 result in a clear distinction between products with high toxicity (insecticides) vs. non-toxic products (herbicides and fungicides) for the honey bee risk assessment.

The sensitivity analysis of repeated exposure studies according OECD GD 239 indicated that in most cases toxicity did not increase during the pupation period between D8 and D22. Thus, the larval growing period between D3 and D8 represents the most sensitive period of the pre-imaginal development.

Keywords: Honey bees, bumble bees, solitary bees, larvae, impact analysis, risk assessment, EFSA Bee GD

Introduction

In 2013 the European Food Safety Authority (EFSA) published a guidance document (GD) on the risk assessment (RA) of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA 2013) (EFSA Bee GD). This GD intends to provide guidance for notifiers and authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009 (EU 2009). However, this guidance document has not been taken note of in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) or implemented by the Commission, and is currently under revision by EFSA.

The European Crop Protection Association (ECPA) impact analysis for larvae by Alix *et al*. (2013), which based on an estimated NOED deriving from 1/10th of adult honey bee's LD_{50} and corrected for body weight (83 mg/larvae) indicated that for the larvae screening risk assessment 44% of all uses would pass for honey bees. Taking into account the estimated NOED for honey bee larvae with an additional safety factor of 10, pass rate would be 0% for non-*Apis* bees. This is due to over-conservative assumptions relating to exposure and the trigger value. In fact, the risk assessment based on EFSA Bee GD does not sufficiently discriminate between toxic and non-toxic compounds, which is driven by exposure assumptions that are much higher than in reality following agricultural use (e.g. residues in unprocessed food, no dilution in the hive). ETRs, as described in the EFSA Bee GD, are considered as very conservative triggers and lead to a considerable number of false positives.

Since 2013, a number of toxicity studies with honey bee larvae have been conducted according to newly developed testing methods for single exposure, *i.e.* OECD TG 237 (2013), repeated exposure studies until the end of the larval development and repeated exposure testing, *i.e.* OECD GD 239 (2016) or their respective draft versions.

Based on the aformentioned experimental data ECPA started a new evaluation of the impact of the proposed screening step and Tier 1 risk assessments on the pass rates of currently available active substances and products on the EU market for honey bees, bumblebees and solitary bees which results are presented here. The analysis considered 138 active substances or formulated products (44 fungicides, 62 herbicides comprising plant growth regulators (hereafter called PGRs) and 28 insecticides comprising insect growth regulators (hereafter called IGRs) and nematicides. Overall, 215 uses were covered.

Next to the presentation of descriptive statistics for NOED and LD_{50} the outcome of alternative risk calculations for honey bees as described by ECPA (2017) to assess the risk to bees are included. These cover an EPPO approach which used more representative conservative nectar content, feeding and residue assumptions (ECPA option 1), and the NOEC rather the NOED (ECPA option 2).

The objective of this paper is to summarize all available experimental data generated by industry to comply with the regulation, to present describing statistics for NOED and LD_{50}, to assess the 'pass' rates according to the EFSA Bee GD as well as to the alternative ECPA calculations and to compare the outcome of experimental data with the original outcome of the impact analysis which used

estimated endpoints. Available adult chronic test data were considered, too, to investigate if larval or chronic adult risk assessment was the more critical one.

Methods and data sources

The analysis from Alix *et al*. (2013) considered 151 active substances covering 163 uses: 60 were herbicides comprising plant growth regulators (PGRs), 52 fungicides, and 51 insecticides comprising acaricides. Because at the time no data were available as test methods were yet to be developed, larval toxicity endpoints ($NOED_{larvae}$ – no observed effect dose) were estimated as follows: $1/10^{th}$ of adult's acute oral LD_{50} corrected for mean larval body weight (83 mg) (*e.g*., an acute oral LD_{50} of 100 µg a.s./bee resulted in a NOED of 8.3 µg a.s./larva).

For the current analysis, experimental data from 138 active substances or formulated products covering 44 fungicides, 62 herbicides plus 4 plant growth regulators (hereafter called PGRs) and 28 insecticides comprising insect growth regulators (hereafter called IGRs) and nematicides. Mixtures of fungicides with insecticides were attributed to insecticides as they drive the toxicity. Overall, 215 uses were covered: 72 fungicide spray and seed treatment uses; 91 herbicide spray uses (incl. 8 PGR uses); and, in total 52 insecticide spray and solid uses, including 2 nematicide and 3 IGR uses.

