STATEMENT

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Statement on risk mitigation measures on cypermethrin

European Food Safety Authority (EFSA)

Abstract

In August 2018, EFSA published its conclusion on the peer review of the pesticide risk assessment of the active substance cypermethrin on the basis of the evaluation of the representative uses of cypermethrin as proposed by the applicant and following the guidance document currently available at EU level. In order to verify the possibility to identify a safe use, at recent meetings of the Standing Committee on Plants, Animals, Food and Feed, exposure reduction measures prepared by the rapporteur Member State (RMS) for cypermethrin (BE) were discussed. In July 2019, the European Commission mandated EFSA to identify conditions of use other than those reported in the original conclusion, which are likely to result in an low risk to aquatic organisms, non-target arthropods and bees, considering the risk assessment performed for the representative uses of cypermethrin. The statement provides the options of exposure reduction and the extent to which a low risk to aquatic organisms, non-target arthropods and bees could be demonstrated. It is confirmed that this required spray drift mitigation measures currently not recommended by the guidance in place for aquatic organisms and non-target arthropods. In addition, exclusion of autumn applications is necessary regarding the risk to aquatic organisms. The in-field exposure to bees is significantly lower when the spray application is made outside of the flowering periods of crops and weeds compared to spray applications during the flowering.

Keywords: cypermethrin, risk assessment, pesticide, insecticide, risk mitigation

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Summary

Cypermethrin is a substance covered by the third stage of the renewal programme ('AIR3') in accordance with Regulation (EC) No 844/2012.

The European Food Safety Authority (EFSA) published its conclusion on the pesticide peer review for cypermethrin on 30 August 2018 following the peer review of the renewal assessment report in line with the provisions of Regulation (EC) No 844/2012.

The EFSA conclusion on cypermethrin identified as critical areas of concern, for the representative uses assessed, a high risk to aquatic organisms, to bees and to off-field non-target arthropods. Drift mitigation measures up to 95% to reduce exposure for some of these organisms, but not for bees, were considered in the EFSA conclusion, according to indications provided in the guidance currently in place.

In order to verify the possibility of identifying additional mitigation measures, other than those currently accepted, allowing the identification of a safe use, at recent meetings of the Standing Committee on Plants, Animals, Food and Feed, exposure reduction measures prepared by the rapporteur Member State (RMS) for cypermethrin (BE) were discussed.

Following the technical discussions, the European Commission asked EFSA on 15 July 2019 for technical support for identifying conditions of use which are likely to result in an acceptable risk for aquatic organisms, non-target arthropods and bees, considering the risk assessment for the representative uses of cypermethrin, even though not supported by the methodologies currently in place.

EFSA accepted the request for technical support on 6 August 2019, to consider the options of exposure reduction and the extent to which a low risk to aquatic organisms, non-target arthropods and bees, could be demonstrated.

Low risk for aquatic organisms and low off-field risk to non-target arthropods could be achieved only by applying risk mitigation measures which are beyond the 95% limit recommended by the FOCUS landscape and mitigation guidance (FOCUS, 2007).

Low off-field risk to bees can be achieved by applying spray drift mitigation up to 54%.

A low in-field risk could be concluded for bees after the flowering period of the crops and when no flowering weeds are present in the field throughout the season. For the situations when the spray applications are performed before the flowering of the crops and the weeds, the in-field exposure of bees can be expected to be significantly lower compared to situations when the spray applications are performed during the flowering.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Background information

Cypermethrin is a substance covered by the third stage of the renewal programme ('AIR3') in accordance with Regulation (EC) No 844/2012[1].

An application for renewal of the active substance cypermethrin by the Cypermethrin Working Group Task Force (consisting of Arysta LifeScience Benelux sprl (previously Agriphar S.A.) and SBM Développement) was assessed by the rapporteur Member State (RMS), Belgium, and the co-rapporteur Member State (co-RMS), Germany.

Following the submission of the renewal assessment report (RAR) to EFSA (received on 8 May 2017), EFSA initiated a peer review of the RAR in line with the provisions of Regulation (EC) No 844/2012. Following the completion of the peer review, including expert discussion, EFSA published its conclusion on the pesticide peer review for cypermethrin on 30 August 2018 (EFSA, 2018a).

The EFSA conclusion on cypermethrin was reached on the basis of the evaluation of the representative uses of cypermethrin as an insecticide on winter and spring cereals, on winter and spring oilseed rape and potato, as proposed by the applicants. The risk assessments in the EFSA conclusion identified as critical areas of concern, for the representative uses assessed, a high risk to aquatic organisms, to bees and to off-field non-target arthropods. Drift mitigation measures up to 95% to reduce exposure for some of these organisms, but not for bees, were considered.

In order to verify the possibility to identify additional mitigation measures other than those currently in place based on the agreed guidance document and allowing the identification of a safe use, at recent meetings of the Standing Committee on Plants, Animals, Food and Feed, exposure reduction measures prepared by the RMS for cypermethrin (BE) were discussed (see Annex A).

