

# REGISTRATION REPORT

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

Product code: CA3301

Product name(s): **JOUST 250 EC**

Chemical active substance(s):

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

New Authorisation (Art.33)

Applicant: NUFARM Polska Sp. z o. o.

Submission date: 23/12/2021

MS Finalisation date: 08/2022

## Version history

| When          | What                          |
|---------------|-------------------------------|
| December 2021 | Applicant: First submission   |
| August 2022   | zRMS finalized dRR evaluation |
|               |                               |
|               |                               |

## Table of Contents

|                   |  |           |
|-------------------|--|-----------|
| <b>8</b>          | <b>Fate and behaviour in the environment (KCP 9).....</b>                                      | <b>4</b>  |
| 8.1               | Critical GAP and overall conclusions.....  | 6         |
| 8.2               | Metabolites considered in the assessment.....  | 12        |
| 8.3               | Rate of degradation in soil (KCP 9.1.1).....   | 12        |
| 8.3.1             | Aerobic degradation in soil (KCP 9.1.1.1) .....  | 12        |
| 8.3.2             | Anaerobic degradation in soil (KCP 9.1.1.1).....   | 14        |
| 8.4               | Field studies (KCP 9.1.1.2).....   | 14        |
| 8.4.1             | Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). .....             | 14        |
| 8.4.2             | Soil accumulation testing (KCP 9.1.1.2.2) .....  | 15        |
| 8.5               | Mobility in soil (KCP 9.1.2) .....   | 15        |
| 8.5.1             | Column leaching (KCP 9.1.2.1).....   | 17        |
| 8.5.2             | Lysimeter studies (KCP 9.1.2.2).....   | 18        |
| 8.5.3             | Field leaching studies (KCP 9.1.2.3) .....   | 18        |
| 8.6               | Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) .....     | 18        |
| 8.7               | Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....        | 18        |
| 8.7.1             | Justification for new endpoints .....  | 19        |
| 8.7.2             | Active substance(s) and relevant metabolite(s) .....   | 19        |
| 8.8               | Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....   | 25        |
| 8.8.1             | Justification for new endpoints .....  | 25        |
| 8.8.2             | Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1).....                              | 26        |
| 8.9               | Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) ..... | 34        |
| 8.9.1             | Justification for new endpoints .....  | 34        |
| 8.9.2             | Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5) .....              | 36        |
| 8.10              | Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....   | 67        |
| <b>Appendix 1</b> | <b>Lists of data considered in support of the evaluation.....</b>                              | <b>69</b> |

## 8 Fate and behaviour in the environment (KCP 9)

This application is in support of the new product CA3301 containing prothioconazole 250 g/L in the Central zone (Article 33 application). Prothioconazole was included to Annex I of Directive 91/414/EEC on 1 August 2008. Prothioconazole is currently undergoing renewal at EU level.

Prothioconazole is fungicide, which is used to treat winter and spring varieties of cereals and oilseed rape. Prothioconazole is applied once or twice to cereals as a foliar spray at up to 200 g as/ha, and once or twice to oilseed rape at up to 175 g as/ha. The proposed GAP for this new product CA3301 includes the same crops (cereals and oilseed rape) and maximum application rates considered at EU level for the active substance prothioconazole, though there are some differences in application timings (see GAP in Table 8.1-1 and Table 8.1-2). In addition, uses on minor crops (mustard, cameline and other seed producing brassicaceae) at rates up to 175 g as/ha are included in the proposed GAP. Environmental exposures from these minor crop uses are covered by the proposed major crop uses on oilseed rape.

This document reviews the environmental fate and behaviour studies for the product CA3301 which is an EC formulation containing the active substance prothioconazole (250 g as/L). Prothioconazole was evaluated under Directive 91/414/EEC and approved under Commission Directive 2008/44/EC. In accordance with Regulation (EC) No 1107/2009 active substances included on Annex I of Council Directive 91/414/EEC of July 1991 concerning the placing of plant protection products on the market are deemed to be approved under Regulation (EU) No 540/2011.

Where appropriate, this document refers to the conclusions of the EU review of prothioconazole. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration. For the environment this includes consideration of the following as specified in the Commission Directive 2008/44/EC :
- *The protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate*

These concerns have been addressed within the current submission.

Note: this Part B document only reviews data (active substance or product) and additional information that has not previously been considered within the EU review process, as part of the EU review of prothioconazole. However, it is intended that this product registration is evaluated prior to the EU renewal of the active substance; existing EU-agreed endpoints therefore apply, unless further justification has been provided.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prothioconazole (SANCO/3923/07 - final), the EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole (EFSA Scientific Report (2007) 106, 1-98) and the associated DAR.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document details any new studies submitted for this evaluation.

Information on the detailed composition of CA3301 can be found in the confidential dossier of this submission (Registration Report - Part C).

**Review Comments:**

This document describes the acceptable use conditions required for registration of Joust (CA3301), an emulsifiable concentration (EC) formulation containing prothioconazole 250 g/L, for use as a fungicide for controls a number of foliar and ear diseases in cereals and oilseed rape.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

## 8.1 Critical GAP and overall conclusions

**Table 8.1-1: Critical use pattern of the formulated product**

Note: Uses marked in bold are used to define the risk envelope.

| 1  | 2                  | 3   | 4  | 5   | 6             | 7   | 8   | 9  | 10   | 11   | 12                    | 13            | 14   | 15                            |
|--|--------------------|---|--|---|---------------|---|---|--|--|--|-----------------------|---------------|--|-------------------------------|
| Use-<br>No.<br>*   | Member<br>state(s) | Crop and/or<br>situation<br>(crop destination<br>/ purpose of crop) | F, Fn,<br>G,<br>Gn,<br>Gpn<br>or<br>I ** | Pests or Group of pests<br>controlled<br>(additionally:<br>developmental stages of<br>the pest or pest group)   | Application   |   |   |  | Application rate   |  |                       | PHI<br>(days) | Remarks:<br>e.g. g saf-<br>ener/ syner-<br>gist per ha | Conclusion<br><br>Groundwater |
|  |                    |   |  |   | Method / Kind | Timing /<br>Growth<br>stage of crop<br>& season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product/ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | Water L/ha<br>min/max |               |  |                               |
| Zonal uses (field or outdoor uses, certain types of protected crops) |                    |   |  |   |               |   |   |  |  |  |                       |               |  |                               |
| 1  | CEU<br>SEU<br>NEU  | Barley winter   | F  | Leaf spot of Barley<br><i>Ramularia collo-cygni</i><br>(RAMUCC)<br>Eyespot<br><i>Oculimacula acuformis</i><br>(PSDCHA)<br>Brown Rust<br><i>Puccinia hordei</i><br>(PUCCHD)<br>Powdery mildew<br><i>Blumeria graminis</i><br>(ERYSGR)<br>Leaf Blotch<br><i>Rhynchosporium<br/>secalis</i> (RHYNSE )<br>Fusarium ear blight<br><i>Fusarium spp.</i><br>(FUSASP)<br>Net Blotch<br><i>Pyrenophora teres</i><br>(PYRNTE) | Foliar spray  | BBCH 30 –<br>61<br>(Spring)                     | a) 1-2<br>b) 1-2                                    | 14 - 21  | a) 0.6<br>b) 1.2   | a) 150<br>b) 300   | 100-400               | 35            |  |                               |
| 2  | CEU<br>SEU<br>NEU  | Barley spring   | F  | Leaf spot of Barley<br><i>Ramularia collo-cygni</i><br>(RAMUCC)<br>Eyespot  | Foliar spray  | BBCH 30 –<br>61                                 | a) 1-2<br>b) 1-2                                    | 14 - 21  | a) 0.6<br>b) 1.2   | a) 150<br>b) 300   | 100-400               | 35            |  |                               |

|   |                   |  |   |   |              |                          |                  |         |                          |                          |         |    |                            |  |
|---|-------------------|--|---|---|--------------|--------------------------|------------------|---------|--------------------------|--------------------------|---------|----|----------------------------|--|
|   |                   |  |   | <i>Oculimacula acuformis</i> (PSDCHA)<br>Brown Rust<br><i>Puccinia hordei</i> (PUCCHD)<br>Powdery mildew<br><i>Blumeria graminis</i> (ERYSGR)<br>Leaf Blotch<br><i>Rhynchosporium secalis</i> (RHYNSE)<br>Net Blotch<br><i>Pyrenophora teres</i> (PYRNTE)   |              |                          |                  |         |                          |                          |         |    |                            |  |
| 3 | CEU<br>SEU<br>NEU | Oat (winter & spring)  | F | Crown Rust<br><i>Puccinia coronata</i> (PUCCCO)<br>Powdery mildew<br><i>Blumeria graminis</i> (ERYSGR)<br>Eyespot<br><i>Oculimacula acuformis</i> (PSDCHA)  | Foliar spray | BBCH 30 – 61<br>(Spring) | a) 1-2<br>b) 1-2 | 14 - 21 | a) 0.6<br>b) 1.2         | a) 150<br>b) 300         | 100-400 | 35 |                            |  |
| 4 | CEU<br>SEU<br>NEU | Wheat (winter & spring)<br><br>Spelt<br><br>+ Einkorn wheat<br><br>Emmer Wheat<br><br>Tritordeum | F | Septoria leaf spot<br><i>Zymoseptoria tritici</i><br><i>Mycosphaerella graminicola</i> (SEPTTR)<br>Glume blotch<br><i>Stagonospora nodorum</i> (LEPTNO)<br>Brown Rust<br><i>Puccinia recondita</i><br><i>Puccinia tritici</i> (PUCCRT)<br>Yellow Rust<br><i>Puccinia striiformis</i> (PUCST)<br>Powdery mildew<br><i>Blumeria graminis</i> (ERYSGR)<br>Eyespot<br><i>Oculimacula acuformis</i> (PSDCHA)<br>Tan Spot | Foliar spray | BBCH 30 – 69<br>(Spring) | a) 1-2<br>b) 1-2 | 14 - 21 | a) 0.6-0.8<br>b) 1.2-1.6 | a) 150-200<br>b) 300-400 | 100-400 | 35 | Risk envelope for uses 1-7 |  |

|   |                   |                             |   |   |              |                          |                  |         |                          |                          |         |    |  |
|---|-------------------|-----------------------------|---|---|--------------|--------------------------|------------------|---------|--------------------------|--------------------------|---------|----|--|
|   |                   |                             |   | <b><i>Pyrenophora tritici-repentis</i> (PYRNTR)<br/>Fusarium ear blight<br/><i>Fusarium spp.</i><br/>(FUSASP)</b>   |              |                          |                  |         |                          |                          |         |    |  |
| 5 | CEU<br>SEU<br>NEU | Durum Wheat                 | F | Septoria leaf spot<br><i>Zymoseptoria tritici</i><br><i>Mycosphaerella graminicola</i><br>(SEPTTR)<br>Brown Rust<br><i>Puccinia recondita</i><br><i>Puccinia tritici</i><br>(PUCCRT)<br>Powdery mildew<br><i>Blumeria graminis</i><br>(ERYSGR)<br>Fusarium ear blight<br><i>Fusarium spp.</i><br>(FUSASP).  | Foliar spray | BBCH 30 – 69<br>(Spring) | a) 1-2<br>b) 1-2 | 14 - 21 | a) 0.6-0.8<br>b) 1.2-1.6 | a) 150-200<br>b) 300-400 | 100-400 | 35 |  |
| 6 | CEU<br>SEU<br>NEU | Triticale (winter & spring) | F | Septoria leaf spot<br><i>Zymoseptoria tritici</i><br><i>Mycosphaerella graminicola</i> (SEPTTR)<br>Brown Rust<br><i>Puccinia recondite</i><br><i>Puccinia tritici</i><br>(PUCCRT)<br>Leaf blotch<br><i>Rhynchosporium secalis</i> (RHYNSE)<br>Yellow Rust<br><i>Puccinia striiformis</i><br>(PUCCST)<br>Glume blotch<br><i>Stagonospora nodorum</i><br>(LEPTNO)<br>Powdery mildew<br><i>Blumeria graminis</i><br>(ERYSGR)<br>Fusarium ear blight<br><i>Fusarium spp.</i><br>(FUSASP). | Foliar spray | BBCH 30 – 69<br>(Spring) | a) 1-2<br>b) 1-2 | 14 - 21 | a) 0.6-0.8<br>b) 1.2-1.6 | a) 150-200<br>b) 300-400 | 100-400 | 35 |  |
| 7 | CEU<br>SEU<br>NEU | Rye (winter & spring),      | F | Septoria leaf spot<br><i>Zymoseptoria tritici</i>   | Foliar spray | BBCH 30 – 69<br>(Spring) | a) 1-2<br>b) 1-2 | 14 - 21 | a) 0.6-0.8<br>b) 1.2-1.6 | a) 150-200<br>b) 300-400 | 100-400 | 35 |  |



|   |                   |                          |   |   |              |  |                  |         |                          |                          |         |    |   |  |
|---|-------------------|--------------------------|---|---|--------------|--|------------------|---------|--------------------------|--------------------------|---------|----|---|--|
|   |                   |                          |   | <i>Mycosphaerella graminicola</i> (SEPTTR)<br>Leaf blotch<br><i>Rhynchosporium secalis</i> (RHYNSE)<br>Crown Rust<br><i>Puccinia coronata</i> (PUCCCO)<br>Eyespot<br><i>Oculimacula acuformis</i> (PSDCHA)<br>Powdery mildew<br><i>Blumeria graminis</i> (ERYSGR)   |              |  |                  |         |                          |                          |         |    |   |  |
| 8 | CEU<br>SEU<br>NEU | Oilseed Rape<br>(winter) | F | Phoma leaf spot/stem canker<br><i>Leptosphaeria maculans</i> (LEPTMA)<br>Sclerotinia stem rot<br><i>Sclerotinia sclerotiorum</i> (SCLESC)<br>Powdery mildew<br><i>Erysiphe cruciferarum</i> (ERYSCR)<br>Alternaria leaf spot<br><i>Alternaria brassicae</i> (ALTEBA)<br>Light leaf spot<br><i>Pyrenopeziza brassicae</i> (PYRPBR) | Foliar spray | BBCH 14-18<br>(Autumn)<br>and/or<br>BBCH 20 – 69<br>(Spring) | a) 1-2<br>b) 1-2 | 90      | a) 0.6-0.7<br>b) 1.2-1.4 | a) 150-175<br>b) 300-350 | 100-400 | 56 | Risk envelope for uses 8 and 11                   |  |
| 9 | CEU<br>SEU<br>NEU | Oilseed Rape<br>(winter) | F | Phoma leaf spot/stem canker<br><i>Leptosphaeria maculans</i> (LEPTMA)<br>Sclerotinia stem rot<br><i>Sclerotinia sclerotiorum</i> (SCLESC)<br>Powdery mildew<br><i>Erysiphe cruciferarum</i> (ERYSCR)<br>Alternaria leaf spot<br><i>Alternaria brassicae</i> (ALTEBA)<br>Light leaf spot<br><i>Pyrenopeziza brassicae</i>          | Foliar spray | BBCH 20 – 69<br>(Spring)                                     | a) 1-2<br>b) 1-2 | 14 - 28 | a) 0.6-0.7<br>b) 1.2-1.4 | a) 150-175<br>b) 300-350 | 100-400 | 56 | Risk envelope for uses 9, 10 and 12<br>Worst case |  |

|   |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |
|---|-------------------|--|---|--|--------------|--|------------------|----------|--------------------------|--------------------------|---------|----|---|--|
|   |                   |  |   | (PYRPBR)   |              |  |                  |          |                          |                          |         |    |   |  |
| 10  | CEU<br>SEU<br>NEU | Oilseed Rape<br>(spring)   | F | Phoma leaf spot/stem<br>canker<br><i>Leptosphaeria<br/>maculans</i> (LEPTMA)<br>Sclerotinia stem rot<br><i>Sclerotinia<br/>sclerotiorum</i><br>(SCLESC)<br>Powdery mildew<br><i>Erysiphe cruciferarum</i><br>(ERYSCR)<br>Alternaria leaf spot<br><i>Alternaria brassicae</i><br>(ALTEBA)<br>Light leaf spot<br><i>Pyrenopeziza brassicae</i><br>(PYRPBR) | Foliar spray | BBCH 20 –<br>69  | a) 1<br>b) 1     | n/a      | a) 0.6-0.7<br>b) 0.6-0.7 | a) 150-175<br>b) 150-175 | 100-400 | 56 | Risk<br>envelope<br>for uses 10<br>and 12 (1-2<br>applications<br>were<br>considered) |  |
| Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms) |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |
| None  |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |
| Minor uses according to Article 51 (zonal uses)   |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |
| 11  | CEU<br>SEU<br>NEU | Mustard,<br>Cameline and<br>other seed-<br>producing<br>Brassicaceae | F | Phoma leaf spot/stem<br>canker<br><i>Leptosphaeria<br/>maculans</i> (LEPTMA)<br>Sclerotinia stem rot<br><i>Sclerotinia<br/>sclerotiorum</i> (SCLESC)<br>Powdery mildew<br><i>Erysiphe cruciferarum</i><br>(ERYSCR)<br>Alternaria leaf spot<br><i>Alternaria brassicae</i><br>(ALTEBA)<br>Light leaf spot<br><i>Pyrenopeziza brassicae</i><br>(PYRPBR)    | Foliar spray | BBCH 14-<br>18 (Autumn)<br>BBCH 20 –<br>69<br>(Spring) | a) 1-2<br>b) 1-2 | 14–28 90 | a) 0.6-0.7<br>b) 1.2-1.4 | a) 150-175<br>b) 300-350 | 100-400 | 56 |   |  |
| 12  | C-EU<br>S-EU      | Flax (for fiber<br>production only)                                  | F | Powdery mildew flax<br><i>Erysiphe spp</i> (ERYSP)   | Foliar spray | BBCH 33 –<br>51  | a) 1-2<br>b) 1-2 | 14-28    | a) 0.6-0.7<br>b) 1.2-1.4 | a) 150-175<br>b) 300-350 | 100-400 | NA |   |  |
| Minor uses according to Article 51 (interzonal uses)  |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |
| None  |                   |  |   |  |              |  |                  |          |                          |                          |         |    |   |  |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

|   |   |
|---|---|
| A | Safe use  |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS                                      |
| N | No safe use   |