As study methods developed throughout the last years, studies on larvae were performed according to different methods and provided different endpoints: single exposure studies until Day 7 (reflected by OECD TG 237, 2013), which results are expressed as 'D7' endpoints, repeated exposure studies until day 8 ('D8' endpoints) and repeated exposure studies until Day 22 (reflected by OECD GD 239, 2016) leading to 'D22' endpoints.

The following parameters were determined for NOED and LD_{50} values differentiated for fungicides, herbicides (incl. PGR) and insecticides (incl. nematicides and IGRs): minima, maxima, means, medians, 90^{th} and 10^{th} percentiles). For this analysis, unbounded ('greater than') endpoints were generally regarded as discrete endpoints. In the case of endpoints deriving from product studies, which contained one or more active ingredient, the NOED and LD_{50} values were transferred into 'µg a.s./larva'. For one fungicide and one insecticide, no LD_{50} values were available. Moreover, descriptive statistics were performed for NOED values on D8 and D22 deriving from repeated exposure feeding D22 studies.

For the risk assessment, 'exposure-toxicity-ratios' (ETRs) were calculated based on the application rate (AR, in kg a.s./ha) and the $NOED_{larvae}$. Whereas for the 'screening step' risk assessment only the application rate and an application-type dependent 'short cut' (SV) value was considered (ETR larva = AR x SV /NOED), the tier 1 risk assessment (RA) takes into account on the one hand crop dependent exposure factors (Ef) and on the other hand SV-values, which depend on default values for pollen and nectar consumption, sugar content in nectar, residues (RUDs) in pollen and nectar and crop attractiveness (ETR larva = AR x Ef X SV /NOED) (for details see EFSA 2013). Moreover, it distinguishes the risk for bees being exposed to different scenarios, from which risk of being exposed to the 'treated crop' and to 'weeds flowering in the field' were regarded as the most relevant. Risk assessment for insecticidal uses were performed separately for spray and solid uses (seed treatments and granules). The pass rates of the screening step and the Tier 1 RA were determined not only for honey bees but also for bumblebees and solitary bees. As standardized test methods for non-*Apis* bee larvae are not available, the risk assessment for bumble bees and solitary bees is based on $1/10^{th}$ of the honey bee endpoint (NOED) as surrogate, as proposed by the EFSA Bee GD. Calculations were done using the EFSA–tool (Excel spreadsheet), Version 3 (October 2015). Adult chronic pass rates were taken from Lückmann et al. (2019).

As a first alternative RA approach (ECPA option 1), which is based upon the method of EPPO 170 (2010a) risk assessment for systemic substances, the NOED was compared to the 'estimated theoretical exposure' (ETE) exposure (dose per development period). The latter based on more representative conservative nectar contents (*e.g*., an overall sugar content of 30% for all exposure routes including flowering weeds according to Pamminger *et al*. (2019), feeding (according to

Rortais *et al*. 2005) and residue assumptions (median RUDs instead of 90th percentile of EFSA Bee GD) and calculates a Toxicity-Exposure-Ratio (TER) rather than an ETR. The ETEs were compared to the larval NOEDs given as 'µg a.s./larva/development period'. As both, acute and repeated exposure test methods were used, NOED values deriving from single exposure larval studies were divided by 4 to account for the number of days of exposure in the repeated exposure studies. Although EPPO (2010a) suggests a chronic TER trigger (NOED/daily dose) of 1 as the entity to be protected is the test species, a trigger of 5 was chosen to be more protective and in line with other areas of ecotoxicology.

The 2nd alternative RA approach (ECPA option 2) was based on the comparison of an assumed exposure concentration based on median RUDs from the EFSA Bee GD to the NOEC values from the acute or repeated exposure larval studies. A trigger of 0.2 was chosen, which corresponds to a trigger of 5 in case the TER would have been calculated. As 12 out of the 138 studies did not provide NOEC values the evaluation could was performed for 200 out of the 215 uses (93%).

Results and Discussion

The compiled data comprised single (*i.e.*, Day 7/8 endpoints) and repeated dosing studies (*i.e.*, Days 7/8 and 22 endpoints).

Overall, the toxicity of fungicides and herbicides to honey bee larvae (expressed as means and medians of NOED and LD_{50} values) was moderate to low, while insecticides as expected displayed stronger toxicity (Tab. 1). Despite the aforementioned overall view, fungicides were approximately twice as toxic as herbicides which ranges within the normal biological variability (factor of 3). In addition, it is unclear, if the difference is related to a slightly higher toxicity or other factors such as different physical chemical properties (*e.g.*, lower solubility). For insecticides, toxicity was approximatley 125 (based on medians) and 6 to 8 (based on means) times higher than herbicides.