Following the technical discussions, the European Commission asked EFSA on 15 July 2019 for technical support in identifying conditions of use which are likely to result in an acceptable risk for aquatic organisms, non-target arthropods and bees, considering the risk assessment for the representative uses of cypermethrin.

Terms of Reference

The European Commission mandated EFSA to deliver a statement to identify conditions of use which are likely to result in a low risk for aquatic organisms, non-target arthropods and bees, considering the risk assessment for the representative uses of cypermethrin.

EFSA accepted the request for technical support on 6 August 2019. This request was to consider the options of exposure reduction as proposed by the RMS (BE) and the extent to which a low risk to aquatic organisms, non-target arthropods and bees, could be demonstrated. EFSA was requested to consider in particular:

- the off-field risk to aquatic organisms and non-target arthropods;
- the spray drift mitigation for off-field risk to bees;
- whether, and, if so, in which circumstances, the in-field exposure for bees can be expected to be significantly reduced.

EFSA agreed to provide a Statement on those issues by 16 September.

The exposure reduction measures prepared by the RMS BE and provided in Annex A, were used as the basis for this statement.

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

2. Assessment

2.1. The extent of off-field exposure to which a low risk to aquatic organisms may be identified and the exposure reduction that would be needed to reach such exposure

The Regulatory Acceptable Concentration (RAC) values for the ecological threshold option (ETO) and ecological recovery option (ERO) for the aquatic organisms as agreed in the conclusion of the pesticide peer review of cypermethrin (EFSA, 2018a) are 0.0017 and 0.0038 μg a.s./L, respectively. This means that the uses of cypermethrin which result in an exposure level in off-field water bodies not higher than 0.0038 μg a.s./L, may be considered to result in a low risk to aquatic organisms. However, as discussed in the pesticides peer review meeting 177 (EFSA, 2018b), the ERO-RAC for cypermethrin is not considered suitable to cover the representative uses that include applications in autumn, because autumn applications were not involved in the available mesocosm studies. Moreover, it should be noted that the ERO-RAC accounts for the observed recovery of the effected taxa and the recovery in the field may vary pending on the agroclimatic conditions (more discussions on this issue can be found in the technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology (EFSA, 2019)).

The following exposure estimations when combining spray drift buffer zone and drift reducing nozzles, performed following FOCUS guidance (2001, 2007), result in predicted exposure concentrations (PEC) in surface water lower than the ERO-RAC (see Tables 1–4).

Table 1: Step 4 PEC_{sw} for cypermethrin after application to cereals – single application at 25 g a.s./ha

Scenario	Water body type	Winter cereals		Spring cereals	
		PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles	PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles
D1 (Lanna)	Ditch	**0.0104**	0.0026	**0.0104**	0.0026
D1 (Lanna)	Stream	**0.0122**	0.0031	**0.0122**	0.0031
D2 (Brimstone)	Ditch	**0.0104**	0.0026	n.r.	n.r.
D2 (Brimstone)	Stream	**0.0124**	0.0031	n.r.	n.r.
D3 (Vreedepeel)	Ditch	**0.0103**	0.0026	**0.0103**	0.0026
D4 (Skousbo)	Pond	0.0020	0.0005	0.0020	0.0005
D4 (Skousbo)	Stream	**0.0119**	0.0030	**0.0119**	0.0030
D5 (La Jailliere)	Pond	0.0020	0.0005	0.0020	0.0005
D5 (La Jailliere)	Stream	**0.0129**	0.0032	**0.0120**	0.0030
D6 (Thiva)	Ditch	**0.0104**	0.0026	n.r.	n.r.
R1 (Weiherbach)	Pond	0.0020	0.0005	n.r.	n.r.
R1 (Weiherbach)	Stream	**0.0091**	0.0023	n.r.	n.r.
R3 (Bologna)	Stream	**0.0128**	0.0032	n.r.	n.r.
R4 (Roujan)	Stream	**0.0091**	0.0023	**0.0091**	0.0023

PEC: predicted exposure concentration; sw: surface water; ERO: ecological recovery option; a.s.: active substance; n.r.: scenario not relevant for spring cereals.
Bold values indicate situations where the PEC is higher than the ERO-RAC.

Table 2: Step 4 PEC_{sw} for cypermethrin after application to winter oilseed rape