**Table 8.1-2: Assessed (critical) uses during approval of prothioconazole concerning the Section Environmental Fate**

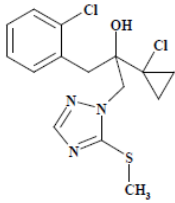
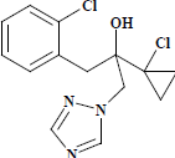

| 1             | 2                  | 3   | 4   | 5   | 6             | 7   | 8   | 9  | 10   | 11   | 12                    | 13            | 14  |
|---------------|--------------------|---|---|---|---------------|---|---|--|--|--|-----------------------|---------------|---|
| Use-<br>No. * | Member<br>state(s) | Crop and/or<br>situation<br>(crop destination<br>/ purpose of crop) | F, Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I ** | Pests or Group of pests<br>controlled<br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application   |   |   |  | Application rate   |  |                       | PHI<br>(days) | Remarks:<br>e.g. g safener/ synergist per<br>ha |
|               |                    |   |   |   | Method / Kind | Timing /<br>Growth<br>stage of crop<br>& season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product/ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | g as/ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | Water L/ha<br>min/max |               |   |
|               | EU                 | Wheat, rye,<br>triticale  | F   | Rusts, Eyespot,<br>Fusarium spp.,<br>Powd. Mildew,<br>Rhynchospor.,<br>Septoria,                              | Overall spray | start 26-29<br>up<br>to BBCH69                  | 3   | 14   |  | 200  | 200-400               | 35            |   |
|               | EU                 | Barley, oat   | F   | Rusts, Eyespot,<br>Pyren. teres,<br>Powd. Mildew,<br>Fusarium spp.,<br>Rhynchospor.                           | Overall spray | start 30 up to<br>BBCH 61                       | 2   | 14   |  | 200  | 200-400               | 35            |   |
|               | EU                 | Oilseed rape  | F   | Sclerotinia,<br>Botrytis,<br>Alternaria,<br>Leptosphaeria   | Overall spray | start BBCH<br>53                                | 2   | 14   |  | 175  | 200-400               | 56            |   |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

## 8.2 Metabolites considered in the assessment

**Table 8.2-1: Metabolites of prothioconazole potentially relevant for exposure assessment**

| Metabolite               | Molar mass | Chemical structure   | Maximum observed occurrence in compartments  | Exposure assessment required due to  |
|--------------------------|------------|--|--|--|
| Prothioconazole-S-methyl | 358.3      |   | Soil (max. 14.6 % at 7d)   | PEC <sub>soil</sub> : GAP different to EU assessment<br>PEC <sub>gw</sub> : leaching potential to groundwater<br>PEC <sub>sw/sed</sub> : Required using FOCUS-STEPS to simulate drainflow/runoff from soil                                 |
| Prothioconazole-desthio  | 312.2      |   | Soil (max. 57.1 % at 7d)<br>Water (max. 32.3 % at 7d)<br>Sediment (max. 26.9 % at 14d)<br>Water/sediment system (54.6 % at 7d) | PEC <sub>soil</sub> : GAP different to EU assessment<br>PEC <sub>gw</sub> : leaching potential to groundwater<br>PEC <sub>sw/sed</sub> : Required using FOCUS-STEPS to simulate drainflow/runoff from soil and formation in water/sediment |
| 1,2,4-triazole           | 69.1       |  | Water (max. 37.2 % at 121d)<br>Sediment (max. 6.1 % at 121d)<br>Water/sediment system (max. 41.8 % at 121d)                    | PEC <sub>sw/sed</sub> : Required using FOCUS-STEPS to simulate formation in water/sediment   |

## 8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### 8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Laboratory soil degradation data are available for 4 soils on prothioconazole and the relevant soil metabolites, prothioconazole-S-methyl and prothioconazole-desthio. The endpoints are summarised below in Table 8.3-1 to Table 8.3-3. The agreed endpoints from the 2007 EFSA conclusion are provided.

**Table 8.3-1: Summary of aerobic degradation rates for prothioconazole - laboratory studies**

| Incubation conditions                                 | Soil                 |          |                       | Statistical evaluation  |                         |          | Report                             |
|---|----------------------|----------|-----------------------|-------------------------|-------------------------|----------|------------------------------------|
|   | Type                 | org. C % | pH (H <sub>2</sub> O) | DT <sub>50</sub> (days) | DT <sub>90</sub> (days) | Kinetics |                                    |
| Dark, 20°C, 48% max. water holding capacity           | Sandy loam (LH)      | 2.0      | 7.2                   | 0.07                    | 5.30                    | FOMC     | Gilges, M. (2000) MR-549/99        |
|   | Silty clay loam (ST) | 1.66     | 5.9                   | 0.70                    | 78.20                   | FOMC     |                                    |
| Dark, 20°C, 50% max. water holding capacity           | Silt (HF)            | 2.14     | 7.1                   | 0.30                    | 0.99                    | SFO      | Hellpointner, E. (2001b) MR-104/01 |
|   | Loamy sand (BV)      | 0.79     | 6.8                   | 1.27                    | 4.22                    | SFO      |                                    |
| <b>Worst-case (persistence, EFSA Conclusion 2007)</b> |                      |          |                       | <b>1.27*</b>            | <b>78.20</b>            |          |                                    |
| <b>Median (EFSA Conclusion 2007)</b>                  |                      |          |                       | <b>0.50*</b>            |                         |          |                                    |
| <b>Geometric mean</b>                                 |                      |          |                       | <b>0.37*</b>            |                         |          |                                    |

\*Note that field data showed longer DT<sub>50</sub> values and was selected by EFSA as a worst-case for risk assessment

**Table 8.3-2: Summary of aerobic degradation rates for prothioconazole-S-methyl - laboratory studies**

| Incubation conditions                                   | Soil            |          |                       | Statistical evaluation  |                         |          | Report                       |
|---|-----------------|----------|-----------------------|-------------------------|-------------------------|----------|------------------------------|
|   | Type            | org. C % | pH (H <sub>2</sub> O) | DT <sub>50</sub> (days) | DT <sub>90</sub> (days) | Kinetics |                              |
| Dark, 20°C, 40% max. water holding capacity             | Loamy silt (HF) | 1.55     | 7.3                   | 5.9                     | 19.6                    | SFO      | Gilges, M. (2001a) MR 340/00 |
|   | Loamy Silt (LH) | 0.98     | 7.9                   | 27.2                    | 90.2                    | SFO      |                              |
|   | Sandy loam (LH) | 1.02     | 7.2                   | 8.2                     | 27.2                    | SFO      |                              |
|   | Silty clay (ST) | 1.46     | 6.3                   | 46.0                    | 153.0                   | SFO      |                              |
| <b>Worst-case (persistence, EFSA Conclusion 2007)</b>   |                 |          |                       | <b>46.0</b>             | <b>153.0</b>            |          |                              |
| <b>Geometric mean (modelling, EFSA Conclusion 2007)</b> |                 |          |                       | <b>15.7</b>             |                         |          |                              |

**Table 8.3-3: Summary of aerobic degradation rates for prothioconazole-dethio - laboratory studies**

| Incubation conditions                                 | Soil            |          |                       | Statistical evaluation  |                         |          | Report                          |
|---|-----------------|----------|-----------------------|-------------------------|-------------------------|----------|---------------------------------|
|   | Type            | org. C % | pH (H <sub>2</sub> O) | DT <sub>50</sub> (days) | DT <sub>90</sub> (days) | Kinetics |                                 |
| Dark, 20°C, 40% max. water holding capacity           | Loamy silt (HF) | 1.55     | 7.3                   | 34.0                    | 113.0                   | SFO      | Gilges, M. (2001b)<br>MR 327/00 |
|   | Loamy Silt (LH) | 0.98     | 7.9                   | 29.6                    | 59.2                    | SFO      |                                 |
|   | Sandy loam (LH) | 1.02     | 7.2                   | 7.0                     | 23.2                    | SFO      |                                 |
|   | Silty clay (ST) | 1.46     | 6.3                   | 18.6                    | 61.9                    | SFO      |                                 |
| <b>Worst-case (persistence, EFSA Conclusion 2007)</b> |                 |          |                       | <b>34.0*</b>            | <b>113.0*</b>           |          |                                 |
| <b>Median (EFSA Conclusion 2007)</b>                  |                 |          |                       | <b>24.1*</b>            |                         |          |                                 |
| <b>Geometric mean</b>                                 |                 |          |                       | <b>20.5*</b>            |                         |          |                                 |

\*Note that field data showed longer DT<sub>50</sub> values and was selected by EFSA as a worst-case for risk assessment

### 8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No data were provided for active substance approval. No studies are required for product assessment.

### 8.4 Field studies (KCP 9.1.1.2)

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow current guidelines (e.g. geometric means). No formulation studies are submitted or required.

#### 8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Field soil degradation data are available for 8 trials on prothioconazole and the relevant soil metabolite, prothioconazole-dethio. The endpoints are summarised below in Table 8.4-1 (as reported in the DAR).

Please note that field data was normalised using the time-step method based on measured daily temperatures and used a Q<sub>10</sub> value of 2.2. There is insufficient data in the DAR study summary to perform re-normalisation using a Q<sub>10</sub> of 2.58, therefore the values with a Q<sub>10</sub> of 2.2 were used in modelling, as they are the current agreed EU endpoint.

**Table 8.4-1: Summary of aerobic degradation rates for prothioconazole and prothioconazole-desthio - field studies**

|  |                 | Actual temperatures  |                      |                |                         |                      |                | Normalised for 20°C  |                |                         |                |
|--|-----------------|----------------------|----------------------|----------------|-------------------------|----------------------|----------------|----------------------|----------------|-------------------------|----------------|
|  |                 | Prothioconazole      |                      |                | Desthio-prothioconazole |                      |                | Prothioconazole      |                | Desthio-prothioconazole |                |
| Trial Location   | Cropped or bare | DT <sub>50</sub> (d) | DT <sub>90</sub> (d) | R <sup>2</sup> | DT <sub>50</sub> (d)    | DT <sub>90</sub> (d) | R <sup>2</sup> | DT <sub>50</sub> (d) | R <sup>2</sup> | DT <sub>50</sub> (d)    | R <sup>2</sup> |
| 51399 Höfchen, Germany                                   | Bare            | 1.9                  | 6.4                  | 1.00           | 16.3                    | 54.1                 | 0.98           | 1.2                  | 1.00           | 10.3                    | 0.99           |
| IP31 3SH, Thurston, Great Britain                        | Bare            | 1.6                  | 5.5                  | 1.00           | 54.7                    | 182                  | 0.96           | 0.8                  | 1.00           | 27.0                    | 0.98           |
| 27700 Fresne l'Archeveque, France (North)                | Bare            | 1.3                  | 4.4                  | 1.00           | 47.6                    | 158                  | 0.94           | 1.6                  | 1.00           | 27.5                    | 0.86           |
| IP31 3SH Thurston, Great Britain                         | Cropped         | 2.8                  | 9.3                  | 0.99           | 50.2                    | 167                  | 0.91           | 1.4                  | 1.00           | 23.4                    | 0.94           |
| 27700 Fresne l'Archeveque France (North)                 | Cropped         | 1.4                  | 4.5                  | 1.00           | 36.8                    | 122                  | 0.93           | 1.6                  | 1.00           | 20.1                    | 0.86           |
| 13103 St. Etienne du Gres, France (South)                | Cropped         | 1.7                  | 5.6                  | 0.99           | 72.3                    | 240                  | 0.91           | 1.1                  | 1.000          | 61.9                    | 0.97           |
| 37060 Nogarole Rocca, VR, Italy                          | Cropped         | 1.6                  | 5.4                  | 0.99           | 30.5                    | 101                  | 0.98           | 1.5                  | 1.00           | 20.7                    | 0.95           |
| 40789 Laacherhof, Germany                                | Bare            | 1.5                  | 5.1                  | 1.00           | 27.9                    | 92.6                 | 0.98           | 0.6                  | 1.00           | 15.2                    | 1.00           |
| <b>Worst-case (persistence)</b>                          |                 | <b>2.8</b>           | <b>9.3</b>           | <b>-</b>       | <b>72.3</b>             | <b>240</b>           | <b>-</b>       |                      |                |                         |                |
| <b>Geometric mean (modelling, EFSA Conclusion 2007))</b> |                 |                      |                      |                |                         |                      |                | <b>1.2</b>           | <b>-</b>       | <b>22.7</b>             | <b>-</b>       |

#### 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No soil accumulation testing was required.

#### 8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow

current guidelines (e.g. geometric means, which in all cases were more conservative if compared with the mean values). No formulation studies are submitted or required.

No batch equilibrium data could be obtained for prothioconazole due to its instability in soil. The  $K_{oc}$  was estimated from column leaching studies. Data are available on 4 soils for each of the relevant metabolites in soil and surface water (prothioconazole-S-methyl, prothioconazole-desthio, and 1,2,4-triazole), which are summarised below.

**Table 8.5-1: Summary of soil adsorption/desorption for prothioconazole**

| Prothioconazole          |            |        |                       |                       |                        |         |  |
|--------------------------|------------|--------|-----------------------|-----------------------|------------------------|---------|--|
| Soil name                | Soil type  | OC (%) | pH (H <sub>2</sub> O) | K <sub>d</sub> (mL/g) | K <sub>oc</sub> (mL/g) | 1/n (-) | Evaluated on EU level y/n/ Reference       |
| Byromville, Georgia, USA | loamy sand | 0.86   | 6.7                   | 15.2                  | 1765                   | N/A*    | Y, EFSA Scientific Report (2007) 106, 1-98 |
| pH-dependency            |            |        |                       |                       | No                     |         |  |

\* Data were taken from a column leaching study so no Freundlich coefficient is available. A worst-case value of 1 is recommended for use in modelling.