When the risk assessment was conducted according to EFSA (2013) the overall pass rate of all uses, which was dominated by the high number of herbicide and fungicide uses, resulted in pass rates of 75.3% in the screening risk assessment and about 85% for the 'treated crop' and 'weed in the field' scenarios in the Tier 1 risk assessment. The majority of fungicide (83.3%) and herbicide uses (95.6%) passed the screening step risk assessment. In the Tier 1 risk assessment these pass rates were slightly higher in the 'treated crop' and 'weed in the field' scenarios, almost being 100%. In contrast, pass rates for all insecticide uses were distinctly lower and amounted to approximately 29% in the screening risk assessment and about 42% for each of the two scenarios in the Tier 1 risk assessment (Tab. 2).

For bumblebee and solitary bee larvae almost no use (0.0 to 5.5%) passed the screening step risk assessment for all types of PPP. For solid insecticides, pass rates for both taxa amounted to be 20% but it must be considered that this was equivalent to only one out of the 5 uses. In the Tier 1 risk assessment, pass rates for bumblebee larvae slightly increased for all types of PPP (treated crop: 4.2 to 14.4%, 20.0% for solid insecticides; weeds: 2.0 to 16.5%; 0.0% for solid insecticides) but were still very low. The overall pass rates for bumblebee and solitary bee larvae amounted to be approximately 4% in the screening risk assessment and about 10% for the 'treated crop' and 'weed in the field' scenarios in the Tier 1 risk assessment (Tab. 2).

Following alternative ECPA approaches, the pass rates in Option 1 only substantially differed for insecticides from those derived from the EFSA Bee GD Tier 1 ('treated crop scenario'), *i.e.*, increased from about 42% to approximately 60% (Tab. 3).

The pass rates in the second alternative (Option 2) did not differ from those derived from EFSA Bee GD for all types of PPPs (Tab. 3). As this option based on default residue values of the EFSA Bee GD, measured residue data, (*e.g.*,

residues in flowers, blossoms or green tissues); residues in pollen and nectar derived from honey bees sampled at flowering plants;residues in pollen and nectar derived from honey bees

sampled at the hive entrance; or residues of in pollen and nectar from in-hive stores) can be used for a risk assessment based on more realistic exposure situations.

Both, the standard risk assessment according to the EFSA Bee GD as well as the alternative ECPA Option 1 and 2 result in a clear distinction between products with high toxicity (insecticides) vs. non-toxic products (herbicides and fungicides) for the honey bee risk assessment.

Without any suitable methods to investigate larval toxicity of bumble bees and solitary bees under laborartory conditions, a safety factor of 10 has to be used for the risk assessment. This will lead to the failure to pass, particularly for insecticides and causes the need for higher-tier data to refine the risk. However, there is still a lack of workable and reliable higher-tier study guidelines for bumble bees and solitary bees, agreement on endpoints and how they should be used to refine the risk assessment. Moreover, even for honey bees were guideline are available, the current requirements of EFSA bee GD on honey bee field testing regarding needed replication (field sites and colonies per field) to detect an effect < 7% on e.g. colony size with a power of 80% and a 5% risk or less to accept a false positive result, distance of fields and the exposure level to reach (> 90th percentile) makes it practically impossible to perform acceptable higher tier studies. In contrast, the current EPPO guideline (EPPO 2010b) is approved for many years.

In D22 studies, the NOED on D22 was equivalent or even higher (less toxic) compared to the D8 endpoint in approximately 70% of the studies, while in approximately 30% the D22 endpoint was lower (Tab. 4, Tab 5). For those NOEDs being lower on D22 than on D8 (n = 19), it was up to 4 times for the majority of the endpoints (n = 16) whih can be regarded within the biological variation. Only 3 displayed higher toxicity between 16 and 150-fold of the D8 NOED (two insecticides, one fungicide). Thus, lower potential pass rates have to be expected, at least for compounds showing toxicity (*i.e.*, many insecticides) compared to compounds of low toxicity (*i.e.*, many fungicides and most herbicides), according to the requirements (repeated exposure, D22 endpoint) of the EFSA Bee GD.

The honey bee risk assessment based on extrapolated larval data (Alix *et al.* 2013) resulted in lower pass rates for all compound groups compared to experimental larval data (Tab. 6), while the pass rates for Bumble and solitary bees based on extrapolation from currently available honey bee data remained at a low level.

Risk assessments using real data confirm that the chronic risk assessment for adults is the key driver of honey bee risk according to the EFSA Bee GD as stated in the original impact analysis (Alix *et al.* 2013). The experimental chronic adult honey bee data (Lückmann *et al.* 2019) showed lower pass rates for all compound groups compared to larval data (Tab. 6).

