## CONCLUSION ON PESTICIDE PEER REVIEW

# Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance pyriproxyfen[1]

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## ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State the Netherlands for the pesticide active substance pyriproxyfen are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory ecotoxicology data. The conclusions were reached on the basis of the evaluation of the representative uses of pyriproxyfen as an insecticide on protected tomato and aubergine and field grown cotton. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. A concern is identified.



## KEY WORDS

pyriproxyfen, peer review, risk assessment, pesticide, insecticide

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## SUMMARY

Pyriproxyfen was included in Annex I to Directive 91/414/EEC on 1 July 2008 by Commission Directive 2008/69/EC, amended by Commission Directive 2010/39/EU and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on aquatic insects and pollinators by 30 June 2012.

In accordance with the specific provision, the applicant, Sumitomo Chemical Agro Europe S.A., submitted an updated dossier in July 2012, to address the risk to aquatic insects from Pyriproxyfen and from the metabolite DPH-PYR and to address the risk to pollinators, which was evaluated by the designated RMS, the Netherlands in the form of an Addendum to the Draft Assessment Report. In compliance with Guidance Document SANCO 5634/2009 rev.4.5, the RMS distributed the Addendum to Member States, the applicant and the EFSA for comments on 23 September 2013. The RMS collated all comments in the format of a Reporting Table, which was submitted to the European Commission in January 2014

Following consideration of the comments received, the European Commission requested the EFSA to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to aquatic insects and pollinators and to deliver its conclusions on the weight of evidence approach to address the risk to aquatic insects from Pyriproxyfen and the validity of the field study on honey bees according to SANCO/10329/2002 rev. 2.

Based on the submitted confirmatory data, a low risk to aquatic organisms including insects was indicated for both pyriproxifen and the pertinent metabolite DPH-PYR for all the representative uses. The risk to pollinators from the insect growth regulator mode of action needs to be addressed further for greenhouse uses on tomato and aubergine in Southern Europe, as the submitted field study was not considered appropriate for the risk assessment for bees.

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## BACKGROUND

Pyriproxyfen was included in Annex I to Directive 91/414/EEC on 1 July 2008 by Commission Directive 2008/69/EC[3], amended by Commission Directive 2010/39/EU[4] and has been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. EFSA previously finalised a Conclusion on this active substance on 21 July 2009 in the EFSA Scientific Report (2009) 336 (EFSA, 2009).

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The Addendum and the Reporting Table were discussed at the Pesticides Peer Review Meeting 115 on ecotoxicology in May 2014. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report.

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in July 2014.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to aquatic insects and pollinators. A key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the Reporting Table to the conclusion. The Peer Review Report (EFSA,

[3] Commission Directive 2008/69/EC/EC of 1 July 2008, amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances. OJ L 172, 2.7.2008, p. 9-14.

[4] Commission Directive 2010/39/EC/EC of 22 June 2010, amending Council Directive 91/414/EEC as regards specific provisions relating to the active substances clofentezione, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen as active substances. OJ L 156, 23.6.2010, p. 7-11.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[6] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

[7] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

2014) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the Reporting Table,
- the report of the scientific consultation with Member State experts
- the comments received on the draft EFSA conclusion.

Given the importance of the Addendum to the DAR including its final addendum (compiled version of July 2014 containing all individually submitted addenda (Netherlands, 2014)) and the Peer Review Report, these documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Pyriproxyfen is the ISO common name for 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether (IUPAC). Pyriproxyfen, belongs to the class of juvenile hormone mimics, other examples of this class are fenoxycarb and methoprene. The mode of action is suppression of embryogenesis, and inhibition of metamorphosis and reproduction. The representative formulated product for the evaluation was 'Pyriproxyfen 10 EC', an emulsifiable concentrate (EC).

The evaluated representative uses are as an insecticide on protected tomato and aubergine and field grown cotton. Full details of the GAP can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

The applicant has submitted to the Commission by the deadline of 30 June 2012 studies on aquatic insects and pollinators.