**Table 8.5-2: Summary of soil adsorption/desorption for prothioconazole-S-methyl**

| Prothioconazole-S-methyl |                 |        |                       |                       |                         |              |  |
|--------------------------|-----------------|--------|-----------------------|-----------------------|-------------------------|--------------|--|
| Soil name                | Soil type       | OC (%) | pH (H <sub>2</sub> O) | K <sub>f</sub> (mL/g) | K <sub>foc</sub> (mL/g) | 1/n (-)      | Evaluated on EU level y/n/ Reference       |
| Laacher Hof              | sandy loam      | 2.02   | 7.2                   | 56.0                  | 2772.4                  | 0.87         | Y, EFSA Scientific Report (2007) 106, 1-98 |
| Höfchen,                 | silt            | 2.14   | 7.1                   | 64.1                  | 2995.0                  | 0.88         |  |
| Stanley                  | silty clay loam | 1.66   | 5.9                   | 41.2                  | 2484.0                  | 0.91         |  |
| Byromville               | loamy sand      | 0.79   | 6.8                   | 15.6                  | 1973.6                  | 0.85         |  |
| Arithmetic mean (n=4)    |                 |        |                       |                       | 2556.3                  | <b>0.88*</b> |  |
| Geometric mean (n=4)     |                 |        |                       |                       | <b>2525.9*</b>          |              |  |
| pH-dependency            |                 |        |                       |                       | No                      |              |  |

\* Used for modelling



**Table 8.5-3: Summary of soil adsorption/desorption for prothioconazole-desthio**

| Prothioconazole-desthio                   |                 |        |                       |                       |                         |              |  |
|---|-----------------|--------|-----------------------|-----------------------|-------------------------|--------------|--|
| Soil Name                                 | Soil Type       | OC (%) | pH (H <sub>2</sub> O) | K <sub>r</sub> (mL/g) | K <sub>foc</sub> (mL/g) | 1/n (-)      | Evaluated on EU level y/n/ Reference       |
| Laacher Hof                               | sandy loam      | 2.02   | 7.2                   | 12.46                 | 616.8                   | 0.79         | Y, EFSA Scientific Report (2007) 106, 1-98 |
| Höfchen,                                  | silt            | 2.14   | 7.1                   | 13.38                 | 625.3                   | 0.83         |  |
| Stanley                                   | silty clay loam | 1.66   | 5.9                   | 8.90                  | 536.4                   | 0.83         |  |
| Byromville                                | loamy sand      | 0.79   | 6.8                   | 4.13                  | 523.0                   | 0.80         |  |
| Arithmetic mean (n=4)                     |                 |        |                       |                       | 575.4                   | <b>0.81*</b> |  |
| Geometric mean (used for modelling) (n=4) |                 |        |                       |                       | <b>573.5*</b>           |              |  |
| pH-dependency                             |                 |        |                       |                       | No                      |              |  |

\* Used for modelling

**Table 8.5-4: Summary of soil adsorption/desorption for 1,2,4-triazole**

| Prothioconazole-desthio                   |                 |        |                       |                       |                         |                    |   |
|---|-----------------|--------|-----------------------|-----------------------|-------------------------|--------------------|---|
| Soil Name                                 | Soil Type       | OC (%) | pH (H <sub>2</sub> O) | K <sub>r</sub> (mL/g) | K <sub>foc</sub> (mL/g) | 1/n (-)            | Evaluated on EU level y/n/ Reference  |
| Alpaugh                                   | silty clay      | 0.70   | 8.8                   | 0.833                 | 120                     | 0.833              | Y, EFSA Scientific Report (2007) 106, 1-98<br>Experts' meeting PRAPeR 12 (2007) |
| Hollister                                 | clay loam       | 1.74   | 6.9                   | 0.748                 | 43                      | 0.748              |   |
| Lakeland                                  | sand            | 0.12   | 4.8                   | 0.234                 | 202 <sup>†</sup>        | 0.234 <sup>†</sup> |   |
| Lawrenceville                             | silty clay loam | 0.70   | 7.0                   | 0.722                 | 104                     | 0.722              |   |
| Pachappa                                  | sandy loam      | 0.81   | 6.9                   | 0.719                 | 89                      | 0.720              |   |
| Arithmetic mean (n=4)                     |                 |        |                       |                       | 89                      | <b>0.91*</b>       |   |
| Geometric mean (used for modelling) (n=4) |                 |        |                       |                       | <b>83*</b>              |                    |   |
| pH-dependency                             |                 |        |                       |                       | No                      |                    |   |

\* Used for modelling

<sup>†</sup> Excluded from mean values as an outlier by EFSA, experts' meeting PRAPeR 12 (2007)

### 8.5.1 Column leaching (KCP 9.1.2.1)

Studies on the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

K<sub>d</sub> and K<sub>oc</sub> values of prothioconazole were determined in aged column leaching studies due to the instability of the compound in standard batch equilibrium studies. Only one soil was tested, giving a K<sub>d</sub> of 15.2 L/kg and a K<sub>oc</sub> of 1765 L/kg.

### 8.5.2 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies were not required to support the risk assessment.

### 8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies were not required to support the risk assessment.

## 8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow current guidelines (e.g. geometric means). No formulation studies are submitted or required.

**Table 8.6-1: Summary of degradation in water/sediment of prothioconazole**

| Prothioconazole Distribution (max. sediment 23.4 % after 1 day) |               |                                    |                                    |              |                               |                               |              |                              |              |  |
|---|---------------|------------------------------------|------------------------------------|--------------|-------------------------------|-------------------------------|--------------|------------------------------|--------------|--|
| Water/sediment system   | pH water/sed. | DegT <sub>50</sub> whole syst. (d) | DegT <sub>90</sub> whole syst. (d) | Kinetic, Fit | DissT <sub>50</sub> water (d) | DissT <sub>90</sub> water (d) | Kinetic, Fit | DissT <sub>50</sub> sed. (d) | Kinetic, Fit | Evaluated on EU level y/n/Reference        |
| Hönniger Weiher   | 7.84          | 2.8                                | 76.4                               | HS           | 0.8                           | 2.7                           | SFO          | n.d.                         | n.d.         | Y, EFSA Scientific Report (2007) 106, 1-98 |
| Angler Weiher   | 7.45          | 1.6                                | 23.6                               | HS           | 1.0                           | 3.4                           | SFO          | n.d.                         | n.d.         |  |
| Geometric mean (n=2)  |               | 2.2                                | 42.5                               |              | 0.9                           | 3.0                           |              | n.d.                         |              |  |

n.d. = not determined

**Table 8.6-2: Summary of observed metabolites**

|                                |   |   |
|--------------------------------|---|---|
| <b>Prothioconazole-desthio</b> | Max. in water 32.3 % after 7 d (Angler Weiher, phenyl label)  | Y, EFSA Scientific Report (2007) 106, 1-98<br>DAR Vol.3B8 |
| <b>Water/sediment system</b>   | Max. in sediment 26.9 % after 14 d (Angler Weiher, phenyl label)<br>Max. in water/sediment 54.6 % after 7 d (Angler Weiher, phenyl label)       |   |
| <b>1,2,4-Triazole</b>          | Max. in water 37.2 % after 121 d (Angler Weiher, triazole label)  |   |
| <b>Water/sediment system</b>   | Max. in sediment 4.6 % after 121 d (Angler Weiher, triazole label)<br>Max. in water/sediment 41.8 % after 121 d (Angler Weiher, triazole label) |   |
|                                |   |   |

## 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

The EU evaluation of groundwater exposure (EFSA Scientific Report (2007) 106, 1-98) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2) Therefore new calculations have been performed and are summarised below.

#### Review Comments:

The  $PEC_{soil}$  calculations for Prothioconazole, its metabolites (Prothioconazole-S-methyl, Prothioconazole-desthio) and for formulation were provided by the Notifier and are considered acceptable. The risk envelope approach was used (for details please refer to GAP table). The EU agreed endpoints were used for  $PEC_{soil}$  calculations of Prothioconazole and its metabolites.

The  $PEC_{soil}$  reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

### 8.7.1 Justification for new endpoints

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR.

### 8.7.2 Active substance(s) and relevant metabolite(s)

$PEC_{soil}$  values have been calculated following the FOCUS guidance in European Commission Document 7617/VI/96.  $PEC_{soil}$  values have been calculated for three uses, providing a risk envelope for all uses in the GAP. The worst-case use is autumn application to winter oilseed rape, due to the earlier crop growth stage and lower crop interception. A second application was simulated for spring with a worst-case interval of 90 days, but degradation over winter and a higher crop interception result in lower PEC values in spring.

The AppDate (v3.06) software was used to confirm a suitable worst-case interval for the use of winter oilseed rape between a first application at BBCH 18 in autumn and a second application when crop growth advances to BBCH 20 after the winter dormancy period. The 90d interval in the GAP, corresponding to a 3-month winter dormancy period, can be considered as conservative compared to standard FOCUS assumptions. This is a suitable worst-case that will be protective of the wide range of oilseed rape varieties available to suit different climates and farming requirements.

**Table 8.7-1: Input parameters related to application for  $PEC_{soil}$  calculations**

| GAP use number  | Covering uses 1-7   | Covering uses 8 and 11.  | Covering uses 9, 10 and 12.                     |
|---|---|--|---|
| Crop  | Cereals   | Winter oilseed rape (autumn and spring use)                        | Spring or winter oilseed rape (spring use only) |
| Application rate (g as/ha)                                    | 200 g a.s./ha   | 175 g a.s./ha  | 175 g a.s./ha                                   |
| Number of applications/interval                               | 2 / 14d   | 2 / 90d  | 2 / 14d   |
| Crop interception (%)   | 80% (BBCH 30)   | 1 <sup>st</sup> : 40% (BBCH 14)<br>2 <sup>nd</sup> : 80% (BBCH 20) | 80% (BBCH 20)                                   |
| Depth of soil layer (relevant for plateau concentration) (cm) | 5 cm (inter-crop tillage not relevant. $DT_{90}$ is < 1 year for all substances, no accumulation) |  |   |

**Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC<sub>soil</sub> calculation**

| Compound                 | Molecular weight (g/mol) | Max. occurrence (%) | DT <sub>50</sub> (days)         | Value in accordance with EU endpoint y/n/ Reference |
|--------------------------|--------------------------|---------------------|---------------------------------|---|
| Prothioconazole          | 344.26                   | -                   | 2.8 d (SFO, worst-case, field)  | Y, EFSA Scientific Report (2007) 106, 1-98          |
| Prothioconazole-S-methyl | 358.3                    | 14.6 %              | 46 d (SFO, worst-case, lab)     |   |
| Prothioconazole-desthio  | 312.2                    | 57.1 %              | 72.3 d (SFO, worst-case, field) |   |

**Table 8.7-3: PEC<sub>soil</sub> for prothioconazole on cereals**

| PEC <sub>soil</sub><br>(mg/kg)  |      | Cereals  |        |                       |        |
|---|------|--|--------|-----------------------|--------|
|   |      | Single application   |        | Multiple applications |        |
|   |      | Actual   | TWA    | Actual                | TWA    |
| Initial   |      | 0.0533   | -      | 0.0550                | -      |
| Short term  | 24h  | 0.0416   | 0.0472 | 0.0429                | 0.0487 |
|   | 2d   | 0.0325   | 0.0421 | 0.0335                | 0.0434 |
|   | 4d   | 0.0198   | 0.0339 | 0.0204                | 0.0349 |
| Long term   | 7d   | 0.0094   | 0.0253 | 0.0097                | 0.0261 |
|   | 14d  | 0.0017   | 0.0149 | 0.0017                | 0.0154 |
|   | 21d  | 0.0003   | 0.0102 | 0.0003                | 0.0105 |
|   | 28d  | 0.0001   | 0.0077 | 0.0001                | 0.0079 |
|   | 50d  | <0.0001  | 0.0043 | <0.0001               | 0.0044 |
|   | 100d | <0.0001  | 0.0022 | <0.0001               | 0.0022 |
| Plateau concentration (20 cm)   |      | Not relevant. DT <sub>90</sub> < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

**Table 8.7-4: PEC<sub>soil</sub> for prothioconazole on winter oilseed rape (autumn + spring use)**

| PEC <sub>soil</sub> (mg/kg) |     | Winter oilseed rape |               |                       |        |
|-----------------------------|-----|---------------------|---------------|-----------------------|--------|
|                             |     | Single application  |               | Multiple applications |        |
|                             |     | Actual              | TWA           | Actual                | TWA    |
| Initial                     |     | <b>0.1400</b>       | -             | 0.0467                | -      |
| Short term                  | 24h | <b>0.1093</b>       | <b>0.1240</b> | 0.0364                | 0.0413 |
|                             | 2d  | <b>0.0853</b>       | <b>0.1104</b> | 0.0284                | 0.0368 |
|                             | 4d  | <b>0.0520</b>       | <b>0.0889</b> | 0.0173                | 0.0296 |
| Long term                   | 7d  | <b>0.0247</b>       | <b>0.0665</b> | 0.0082                | 0.0222 |
|                             | 14d | <b>0.0044</b>       | <b>0.0391</b> | 0.0015                | 0.0130 |

|   |      |  |               |         |        |
|---|------|--|---------------|---------|--------|
|   | 21d  | <b>0.0008</b>  | <b>0.0268</b> | 0.0003  | 0.0089 |
|   | 28d  | <b>0.0001</b>  | <b>0.0202</b> | <0.0001 | 0.0067 |
|   | 50d  | <b>&lt;0.0001</b>  | <b>0.0113</b> | <0.0001 | 0.0038 |
|   | 100d | <b>&lt;0.0001</b>  | <b>0.0057</b> | <0.0001 | 0.0019 |
| Plateau concentration (20 cm)   |      | Not relevant. DT <sub>90</sub> < 1 year, does not accumulate |               |         |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |               |         |        |

**Bold = worst-case of all uses**

**Table 8.7-5: PEC<sub>soil</sub> for prothioconazole on spring or winter oilseed rape (spring use only)**

| PEC <sub>soil</sub><br>(mg/kg)  |      | Spring oilseed rape  |        |                       |        |
|---|------|--|--------|-----------------------|--------|
|   |      | Single application   |        | Multiple applications |        |
|   |      | Actual   | TWA    | Actual                | TWA    |
| Initial   |      | 0.0467   | -      | 0.0481                | -      |
| Short term  | 24h  | 0.0364   | 0.0413 | 0.0376                | 0.0426 |
|   | 2d   | 0.0284   | 0.0368 | 0.0293                | 0.0380 |
|   | 4d   | 0.0173   | 0.0296 | 0.0179                | 0.0305 |
| Long term   | 7d   | 0.0082   | 0.0222 | 0.0085                | 0.0229 |
|   | 14d  | 0.0015   | 0.0130 | 0.0015                | 0.0135 |
|   | 21d  | 0.0003   | 0.0089 | 0.0003                | 0.0092 |
|   | 28d  | <0.0001  | 0.0067 | <0.0001               | 0.0069 |
|   | 50d  | <0.0001  | 0.0038 | <0.0001               | 0.0039 |
|   | 100d | <0.0001  | 0.0019 | <0.0001               | 0.0019 |
| Plateau concentration (20 cm)   |      | Not relevant. DT <sub>90</sub> < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

### PEC<sub>soil</sub> of metabolites

Metabolite PEC values were determined by multiplying the parent application rate by the maximum observed level (adjusted for any molecular weight differences) and assuming SFO degradation from this peak.