Scenario	Water body type	Single application at 25 g a.s./ha		Multiple applications at 25 g a.s./ha	
		PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles	PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles
BBCH +9					
D2 (Brimstone)	Ditch	**0.0103**	0.0026	**0.0084**	0.0021
D2 (Brimstone)	Stream	**0.0107**	0.0027	**0.0101**	0.0025
D3 (Vreedepeel)	Ditch	**0.0103**	0.0026	**0.0083**	0.0021
D4 (Skousbo)	Pond	0.0020	0.0005	0.0017	0.0004
D4 (Skousbo)	Stream	**0.0117**	0.0029	**0.0095**	0.0024
D5 (La Jailliere)	Pond	0.0020	0.0005	0.0017	0.0004
D5 (La Jailliere)	Stream	**0.0129**	0.0032	**0.0105**	0.0026
R1 (Weiherbach)	Pond	0.0020	0.0005	0.0017	0.0004
R1 (Weiherbach)	Stream	**0.0091**	0.0023	**0.0074**	0.0019
R3 (Bologna)	Stream	**0.0124**	0.0031	**0.0105**	0.0026
BBCH 9–31					
D2 (Brimstone)	Ditch	**0.0104**	0.0026	**0.0083**	0.0021
D2 (Brimstone)	Stream	**0.0115**	0.0029	**0.0910**	0.0228
D3 (Vreedepeel)	Ditch	**0.0103**	0.0026	**0.0830**	0.0208
D4 (Skousbo)	Pond	0.0020	0.0005	0.0016	0.0004
D4 (Skousbo)	Stream	**0.0116**	0.0029	**0.0095**	0.0024
D5 (La Jailliere)	Pond	0.0020	0.0005	0.0016	0.0004
D5 (La Jailliere)	Stream	**0.0112**	0.0028	**0.0105**	0.0026
R1 (Weiherbach)	Pond	0.0020	0.0005	0.0016	0.0004
R1 (Weiherbach)	Stream	**0.0091**	0.0023	**0.0074**	0.0019
R3 (Bologna)	Stream	**0.0129**	0.0032	**0.0104**	0.0026
BBCH 9–77					
D2 (Brimstone)	Ditch	**0.0104**	0.0026	**0.0084**	0.0021
D2 (Brimstone)	Stream	**0.0124**	0.0031	**0.0098**	0.0025
D3 (Vreedepeel)	Ditch	**0.0103**	0.0026	**0.0083**	0.0021
D4 (Skousbo)	Pond	0.0020	0.0005	0.0016	0.0004
D4 (Skousbo)	Stream	**0.0116**	0.0029	**0.0095**	0.0024
D5 (La Jailliere)	Pond	0.0020	0.0005	0.0016	0.0004
D5 (La Jailliere)	Stream	**0.0118**	0.0030	**0.0105**	0.0026
R1 (Weiherbach)	Pond	0.0020	0.0005	0.0016	0.0004
R1 (Weiherbach)	Stream	**0.0091**	0.0023	**0.0074**	0.0019
R3 (Bologna)	Stream	**0.0127**	0.0032	**0.0105**	0.0026

PEC: predicted exposure concentration; sw: surface water; ERO: ecological recovery option; a.s.: active substance; BBCH: growth stages of mono- and dicotyledonous plants.
Bold values indicate situations where the PEC is higher than the ERO-RAC.

Table 3: Step 4 PEC_{sw} for cypermethrin after application to spring oilseed rape – single application at 25 g a.s./ha

Scenario	Water body type	PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles
D1 (Lanna)	Ditch	**0.0104**	0.0026
D1 (Lanna)	Stream	**0.0122**	0.0031
D3 (Vreedepeel)	Ditch	**0.0103**	0.0026
D4 (Skousbo)	Pond	0.0020	0.0005

Scenario	Water body type	PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 75% drift reducing nozzles
D4 (Skousbo)	Stream	**0.0119**	0.0030
D5 (La Jailliere)	Pond	0.0020	0.0005
D5 (La Jailliere)	Stream	**0.0121**	0.0030
R1 (Weiherbach)	Pond	0.0020	0.0005
R1 (Weiherbach)	Stream	**0.0091**	0.0023

PEC: predicted exposure concentration; sw: surface water; ERO: ecological recovery option; a.s.: active substance.
Bold values indicate situations where the PEC is higher than the ERO-RAC.

Table 4: Step 4 PEC_{sw} for cypermethrin after application to potatoes – single application at 50 g a.s./ha

Scenario	Water body type	PEC_{sw} with buffer zone of 20 m	PEC_{sw} with buffer zone of 20 m + 90% drift reducing nozzles
Early application			
D3 (Vreedepeel)	Ditch	**0.0206**	0.0021
D4 (Skousbo)	Pond	**0.0039**	0.0004
D4 (Skousbo)	Stream	**0.0221**	0.0022
D6 (Thiva, 1st crop)	Ditch	**0.0203**	0.0020
D6 (Thiva, 2nd crop)	Ditch	**0.0202**	0.0020
R1 (Weiherbach)	Pond	**0.0039**	0.0004
R1 (Weiherbach)	Stream	**0.0179**	0.0018
R2 (Porto)	Stream	**0.0241**	0.0024
R3 (Bologna)	Stream	**0.0257**	0.0026
Late application			
D3 (Vreedepeel)	Ditch	**0.0206**	0.0021
D4 (Skousbo)	Pond	**0.0039**	0.0004
D4 (Skousbo)	Stream	**0.0198**	0.0020
D6 (Thiva, 1st crop)	Ditch	**0.0204**	0.0020
D6 (Thiva, 2nd crop)	Ditch	**0.0205**	0.0021
R1 (Weiherbach)	Pond	**0.0039**	0.0004
R1 (Weiherbach)	Stream	**0.0182**	0.0018
R2 (Porto)	Stream	**0.0245**	0.0025
R3 (Bologna)	Stream	**0.0256**	0.0026

PEC: predicted exposure concentration; sw: surface water; ERO: ecological recovery option; a.s.: active substance.
Bold values indicate situations where the PEC is higher than the ERO-RAC.