The assessment of the information was presented form of an Addendum to the Draft Assessment Report (Netherlands, 2013).

The addendum for the ecotoxicological chapter included updated risk assessment for aquatic organisms and bees using the pertinent European Commission (2002a and 2002b) which were in place at the time of the approval of pyriproxyfen.

In the previous peer review of pyriproxyfen it was concluded that the risk to aquatic insects both from pyriproxyfen and the metabolite DPH-PYR for all the representative uses could not be considered addressed by the microcosm study (Wijngaarden, 2004) included in the DAR (Netherlands, 2005) as insects were not covered. In the EFSA conclusion of pyriproxyfen issued in 2009 (EFSA, 2009) it was also concluded that the assessment factor to be applied to the microcosm endpoint should be further considered and agreed when more data on insects would become available.

To address the request for confirmatory data a chronic study with aquatic insects (Ephemeroptera) together with other four mesocosm studies from the open literature were submitted. Moreover, acute toxicity data on fish, invertebrates and algae with the metabolite DPH-PYR were also submitted.

All the available mesocosm studies including the microcosm presented in the DAR were discussed at the Pesticides Peer Review Experts' meeting 115 (May 2014). In the indoor microcosm, which is included in the DAR, the biological effects of a single application of pyriproxyfen on a plankton-dominated community consisting of algae, cladocerans, copepods, ostracods, and rotifers, were investigated. The experts noted that all the additional data showed a comparable sensitivity of crustaceans and insects to pyriproxyfen. However, it was also highlighted that all the publicly available studies were from outside Europe (3 from USA and 1 from Australia). Therefore, the endpoints from these studies were not considered suitable for risk assessment due to the uncertainties in the results extrapolation (e.g. differences in the abiotic conditions). The available additional studies, however, can be used as supportive information.

Overall, it was agreed that the endpoint to be selected for the risk assessment should be the $NOEC_{population}$ of 1.2 µg/L instead of the NOEAEC of 5 µg/L, as previously, from the microcosm study originally included in the DAR. An assessment factor of 2 should be applied to this endpoint.

Based on the additional data and on the agreed endpoint, a low risk with FOCUS Step 3 PECsw was concluded for aquatic organisms including insects for the representative use on cotton. The risk to aquatic insects from the metabolite DPH-PYR can be also considered low, as it is likely that the

metabolite was present in the microcosm study, and therefore is considered to be covered. This is also in line with the previous conclusion on pyriproxyfen (EFSA, 2009).

For the use on tomato and aubergine (e.g. eggplant) in glasshouse a high risk to aquatic invertebrates was identified in the EFSA conclusion of 2009. For these representative uses 2 applications are proposed. However, assuming a single emission of 0.1% of the annual total application, a low risk was also concluded for aquatic organisms for the representative uses on tomato and aubergine (e.g. eggplant) using the agreed $NOEC_{population}$ of 1.2 µg/L from the microcosm study.

In the previous conclusion on pyriproxyfen it was concluded that further studies were needed to address the risk to bee brood for the representative uses on tomato and eggplant in glasshouse in Southern Europe (1-2 applications 112.5 g a.s./ha).

A new field study at the relevant application rate for the use in glasshouse was submitted (Bakker, F., 2011). The study was conducted in *Phacelia* fields in the South-West of France in June. The study was discussed at the Pesticides Peer Review Experts' meeting 115 (May 2014). The experts agreed that the study cannot be considered appropriate for the risk assessment for bees, as it showed some limitations, i.e. lacking of a separate analysis of the results for colonies having received one or two treatments, lower average brood index for cohort 1 compared to the control but no differences for cohort 2 and 3 and deviations from the EPPO 170 (4) Bulletin 40 (2010) in the study design. Therefore, the risk to bees for the uses in tomato and aubergine (e.g. eggplant) in glasshouse in Southern Europe cannot be considered addressed. Risk mitigation measures such as covering or removing bumble bee colonies should be considered for the representative uses in glasshouse where these pollinators are used. EFSA noted that protection measures for the wild pollinators visiting the glasshouses should also be considered (e.g. keeping the glasshouses closed).