**Table 8.7-6: PEC<sub>soil</sub> for prothioconazole-S-methyl on cereals**

| PEC <sub>soil</sub><br>(mg/kg) |     | Cereals            |        |                       |        |
|--------------------------------|-----|--------------------|--------|-----------------------|--------|
|                                |     | Single application |        | Multiple applications |        |
|                                |     | Actual             | TWA    | Actual                | TWA    |
| Initial                        |     | 0.0081             | -      | 0.0147                | -      |
| Short term                     | 24h | 0.0080             | 0.0080 | 0.0144                | 0.0146 |
|                                | 2d  | 0.0079             | 0.0080 | 0.0142                | 0.0144 |
|                                | 4d  | 0.0076             | 0.0079 | 0.0138                | 0.0142 |
| Long term                      | 7d  | 0.0073             | 0.0077 | 0.0132                | 0.0139 |
|                                | 14d | 0.0066             | 0.0073 | 0.0119                | 0.0132 |

|   |      |  |        |        |        |
|---|------|--|--------|--------|--------|
|   | 21d  | 0.0059   | 0.0069 | 0.0107 | 0.0126 |
|   | 28d  | 0.0053   | 0.0066 | 0.0096 | 0.0120 |
|   | 50d  | 0.0038   | 0.0057 | 0.0069 | 0.0103 |
|   | 100d | 0.0018   | 0.0042 | 0.0033 | 0.0076 |
| Plateau concentration (20 cm)   |      | Not relevant. DT90 < 1 year, does not accumulate |        |        |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |        |        |

**Table 8.7-7: PEC<sub>soil</sub> for prothioconazole-S-methyl on winter oilseed rape (autumn + spring use)**

| PEC <sub>soil</sub><br>(mg/kg)  |      | Winter oilseed rape                              |        |                       |        |
|---|------|--|--------|-----------------------|--------|
|   |      | Single application                               |        | Multiple applications |        |
|   |      | Actual   | TWA    | Actual                | TWA    |
| Initial   |      | 0.0213   | -      | 0.0126                | -      |
| Short term  | 24h  | 0.0210   | 0.0211 | 0.0124                | 0.0125 |
|   | 2d   | 0.0206   | 0.0210 | 0.0122                | 0.0124 |
|   | 4d   | 0.0200   | 0.0206 | 0.0118                | 0.0122 |
| Long term   | 7d   | 0.0191   | 0.0202 | 0.0113                | 0.0119 |
|   | 14d  | 0.0172   | 0.0192 | 0.0102                | 0.0113 |
|   | 21d  | 0.0155   | 0.0182 | 0.0092                | 0.0108 |
|   | 28d  | 0.0140   | 0.0174 | 0.0082                | 0.0103 |
|   | 50d  | 0.0100   | 0.0149 | 0.0059                | 0.0088 |
|   | 100d | 0.0047   | 0.0110 | 0.0028                | 0.0065 |
| Plateau concentration (20 cm)   |      | Not relevant. DT90 < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

**Bold = worst-case of all uses**

**Table 8.7-8:  $PEC_{soil}$  for prothioconazole-S-methyl on spring or winter oilseed rape (spring use only)**

| PEC <sub>soil</sub><br>(mg/kg)  |      | Spring oilseed rape                              |        |                       |        |
|---|------|--|--------|-----------------------|--------|
|   |      | Single application                               |        | Multiple applications |        |
|   |      | Actual   | TWA    | Actual                | TWA    |
| Initial   |      | 0.0071   | -      | 0.0128                | -      |
| Short term  | 24h  | 0.0070   | 0.0070 | 0.0126                | 0.0127 |
|   | 2d   | 0.0069   | 0.0070 | 0.0125                | 0.0126 |
|   | 4d   | 0.0067   | 0.0069 | 0.0121                | 0.0125 |
| Long term   | 7d   | 0.0064   | 0.0067 | 0.0115                | 0.0122 |
|   | 14d  | 0.0057   | 0.0064 | 0.0104                | 0.0116 |
|   | 21d  | 0.0052   | 0.0061 | 0.0094                | 0.0110 |
|   | 28d  | 0.0047   | 0.0058 | 0.0084                | 0.0105 |
|   | 50d  | 0.0033   | 0.0050 | 0.0060                | 0.0090 |
|   | 100d | 0.0016   | 0.0037 | 0.0028                | 0.0066 |
| Plateau concentration (20 cm)   |      | Not relevant. DT90 < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

**Table 8.7-9:  $PEC_{soil}$  for prothioconazole-desthio on cereals**

| PEC <sub>soil</sub><br>(mg/kg)  |      | Cereals  |        |                       |        |
|---|------|--|--------|-----------------------|--------|
|   |      | Single application                               |        | Multiple applications |        |
|   |      | Actual   | TWA    | Actual                | TWA    |
| Initial   |      | 0.0276   | -      | 0.0500                | -      |
| Short term  | 24h  | 0.0272   | 0.0274 | 0.0492                | 0.0496 |
|   | 2d   | 0.0268   | 0.0272 | 0.0485                | 0.0492 |
|   | 4d   | 0.0260   | 0.0268 | 0.0471                | 0.0485 |
| Long term   | 7d   | 0.0249   | 0.0262 | 0.0450                | 0.0474 |
|   | 14d  | 0.0224   | 0.0249 | 0.0405                | 0.0451 |
|   | 21d  | 0.0201   | 0.0237 | 0.0364                | 0.0428 |
|   | 28d  | 0.0181   | 0.0225 | 0.0328                | 0.0408 |
|   | 50d  | 0.0130   | 0.0194 | 0.0235                | 0.0351 |
|   | 100d | 0.0061   | 0.0143 | 0.0111                | 0.0258 |
| Plateau concentration (20 cm)   |      | Not relevant. DT90 < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

**Table 8.7-10: PEC<sub>soil</sub> for prothioconazole-desthio on winter oilseed rape (autumn + spring use)**

| PEC <sub>soil</sub><br>(mg/kg)   |      | Winter oilseed rape                              |        |                       |        |
|--|------|--|--------|-----------------------|--------|
|  |      | Single application                               |        | Multiple applications |        |
|  |      | Actual   | TWA    | Actual                | TWA    |
| Initial  |      | 0.0725   | -      | 0.0428                | -      |
| Short term   | 24h  | 0.0714   | 0.0720 | 0.0422                | 0.0425 |
|  | 2d   | 0.0703   | 0.0714 | 0.0416                | 0.0422 |
|  | 4d   | 0.0683   | 0.0704 | 0.0403                | 0.0416 |
| Long term  | 7d   | 0.0652   | 0.0688 | 0.0386                | 0.0407 |
|  | 14d  | 0.0587   | 0.0654 | 0.0347                | 0.0386 |
|  | 21d  | 0.0528   | 0.0621 | 0.0312                | 0.0367 |
|  | 28d  | 0.0475   | 0.0591 | 0.0281                | 0.0350 |
|  | 50d  | 0.0341   | 0.0509 | 0.0202                | 0.0301 |
|  | 100d | 0.0161   | 0.0374 | 0.0095                | 0.0221 |
| Plateau concentration (20 cm)  |      | Not relevant. DT90 < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

**Bold = worst-case of all uses**

**Table 8.7-11: PEC<sub>soil</sub> for prothioconazole-desthio on spring or winter oilseed rape (spring use only)**

| PEC <sub>soil</sub><br>(mg/kg)   |      | Spring oilseed rape                              |        |                       |        |
|--|------|--|--------|-----------------------|--------|
|  |      | Single application                               |        | Multiple applications |        |
|  |      | Actual   | TWA    | Actual                | TWA    |
| Initial  |      | 0.0242   | -      | 0.0437                | -      |
| Short term   | 24h  | 0.0238   | 0.0240 | 0.0431                | 0.0434 |
|  | 2d   | 0.0234   | 0.0238 | 0.0424                | 0.0431 |
|  | 4d   | 0.0228   | 0.0235 | 0.0412                | 0.0424 |
| Long term  | 7d   | 0.0217   | 0.0229 | 0.0394                | 0.0415 |
|  | 14d  | 0.0196   | 0.0218 | 0.0354                | 0.0394 |
|  | 21d  | 0.0176   | 0.0207 | 0.0319                | 0.0375 |
|  | 28d  | 0.0158   | 0.0197 | 0.0287                | 0.0357 |
|  | 50d  | 0.0114   | 0.0170 | 0.0206                | 0.0307 |
|  | 100d | 0.0054   | 0.0125 | 0.0097                | 0.0226 |
| Plateau concentration (20 cm)  |      | Not relevant. DT90 < 1 year, does not accumulate |        |                       |        |
| PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> ) |      |  |        |                       |        |

#### PEC<sub>soil</sub> of formulation

Please note that only the instantaneous PEC<sub>soil</sub> following a single application is relevant, since the formulation will immediately separate into its components, which then degrade at different rates. The calculation of winter oilseed rape at its earliest stage can be considered as a risk envelope for all other uses.



**Table 8.7-12: PEC<sub>soil</sub> for formulation**

| Preparation                | Use/Crop                                | Application rate (L/ha) | Product density (g/L)* | Application rate (g/ha) | Crop interception | PEC <sub>act</sub> (mg/kg) |
|----------------------------|---|-------------------------|------------------------|-------------------------|-------------------|----------------------------|
| Prothioconazole<br>250 g/L | Winter oilseed<br>rape (worst-<br>case) | 0.7                     | 994.8                  | 696.4                   | 40%               | 0.557                      |

\* Taken from KCP 2.6.1 (Ge, H., 2019a)

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

The EU evaluation of groundwater exposure (EFSA Scientific Report (2007) 106, 1-98) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2) and did not include modelling according to current FOCUS and EFSA guidelines. Therefore new modelling has been performed and is summarised below.

### Review Comments:

The PEC<sub>GW</sub> calculations for Prothioconazole and its metabolites (Prothioconazole-S-methyl, Prothioconazole-desthio) were provided by the Notifier and are considered acceptable.

For active substance and its relevant metabolites PEC<sub>GW</sub> calculations were performed with FOCUS MACRO 5.5.4 and new versions of models: FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. The EU agreed endpoints were used. Geometric mean K<sub>foc</sub> and K<sub>fom</sub> (instead of an arithmetic mean K<sub>foc</sub> and K<sub>fom</sub>) for all compounds were derived from the datasets presented in the EFSA Scientific Report (2007) 106, 1-98 for consistency with current EU Guidance [EFSA (2014): *EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3362*].

The PEC<sub>GW</sub> of Prothioconazole (80<sup>th</sup> percentile) at 1 m depth following uses on cereals and oilseed rape at the proposed maximum rates, were less than 0.001 µg/L in all scenarios. The potential for the metabolites Prothioconazole-S-methyl and Prothioconazole-desthio to leach to ground water has been assessed using the same approach. The PEC<sub>GW</sub> of Prothioconazole-S-methyl and Prothioconazole-desthio were less than 0.001 µg/L in all scenarios.

In conclusion, the results demonstrate that JOUST can be applied safely according to the recommended use patterns without risk of Prothioconazole, Prothioconazole-S-methyl and Prothioconazole-desthio exceeding acceptable levels in groundwater.

### 8.8.1 Justification for new endpoints

All endpoints are taken from the data in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR. In general, the selection of modelling endpoints followed the EFSA 2007 modelling values for PELMO modelling. However, a minor change to the FOCUS guidance now requires geometric means to be used for K<sub>foc</sub>. EU member states have varying requirements for the recalculation of geometric means in cases where older EFSA conclusions have used an arithmetic mean. The applicant has chosen to use geometric means, as these provide a more conservative endpoint (higher soil mobility) and avoid the need for evaluating separate models for each EU zone and member state. In all cases, the differences between geometric and arithmetic mean values are very

small and are not expected to result in significantly different PEC values. The differences are summarised below in Table 8.8-1.

**Table 8.8-1: Justification of new  $K_{foc}$  endpoints used in modelling**

| Substance                | Endpoint  | EFSA (2007) modelling endpoint | New modelling endpoint  | Justification  |
|--------------------------|-----------|--------------------------------|-------------------------|--|
| Prothioconazole-S-methyl | $K_{foc}$ | 2556.3 (arithmetic mean)       | 2525.9 (geometric mean) | EFSA 2007 did not include suitable FOCUS modelling and new models were required. Geometric means follow current modelling guidelines and result in a more conservative risk assessment. Differences are small and will not result in significantly different PEC values. |
| Prothioconazole-desthio  | $K_{foc}$ | 575.4 (arithmetic mean)        | 573.5 (geometric mean)  |  |

## 8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

PEC<sub>gw</sub> values have been calculated for uses on winter and spring varieties of both oilseed rape and cereals, providing a risk envelope for all uses in the GAP. The application scenarios are summarised in Table 8.8-2 and the modelling was provided in the report summarised below.

**Table 8.8-2: Input parameters related to application for PEC<sub>gw</sub> calculations**

| GAP use number                      | 8 (covering 11)   | 9                         | 10 (covering 12)         |
|-------------------------------------|---|---------------------------|--------------------------|
| Crop                                | Winter OSR (autumn/spring)  | Winter OSR (spring)       | Spring OSR (spring)      |
| Application rate (g as/ha)          | 175   | 175                       | 175                      |
| Number of applications/interval (d) | 2 / Scenario specific, based on length of winter dormancy period* | 2 / 14                    | 2 / 14**                 |
| Relative application date           | AppDate (v3.06): BBCH 14 + BBCH 21*                               | AppDate (v3.06): BBCH 21* | AppDate (v3.06): BBCH 20 |
| Crop interception (%)               | 40 (BBCH 14)<br>80 (BBCH 21)                                      | 80                        | 80                       |
| Application to soil (g as/ha)       | 105 (BBCH 14)<br>35 (BBCH 21)                                     | 35                        | 35                       |
| Frequency of application            | Annual  |                           |                          |
| Models used for calculation         | FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4        |                           |                          |

\* Note that AppDate assumes that BBCH 20 is reached in autumn, so BBCH 21 was used to determine the re-start of growth after the winter dormancy period, when the product would be applied. In some southern EU winter OSR scenarios (Piacenza, Porto), BBCH 21 is reached before spring, which would result in applications during winter. The product GAP requires applications to be made in spring, therefore 1<sup>st</sup> March is used as a conservative worst-case timing.

\*\* The GAP for Spring OSR includes only one application. Two applications were used as a worst-case to cover minor crops that use OSR as a surrogate. The use of 2 applications provides a protective risk envelope for spring OSR.

| GAP use number                      | 4 (covering 1, 3, 5, 6, 7)                                    | 4 (covering 2, 3, 5, 6, 7)  |
|-------------------------------------|---|-----------------------------|
| Crop                                | Winter cereals  | Spring cereals              |
| Application rate (g as/ha)          | 200   | 200                         |
| Number of applications/interval (d) | 2 / 14  | 2 / 14                      |
| Relative application date           | AppDate (v3.06):<br>BBCH 30*                                  | AppDate (v3.06):<br>BBCH 30 |
| Crop interception (%)               | 80  | 80                          |
| Application to soil (g as/ha)       | 40  | 40                          |
| Frequency of application            | Annual  |                             |
| Models used for calculation         | FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4,<br>FOCUS MACRO v5.5.4 |                             |

\* In some EU winter cereals scenarios (Porto, Sevilla, Thiva), BBCH 30 is reached before spring, which would result in applications during winter. The product GAP requires applications to be made in spring, therefore 1<sup>st</sup> March is used as a conservative worst-case timing.

|   |  |
|---|--|
| <b>Data point:</b>                                  | K-CP 9.2.4/01  |
| <b>Report author</b>                                | M. Hale  |
| <b>Report year</b>                                  | 2021   |
| <b>Report title</b>                                 | Prothioconazole: Predicted Environmental Concentrations in Groundwater Following Application to Cereals and Oilseed Rape, Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO |
| <b>Report No</b>                                    | 21/122   |
| <b>Document No</b>                                  | Not applicable   |
| <b>Guidelines followed in study</b>                 | FOCUS  |
| <b>Deviations from current test guideline</b>       | None   |
| <b>Previous evaluation</b>                          | None   |
| <b>GLP/Officially recognised testing facilities</b> | NA   |
| <b>Acceptability/Reliability:</b>                   | Yes  |

The risk to groundwater was assessed through simulations using the environmental fate models FOCUS-PEARL (v5.5.5), FOCUS-PELMO (v6.6.4) and FOCUS-MACRO (v5.5.4). For uses that span a large range of growth stages, the earliest growth stage was used as a worst-case to determine the crop interception. Application dates were set using AppDate (v3.06) to provide the date at which the target BBCH stage is reached in each FOCUS scenario, while remaining within the seasonal timings specified in the GAP. The absolute application timings are given in Table 8.8-3.

**Table 8.8-3: Application dates used for groundwater risk assessment**

| Application dates (absolute) |                               |                     |                     |
|------------------------------|-------------------------------|---------------------|---------------------|
| Scenario                     | Winter OSR<br>(autumn/spring) | Winter OSR (spring) | Spring OSR (spring) |
| Châteaudun                   | 14/09, 02/03                  | 02/03, 16/03        | -                   |
| Hamburg                      | 09/09, 09/04                  | 09/04, 23/04        | -                   |
| Jokioinen                    | -                             | -                   | 01/06, 15/06        |
| Kremsmünster                 | 09/09, 06/04                  | 06/04, 20/04        | -                   |
| Okehampton                   | 21/08, 31/03                  | 31/03, 14/04        | 11/04, 25/04        |
| Piacenza                     | 12/10, 01/03                  | 01/03, 15/03        | -                   |
| Porto                        | 30/09, 01/03                  | 01/03, 15/03        | 09/04, 23/04        |
| Sevilla                      | -                             | -                   | -                   |
| Thiva                        | -                             | -                   | -                   |

| Application dates (absolute) |                |                |
|------------------------------|----------------|----------------|
| Scenario                     | Winter cereals | Spring cereals |
| Châteaudun                   | 15/04, 29/04   | 16/04, 30/04   |
| Hamburg                      | 04/05, 18/05   | 28/04, 12/05   |
| Jokioinen                    | 04/05, 18/05   | 05/06, 19/06   |
| Kremsmünster                 | 24/04, 08/05   | 27/04, 11/05   |
| Okehampton                   | 21/04, 05/05   | 22/04, 06/05   |
| Piacenza                     | 19/03, 02/04   | -              |
| Porto                        | 01/03, 15/03   | 02/04, 16/04   |
| Sevilla                      | 01/03, 15/03   | -              |
| Thiva                        | 01/03, 15/03   | -              |

Input parameters for prothioconazole and its relevant metabolites were taken from the EU agreed endpoints in the EFSA conclusion and the associated data in the DAR. A summary of the environmental fate parameters is given in Table 8.8-4 to Table 8.8-6. Any parameters not mentioned below were left at the default recommendation of the models.