It should be noted that the risk mitigation measures taken into account (Tables 1–4) are greater than the limit of 95% that is recommended by the FOCUS landscape and mitigation guidance (FOCUS, 2007) usually used for risk assessment. For the representative uses on winter and spring cereals and oilseed rape, the combined mitigations measures (75% drift reducing nozzles + 20-m no-spray buffer zone) result in a total reduction of 98.7%, while for the representative use on potatoes the combined mitigations measures (90% drift reducing nozzles + 20-m no-spray buffer zone) result in a total reduction of 99.5% (see Annex A).

2.2. The extent of off-field exposure to which a low risk to non-target arthropods may be identified and the exposure reduction that would be needed to reach such exposure

Based on the risk assessment methodology recommended by the Guidance Document on Terrestrial Ecotoxicology (European Commission, 2002) and considering the results of the Tier 1 toxicity studies for the standard species (EFSA, 2018a), the off-field exposure which results in a low risk to non-target arthropods was calculated to be 5.8 mg a.s./ha (the endpoint for *Typhlodromus pyri* multiplied by the trigger values of 2). This level of off-field exposure could theoretically be achieved using a no-spray buffer zone of 133 m width for the representative uses in winter and spring cereals and winter and spring oilseed rape. For the representative use in potatoes, however, this would require a no-spray buffer zone of 270 m. Alternatively, the exposure of 5.8 mg a.s./ha may be achieved with a combination of drift reducing nozzles and different size of no-spray buffer zones as indicated in Table 5.

Table 5: Size of no-spray buffer zones needed in combination with drift reducing nozzles in order to result in an exposure level lower than 5.8 mg a.s./ha

	Cereal and oilseed rape (winter and spring)			Potato		
	50% drift reducing nozzles	75% drift reducing nozzles	90% drift reducing nozzles	50% drift reducing nozzles	75% drift reducing nozzles	90% drift reducing nozzles
Width of buffer zone (m)	66	33	13	133	66	26

It is noted that all combinations of risk mitigation measures presented above are greater than the limit of 95% which is recommended by the FOCUS Landscape and mitigation guidance document (FOCUS, 2007). It might be expected that achieving this low level of off-field contamination is challenging in practice (for example considering that the wind velocity and direction is variable during the spray applications, the soil surface of the agriculture fields are typically irregular causing movements of the boom of the sprayers making the spraying rate inhomogeneous during the application). Further discussion regarding these and other uncertainties can be found in the above-mentioned guidance.

Nevertheless, these calculations are conservative, as they are based on Tier 1 endpoints. Tier 2 (extended laboratory) studies were not available and from the relevant field studies a no-effect rate (NOER) could not be derived (EFSA, 2018a). The lowest tested rate in these field studies was 0.4 mL product/ha (equivalent to 200 mg a.s./ha) where slight and transient effects were observed on some taxa. Achieving this level of off-field contamination (where some effects were observed), the application of at least a 2-m no-spray buffer zone would be necessary for the representative uses in cereals and oilseed rape. For the representative use in potatoes, however, this would require a no-spray buffer zone with at least 4 m width. As indicated in the EFSA conclusion (EFSA, 2018a), establishing precise risk mitigation measures that result in a low risk is not possible with the available data from the field studies (since a NOER could not be established). However, the above calculations provide some indications for the necessary effectiveness of possible risk mitigation measures.

Regarding the representative uses in cereals and oilseed rape, the effectiveness of exposure reduction should be more than the effect of applying a 2-m no-spray buffer zone but should not be more than the effectiveness of a 133-m no-spray buffer zone. This range for the potato use is 4–270 m.

2.3. The extent of spray drift mitigation resulting in a low risk to bees from off-field exposure

The risk to bees visiting field margin and adjacent crop areas can be mitigated by spray drift mitigation. For the risk categories that had been quantitatively addressed in the EFSA (2018a) up to 54% drift mitigation would be sufficient to demonstrate a low risk for the representative uses of cypermethrin. Details are indicated in Tables 6 and 7 below.

Table 6: Drift mitigation expressed in percentage (%) that would be necessary to demonstrate a low risk from the contact route of exposure for the different risk categories

	Honey bee	Bumble bee
Field margin scenario – representative uses on cereals and oilseed rape	No mitigation is necessary	
Field margin scenario – representative use on potato	39	41

Table 7: Drift mitigation expressed in percentage (%) that would be necessary to demonstrate a low risk from the oral route of exposure for the different risk categories

	Honey bee			Bumble bee
	Acute adult	**Chronic adult**	**Larva**	**Acute adult**
Field margin scenario – representative uses to cereals and oilseed rape	No mitigation is necessary			
Adjacent crop scenario – representative uses to cereals and oilseed rape	No mitigation is necessary	7	No mitigation is necessary	No mitigation is necessary
Field margin scenario – representative use to potato	No mitigation is necessary	54	No mitigation is necessary	No mitigation is necessary
Adjacent crop scenario – representative use to potato	No mitigation is necessary	36	No mitigation is necessary	No mitigation is necessary

2.4. Circumstances when the in-field exposure for bees can be expected to be significantly reduced compared to the risk assessment scenarios performed in the peer-review

Risk from contact exposure

The exposure of bees to the spray solutions is regarded as negligible outside of the flowering period(s) (i.e. outside BBCH 60–69) of the crop and the weeds. As regards the weed scenario only, based on EFSA (2013), the exposure is not considered to be significant when less than 10% of the field is covered by attractive, flowering weeds at the time of the spray application. Therefore, a low risk to bees can be concluded for these situations.