## Concerns

### 1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[8], and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The risk to pollinators from the insect growth regulator mode of action needs to be addressed further for greenhouse uses on tomato and aubergine in Southern Europe, as the submitted field study was not considered appropriate for the risk assessment for bees.

### 2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

### 3. Overview of the concerns identified for each representative use considered

| **Representative use** | | **Cotton** | **Tomato, Aubergine North EU** | **Tomato, Aubergine South EU** |
|---|---|---|---|---|
| | Assessment not finalised | | | |
| **Risk to wild non target terrestrial organisms other than vertebrates** | Risk identified | | | |
| | Assessment not finalised | | | X[1] |
| **Risk to aquatic organisms** | Risk identified | | | |
| | Assessment not finalised | | | |
| **Comments/Remarks** | | | | |

The superscript numbers in this table relate to the numbered points indicated in Section 1.1.

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

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# APPENDICES

## APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

**Toxicity data for aquatic species (most sensitive species of each group)** (Annex IIA, point 8.2, Annex IIIA, point 10.2)

| Group | Test substance | Time-scale (Test type[(D)]) | Endpoint | Toxicity (µg a.s./l) |
|---|---|---|---|---|
| Laboratory tests | | | | |
| Fish | | | | |
| *Lepomis macrochirus* | pyriproxyfen | 96 h (f-t) | Mortality, $LC_{50}$ | >270 [(A)] |
| *Oncorhynchis mykiss* | pyriproxyfen | 95 d (f-t) | NOEC | 4.3 [(A)] |
| *Oncorhynchus mykiss* | S-71639 10EC | 96 h (s) | Mortality, $LC_{50}$ | 220 [(A)] (2100 µg form./L) |
| *Oncorhynchus mykiss* | 4'-OH-Pyr | 96 h (f-t) | Mortality, $LC_{50}$ | 270 [(A)] |
| *Oncorhynchus mykiss* | PYPAC | 96 h (s) | Mortality, $LC_{50}$ | >93000 [(A)] |
| *Oncorhynchus mykiss* | DPH-PYR | 96 h (s) | Mortality, $LC_{50}$ | 51000 [(A)] |
| Aquatic invertebrates | | | | |
| *Daphnia magna* | pyriproxyfen | 48 h (f-t) | Immobility, $EC_{50}$ | 400 [(A)] |
| *Daphnia magna* | pyriproxyfen | 21 d (f-t) | Reproduction, NOEC | 0.015 [(A)] |
| *Mysidopsis bahia* | pyriproxyfen | 28 d (f-t) | Reproduction, NOEC | 0.81 [(A)] |
| *Cloeon dipterum* | pyriproxyfen | 30 d (ss) | Nymph emergence, survival, development NOEC | ≥ 0.202 [(A)] |
| *Daphnia magna* | S-71639 10EC | 48 h (s) | Immobility, $EC_{50}$ | 190 [(A)] (1800 µg form./L) |
| *Daphnia magna* | 4'-OH-Pyr | 48 h (f-t) | Immobility, $EC_{50}$ | 1800 [(A)] |
| *Daphnia magna* | PYPAC | 48 h (s) | Immobility, $EC_{50}$ | >95000 [(A)] |
| *Daphnia magna* | DPH-PYR | 48 h (s) | Immobility, $EC_{50}$ | >9800 [(A)] |
| Sediment dwelling organisms | | | | |
| *Chironomus riparius* | pyriproxyfen | 28 d (s, spiked water) | Emergence, NOEC | 10 [(B)] |
| Algae | | | | |
| *Selenastrum capricornutum* | pyriproxyfen | 72 h (s) | Biomass $EbC_{50}$<br>growth rate $ErC_{50}$ | 94[(B)]<br>150 [(B)] |
| *Selenastrum capricornutum* | S-71639 10EC | 72 h (s) | Biomass $EbC_{50}$<br>growth rate $ErC_{50}$ | 74[(B)] 710 µg form./L)<br>110 [(B)] (1100 µg form./L)) |
| *Pseudokirchneriella subcapitata* | 4'-OH-Pyr | 72 h (s) | Biomass $EbC_{50}$<br>growth rate $ErC_{50}$ | >2500 [(C)]<br>>2500 [(C)] |
| *Pseudokirchneriella subcapitata* | PYPAC | 72 h (s) | Biomass $EbC_{50}$<br>growth rate $ErC_{50}$ | 26000[(A)]<br>30000 [(A)] |
| *Pseudokirchneriella* | DPH-PYR | 72 h (s) | Biomass $EbC_{50}$ | >9500[(A)] |