**Table 8.8-4: Input parameters related to prothioconazole for  $PEC_{gw}$   $PEC_{sw/sed}$  calculations**

| Parameter                                  | Prothioconazole   | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
| Molecular weight (g/mol)                   | 344.26  | Y, EFSA (2007)   |
| Saturated vapour pressure (Pa)             | 0 (20°C)  | Y, EFSA (2007)*<br>(default worst-case)                |
| Water solubility (mg/L)                    | 2000 (20°C, pH 9, worst-case)   | Y, EFSA (2007)   |
| DT <sub>50,soil</sub> (d)                  | 1.2 (geomean, field, normalisation to 20°C with Q <sub>10</sub> of 2.2, n =8) | Y, EFSA (2007), RAR (2005)**                           |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g) | 1765/1024 (n=1)   | Y, EFSA (2007)   |
| Freundlich Exponent 1/n                    | 1   | Y, EFSA (2007)<br>(default worst-case)                 |
| Plant Uptake                               | 0   | Default  |

\* EFSA (2007) gives a vapour pressure of “ $<< 4 \times 10^{-7}$  Pa”, below the minimum detectable is testing. A value of 0 was used as a worst-case to prevent volatile losses from soil and water.

\*\* Field DT<sub>50</sub> is significantly greater than lab value and is a worst-case even with Q<sub>10</sub> of 2.2. The RAR does not contain sufficient data to renormalise the field DT<sub>50</sub> using a Q<sub>10</sub> of 2.58.

**Table 8.8-5: Input parameters related to prothioconazole-S-methyl for  $PEC_{sw/sed}$  calculations**

| Parameter                                  | Prothioconazole-S-methyl                | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
| Molecular weight (g/mol)                   | 358.3                                   | Y, EFSA (2007)   |
| Saturated vapour pressure (Pa)             | 0 (20°C)                                | Worst-case default                                     |
| Water solubility (mg/L)                    | $1 \times 10^6$ (20°C)                  | Worst-case default                                     |
| DT <sub>50,soil</sub> (d)                  | 15.7 (geometric mean, n=4)              | Y, EFSA (2007), RAR (2005)                             |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g) | 2525.9 / 1465.1 (geometric mean, n = 4) | Y, EFSA (2007), RAR (2005)*                            |
| Freundlich Exponent, 1/n                   | 0.88 (arithmetic mean, n = 4)           | Y, EFSA (2007), RAR (2005)                             |
| Plant Uptake                               | 0                                       | Default  |
| Formation fraction in soil:                | 0.146 (from prothioconazole)            | Y, EFSA (2007)   |

\* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU value in EFSA (2007) which was 2556.3 mL/g.

**Table 8.8-6: Input parameters related to prothioconazole-desthio for PEC<sub>sw/sed</sub> calculations**

| Parameter                                  | Prothioconazole-desthio   | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
| Molecular weight (g/mol)                   | 312.2   | Y, EFSA (2007), RAR (2005)                             |
| Saturated vapour pressure (Pa)             | 0 (20°C)  | Worst-case default                                     |
| Water solubility (mg/L)                    | 1×10 <sup>6</sup> (20°C)  | Worst-case default                                     |
| DT <sub>50,soil</sub> (d)                  | 22.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q <sub>10</sub> of 2.2, n =8)** | Y, EFSA (2007), RAR (2005)                             |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g) | 573.5 / 332.7 (geometric mean, n = 4)   | Y, EFSA (2007), RAR (2005)*                            |
| Freundlich Exponent 1/n                    | 0.81 (arithmetic mean, n = 4)   | Y, EFSA (2007), RAR (2005)                             |
| Plant Uptake                               | 0   | Worst-case default                                     |
| Formation fraction in soil:                | 0.571 (from prothioconazole)  | Y, EFSA (2007)   |

\* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU value in EFSA (2007) which was 575.4 mL/g.

\*\* Field DT<sub>50</sub> is significantly greater than lab value and is a worst-case even with Q<sub>10</sub> of 2.2. The RAR does not contain sufficient data to renormalise the field DT<sub>50</sub> using a Q<sub>10</sub> of 2.58.

The PEC<sub>gw</sub> results from FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO are summarised in Table 8.8-7, Table 8.8-8, and Table 8.8-9 for prothioconazole, prothioconazole-S-methyl, and prothioconazole-desthio, respectively.

**Table 8.8-7: PEC<sub>gw</sub> for prothioconazole**

| Crop                                     | Scenario     | 80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L) |               |               |
|--|--------------|--|---------------|---------------|
|  |              | PEARL (5.5.5)  | PELMO (6.6.4) | MACRO (5.5.4) |
| Winter OSR (autumn + spring application) | Châteaudun   | <0.001   | <0.001        | <0.001        |
|  | Hamburg      | <0.001   | <0.001        | -             |
|  | Kremsmünster | <0.001   | <0.001        | -             |
|  | Okehampton   | <0.001   | <0.001        | -             |
|  | Piacenza     | <0.001   | <0.001        | -             |
|  | Porto        | <0.001   | <0.001        | -             |
|  | Sevilla      | <0.001   | <0.001        | -             |
|  | Thiva        | <0.001   | <0.001        | -             |
| Winter OSR (two spring applications)     | Châteaudun   | <0.001   | <0.001        | <0.001        |
|  | Hamburg      | <0.001   | <0.001        | -             |
|  | Kremsmünster | <0.001   | <0.001        | -             |
|  | Okehampton   | <0.001   | <0.001        | -             |
|  | Piacenza     | <0.001   | <0.001        | -             |
|  | Porto        | <0.001   | <0.001        | -             |

| Crop           | Scenario     | 80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L) |               |               |
|----------------|--------------|--|---------------|---------------|
|                |              | PEARL (5.5.5)  | PELMO (6.6.4) | MACRO (5.5.4) |
|                | Sevilla      | <0.001   | <0.001        | -             |
|                | Thiva        | <0.001   | <0.001        | -             |
|                |              |  |               |               |
| Spring OSR     | Jokioinen    | <0.001   | <0.001        | <0.001        |
|                | Okehampton   | <0.001   | <0.001        | -             |
|                | Piacenza     | <0.001   | <0.001        | -             |
|                | Porto        | <0.001   | <0.001        | -             |
| Winter cereals | Châteaudun   | <0.001   | <0.001        | <0.001        |
|                | Hamburg      | <0.001   | <0.001        | -             |
|                | Jokioinen    | <0.001   | <0.001        | -             |
|                | Kremsmünster | <0.001   | <0.001        | -             |
|                | Okehampton   | <0.001   | <0.001        | -             |
|                | Piacenza     | <0.001   | <0.001        | -             |
|                | Porto        | <0.001   | <0.001        | -             |
|                | Sevilla      | <0.001   | <0.001        | -             |
|                | Thiva        | <0.001   | <0.001        | -             |
| Spring cereals | Châteaudun   | <0.001   | <0.001        | <0.001        |
|                | Hamburg      | <0.001   | <0.001        | -             |
|                | Jokioinen    | <0.001   | <0.001        | -             |
|                | Kremsmünster | <0.001   | <0.001        | -             |
|                | Okehampton   | <0.001   | <0.001        | -             |
|                | Porto        | <0.001   | <0.001        | -             |

**Table 8.8-8: PEC<sub>gw</sub> for prothioconazole-S-methyl**

| Crop  | Scenario     | 80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L) |               |               |
|---|--------------|--|---------------|---------------|
|   |              | PEARL (5.5.5)  | PELMO (6.6.4) | MACRO (5.5.4) |
| Winter OSR<br>(autumn +<br>spring<br>application) | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |

| Crop                                    | Scenario     | 80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L) |               |               |
|---|--------------|--|---------------|---------------|
|   |              | PEARL (5.5.5)  | PELMO (6.6.4) | MACRO (5.5.4) |
| Winter OSR<br>(two spring applications) | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |
| Spring OSR                              | Jokioinen    | <0.001   | <0.001        | <0.001        |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
| Winter cereals                          | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Jokioinen    | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |
| Spring cereals                          | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Jokioinen    | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |



**Table 8.8-9: PEC<sub>gw</sub> for prothioconazole-desthio**

| Crop  | Scenario     | 80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L) |               |               |
|---|--------------|--|---------------|---------------|
|   |              | PEARL (5.5.5)  | PELMO (6.6.4) | MACRO (5.5.4) |
| Winter OSR<br>(autumn +<br>spring<br>application) | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |
| Winter OSR<br>(two spring<br>applications)        | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |
| Spring OSR  | Jokioinen    | <0.001   | <0.001        | <0.001        |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
| Winter<br>cereals                                 | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Jokioinen    | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Piacenza     | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |
|   | Sevilla      | <0.001   | <0.001        | -             |
|   | Thiva        | <0.001   | <0.001        | -             |
| Spring<br>cereals                                 | Châteaudun   | <0.001   | <0.001        | <0.001        |
|   | Hamburg      | <0.001   | <0.001        | -             |
|   | Jokioinen    | <0.001   | <0.001        | -             |
|   | Kremsmünster | <0.001   | <0.001        | -             |
|   | Okehampton   | <0.001   | <0.001        | -             |
|   | Porto        | <0.001   | <0.001        | -             |

PEC<sub>gw</sub> values were <0.001 µg/L in all models, for all substances, scenarios, and crops. The risk to groundwater was determined to be acceptable for all simulated uses of CA3301.

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

The EU evaluation of surface water exposure (EFSA Scientific Report (2007) 106, 1-98) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2) and did not include modelling according to current FOCUS and EFSA guidelines. Therefore, new modelling has been performed and is summarised below.

### Review Comments:

The PEC<sub>SW/SED</sub> calculations for Prothioconazole and its metabolites (Prothioconazole-S-methyl, Prothioconazole-desthio, 1,2,4-Triazole) were provided by the Notifier and are considered acceptable. For active substance and its relevant metabolites PEC<sub>sw</sub> calculations were performed with FOCUS STEPS 1-2 (active substance and all its metabolites) and FOCUS STEP 3 (active substance and Prothioconazole-desthio) and FOCUS STEP 4 (Prothioconazole-desthio).

The EU agreed endpoints were used. Geometric mean K<sub>foc</sub> and K<sub>fom</sub> (instead of an arithmetic mean K<sub>foc</sub> and K<sub>fom</sub>) for all compounds were derived from the datasets presented in the EFSA Scientific Report (2007) 106, 1-98 for consistency with current EU Guidance [EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3362].

The formulation PEC<sub>sw</sub> calculations were accepted.

The PEC<sub>sw</sub> reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

### 8.9.1 Justification for new endpoints

All endpoints are taken from the data in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR. FOCUS modelling was not used in the EFSA 2007 conclusion, so agreed modelling endpoints were not available. The selection of surface water modelling endpoints followed the EFSA 2007 groundwater modelling values for FOCUS-PELMO (e.g. geometric mean DT<sub>50</sub> values). However, a minor change to the FOCUS guidance now requires geometric means to be used for K<sub>foc</sub>. EU member states have varying requirements for the recalculation of geometric means in cases where older EFSA conclusions have used an arithmetic mean. The applicant has chosen to use geometric means, as these provide a more conservative endpoint (higher soil mobility) and avoid the need for evaluating separate models for each EU zone and member state. In all cases, the differences between geometric and arithmetic mean values are very small and are not expected to result in significantly different PEC values. The differences are summarised below in Table 8.9-1.

**Table 8.9-1: Justification of new  $K_{\text{foc}}$  endpoints used in modelling**

| Substance                | Endpoint         | EFSA (2007) modelling endpoint | New modelling endpoint  | Justification  |
|--------------------------|------------------|--------------------------------|-------------------------|--|
| Prothioconazole-S-methyl | $K_{\text{foc}}$ | 2556.3 (arithmetic mean)       | 2525.9 (geometric mean) | EFSA 2007 did not include suitable FOCUS modelling and new models were required. Geometric means follow current modelling guidelines and result in a more conservative risk assessment. Differences are small and will not result in significantly different PEC values. |
| Prothioconazole-desthio  | $K_{\text{foc}}$ | 575.4 (arithmetic mean)        | 573.5 (geometric mean)  |  |
| 1,2,4-Triazole           | $K_{\text{foc}}$ | 89 (arithmetic mean)           | 83 (geometric mean)     |  |

### 8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

PEC values for prothioconazole and all relevant metabolites were determined at FOCUS STEPS 1-2. FOCUS STEP 3 and 4 models were required for prothioconazole and the metabolite prothioconazole-desthio, with the metabolite being the most significant compound for risk assessment due to its relatively high ecotoxicity compared to the active substance (please refer to Part B9 for further information on ecotoxicity).  $PEC_{sw}$  values were calculated for single and multiple applications for uses on spring cereals, winter cereals, spring oilseed rape and winter oilseed rape, which provide a risk envelope for all uses in the GAP. The modelling was provided in the report below. The report contains calculations for all available FOCUS scenarios, while this summary is restricted to the scenarios relevant in the Central Zone.

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|   |   |
|---|---|
| <b>Data point:</b>                                  | K-CP 9.2.5/01   |
| <b>Report author</b>                                | M. Hale   |
| <b>Report year</b>                                  | 2021  |
| <b>Report title</b>                                 | Prothioconazole: Predicted Environmental Concentrations in Surface Water Following Application to Cereals and Oilseed Rape, Using FOCUS STEPS 1-4 |
| <b>Report No</b>                                    | 21/119  |
| <b>Document No</b>                                  | Not applicable  |
| <b>Guidelines followed in study</b>                 | FOCUS   |
| <b>Deviations from current test guideline</b>       | None  |
| <b>Previous evaluation</b>                          | None  |
| <b>GLP/Officially recognised testing facilities</b> | NA  |
| <b>Acceptability/Reliability:</b>                   | Yes   |

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For simulations at STEPS 1 to 4, modelling was performed for all available FOCUS scenarios that are defined for the relevant crop type. Application windows were set by using AppDate (v3.06) program to provide dates for the BBCH recommendations in the GAP. The exact application timings were automatically selected by the model, based on the application window and method of application. Full details are given in Table 8.9-2.