Risk from dietary exposure – treated crop scenario

The exposure of bees is regarded as negligible after the flowering period of the crop. Therefore, a low risk could be concluded for these situations. According to the Good Agricultural Practice (GAP) table, cypermethrin may be sprayed at the period of BBCH 70–77 to cereals and oilseed rape.[2] The representative use for potato is for the whole season up to 3 days before harvest; therefore, the period after the flowering falls between BBCH 70 and ca. BBCH 97. Regarding potato, for the spray application before emergence (BBCH < 10) a low risk is indicated in EFSA (2018a).

For the other situations when the spray applications are made before flowering and during the flowering,[3] the exposure characterisations are not distinguished by the available quantitative risk assessments (Tier 1 calculations) as presented in EFSA (2018a).[4] The low or lower exposure, hence the low risk for those situations could be demonstrated by higher tier assessments, but the additional data that were available for cypermethrin were insufficient to demonstrate this for either situations. Regarding the spray applications performed during the flowering period (cereals and potato), it is not expected that the exposure to bees was significantly reduced compared to the risk assessment as presented in EFSA (2018a).

However, EFSA (2013) suggests that for the before flowering situations, low residue levels in pollen and nectar maybe expected especially for such chemicals with low potential for mobility in plants and with low persistence. To reflect on this, some relevant information of cypermethrin was considered and presented below:

- Cypermethrin has a relatively low water solubility < 11 μg/L and it is lipophilic (Log P_{ow} > 5.5). This indicates a rather low potential for mobility from soil via roots to the xylem and then to plant shoots leaves and flowers. However, some redistribution via phloem cannot be excluded.

[2] For oilseed rape, the low risk for the treated crop scenario was indicated in EFSA (2018a) as one of the GAP referred exclusively to BBCH 70–77.

[3] For oilseed rape, no application is envisaged during the flowering according to the GAP table.

[4] This is because even when the spray application(s) are performed before the flowering, residues still can be present in pollen and nectar (if produced) when the crops are in bloom.

- Cypermethrin was indicated to exhibit low to moderate persistence in aerobic soil and low persistence in water sediment systems. In anaerobic soil incubations, degradation of cypermethrin was similar to the one under aerobic conditions.
- Plant residue trials (performed at rather late grows stages) indicated a rather slow degradation of cypermethrin in plants.
- The residue data package (for human consumption) contained insufficient information regarding potential residues in pollen and bee products.
- Cypermethrin is able to absorb the ultraviolet (UV) light. Degradation was observed in the soil photolysis study and the rate of decline in sterile aqueous photolysis experiments was similar to that occurred in the aerobic sediment water system. This information may suggest that high persistence on plant surfaces may not be expected. However, cypermethrin molecules that absorbs into waxes on leaves and shoots may not readily photodegrade.

Overall, the information above suggests that the level of residue in pollen and nectar is expected to be significantly lower for the situations when the spray applications are performed several days or weeks before the bud formation compared to situations when the applications are performed during the flowering. However, it is not possible to draw a solid conclusion without, e.g. residue measurements as suggested by EFSA (2013).

Table 8 includes a summary of the situations for the different crop stages for the representative uses.

Table 8: The dietary risk to bees for the different crop stages in the context of the risk assessments performed in EFSA (2018a,b)

Crop stage	Uses on cereals	Uses on oilseed rape	Use on potato
BBCH 00–09	Not applicable	Not applicable	Low risk was indicated in EFSA (2018a,b)
BBCH 10[(a)]–59	See qualitative assessments above		
BBCH 60–69	Risk is not expected to be significantly reduced compared to the risk assessment as presented in EFSA (2018a)		
BBCH > 70	Risk is considered to be low	Low risk was indicated in EFSA (2018a)	Risk is considered to be low

(a): According to the GAP table, oilseed rape maybe sprayed from BBCH 09.

Risk from dietary exposure – weed scenario

The exposure to bees is not considered to be significant when less than 10% of the fields are covered by attractive, flowering weeds throughout the whole vegetative season. When this cannot be guaranteed, the considerations as indicated above for the treated crop scenario are applicable. However, it should be noted that the flowering periods of the weeds may be considerably longer than the flowering periods of the crops. Notable presence of flowering weeds cannot be excluded for the whole vegetative season of the representative crops except for the winter period (uses on winter cereals and winter oilseed rape) in certain regions of the EU (e.g. where the winter climate is too unfavourable for the growth and for the flowering of the weeds; also the activity of the bees and pests maybe reduced in those regions for that period). In those situations, for spray applications performed in late autumn, it is reasonable to assume that the exposure of the bees will be significantly reduced compared to the risk assessment as performed in EFSA (2013). However, the regions for which this can be reasonably assumed cannot be defined without supportive data.