| | | | | |
|---|---|---|---|---|
| *subcapitata* | | | growth rate $ErC_{50}$ | >9500 (A) |
| Higher plant | | | | |
| *Lemna gibba* | pyriproxyfen | 14 d (s-s) | Fronds, $EC_{50}$ | >180 (A) |
| Microcosm or mesocosm tests | | | | |
| Pyriproxyfen 10EC: $NOEC_{population}$ 1.2 µg a.s./L (B) | | | | |

(A) Based on mean measured concentrations.
(B) Based on nominal concentrations (analytically confirmed for initial concentrations).
(C) Based on measured initial concentrations.
(D) f-t = flow through, s = static, s-s = semi=static

**Toxicity/exposure ratios for the most sensitive aquatic organism per group for pyriproxyfen** (Annex IIIA, point 10.2)

**1st Tier**

**Tomato & Aubergine (T&A), 2*0.1125 kg as/ha:** distance 1 m; 0.1% drift for greenhouse application
**Cotton, 1*0.075 kg as/ha**: distance 1 m; FOCUS Step 1 **(**2.77% drift and 10% run-off/drainage)

| Crop | Organism | Test substance | Toxicity endpoint (µg a.s./L) | Time-scale | $PEC_i$ (µg a.s./L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|
| T&A | *O. mykiss* | product | 220 | 96 h | 0.0382 | 5765 | 100 |
| Cotton | *O. mykiss* | product | 220 | 96 h | 1.5449 | 142 | 100 |
| T&A | *O. mykiss* | a.s. | 4.3 | 95 d | 0.0382 | 113 | 10 |
| Cotton | *O. mykiss* | a.s. | 4.3 | 95 d | 1.5449 | **2.8** | 10 |
| T&A | *Daphnia* | product | 190 | 48 h | 0.0382 | 4979 | 100 |
| Cotton | *Daphnia* | product | 190 | 48 h | 1.5449 | 123 | 100 |
| T&A | *Daphnia* | a.s. | 0.015 | 21 d | 0.0382 | **0.39** (A) | 10 |
| Cotton | *Daphnia* | a.s. | 0.015 | 21 d | 1.5449 | **0.01** | 10 |
| T&A | *C.riparius* | a.s. | 10 | 28 d | 0.0382 | 262 | 10 |
| Cotton | *C.riparius* | a.s. | 10 | 28 d | 1.5449 | **6.5** | 10 |
| T&A | *S. capri-cornutum* | product | 74 | 72 h | 0.0382 | 1939 | 10 |
| Cotton | *S. capri-cornutum* | product | 74 | 72 h | 1.5449 | 48 | 10 |
| T&A | *Lemna* | a.s. | >180 | 14 d | 0.0382 | >4717 | 10 |
| Cotton | *Lemna* | a.s. | >180 | 14 d | 1.5449 | >117 | 10 |

(A) Assuming a single emission of 0.1% of the total annual application and using the $NOEC_{population}$ of 1.2 µg/L derived from the microcosm a low risk to aquatic invertebrates can be concluded for the representative uses on tomato and aubergine.