Tab. 3 Descriptive statistics of NOED and LD_{50} values deriving from larval feeding studies irrespective the study type

Parameter	Toxicity [µg a.s./larva] of							
	Fungicides		Herbicides*		Insecticides**		All types of PPP	
	NOED	LD_{50}	NOED	LD_{50}	NOED	LD_{50}	NOED	LD_{50}
Min	1.30	5.00	0.60	4.80	0.003	0.008	0.003	0.008
Max	172	188	303	303	202	202	303	303
Mean	34.5	57.8	63.9	104	9.75	13.0	43.5	71.0
Median	24.3	48.9	41.7	100	0.315	0.810	24.9	50.0
95th percentile	99.9	123.7	204	238	17.8	31.3	161	199
90th percentile	80.1	99.8	116	197	11.4	25.1	100	176.6
10th percentile	4.55	16.6	12.2	17.4	0.013	0.029	0.369	0.828
Data [n]	44	43	66	66	28	27	137	136

* including four PGRs; ** including one IGR and two nematicides

Tab. 4 Overall pass rates of screening step and tier 1 RA for oral exposure of bee larvae

Use type (n)	Pass rates [%] for								
	screening step RA			Tier 1 RA, 'treated crop'[1]			Tier 1 RA, 'weeds in the field'[2]		
	HB	BB[3]	SB[3]	HB	BB[3]	SB[3]	HB	BB[3]	SB[3]
Fungicides (72)	83.3	2.8	4.2	94.4	4.2	9.7	97.0	11.9	10.4
Herbicides & PGRs (91)	95.6	5.5	5.5	97.8	14.4	16.7	96.7	16.5	13.2
Insecticides (spray uses) (47)	29.8	0.0	0.0	40.4	8.5	12.8	44.7	2.1	2.1
Insecticides (solid uses) (5)	20.0	20.0	20.0	60.0	20.0	20.0	0.0	0.0	0.0
Insecticides, total (52)	28.8	1.9	1.9	42.3	9.6	13.5	42.9	2.0	2.0
Total (215)	75.3	3.7	4.2	83.2	9.8	13.6	84.1	11.6	9.7

[1]data set reduced for herbicides to n = 90, as 'under crop applications' are not relevant for the treated crop scenario;
[2]data set reduced for fungicides to n = 67 and solid insecticides to n=2 as `seed treatment uses' are not relevant for the 'weed in the field scenario' (only relevant for granule use);
[3]endpoint derived from HB testing by dividing the endpoint by 10.

Tab. 5 Summary of pass rates for honey bees based on EFSA Bee GD risk assessment and alternative risk assessment approaches

Use type	Pass rates [%] based on				
	EFSA Bee GD			Option 1 (modified EPPO)	Option 2 (NOEC approach - RUDs)
	screening RA	Tier 1 RA, 'treated crop'	Tier 1 RA, 'weeds'		
Fungicides (spray uses)	83.3	94.4	97.0	98.6	92.9
Herbicides & others (spray uses)	95.6	97.8	96.7	100	95.2
Insecticides (spray uses)	29.8	40.4	44.7	48.9	37.8
Insecticides (solid uses)	20.0	60.0	0.0	80.0	100
Insecticides (total)	28.8	42.3	42.9	51.9	40.4
Total	75.3	83.2	84.1	87.9	81.5

Tab. 6 Sensitivity comparison of D8 and D22 endpoint in repeated exposure larval feeding studies (OECD GD 239)

Use (n)	NOED Proportion [%]		
	D8 > D22	D8 ≙ D22	D8 < D22
Fungicides (21)	23.8	76.2	0.0
Herbicides (29)	31.0	62.1	6.9
Insecticides (12)	41.7	58.3	0.0
Overall (62)	30.6	66.1	3.2

Tab. 7 Descriptive statistics of D8 and D22 endpoints in repeated exposure larval feeding studies (OECD GD 239)

Parameter	NOED [µg a.s./larva] of							
	Fungicides		Herbicides*		Insecticides**		All types	
	D8	D22	D8	D22	D8	D22	D8	D22
Min	5.00	1.30	2.60	2.60	0.010	0.010	0.010	0.010
Max	278	172	133	100	12.5	10.3	278	172
Mean	52.9	37.1	52.2	40.9	3.27	2.57	43.0	32.2
Median	33.0	24.9	35.5	31.0	0.356	0.124	25.0	24.9
95th percentile	172	80.1	112	100	11.3	8.51	119	100
90th percentile	80.1	80.0	100	100	9.97	6.97	100	79.5
10th percentile	10.0	10.0	12.8	11.0	0.110	0.018	0.594	0.169
Data [n]	21	21	29	29	12	12	62	62