3. Conclusions

As regards aquatic organisms a low risk could be concluded only by applying risk mitigation measures which are beyond the 95% limit recommended by the FOCUS landscape and mitigation guidance (FOCUS, 2007). In addition, it should be noted that the relevant calculations considered the ERO-RAC – derived from the available mesocosm studies – that is not suitable to cover the representative uses which include autumn applications.

The off-field exposure that results in a low risk to non-target arthropods and which could reliably be estimated, could be achieved only by applying risk mitigation measures which are beyond the 95% limit (e.g. no-spray buffer zones up to 133 m for cereals and oilseed rape or up to 270 m for potatoes).

By applying spray drift mitigation up to 54%, a low off-field risk to bees could be achieved for the risk categories which had been assessed in EFSA (2018a).

The exposure of bees is regarded as negligible after the flowering period of the crops and when no flowering weeds are present in the field throughout the season. Therefore, a low risk could be concluded for those situations. It was also concluded that when the spray applications are performed several days or weeks before the flowering of the crops and the weeds, the exposure of bees to cypermethrin is expected to be significantly lower compared to situations when the spray applications are performed during the flowering (as in tier 1 risk assessments in EFSA, 2018a).

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Abbreviations

a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
EEC	European Economic Community
ERO	ecological recovery option
ETO	ecological threshold option
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HQ	hazard quotient
LR_{50}	lethal rate, median
NOER	no-effect rate
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PEC	predicted environmental concentration
PEC_{sw}	predicted environmental concentration in surface water
PER	predicted environmental residue
P_{ow}	partition coefficient between *n*-octanol and water
RAC	Regulatory Acceptable Concentration
RAR	Renewal Assessment Report
RMS	rapporteur Member State
UV	ultraviolet
WHO	World Health Organization

Annex A – Total drift reduction necessary to obtain an acceptable risk for aquatic organisms (based on ERO-RAC) and non-target arthropods (off-field), provided by the RMS for cypermethrin (BE)

Aquatic organisms

In the RAR for cypermethrin, an acceptable risk for aquatic organisms was obtained for all FOCUS scenarios at FOCUS Step 4 if the following risk mitigation measures were applied:

- For the proposed uses in cereals and oilseed rape: 75% drift reducing nozzles + 20-m no-spray buffer zone + vegetated filter strip.
- For the proposed use in potatoes: 90% drift reducing nozzles + 20-m no-spray buffer zone + vegetated filter strip.

These risk mitigation measures intend to reduce the entry of residues in the surface water through different routes: spray drift, drainage and runoff. Drift reducing nozzles and no-spray buffer zones reduce entry via spray drift, while a vegetated filter strip reduces entry through drainage and runoff.

The total amount of drift reduction that is obtained through combining the proposed drift reducing nozzles (75% or 90%) and no-spray buffer zone (20 m) exceeds 95%. Because the FOCUS Landscape and mitigation guidance document (SANCO/10422/2005, version 2.0, September 2007) states that the maximum reduction in exposure for spray drift should be limited to 95%, the above measures were not taken into account in the EFSA Conclusion for cypermethrin (EFSA Journal 2018;16(8):5402).

However, in preparation of a draft renewal report for cypermethrin, RMS BE was asked by the Commission to calculate the exact total % of drift reduction that is obtained by combining the mitigation measures listed above. These calculations are shown below.

It should be noted that the above listed risk mitigation measures resulted in an acceptable risk to aquatic organisms only if the risk assessment is based on the ERO-RAC, which was derived from the available mesocosm studies and which takes into account recovery. For those situations where this ERO-RAC is not applicable, these combined risk mitigation measures were not sufficient to obtain an acceptable risk!

Cereal and oilseed rape – 75% drift reducing nozzles + 20 m no-spray buffer zone

Based on data presented in Rautmann et al. (2001),[5] the percentage of the application rate that is deposited as sediment at the edge of the field (y) can be calculated for a certain no-spray buffer zone of a distance x with the following formula:

$$y = a \times x^{b}$$

where y: the soil sediment expressed in % of a distance x in m
a: crop specific parameter. For field crops, a = 2.7705
b: crop specific parameter. For field crops, b = −0.9787.

For the standard distance of 1 m, the percentage sediment deposit is 2.771%. Based on the same equation, a buffer zone of 20 m would result in a sediment deposit of 0.15% at the edge of the field. Compared to the standard distance of 1 m, a buffer zone of 20 m would thus result in a drift reduction of 94.7% (i.e. 0.15 is 5.3% of 2.771).