**2nd Tier**

**Cotton: 1*0.075 kg as/ha**: distance 1 m; FOCUS Step 2 (2.77% drift and 3% run-off/drainage)

| Crop | Organism | Test substance | Toxicity endpoint (µg a.s./L) | Time-scale | $PEC_i$ (µg a.s./L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|
| Cotton | *O. mykiss* | a.s. | 4.3 | 95 d | 0.6898 | **6.2** | 10 |
| Cotton | *Daphnia* | a.s. | 0.015 | 21 d | 0.6898 | **0.02** | 1 |
| Cotton | *C.riparius* | a.s. | 10 | 28 d | 0.6898 | 14 | 10 |

**3rd Tier**

**Cotton: 1*0.075 kg as/ha**: distance 1.3 m; FOCUS Step 3 (2.77% drift and substance-dependent drainage)

| Crop | Organism | Test substance | Toxicity endpoint (µg a.s./L) | Time-scale | $PEC_i$ (µg a.s./L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|
| Cotton | *O. mykiss* | a.s. | 4.3 | 95 d | 0.381 | 11 | 10 |
| Cotton | *Daphnia* | a.s. | 0.015 | 21 d | 0.381 | **0.04** | 10 |

**4th Tier**

**Cotton: 1*0.075 kg as/ha**: distance 1.3 m; FOCUS Step 3 (2.77% drift and substance-dependent drainage)

| Crop | Organism | Test substance | Toxicity endpoint (µg a.s./L) | Time-scale | $PEC_i$ (µg a.s./L) | TER | Annex VI Trigger |
|---|---|---|---|---|---|---|---|
| Cotton | *Daphnia* | a.s. | 1.2* | 56 d | 0.381 | 3.15 | 2 |

* The endpoint is derived from a microcosm only covering zooplankton, not aquatic insects. However, it is shown with the new chronic toxicity study wth *Cloeon dipterum* and with higher tier tests from public literature that that aquatic insects show a similar level of susceptibility to pyriproxyfen when compared with cladocerans. In the field studies many species are taken into account and crustaceans belong to the most sensitive organisms. Therefore, the $NOEC_{population}$ of 1.2 µg/L derived from the microcosm is considered adequate for the higher tier risk assessment of all aquatic invertebrates. This was agreed by the experts at Pesticide Peer Review Meeting 115; they also agreed with a safety factor of 2 on this endpoint.

**Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)**

| Test substance | Acute oral toxicity ($LD_{50}$ µg/bee) | Acute contact toxicity ($LD_{50}$ µg/bee) |
|---|---|---|
| a.s. pyriproxyfen | N/A | N/A |
| Preparation Pyriproxyfen 10EC | $LD_{50}$ 74 µg a.s./bee | $LD_{50}$ >100 µg a.s./bee |
| Field or semi-field tests | | |
| In a field study in Germany (dose rate 1* 75 g a.s./ha), Pyriproxyfen 10% EC did not affect mortality of adults or juvenile stages, overall colony performance or survival and development of eggs and larvae through to adult emergence. | | |

**Hazard quotients for honey bees** (Annex IIIA, point 10.4)

| Application rate (g as/ha) | Crop | Route | Hazard quotient | Annex VI Trigger |
|---|---|---|---|---|
| Laboratory tests | | | | |
| 112.5 | Tomato and Aubergine (e.g. eggplant) | Oral<br>Contact | 1.5<br><1.1 | 50<br>50 |
| 75 | Cotton | Oral<br>Contact | 1.0<br><0.75 | 50<br>50 |