**Table 8.9-2: Input parameters related to application for  $PEC_{sw/sed}$  calculations**

| GAP use number                      | 8 (covering 11)   | 9   | 10 (covering 12)  |
|-------------------------------------|---|---|---|
| Crop                                | Winter OSR<br>(autumn/spring use)   | Winter OSR (spring use)   | Spring OSR (spring use)   |
| FOCUS-STEPS Crop Group              | Winter OSR  | Winter OSR  | Spring OSR  |
| FOCUS STEPS 1-2 parameters          | Oct-Feb<br>Minimal crop cover   | Mar-May, Jun-Sep<br>Average crop cover  | Mar-May, Jun-Sep<br>Average crop cover  |
| FOCUS STEP 3 Locations              | Scenarios relevant in the Central zone  | Scenarios relevant in the Central zone  | Scenarios relevant in the Central zone  |
| Application window                  | BBCH 14 (autumn)<br>BBCH 21 (spring)<br><br>2 Applications:<br>D3: 252-73 (156)<br>D4: 253-81 (163)<br>D5: 270-81 (146)<br>R1: 254-126 (207)<br>R3: 285-87 (137)<br>1 Application:<br>D3: 252-282<br>D4: 253-283<br>D5: 270-300<br>R1: 254-284<br>R3: 285-315 | BBCH 20 (spring)<br><br>(Appdate BBCH 21)<br><br>2 Applications:<br>D3: 43-87<br>D4: 51-95<br>D5: 51-95<br>R1: 96-140<br>R3: 57-101<br>1 Application:<br>D3: 43-73<br>D4: 51-81<br>D5: 51-81<br>R1: 96-126<br>R3: 57-87 | BBCH 20 (spring)<br><br>2 Applications:<br>D3: 117-161<br>D4 : 134-178<br>D5 : 93-137<br>R1 : 115-159<br>1 Application:<br>D3: 117-147<br>D4 : 134-164<br>D5 : 93-123<br>R1 : 115-145 |
| Application method                  | Foliar spray  | Foliar spray  | Foliar spray  |
| Application rate (g as/ha)          | 175   | 175   | 175   |
| Number of applications/interval (d) | 2 / (see above)*  | 2 / 14 **   | 2 / 14 d **   |
| CAM (Chemical application method)   | 2   | 2   | 2   |
| Soil depth (cm)                     | 4   | 4   | 4   |
| Models used for calculation         | FOCUS SWASH v5.3, FOCUS PRZM v4.3.1,<br>FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3  |   |   |

| GAP use number                      | 4 (covering 1, 3, 5, 6, 7)  | 4 (covering 2, 3, 5, 6, 7)   |
|-------------------------------------|---|--|
| Crop                                | Winter cereals  | Spring cereals   |
| FOCUS-STEPS Crop Group              | Winter cereals  | Spring cereals   |
| FOCUS STEPS 1-2 parameters          | Mar-May, Jun-Sep<br>Average crop cover  | Mar-May, Jun-Sep<br>Average crop cover   |
| FOCUS Locations                     | Scenarios relevant in the Central zone  | Scenarios relevant in the Central zone   |
| Application window                  | BBCH 30<br><br>2 Applications:<br>D3: 106-150<br>D4: 77-121<br>D5: 74-118<br>R1: 114-158<br>R3: 78-122<br>R4: 60-104†<br>1 Application:<br>D3: 106-136<br>D4: 77-107<br>D5: 74-104<br>R1: 114-144<br>R3: 78-108<br>R4: 30-60† | BBCH 30<br><br>2 Applications:<br>D3: 118-162<br>D4: 138-182<br>D5: 99-143<br>R4: 99-143<br>1 Application:<br>D3: 118-148<br>D4: 138-168<br>D5: 99-129<br>R4: 99-129 |
| Application method                  | Foliar spray  | Foliar spray   |
| Application rate (kg as/ha)         | 200   | 200  |
| Number of applications/interval (d) | 2 / 14 d **   | 2 / 14 d **  |
| CAM (Chemical application method)   | 2   | 2  |
| Soil depth (cm)                     | 4   | 4  |
| Models used for calculation         | FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3   |  |

\* At STEPS 1-2, a 90d interval was used. At STEPS 3-4, intervals were set such that FOCUS STEPS will simulate the applications in a 30d window around BBCH 14 (in autumn) and BBCH 21 (in spring), using timings from AppDate. Note that AppDate assumes that BBCH 20 is reached in autumn, so BBCH 21 was used. Some spring applications are predicted to occur before spring (in late February), but this was considered a protective worst-case, given the difficulty of modelling autumn and spring use in the FOCUS model

\*\* An additional set of modelling was performed using 1 application, since this can result in higher PEC values as TOXSWA uses a lower spray-drift percentage for multiple applications.

† BBCH 30 is reached very early in these scenarios (e.g. R4 = 24<sup>th</sup> Jan), which is not compatible with the GAP requirement of spring application. Start of window was set to 1<sup>st</sup> March as a realistic earliest date for spring application.

It should be noted that the application intervals for winter oilseed rape are generally longer than the minimum of 90d specified in the GAP. Application timings are based on crop growth stages and such a short interval is only agronomically possible if the weather is very mild, with a short winter dormancy period before crops resume growth in spring. Prothioconazole is only agronomically effective when applied to growing crops and will not be applied during the winter dormancy period. The FOCUS scenarios use worst-case (cold/wet) weather for every scenario, which results in longer winter dormancy. Thus, a longer interval is required to simulate applications at the correct crop growth stages and climate. The longer intervals are considered protective of a shorter interval, as a mild winter and “early spring” with a short dormancy period would result in greater degradation due to warmer weather. The application timings chosen by the model are given below in Table 8.9-3.

**Table 8.9-3: FOCUS STEP 3 application timings**

| Crop                                     | Scenario | Application window used in modelling<br>(Day numbers)* | Actual dates selected by the model |
|--|----------|--|------------------------------------|
| Winter oilseed rape<br>(autumn + spring) | D3       | 252-73   | 26 Sept, 1 Mar                     |
|  | D4       | 253-81   | 10 Sep, 14 Mar                     |
|  | D5       | 270-81   | 26 Oct, 21 Mar                     |
|  | R1       | 254-126  | 17 Sep, 13 Apr                     |
|  | R3       | 285-87   | 27 Oct, 20 Mar                     |
| Winter oilseed rape<br>(spring-only)     | D3       | 43-87  | 29 Feb, 16 Mar                     |
|  | D4       | 51-95  | 24 Feb, 19 Mar                     |
|  | D5       | 51-95  | 21 Feb, 7 Mar                      |
|  | R1       | 96-140   | 7 Apr, 26 Apr                      |
|  | R3       | 57-101   | 26 Feb, 20 Mar                     |
| Spring oilseed rape                      | D3       | 117-161  | 4 May, 22 May                      |
|  | D4       | 134-178  | 30 May, 16 Jun                     |
|  | D5       | 93-123   | 8 Apr, 22 Apr                      |
|  | R1       | 115-145  | 26 Apr, 10 May                     |
| Winter cereals                           | D3       | 106-150  | 20 Apr, 4 May                      |
|  | D4       | 77-121   | 19 Mar, 18 Apr                     |
|  | D5       | 74-118   | 8 Apr, 22 Apr                      |
|  | R1       | 114-158  | 26 Apr, 10 May                     |
|  | R3       | 78-122   | 28 Mar, 11 Apr                     |
|  | R4       | 60-104   | 5 Mar, 21 Mar                      |
| Spring cereals                           | D3       | 118-162  | 4 May, 18 May                      |
|  | D4       | 138-182  | 30 May, 16 Jun                     |
|  | D5       | 99-143   | 14 Apr, 11 May                     |
|  | R4       | 99-143   | 4 May, 20 May                      |

\* Single application models used a 30d window starting at the earliest day number

At STEP 4, the SWAN tool was used to modify the drift and runoff input factors used by TOXSWA, based on vegetated buffer strips of 10 and 20 meters. Runoff mitigation factors were taken from the guidance document SANCO/10422/2005 and are summarised below in Table 8.9-4. The SWAN tool applies these factors to the PRZM runoff loading file.

**Table 8.9-4: Runoff mitigation factors**

|                            | 10m vegetated filter strip | 20m vegetated filter strip |
|----------------------------|----------------------------|----------------------------|
| Reduction in runoff volume | 60%                        | 80%                        |
| Reduction in runoff volume | 60%                        | 80%                        |
| Reduction in erosion mass  | 85%                        | 95%                        |
| Reduction in erosion flux  | 85%                        | 95%                        |

Input parameters for prothioconazole and its relevant metabolites were taken from the EU agreed endpoints in the EFSA conclusion and the associated data in the DAR. A summary of the environmental fate parameters is given in Table 8.9-5 to Table 8.9-8. Any parameters not mentioned below were left at the default recommendation of the models.

**Table 8.9-5: Input parameters related to prothioconazole for  $PEC_{sw/sed}$  calculations**

| Parameter  | Prothioconazole   | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
| Molecular weight (g/mol)                           | 344.26  | Y, EFSA (2007)   |
| Saturated vapour pressure (Pa)                     | 0 (20°C)  | Y, EFSA (2007)*<br>(default worst-case)                |
| Water solubility (mg/L)                            | 2000 (20°C, pH 9, worst-case)   | Y, EFSA (2007)   |
| Diffusion coefficient in water (m <sup>2</sup> /d) | not required for Step 1+2/<br>4.3 x 10 <sup>-5</sup>                            | default  |
| Diffusion coefficient in air (m <sup>2</sup> /d)   | not required for Step 1+2/0.43  | default  |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g)         | 1765/1024 (n=1)   | Y, EFSA (2007)   |
| Freundlich Exponent<br>1/n                         | 1   | Y, EFSA (2007)<br>(default worst-case)                 |
| Plant Uptake                                       | 0   | Default  |
| Wash-Off factor from Crop (1/mm)                   | not required for Step 1+2/<br>0.05 (MACRO)<br>0.50 (PRZM)                       |  |
| DT <sub>50,soil</sub> (d)                          | 1.2 (geomean, field, normalisation to<br>20°C with Q <sub>10</sub> of 2.2, n=8) | Y, EFSA (2007), RAR<br>(2005)**                        |
| DT <sub>50,water</sub> (d)                         | 2.2 (geomean whole system, n=2)   | Y, EFSA (2007)   |
| DT <sub>50,sed</sub> (d)                           | 2.2 (geomean whole system, n=2)   | Y, EFSA (2007)   |
| DT <sub>50,whole system</sub> (d)                  | STEPS 1-2: 2.2 (geomean whole<br>system, n=2)<br>STEPS 3-4: Not used            | Y, EFSA (2007)   |

\* EFSA (2007) gives a vapour pressure of “<< 4 × 10<sup>-7</sup> Pa”, below the minimum detectable is testing. A value of 0 was used as a worst-case to prevent volatile losses from soil and water.

\*\* Field DT<sub>50</sub> is significantly greater than lab value and is a worst-case even with Q<sub>10</sub> of 2.2. The RAR does not contain sufficient data to renormalise the field DT<sub>50</sub> using a Q<sub>10</sub> of 2.58.

**Table 8.9-6: Input parameters related to prothioconazole-S-methyl for  $PEC_{sw/sed}$  calculations**

| Parameter  | Prothioconazole-S-methyl             | Value in accordance with EU endpoint y/n/<br>Reference |
|--|--------------------------------------|--|
| Molecular weight (g/mol)                           | 358.3                                | Y, EFSA (2007)   |
| Saturated vapour pressure (Pa)                     | 0 (20°C)                             | Worst-case default                                     |
| Water solubility (mg/L)                            | 1 × 10 <sup>6</sup> (20°C)           | Worst-case default                                     |
| Diffusion coefficient in water (m <sup>2</sup> /d) | not required for Step 1+2            | -  |
| Diffusion coefficient in air (m <sup>2</sup> /d)   | not required for Step 1+2            | -  |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g)         | 2525.9 / 1465.1 (geometric mean, n = | Y, EFSA (2007), RAR                                    |



| Parameter  | Prothioconazole-S-methyl                            | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
|  | 4)  | (2005)*  |
| Freundlich Exponent<br>1/n   | 0.88 (arithmetic mean, n = 4)                       | Y, EFSA (2007), RAR (2005)                             |
| Plant Uptake   | 0   | Default  |
| Wash-Off factor from Crop (1/mm)                                       | not required for Step 1+2                           | -  |
| DT <sub>50,soil</sub> (d)  | 15.7 (geometric mean, n=4)                          | Y, EFSA (2007), RAR (2005)                             |
| DT <sub>50,water</sub> (d)   | 1000  | Worst-case default                                     |
| DT <sub>50,sed</sub> (d)   | 1000  | Worst-case default                                     |
| DT <sub>50,whole system</sub> (d)                                      | 1000  | Worst-case default                                     |
| Maximum occurrence observed (% molar basis with respect to the parent) | Soil: 14.6<br>Water/sediment: Not relevant in water | Y, EFSA (2007)   |
| Formation fraction in soil:  | not required for Step 1+2                           | -  |
| Formation fraction in water/sediment:                                  | not required for Step 1+2                           | -  |

\* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU value in EFSA (2007) which was 2556.3 mL/g.

**Table 8.9-7: Input parameters related to prothioconazole-desthio for PEC<sub>sw/sed</sub> calculations**

| Parameter  | Prothioconazole-desthio   | Value in accordance with EU endpoint y/n/<br>Reference |
|--|---|--|
| Molecular weight (g/mol)                           | 312.2   | Y, EFSA (2007), RAR (2005)                             |
| Saturated vapour pressure (Pa)                     | 0 (20°C)  | Worst-case default                                     |
| Water solubility (mg/L)                            | 1×10 <sup>6</sup> (20°C)  | Worst-case default                                     |
| Diffusion coefficient in water (m <sup>2</sup> /d) | not required for Step 1+2/<br>4.3 x 10 <sup>-5</sup>                                      | Default  |
| Diffusion coefficient in air (m <sup>2</sup> /d)   | not required for Step 1+2/0.43  | Default  |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g)         | 573.5 / 332.7 (geometric mean, n = 4)   | Y, EFSA (2007), RAR (2005)*                            |
| Freundlich Exponent<br>1/n                         | 0.81 (arithmetic mean, n = 4)   | Y, EFSA (2007), RAR (2005)                             |
| Plant Uptake                                       | 0   | Worst-case default                                     |
| Wash-Off factor from Crop (1/mm)                   | not required for Step 1+2/<br>0.05 (MACRO)<br>0.50 (PRZM)                                 | Default  |
| DT <sub>50,soil</sub> (d)                          | 22.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q <sub>10</sub> of 2.2, n =8)** | Y, EFSA (2007), RAR (2005)                             |

| Parameter  | Prothioconazole-desthio                             | Value in accordance with EU endpoint y/n/ Reference |
|--|---|---|
| DT <sub>50,water</sub> (d)   | 1000  | Worst-case default                                  |
| DT <sub>50,sed</sub> (d)   | 1000  | Worst-case default                                  |
| DT <sub>50,whole system</sub> (d)                                      | 1000  | Worst-case default                                  |
| Maximum occurrence observed (% molar basis with respect to the parent) | Soil: 57.1%<br>Water/sediment (total system): 54.6% | Y, EFSA (2007), RAR (2005)                          |
| Formation fraction in soil:  | 0.571 (from prothioconazole)                        | Y, EFSA (2007)                                      |
| Formation fraction in water/sediment:                                  | 1 (from prothioconazole)                            | Worst-case default                                  |

\* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU value in EFSA (2007) which was 575.4 mL/g.

\*\* Field DT<sub>50</sub> is significantly greater than lab value and is a worst-case even with Q<sub>10</sub> of 2.2. The RAR does not contain sufficient data to renormalise the field DT<sub>50</sub> using a Q<sub>10</sub> of 2.58.

**Table 8.9-8: Input parameters related to 1,2,4-triazole for PEC<sub>sw/sed</sub> calculations**

| Parameter  | 1,2,4-Triazole                                     | Value in accordance with EU endpoint y/n/ Reference |
|--|--|---|
| Molecular weight (g/mol)   | 69.1   | Y, EFSA (2007), RAR (2005)                          |
| Saturated vapour pressure (Pa)   | 0 (20°C)   | Worst-case default                                  |
| Water solubility (mg/L)  | 1×10 <sup>6</sup> (20°C)                           | Worst-case default                                  |
| Diffusion coefficient in water (m <sup>2</sup> /d)                     | not required for Step 1+2                          | -   |
| Diffusion coefficient in air (m <sup>2</sup> /d)                       | not required for Step 1+2                          | -   |
| K <sub>foc</sub> / K <sub>fom</sub> (mL/g)                             | 83 / 48 (geometric mean, n = 4)                    | Y, EFSA (2007), PRAPeR 12 (Jan 2007)*               |
| Freundlich Exponent 1/n  | 0.916 (arithmetic mean, n = 4)                     | Y, EFSA (2007)                                      |
| Plant Uptake   | 0  | Worst-case default                                  |
| Wash-Off factor from Crop (1/mm)                                       | not required for Step 1+2                          | -   |
| DT <sub>50,soil</sub> (d)  | 1000   | Worst-case default                                  |
| DT <sub>50,water</sub> (d)   | 1000   | Worst-case default                                  |
| DT <sub>50,sed</sub> (d)   | 1000   | Worst-case default                                  |
| DT <sub>50,whole system</sub> (d)                                      | 1000   | Worst-case default                                  |
| Maximum occurrence observed (% molar basis with respect to the parent) | Soil: Not formed in soil<br>Water/sediment: 41.8 % | Y, EFSA (2007), RAR (2005)                          |
| Formation fraction in soil:  | not required for Step 1+2                          | -   |
| Formation fraction in water/sediment:                                  | not required for Step 1+2                          | -   |

\* value changed to geometric mean, as requested by zRMS:EL (EFSA 2007 used an arithmetic mean) . Geomean value more conservative than original EU value in EFSA (2007) which was 89 mL/g.

### Prothioconazole PEC<sub>sw/sed</sub>

Results from the FOCUS STEPS 1-3 surface water modelling for prothioconazole are presented in Table 8.9-9 to Table 8.9-18.