If 75% drift reducing nozzles are used, the amount of sediment deposit at the edge of the field would be only 25% of the value with standard nozzles (i.e. 0.25 × 2.771 = 0.693%). If a 20-m buffer zone would then be used in combination with the drift reducing nozzles, the sediment deposits at the edge of the field would further be reduced by 94.7%, resulting in a percentage deposit of 0.0367% (0.053 × 0.693%). Compared to the standard distance of 1 m, **the combination of 75% drift reducing nozzles and 20-m buffer zone therefore results in a (theoretical) total drift reduction of 98.7%** (0.0367 is 1.3% of 2.771).

[5] Rautman D, Streloke M and Winkler R, 2001. New basic drift values in the authorization procedure for plant protection products. In: Forster R and Streloke M (eds.). Workshop on Risk Assessment and Risk Mitigation in the Context of the Authorization of Plant Protection Products (WORMM): 27–29. September 1999. *Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft Berlin-Dahlem; H. 383*.

Potatoes – 90% drift reducing nozzles + 20-m no-spray buffer zone

If 90% drift reducing nozzles are used, the amount of sediment deposit at the edge of the field would be only 10% of the value with standard nozzles (i.e. 0.10 × 2.771 = 0.2771%). If a 20-m buffer zone would then be used in combination with the drift reducing nozzles, the sediment deposits at the edge of the field would further be reduced by 94.7%, resulting in a percentage deposit of 0.0147% (0.053 × 0.2771%). Compared to the standard distance of 1 m, **the combination of 90% drift reducing nozzles and 20-m buffer zone therefore results in a (theoretical) total drift reduction of 99.5%** (0.0147 is 0.53% of 2.771).

Non-target arthropods

In addition to the calculations for aquatic organisms, RMS be was asked by the Commission to calculate how much % drift reduction would be needed to demonstrate a safe use for non-target organisms (off-field), and to compare this with the percentage needed for aquatic organisms.

The Tier 1 risk assessment for non-target arthropods (off field) for the proposed uses of cypermethrin, as presented in the RAR, resulted in an unacceptable risk for *Typhlodromus pyri*. To demonstrate an acceptable risk to non-target arthropods, further consideration is necessary. In a first instance, higher tier studies are considered. For cypermethrin, no Tier 2 (extended laboratory studies) are available. Higher field studies for the off-field situation were submitted and were considered in the risk assessment. However, from these studies no NOER (no observed effect rate) could be derived, and as a result no acceptable risk could be demonstrated for non-target arthropods.

Another possibility to demonstrate an acceptable risk is to take into account risk mitigation measures. As no Tier 2 (extended laboratory) studies are available for cypermethrin, the only studies that can be used to calculate the necessary risk mitigation measures are the Tier 1 (standard laboratory) studies. Below, it is calculated which risk mitigations would be necessary for the proposed uses in winter and spring cereals, winter and spring oilseed rape and potatoes.

Tier 1 risk assessment

The Tier 1 risk assessment non-target arthropods (off-field), based on the available standard laboratory studies, resulted in the HQ values shown in Table A.1.

Table A.1: Off-field risk to non-target terrestrial arthropods based on laboratory studies (Tier I) from exposure to cypermethrin following the use of Cypermethrin 500 EC in winter and spring cereals, winter and spring oilseed rape, and potatoes

Crop	Test species	LR_{50} (g a.s./ha)	Off-field foliar			Trigger value
			PER (g a.s./ha)	Correction factor	HQ	
Cereals/Oilseed rape	*Typhlodromus pyri*	0.0029	0.0693	10	239	2
	Aphidius rhopalosiphi	0.822			0.84	
Potato	*Typhlodromus pyri*	0.0029	0.1385	10	478	
	Aphidius rhopalosiphi	0.822			1.68	

LR_{50}: lethal rate, median; PER: predicted environmental residue; a.s.: active substance; HQ: hazard quotient.

For *Aphidius rhopalosiphi*, the risk is acceptable as the HQ value is below the trigger of 2. For *Typhlodromus pyri*, however, the HQ largely exceeds the trigger of 2, indicating an unacceptable risk.

Consideration of risk mitigation measures – no-spray buffer zones

In the risk assessment for non-target arthropods (off-field), the $PER_{off\text{-}field}$ (predicted environmental residue) is calculated using the following equation:

$$\text{Foliar PER}_{off-field} = \text{maximum foliar PER}_{in-field} \times \frac{\textit{driftfactor}}{\textit{vegetationdistributionfactor}}.$$

The drift factor is obtained from Appendix VI of the ESCORT II guidance document. For the Tier 1 risk assessment for field crops, the drift values for a standard distance of 1 m from the edge of the field are used.

Considering larger distances from the edge of the treated field (i.e. assuming the implementation of a no-spray buffer zone) would reduce the drift factor and consequently the $PER_{off\text{-}field}$. In Table A.2 below, the $PER_{off\text{-}field}$ for a number of no-spray buffer zones are shown, together with the corresponding HQ value. Only the HQ values for *Typhlodromus pyri* are shown, as this is the most sensitive species.