**Summary of representative uses evaluated (pyriproxyfen)***

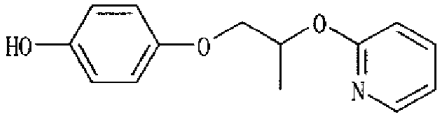
| Crop and/ or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks: (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc. of as (i) | method kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | kg as/hL min max | water L/ha min max | kg as/ha min max | | |
| Tomato (greenhouse) | South Europe | Pyriproxyfen 10 EC | G | Greenhouse and cotton whitefly | EC | 100 g/L | Foliar spray (High Volume Spraying) | BBCH 89 | 1-2 | 10 days | 0.005-0.0075 | 1000-1500 | 0.05-0.1125 | 3 | First application: as soon as adults are observed |
| Tomato (greenhouse) | North Europe | Pyriproxyfen 10 EC | G | Greenhouse and cotton whitefly | EC | 100g/L | Foliar spray (High Volume Spraying) | BBCH 89 | 1-2 | 10 days | 0.002-0.003 | 800-1200 | 0.02-0.03 | 3 | |
| Aubergine (e.g. eggplant) (greenhouse) | South Europe | Pyriproxyfen 10 EC | G | Greenhouse and cotton whitefly | EC | 100g/L | Foliar spray (High Volume Spraying) | BBCH 89 | 1-2 | 10 days | 0.005-0.0075 | 1000-1500 | 0.05-0.1125 | 3 | |
| Aubergine( e.g. eggplant) (greenhouse) | North Europe | Pyriproxyfen 10 EC | G | Greenhouse and cotton whitefly | EC | 100g/L | Foliar spray (High Volume Spraying) | BBCH 89 | 1-2 | 10 days | 0.002-0.003 | 800-1200 | 0.02-0.03 | 3 | |
| Cotton | South Europe | Pyriproxyfen 10 EC | F | Cotton whitefly | EC | 100g/L | Foliar spray (High Volume Spraying) | BBCH 78-79 | 1 | n.a. | 0.009-0.015 | 500-800 | 0.075 | n.a. | |

Remarks: * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(g) All abbreviations used must be explained
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

## APPENDIX B – USED COMPOUND CODE(S)

| Code/Trivial name* | Chemical name/SMILES notation** | Structural formula** |
|---|---|---|
| **DPH-PYR** | 4-hydroxyphenyl (RS)-2-(2-pyridyloxy)propyl ether |  |

* The metabolite name in bold is the name used in the conclusion.

## ABBREVIATIONS

| | |
|---|---|
| 1/n | slope of Freundlich isotherm |
| λ | wavelength |
| ε | decadic molar extinction coefficient |
| °C | degree Celsius (centigrade) |
| µg | microgram |
| µm | micrometer (micron) |
| a.s. | active substance |
| AChE | acetylcholinesterase |
| ADE | actual dermal exposure |
| ADI | acceptable daily intake |
| AF | assessment factor |
| AOEL | acceptable operator exposure level |
| AP | alkaline phosphatase |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| AST | aspartate aminotransferase (SGOT) |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| BUN | blood urea nitrogen |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CFU | colony forming units |
| ChE | cholinesterase |
| CI | confidence interval |
| CIPAC | Collaborative International Pesticides Analytical Council Limited |
| CL | confidence limits |
| cm | centimetre |
| d | day |
| DAA | days after application |
| DAR | draft assessment report |
| DAT | days after treatment |
| DDD | daily dietary dose |
| DM | dry matter |
| $DT_{50}$ | period required for 50 percent disappearance (define method of estimation) |
| $DT_{90}$ | period required for 90 percent disappearance (define method of estimation) |
| dw | dry weight |
| $EbC_{50}$ | effective concentration (biomass) |
| $EC_{50}$ | effective concentration |
| ECHA | European Chemicals Agency |
| EEC | European Economic Community |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of New Chemical Substances |
| EMDI | estimated maximum daily intake |
| $ER_{50}$ | emergence rate/effective rate, median |
| $ErC_{50}$ | effective concentration (growth rate) |
| EU | European Union |
| EUROPOEM | European Predictive Operator Exposure Model |
| f(twa) | time weighted average factor |
| FAO | Food and Agriculture Organization of the United Nations |
| fd | feed |
| FIR | Food intake rate |
| FOB | functional observation battery |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |

| | |
|---|---|
| g | gram |
| GAP | good agricultural practice |
| GC | gas chromatography |
| GCPF | Global Crop Protection Federation (formerly known as GIFAP) |
| GGT | gamma glutamyl transferase |
| GM | geometric mean |
| GS | growth stage |
| GSH | glutathion |
| h | hour(s) |
| ha | hectare |
| Hb | haemoglobin |
| Hct | haematocrit |
| hL | hectolitre |
| HPLC | high pressure liquid chromatography or high performance liquid chromatography |
| HPLC-MS | high pressure liquid chromatography – mass spectrometry |
| HQ | hazard quotient |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| $K_{doc}$ | organic carbon linear adsorption coefficient |
| kg | kilogram |
| $K_{Foc}$ | Freundlich organic carbon adsorption coefficient |
| L | litre |
| LC | liquid chromatography |
| $LC_{50}$ | lethal concentration, median |
| LC-MS | liquid chromatography-mass spectrometry |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LDH | lactate dehydrogenase |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| LOQ | limit of quantification (determination) |
| m | metre |
| M/L | mixing and loading |
| MAF | multiple application factor |
| MATC | maximum allowable toxicant concentration |
| MCH | mean corpuscular haemoglobin |
| MCHC | mean corpuscular haemoglobin concentration |
| MCV | mean corpuscular volume |
| mg | milligram |
| mL | millilitre |
| mm | millimetre (also used for mean measured concentrations) |
| mN | milli-newton |
| MRL | maximum residue limit or level |
| MS | mass spectrometry |
| MSDS | material safety data sheet |
| MTD | maximum tolerated dose |
| MWHC | maximum water holding capacity |
| NESTI | national estimated short-term intake |
| ng | nanogram |

| | |
|---|---|
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEAEC | no observed ecological adverse effect concentration |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| OD | oil dispersion |
| OECD | Organisation for Economic Co-operation and Development |
| OM | organic matter content |
| Pa | pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_{air}$ | predicted environmental concentration in air |
| $PEC_{gw}$ | predicted environmental concentration in ground water |
| $PEC_{sed}$ | predicted environmental concentration in sediment |
| $PEC_{soil}$ | predicted environmental concentration in soil |
| $PEC_{sw}$ | predicted environmental concentration in surface water |
| pH | pH-value |
| PHED | pesticide handler's exposure data |
| PHI | pre-harvest interval |
| PIE | potential inhalation exposure |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| $P_{ow}$ | partition coefficient between *n*-octanol and water |
| PPE | personal protective equipment |
| ppm | parts per million ($10^{-6}$) |
| PT | proportion of diet obtained in the treated area |
| PTT | partial thromboplastin time |
| QSAR | quantitative structure-activity relationship |
| $r^2$ | coefficient of determination |
| REACH | Registration, Evaluation, Authorisation of Chemicals Regulation |
| RPE | respiratory protective equipment |
| RUD | residue per unit dose |
| SC | suspension concentrate |
| SD | standard deviation |
| SFO | single first-order |
| SMILES | simplified molecular-input line-entry system |
| SSD | species sensitivity distribution |
| STMR | supervised trials median residue |
| $t_{1/2}$ | half-life (define method of estimation) |
| TER | toxicity exposure ratio |
| $TER_A$ | toxicity exposure ratio for acute exposure |
| $TER_{LT}$ | toxicity exposure ratio following chronic exposure |
| $TER_{ST}$ | toxicity exposure ratio following repeated exposure |
| TK | technical concentrate |
| TLV | threshold limit value |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| TSH | thyroid stimulating hormone (thyrotropin) |
| TWA | time weighted average |
| UDS | unscheduled DNA synthesis |
| UV | ultraviolet |
| W/S | water/sediment |
| w/v | weight per volume |
| w/w | weight per weight |
| WBC | white blood cell |
| WG | water dispersible granule |

| | |
|---|---|
| WHO | World Health Organization |
| wk | week |
| yr | year |