**Table 8.9-9: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter OSR (autumn and spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 1.42                         | 10.98                          |
| Southern Europe         | Oct-Feb             | -                    | 1.42                         | 9.15                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.9721                       | 0.5028                         |
| D4                      | pond                | Drift                | 0.03128                      | 0.04336                        |
| D4                      | stream              | Drift                | 0.8285                       | 0.1496                         |
| D5                      | pond                | Drift                | 0.03129                      | 0.03581                        |
| D5                      | stream              | Drift                | 0.8939                       | 0.2011                         |
| R1                      | pond                | Drift                | 0.03126                      | 0.04750                        |
| R1                      | stream              | Drift                | 0.6335                       | 0.2140                         |
| R3                      | stream              | Drift                | 0.8898                       | 0.2790                         |

**Table 8.9-10: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter OSR (single autumn application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 1.61                         | 11.22                          |
| Southern Europe         | Oct-Feb             | -                    | 1.61                         | 9.39                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.112                        | 0.5753                         |
| D4                      | pond                | Drift                | 0.03824                      | 0.03371                        |
| D4                      | stream              | Drift                | 0.9580                       | 0.1730                         |
| D5                      | pond                | Drift                | 0.03825                      | 0.02773                        |
| D5                      | stream              | Drift                | 1.034                        | 0.2257                         |
| R1                      | pond                | Drift                | 0.03822                      | 0.03118                        |
| R1                      | stream              | Drift                | 0.7325                       | 0.1004                         |
| R3                      | stream              | Drift                | 1.024                        | 0.1742                         |

**Table 8.9-11: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter OSR (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.43                         | 3.70                           |
| Europe                  | June-Sept           | -                    | 1.43                         | 3.70                           |
| Southern                | March-May           | -                    | 1.43                         | 5.52                           |
| Europe                  | June-Sept           | -                    | 1.43                         | 4.61                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.9672                       | 0.4432                         |
| D4                      | pond                | Drift                | 0.03621                      | 0.06022                        |
| D4                      | stream              | Drift                | 0.7441                       | 0.02947                        |
| D5                      | pond                | Drift                | 0.03752                      | 0.05074                        |
| D5                      | stream              | Drift                | 0.7621                       | 0.02137                        |
| R1                      | pond                | Drift                | 0.03456                      | 0.04432                        |
| R1                      | stream              | Drift                | 0.6299                       | 0.07837                        |
| R3                      | stream              | Drift                | 0.8928                       | 0.2025                         |

**Table 8.9-12: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter OSR (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.61                         | 4.12                           |
| Europe                  | June-Sept           | -                    | 1.61                         | 4.12                           |
| Southern                | March-May           | -                    | 1.61                         | 5.74                           |
| Europe                  | June-Sept           | -                    | 1.61                         | 4.83                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.105                        | 0.4417                         |
| D4                      | pond                | Drift                | 0.03822                      | 0.05267                        |
| D4                      | stream              | Drift                | 0.8605                       | 0.03408                        |
| D5                      | pond                | Drift                | 0.03816                      | 0.04459                        |
| D5                      | stream              | Drift                | 0.7177                       | 0.008954                       |
| R1                      | pond                | Drift                | 0.03822                      | 0.04204                        |
| R1                      | stream              | Drift                | 0.7284                       | 0.08837                        |
| R3                      | stream              | Drift                | 1.032                        | 0.2341                         |

**Table 8.9-13: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Spring OSR (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.43                         | 3.70                           |
| Europe                  | June-Sept           | -                    | 1.43                         | 3.70                           |
| Southern                | March-May           | -                    | 1.43                         | 5.52                           |
| Europe                  | June-Sept           | -                    | 1.43                         | 4.61                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.9694                       | 0.4262                         |
| D4                      | pond                | Drift                | 0.03246                      | 0.02801                        |
| D4                      | stream              | Drift                | 0.8109                       | 0.08865                        |
| D5                      | pond                | Drift                | 0.03698                      | 0.0489                         |
| D5                      | stream              | Drift                | 0.8341                       | 0.04997                        |
| R1                      | pond                | Drift                | 0.03537                      | 0.03934                        |
| R1                      | stream              | Drift                | 0.6310                       | 0.1245                         |

**Table 8.9-14: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Spring OSR (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 19.01                        | 307.03                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.61                         | 4.12                           |
| Europe                  | June-Sept           | -                    | 1.61                         | 4.12                           |
| Southern                | March-May           | -                    | 1.61                         | 5.74                           |
| Europe                  | June-Sept           | -                    | 1.61                         | 4.83                           |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.109                        | 0.4772                         |
| D4                      | pond                | Drift                | 0.03823                      | 0.03348                        |
| D4                      | stream              | Drift                | 0.9072                       | 0.06009                        |
| D5                      | pond                | Drift                | 0.03822                      | 0.0415                         |
| D5                      | stream              | Drift                | 0.8794                       | 0.02400                        |
| R1                      | pond                | Drift                | 0.03822                      | 0.04204                        |
| R1                      | stream              | Drift                | 0.7296                       | 0.09240                        |

**Table 8.9-15: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter Cereals (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 21.72                        | 350.89                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 1.63                         | 7.70                           |
|                         | June-Sept           | -                    | 1.63                         | 7.70                           |
| Southern Europe         | March-May           | -                    | 1.63                         | 13.27                          |
|                         | June-Sept           | -                    | 1.63                         | 10.49                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.107                        | 0.4940                         |
| D4                      | pond                | Drift                | 0.03857                      | 0.05845                        |
| D4                      | stream              | Drift                | 0.8366                       | 0.0298                         |
| D5                      | pond                | Drift                | 0.04227                      | 0.05597                        |
| D5                      | stream              | Drift                | 0.9651                       | 0.06818                        |
| R1                      | pond                | Drift                | 0.04052                      | 0.04511                        |
| R1                      | stream              | Drift                | 0.7210                       | 0.2360                         |
| R3                      | stream              | Drift                | 1.019                        | 0.7343                         |
| R4                      | stream              | Drift                | 0.7212                       | 0.09471                        |



**Table 8.9-16: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Winter Cereals (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 21.72                        | 350.89                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 1.84                         | 7.95                           |
|                         | June-Sept           | -                    | 1.84                         | 7.95                           |
| Southern Europe         | March-May           | -                    | 1.84                         | 13.52                          |
|                         | June-Sept           | -                    | 1.84                         | 10.74                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.265                        | 0.5652                         |
| D4                      | pond                | Drift                | 0.04367                      | 0.05973                        |
| D4                      | stream              | Drift                | 0.9347                       | 0.02684                        |
| D5                      | pond                | Drift                | 0.04368                      | 0.04746                        |
| D5                      | stream              | Drift                | 1.010                        | 0.02848                        |
| R1                      | pond                | Drift                | 0.04368                      | 0.04805                        |
| R1                      | stream              | Drift                | 0.8338                       | 0.1054                         |
| R3                      | stream              | Drift                | 1.171                        | 0.2086                         |
| R4                      | stream              | Drift                | 0.8339                       | 0.1059                         |

**Table 8.9-17: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Spring Cereals (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 21.72                        | 350.89                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 1.63                         | 7.70                           |
|                         | June-Sept           | -                    | 1.63                         | 7.70                           |
| Southern Europe         | March-May           | -                    | 1.63                         | 13.27                          |
|                         | June-Sept           | -                    | 1.63                         | 10.49                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.107                        | 0.4786                         |
| D4                      | pond                | Drift                | 0.0371                       | 0.032                          |
| D4                      | stream              | Drift                | 0.9247                       | 0.09699                        |
| D5                      | pond                | Drift                | 0.03647                      | 0.03898                        |
| D5                      | stream              | Drift                | 0.9555                       | 0.05759                        |
| R4                      | stream              | Drift                | 0.8864                       | 0.6665                         |

**Table 8.9-18: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole following application to Spring Cereals (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 21.72                        | 354.30                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 1.84                         | 7.95                           |
|                         | June-Sept           | -                    | 1.84                         | 7.95                           |
| Southern Europe         | March-May           | -                    | 1.84                         | 13.52                          |
|                         | June-Sept           | -                    | 1.84                         | 10.74                          |
| STEP 3                  |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 1.267                        | 0.5316                         |
| D4                      | pond                | Drift                | 0.04369                      | 0.03826                        |
| D4                      | stream              | Drift                | 1.036                        | 0.06755                        |
| D5                      | pond                | Drift                | 0.04369                      | 0.04766                        |
| D5                      | stream              | Drift                | 1.064                        | 0.04372                        |
| R4                      | stream              | Drift                | 0.8374                       | 0.5007                         |

The PEC<sub>sw</sub> and PEC<sub>sed</sub> values at STEPS 1-3 were suitable for use in ecotoxicological risk assessment.

#### Prothioconazole-S-methyl PEC<sub>sw/sed</sub>

Results from the FOCUS STEPS 1-2 surface water modelling for Prothioconazole-S-methyl are presented in Table 8.9-19 to Table 8.9-28. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2.

**Table 8.9-19: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter OSR (autumn and spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 4.06                         | 102.52                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 0.52                         | 13.13                          |
| Southern Europe         | Oct-Feb             | -                    | 0.42                         | 10.50                          |

**Table 8.9-20: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter OSR (single autumn application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.03                         | 51.26                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 0.51                         | 12.89                          |
| Southern Europe         | Oct-Feb             | -                    | 0.41                         | 10.31                          |

**Table 8.9-21: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter OSR (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 4.06                         | 105.52                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 0.16                         | 3.97                           |
|                         | June-Sept           | -                    | 0.16                         | 3.97                           |
| Southern                | March-May           | -                    | 0.31                         | 7.93                           |
| Europe                  | June-Sept           | -                    | 0.24                         | 5.95                           |

**Table 8.9-22: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter OSR (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.03                         | 51.26                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 0.10                         | 2.58                           |
|                         | June-Sept           | -                    | 0.10                         | 2.58                           |
| Southern                | March-May           | -                    | 0.20                         | 5.16                           |
| Europe                  | June-Sept           | -                    | 0.15                         | 3.87                           |

**Table 8.9-23: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Spring OSR (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 4.06                         | 105.52                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.16                         | 3.97                           |
| Europe                  | June-Sept           | -                    | 0.16                         | 3.97                           |
| Southern                | March-May           | -                    | 0.31                         | 7.93                           |
| Europe                  | June-Sept           | -                    | 0.24                         | 5.95                           |

**Table 8.9-24: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Spring OSR (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.03                         | 51.26                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.10                         | 2.58                           |
| Europe                  | June-Sept           | -                    | 0.10                         | 2.58                           |
| Southern                | March-May           | -                    | 0.20                         | 5.16                           |
| Europe                  | June-Sept           | -                    | 0.15                         | 3.87                           |

**Table 8.9-25: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter Cereals (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 4.64                         | 117.17                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.48                         | 12.09                          |
| Europe                  | June-Sept           | -                    | 0.48                         | 12.09                          |
| Southern                | March-May           | -                    | 0.96                         | 24.18                          |
| Europe                  | June-Sept           | -                    | 0.72                         | 18.13                          |

**Table 8.9-26: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Winter Cereals (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.32                         | 58.58                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.31                         | 7.86                           |
| Europe                  | June-Sept           | -                    | 0.31                         | 7.86                           |
| Southern                | March-May           | -                    | 0.62                         | 15.71                          |
| Europe                  | June-Sept           | -                    | 0.47                         | 11.78                          |

**Table 8.9-27: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Spring Cereals (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 4.64                         | 117.17                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.48                         | 12.09                          |
| Europe                  | June-Sept           | -                    | 0.48                         | 12.09                          |
| Southern                | March-May           | -                    | 0.96                         | 24.18                          |
| Europe                  | June-Sept           | -                    | 0.72                         | 18.13                          |

**Table 8.9-28: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-S-methyl following application to Spring Cereals (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.32                         | 58.58                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.31                         | 7.86                           |
| Europe                  | June-Sept           | -                    | 0.31                         | 7.86                           |
| Southern                | March-May           | -                    | 0.62                         | 15.71                          |
| Europe                  | June-Sept           | -                    | 0.47                         | 11.78                          |

### 1,2,4-Triazole PEC<sub>sw/sed</sub>

Results from the FOCUS STEPS 1-2 surface water modelling for 1,2,4-Triazole are presented in Table 8.9-29 to Table 8.9-38. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2.

**Table 8.9-29: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter OSR (autumn and spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 5.82                         | 32.67                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 0.24                         | 1.22                           |
| Southern Europe         | Oct-Feb             | -                    | 0.22                         | 1.13                           |

**Table 8.9-30: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter OSR (single autumn application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.91                         | 16.33                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 0.17                         | 0.91                           |
| Southern Europe         | Oct-Feb             | -                    | 0.16                         | 0.82                           |

**Table 8.9-31: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter OSR (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 5.82                         | 32.67                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 0.20                         | 0.86                           |
|                         | June-Sept           | -                    | 0.20                         | 0.86                           |
| Southern Europe         | March-May           | -                    | 0.20                         | 0.96                           |
|                         | June-Sept           | -                    | 0.20                         | 0.91                           |

**Table 8.9-32: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter OSR (spring application only)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.91                         | 16.33                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.14                         | 0.53                           |
| Europe                  | June-Sept           | -                    | 0.14                         | 0.53                           |
| Southern                | March-May           | -                    | 0.14                         | 0.63                           |
| Europe                  | June-Sept           | -                    | 0.14                         | 0.58                           |

**Table 8.9-33: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Spring OSR (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 5.82                         | 32.67                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.20                         | 0.86                           |
| Europe                  | June-Sept           | -                    | 0.20                         | 0.86                           |
| Southern                | March-May           | -                    | 0.20                         | 0.96                           |
| Europe                  | June-Sept           | -                    | 0.20                         | 0.91                           |

**Table 8.9-34: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Spring OSR (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 2.91                         | 16.33                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.14                         | 0.53                           |
| Europe                  | June-Sept           | -                    | 0.14                         | 0.53                           |
| Southern                | March-May           | -                    | 0.14                         | 0.63                           |
| Europe                  | June-Sept           | -                    | 0.14                         | 0.58                           |

**Table 8.9-35: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter Cereals (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 6.65                         | 37.33                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.23                         | 1.17                           |
| Europe                  | June-Sept           | -                    | 0.23                         | 1.17                           |
| Southern                | March-May           | -                    | 0.28                         | 1.46                           |
| Europe                  | June-Sept           | -                    | 0.25                         | 1.31                           |

**Table 8.9-36: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Winter Cereals (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 3.32                         | 18.67                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.15                         | 0.79                           |
| Europe                  | June-Sept           | -                    | 0.15                         | 0.79                           |
| Southern                | March-May           | -                    | 0.20                         | 1.08                           |
| Europe                  | June-Sept           | -                    | 0.18                         | 0.93                           |

**Table 8.9-37: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Spring Cereals (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 6.65                         | 37.33                          |
| STEP 2                  |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 0.23                         | 1.17                           |
| Europe                  | June-Sept           | -                    | 0.23                         | 1.17                           |
| Southern                | March-May           | -                    | 0.28                         | 1.46                           |
| Europe                  | June-Sept           | -                    | 0.25                         | 1.31                           |



**Table 8.9-38: FOCUS STEP 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-Triazole following application to Spring Cereals (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 3.32                         | 18.67                          |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 0.15                         | 0.79                           |
|                         | June-Sept           | -                    | 0.15                         | 0.79                           |
| Southern Europe         | March-May           | -                    | 0.20                         | 1.08                           |
|                         | June-Sept           | -                    | 0.18                         | 0.93                           |

#### Prothioconazole-desthio PEC<sub>sw/sed</sub>

Results from the FOCUS STEPS 1-3 surface water modelling for prothioconazole-desthio are presented in Table 8.9-39 to Table 8.9-48. Additional STEP 4 modelling was required, which is summarised in Table 8.9-49 to Table 8.9-53. Note that an entry route of “drift” refers to the metabolite forming in surface water from the drift entry of the active substance. Relatively little active substance enters via drainflow and runoff. Entry routes via “drainflow” and “runoff” involve the formation of the metabolite in soil, which is then transferred to surface water.