Table A.2: HQ values for the off-field risk to non-target terrestrial arthropods based on laboratory studies (Tier I) from exposure to cypermethrin following the use of Cypermethrin 500 EC in winter and spring cereals, winter and spring oilseed rape, and potatoes, taking into account buffer zone of up to 250 m

Crop	Appl. rate (g a.s./ha)	Distance from the edge of the crop (i.e. buffer zone) (m)	Drift factor	Off-field PER (2D)	Correction factor	HQ
Cereals/ Oilseed rape	25	1	0,0277	0,06925	10	239
		5	0,0057	0,01425	10	49
		10	0,0029	0,00725	10	25
		15	0,002	0,005	10	17
		20	0,0015	0,00375	10	13
		30	0,001	0,0025	10	8,6
		40	0,0007	0,00175	10	6,0
		50	0,0006	0,0015	10	5,2
		75	0,0004	0,001	10	3,4
		100	0,0003	0,00075	10	2,6
		125	0,00025	0,000625	10	2,2
		150	0,00021	0,000525	10	1,8
		175	0,00018	0,00045	10	1,6
		200	0,00016	0,0004	10	1,4
		225	0,00014	0,00035	10	1,2
		250	0,00012	0,0003	10	1,0
Potato	50	1	0,0277	0,1385	10	478
		5	0,0057	0,0285	10	98
		10	0,0029	0,0145	10	50
		15	0,002	0,01	10	34
		20	0,0015	0,0075	10	26
		30	0,001	0,005	10	17
		40	0,0007	0,0035	10	12
		50	0,0006	0,003	10	10
		75	0,0004	0,002	10	6,9
		100	0,0003	0,0015	10	5,2
		125	0,00025	0,00125	10	4,3
		150	0,00021	0,00105	10	3,6
		175	0,00018	0,0009	10	3,1
		200	0,00016	0,0008	10	2,8
		225	0,00014	0,0007	10	2,4
		250	0,00012	0,0006	10	2,1

Based on the HQ values shown in Table A.2, the off-field risk to non-target arthropods is acceptable (i.e. HQ values < 2) for the proposed uses in winter and spring cereals and winter and spring oilseed rape when a no-spray buffer zone of 150 m is applied. For the proposed use in potatoes, however, the risk remains unacceptable even with a buffer zone of 250 m.

It has to be noted that these values are very conservative, as they are based on a standard laboratory study with a sensitive indicator species. When Tier 2 (extended laboratory studies) would be available, the necessary buffer zones are likely to be smaller.

Consideration of risk mitigation measures – drift reduction

Apart from no-spray buffer zones, drift reducing measures (i.e. drift reducing spray nozzles) could also be applied as a risk mitigation measure. The necessary percentage of drift reduction can be calculated from the no-spray buffer zone, as described below.

Based on the following formula from Rautmann et al. (2001)[5]:

$$y = a \times x^b$$

where y: the soil sediment expressed in % of a distance x in m

a: crop specific parameter. For field crops, a = 2.7705

b: crop specific parameter. For field crops, b = −0.9787.

the percentage of the application rate that is deposited as sediment at the edge of the field (y) can be calculated for a certain no-spray buffer zone of a distance x.

The percentage drift reduction can then be calculated by comparing the percentage sediment deposit for a certain buffer zone to the percentage sediment deposit for the standard distance of 1 m.

For the proposed use in cereals and oilseed rape, a 150-m no-spray buffer zone is necessary to obtain an acceptable risk. At 150 m, the calculated percentage sediment deposit is 0.021%, which corresponds to 0.7% of the value for the standard distance of 1 m (2.771%). Consequently, a buffer zone of 150 m **corresponds to a drift reduction of 99.3%**.

For the proposed use in potato, a no-spray buffer zone of 250 m (which corresponds to 99.6% drift reduction) was not sufficient to obtain an acceptable risk.

Conclusion

For the proposed use in cereals and oilseed rape, an acceptable risk to aquatic organisms was demonstrated in the RAR based on the ERO-RAC when 75% drift reducing nozzles + 20-m no-spray buffer zone + vegetated filter strip are applied as risk mitigation measures. The combination of the measures for drift reduction (nozzles + no-spray buffer zone) results in a total drift reduction of 98.7%. For non-target arthropods, however, a total drift reduction of 99.3% would be necessary for the risk to be acceptable (based on the available Tier 1 laboratory data). Overall, **for the proposed use in cereals and oilseed rape, a minimal drift reduction of 99.3% would be necessary for an overall acceptable risk**.

For the proposed use in potatoes, an acceptable risk to aquatic organisms was demonstrated in the RAR based on the ERO-RAC when 90% drift reducing nozzles + 20-m no-spray buffer zone + vegetated filter strip are applied as risk mitigation measures. The combination of the measures for drift reduction (nozzles + no-spray buffer zone) results in a total drift reduction of 99.5%. For non-target arthropods, however, a total drift reduction of 99.6% (the maximum that could be calculated) did not result in an acceptable risk (based on the available Tier 1 laboratory data). Consequently, **based on the data currently available for cypermethrin, it is not possible to obtain an overall acceptable risk for the proposed use in potatoes, even when drift is reduced by 99.6%**.