* including one PGR; ** including one IGR and one nematicide

Tab. 8 Comparison of pass rates deriving from extrapolated and real larval endpoints as well as adult chronic studies

Use	Pass rates [%]		
	Honey bee larvae		Adult honey bees
	Screening * (Alix et al. 2013)	Tier 1 ** ('treated crop' scenario)	Tier 1 (Lückmann et al. 2019, ('treated crop' scenario) Chronic exposure
Fungicides	58	94.4	56.9
Herbicides	47	97.8	75.0
Insecticides	26	42.3	18.6
All	44	83.2	53.8

* endpoint derived from acute oral testing

** derived from all uses and including single exposure (lasting until D7) and repeated exposure studies (lasting until D8 or D22)

Summary and Conclusions

Risk assessments using experimental larval data confirm that the chronic risk assessment for adults is the key driver of honey bee risk in the EFSA Bee GD as stated in the original impact analysis by Alix et al. (2013) and verified by Lückmann *et al*. (2019) using experimental data.

Based on the data with different larval endpoints it can be concluded that larval tests providing D7/D8 endpoints can be used in the risk assessment for non-toxic compounds.

For toxic compounds, the differences between sensitivity on D8 and on D22 will likely increase the risk assessment failure rates, if exclusively D22 endpoint would be used for the Tier 1 RA.

Insecticide failure in the larval Tier 1 risk assessment triggers the need for higher-tier data to refine the risk. However, there is still a lack of workable higher-tier study guidelines, agreement on endpoints or how they should be used to refine the risk assessment.

Like the standard risk assessment according to the EFSA Bee GD, the alternative ECPA Option 1 and 2 result in a clear distinction between products with high toxicity (insecticides) vs. non-toxic products (herbicides and fungicides) for the honey bee risk assessment. The alternative proposals led only for insecicides resp. more toxic compounds and products to significant different pass rates compared to the EFSA standard risk assessment.

When basing the risk assessment of bumblebee and solitary bee larvae on 1/10th of the honey bee endpoint, the majority of active substances and their respective products will fail the risk assessment. As valid larval laboratory guidelines for bumblebees and solitary bees are currently not available and it is not foreseeable when they will be, and because the development of reliable higher tier study designs are long-term research projects, the risk assessment in these areas cannot be completed.

Thus, the need to develop internationally recognised guidelines remains. New guidance should be built on existing guidance, recent research results as well as experiences and recommendations of all stakeholders.

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1.3.P Chronic oral exposure of adult honey bees to PPPs: sensitivity and impact analysis of EFSA Bee GD

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Abstract

Based on EU Regulation 1107/2009/EC the current regulatory risk assessment on bees has to address the chronic risk on adult honeybees.

In July 2013 the European Food Safety Authority (EFSA) published a guidance document on the risk assessment of plant protection products on bees (EFSA 2013). This document is intended to provide guidance for notifiers and authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009 (EC 2009).

The first aim of this poster is to summarize industry data based on studies conducted up to 2018, for active substances and formulated products on the chronic oral testing of adult honeybees according to OECD test guideline 245 and its previously drafts, in order to gain an overview of these results and the selectivity of different product groups.

As a first step in the risk assessment, EFSA requires a screening step which consists of the calculation of risk quotients (ETRs) for the chronic exposure based on the application rate, an application depending shortcut value, an exposure factor and the endpoint (LDD_{50}). This considers exposure routes for the in-field (PPPs applied as sprays) and off-field (PPPs used as seed treatments and granules) scenarios. Where a use does not pass one of the screening level risk quotients, EFSA offers the possibility for refinement in a tier I risk assessment. This includes refinement of the exposure estimates from the screening step and also additional exposure routes, such as the exposure to flowering weeds in the field and adjacent flowering crops. Screening step and tier I risk assessment were also conducted for bumble bees and solitary bees, using 1/10th of the honeybee endpoint.

The second aim of this poster is to evaluate the impact of the proposed screening and tier I risk assessments on the pass rate of currently available active substances and formulated products, thereby testing the ability of the scheme to correctly identify compounds of potential concern and consequently screen out those of low concern. The third objective of this work is to present the outcome of alternative calculations as described by ECPA (2017).

The aforementioned analysis follows the principles described in the ECPA impact analysis (Alix et al. 2013) which used theoretical data due to lack of real data. The present analysis compares the pass rates from this first approach with the outcome based on real laboratory data which are now available.