**Table 8.9-39: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Winter OSR (autumn and spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 68.56                        | 388.99                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 6.23                         | 34.93                          |
| Southern Europe         | Oct-Feb             | -                    | 5.16                         | 28.83                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1337                       | 0.3826                         |
| D4                      | pond                | Drift                | 0.0229                       | 0.4293                         |
| D4                      | stream              | Drift                | 0.07624                      | 0.05303                        |
| D5                      | pond                | Drift                | 0.02225                      | 0.3907                         |
| D5                      | stream              | Drift                | 0.1145                       | 0.07505                        |
| R1                      | pond                | Runoff               | 0.06451                      | 0.9823                         |
| R1                      | stream              | Runoff               | 0.4671                       | 0.4521                         |
| R3                      | stream              | Runoff               | 0.7388                       | 1.007                          |

**Table 8.9-40: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Winter OSR (single autumn application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 34.28                        | 194.49                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | Oct-Feb             | -                    | 5.56                         | 31.42                          |
| Southern Europe         | Oct-Feb             | -                    | 4.55                         | 25.65                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1531                       | 0.4343                         |
| D4                      | pond                | Drift                | 0.02426                      | 0.3105                         |
| D4                      | stream              | Drift                | 0.08817                      | 0.05683                        |
| D5                      | pond                | Drift                | 0.02535                      | 0.3169                         |
| D5                      | stream              | Drift                | 0.1411                       | 0.1007                         |
| R1                      | pond                | Runoff               | 0.03322                      | 0.4503                         |
| R1                      | stream              | Runoff               | 0.2701                       | 0.1647                         |
| R3                      | stream              | Runoff               | 0.7388                       | 1.011                          |

**Table 8.9-41: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Winter OSR (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 68.56                        | 388.99                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 2.53                         | 13.70                          |
|                         | June-Sept           | -                    | 2.53                         | 13.70                          |
| Southern Europe         | March-May           | -                    | 4.12                         | 22.87                          |
|                         | June-Sept           | -                    | 3.32                         | 18.29                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.03673                      | 0.2117                         |
| D4                      | pond                | Drift                | 0.02883                      | 0.4220                         |
| D4                      | stream              | Drift                | 0.05739                      | 0.009331                       |
| D5                      | pond                | Drift                | 0.03415                      | 0.4643                         |
| D5                      | stream              | Drift                | 0.08374                      | 0.007311                       |
| R1                      | pond                | Runoff               | 0.08332                      | 0.9042                         |
| R1                      | stream              | Runoff               | 0.5814                       | 0.5694                         |
| R3                      | stream              | Runoff               | 0.4811                       | 0.2650                         |

**Table 8.9-42: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Winter OSR (spring application only)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 34.28                        | 194.49                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.53                         | 8.35                           |
| Europe                  | June-Sept           | -                    | 1.53                         | 8.35                           |
| Southern                | March-May           | -                    | 2.54                         | 14.12                          |
| Europe                  | June-Sept           | -                    | 2.04                         | 11.23                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.03272                      | 0.1170                         |
| D4                      | pond                | Drift                | 0.01860                      | 0.2655                         |
| D4                      | stream              | Drift                | 0.06637                      | 0.00657                        |
| D5                      | pond                | Drift                | 0.02040                      | 0.2842                         |
| D5                      | stream              | Drift                | 0.07887                      | 0.002284                       |
| R1                      | pond                | Runoff               | 0.04588                      | 0.5163                         |
| R1                      | stream              | Runoff               | 0.2787                       | 0.3387                         |
| R3                      | stream              | Runoff               | 0.4811                       | 0.2360                         |

**Table 8.9-43: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Spring OSR (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 68.56                        | 388.99                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 2.53                         | 13.70                          |
| Europe                  | June-Sept           | -                    | 2.53                         | 13.70                          |
| Southern                | March-May           | -                    | 4.12                         | 22.87                          |
| Europe                  | June-Sept           | -                    | 3.32                         | 18.29                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1009                       | 0.4222                         |
| D4                      | pond                | Drift                | 0.03890                      | 0.4710                         |
| D4                      | stream              | Drift                | 0.06898                      | 0.04241                        |
| D5                      | pond                | Drift                | 0.03767                      | 0.5051                         |
| D5                      | stream              | Drift                | 0.09166                      | 0.01775                        |
| R1                      | pond                | Runoff               | 0.1229                       | 1.215                          |
| R1                      | stream              | Runoff               | 1.073                        | 0.9574                         |

**Table 8.9-44: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Spring OSR (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 34.28                        | 194.49                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 1.53                         | 8.35                           |
| Europe                  | June-Sept           | -                    | 1.53                         | 8.35                           |
| Southern                | March-May           | -                    | 2.54                         | 14.12                          |
| Europe                  | June-Sept           | -                    | 2.04                         | 11.23                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1115                       | 0.2810                         |
| D4                      | pond                | Drift                | 0.02449                      | 0.2960                         |
| D4                      | stream              | Drift                | 0.07228                      | 0.01836                        |
| D5                      | pond                | Drift                | 0.02225                      | 0.3136                         |
| D5                      | stream              | Drift                | 0.09664                      | 0.006363                       |
| R1                      | pond                | Runoff               | 0.05223                      | 0.5653                         |
| R1                      | stream              | Runoff               | 0.4081                       | 0.3594                         |

**Table 8.9-45: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-dethio following application to Winter Cereals (two spring applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 78.36                        | 444.56                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern                | March-May           | -                    | 5.93                         | 33.12                          |
| Europe                  | June-Sept           | -                    | 5.93                         | 33.12                          |
| Southern                | March-May           | -                    | 10.81                        | 61.05                          |
| Europe                  | June-Sept           | -                    | 8.37                         | 47.08                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1055                       | 0.4147                         |
| D4                      | pond                | Drift                | 0.03537                      | 0.4930                         |
| D4                      | stream              | Drift                | 0.06452                      | 0.009932                       |
| D5                      | pond                | Drift                | 0.04375                      | 0.5844                         |
| D5                      | stream              | Drift                | 0.1072                       | 0.02322                        |
| R1                      | pond                | Runoff               | 0.1397                       | 1.382                          |
| R1                      | stream              | Runoff               | 1.058                        | 1.167                          |
| R3                      | stream              | Runoff               | 1.136                        | 1.365                          |
| R4                      | stream              | Runoff               | 0.7137                       | 0.7617                         |

**Table 8.9-46: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-dethio following application to Winter Cereals (single spring application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 39.18                        | 222.28                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 3.67                         | 20.53                          |
|                         | June-Sept           | -                    | 3.67                         | 20.53                          |
| Southern Europe         | March-May           | -                    | 6.74                         | 38.10                          |
|                         | June-Sept           | -                    | 5.20                         | 29.32                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.05982                      | 0.1895                         |
| D4                      | pond                | Drift                | 0.02054                      | 0.2981                         |
| D4                      | stream              | Drift                | 0.0721                       | 0.005182                       |
| D5                      | pond                | Drift                | 0.02574                      | 0.3627                         |
| D5                      | stream              | Drift                | 0.1110                       | 0.007477                       |
| R1                      | pond                | Runoff               | 0.05443                      | 0.5931                         |
| R1                      | stream              | Runoff               | 0.3520                       | 0.3898                         |
| R3                      | stream              | Runoff               | 0.4567                       | 0.6059                         |
| R4                      | stream              | Runoff               | 0.2455                       | 0.2972                         |

**Table 8.9-47: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-dethio following application to Spring Cereals (two applications)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| <b>STEP 1</b>           | -                   | -                    | 78.36                        | 444.56                         |
| <b>STEP 2</b>           |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 5.93                         | 33.12                          |
|                         | June-Sept           | -                    | 5.93                         | 33.12                          |
| Southern Europe         | March-May           | -                    | 10.81                        | 61.05                          |
|                         | June-Sept           | -                    | 8.37                         | 47.08                          |
| <b>STEP 3</b>           |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1103                       | 0.4647                         |
| D4                      | pond                | Drift                | 0.04453                      | 0.5172                         |
| D4                      | stream              | Drift                | 0.07733                      | 0.0463                         |
| D5                      | pond                | Drift                | 0.04304                      | 0.5821                         |
| D5                      | stream              | Drift                | 0.1054                       | 0.02729                        |
| R4                      | stream              | Runoff               | 1.315                        | 1.898                          |

**Table 8.9-48: FOCUS STEP 1, 2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Prothioconazole-desthio following application to Spring Cereals (single application)**

| FOCUS STEP and Scenario | Waterbody or Season | Dominant entry route | Max PEC <sub>sw</sub> (µg/L) | Max PEC <sub>sed</sub> (µg/kg) |
|-------------------------|---------------------|----------------------|------------------------------|--------------------------------|
| STEP 1                  | -                   | -                    | 39.18                        | 222.28                         |
| STEP 2                  |                     |                      |                              |                                |
| Northern Europe         | March-May           | -                    | 3.67                         | 20.53                          |
|                         | June-Sept           | -                    | 3.67                         | 20.53                          |
| Southern Europe         | March-May           | -                    | 6.74                         | 38.10                          |
|                         | June-Sept           | -                    | 5.20                         | 29.32                          |
| STEP 3                  |                     |                      |                              |                                |
| D3                      | ditch               | Drift                | 0.1218                       | 0.3013                         |
| D4                      | pond                | Drift                | 0.02803                      | 0.3270                         |
| D4                      | stream              | Drift                | 0.08232                      | 0.02049                        |
| D5                      | pond                | Drift                | 0.02639                      | 0.3609                         |
| D5                      | stream              | Drift                | 0.1169                       | 0.01141                        |
| R4                      | stream              | Runoff               | 0.6792                       | 1.210                          |

#### FOCUS Step 4

Surface water exposure at STEP 3 indicated potential risks for aquatic organisms due to the metabolite, prothioconazole-desthio. The worst-case PEC values occurred due to runoff. Therefore, STEP 4 models were performed using vegetated filter strips (VFS) to mitigate the exposures. Mitigation measures were applied using SWAN (v5.0.0) to modify the SWASH input files.

Global maximum PEC<sub>sw</sub> values from the FOCUS-STEP 4 models are presented in Table 8.9-49 to Table 8.9-53. It should be noted that where drift is the dominant entry route, the single application models will often result in a higher PEC<sub>sw</sub>. In such cases, the single application PEC<sub>sw</sub> should be used when assessing the risk from multiple applications

**Table 8.9-49: FOCUS STEP 4 global maximum PEC<sub>sw</sub> values for prothioconazole-desthio, following application to Winter Oilseed Rape in Autumn**

| Scenario                   | Winter OSR<br>(autumn and spring application) |                |                | Winter OSR<br>(single autumn application) |                |                |
|----------------------------|---|----------------|----------------|---|----------------|----------------|
|                            | None  | 10             | 20             | None                                      | 10             | 20             |
| <b>Vegetated strip (m)</b> | <b>None</b>                                   | <b>10</b>      | <b>20</b>      | <b>None</b>                               | <b>10</b>      | <b>20</b>      |
| <b>No spray buffer (m)</b> | <b>STEP 3</b>                                 | <b>10</b>      | <b>20</b>      | <b>STEP 3</b>                             | <b>10</b>      | <b>20</b>      |
| D3 ditch                   | 0.1337  | 0.01793        | 0.009102       | <b>0.1531</b>                             | <b>0.02190</b> | <b>0.01136</b> |
| D4 pond                    | 0.02290                                       | 0.01457        | 0.01186        | <b>0.02426</b>                            | <b>0.01583</b> | <b>0.01302</b> |
| D4 stream                  | 0.07624                                       | 0.05014        | 0.05014        | <b>0.08817</b>                            | <b>0.05014</b> | <b>0.05014</b> |
| D5 pond                    | 0.02225                                       | 0.01393        | 0.009524       | <b>0.02535</b>                            | <b>0.01575</b> | <b>0.01054</b> |
| D5 stream                  | 0.1145  | 0.02377        | <b>0.02377</b> | <b>0.1411</b>                             | <b>0.02732</b> | 0.02307        |
| R1 pond                    | <b>0.06451</b>                                | <b>0.03026</b> | <b>0.01707</b> | 0.03322                                   | 0.01568        | 0.009773       |
| R1 stream                  | <b>0.4671</b>                                 | <b>0.2123</b>  | <b>0.1111</b>  | 0.2701                                    | 0.1184         | 0.06116        |
| R3 stream                  | <b>0.7388</b>                                 | <b>0.3362</b>  | <b>0.1762</b>  | <b>0.7388</b>                             | <b>0.3362</b>  | <b>0.1762</b>  |

**Bold** = worst-case application pattern

**Table 8.9-50: FOCUS STEP 4 global maximum PEC<sub>sw</sub> values for prothioconazole-desthio, following application to Winter Oilseed Rape in Spring**

| Scenario                   | Winter OSR<br>(two spring applications) |                |                 | Winter OSR<br>(single spring application) |                 |                 |
|----------------------------|---|----------------|-----------------|---|-----------------|-----------------|
|                            | None                                    | 10             | 20              | None                                      | 10              | 20              |
| <b>Vegetated strip (m)</b> | <b>None</b>                             | <b>10</b>      | <b>20</b>       | <b>None</b>                               | <b>10</b>       | <b>20</b>       |
| <b>No spray buffer (m)</b> | <b>STEP 3</b>                           | <b>10</b>      | <b>20</b>       | <b>STEP 3</b>                             | <b>10</b>       | <b>20</b>       |
| D3 ditch                   | <b>0.03673</b>                          | 0.004937       | <b>0.002508</b> | 0.03272                                   | <b>0.004696</b> | 0.002437        |
| D4 pond                    | <b>0.02883</b>                          | <b>0.01738</b> | <b>0.01132</b>  | 0.01860                                   | 0.01144         | 0.007567        |
| D4 stream                  | 0.05739                                 | 0.01052        | 0.005346        | <b>0.06637</b>                            | <b>0.01285</b>  | <b>0.006671</b> |
| D5 pond                    | <b>0.03415</b>                          | <b>0.02062</b> | <b>0.01345</b>  | 0.0204                                    | 0.01256         | 0.008311        |
| D5 stream                  | <b>0.08374</b>                          | <b>0.01535</b> | 0.007801        | 0.07887                                   | 0.01527         | <b>0.007928</b> |
| R1 pond                    | <b>0.08332</b>                          | <b>0.03968</b> | <b>0.02261</b>  | 0.04588                                   | 0.02275         | 0.01335         |
| R1 stream                  | <b>0.5814</b>                           | <b>0.2637</b>  | <b>0.1381</b>   | 0.2787                                    | 0.1265          | 0.0662          |
| R3 stream                  | <b>0.4811</b>                           | <b>0.2126</b>  | <b>0.1101</b>   | <b>0.4811</b>                             | <b>0.2126</b>   | <b>0.1101</b>   |

**Bold** = worst-case application pattern



**Table 8.9-51: FOCUS STEP 4 global maximum PEC<sub>sw</sub> values for prothioconazole-desthio, following application to Spring Oilseed Rape**

| Scenario                   | Spring OSR<br>(two applications) |                |                | Spring OSR<br>(single application) |                |                 |
|----------------------------|----------------------------------|----------------|----------------|------------------------------------|----------------|-----------------|
|                            | None                             | 10             | 20             | None                               | 10             | 20              |
| <b>Vegetated strip (m)</b> | <b>None</b>                      | <b>10</b>      | <b>20</b>      | <b>None</b>                        | <b>10</b>      | <b>20</b>       |
| <b>No spray buffer (m)</b> | <b>STEP 3</b>                    | <b>10</b>      | <b>20</b>      | <b>STEP 3</b>                      | <b>10</b>      | <b>20</b>       |
| D3 ditch                   | 0.1009                           | 0.01356        | 0.00689        | <b>0.1115</b>                      | <b>0.01599</b> | <b>0.008301</b> |
| D4 pond                    | <b>0.03890</b>                   | <b>0.02350</b> | <b>0.01534</b> | 0.02449                            | 0.01511        | 0.01002         |
| D4 stream                  | 0.06898                          | 0.01265        | 0.006426       | <b>0.07228</b>                     | <b>0.01399</b> | <b>0.007265</b> |
| D5 pond                    | <b>0.03767</b>                   | <b>0.02275</b> | <b>0.01485</b> | 0.02225                            | 0.0137         | 0.00906         |
| D5 stream                  | 0.09166                          | 0.01680        | 0.008539       | <b>0.09664</b>                     | <b>0.01871</b> | <b>0.009715</b> |
| R1 pond                    | <b>0.1229</b>                    | <b>0.05655</b> | <b>0.03152</b> | 0.05223                            | 0.02531        | 0.01464         |
| R1 stream                  | <b>1.073</b>                     | <b>0.4871</b>  | <b>0.2550</b>  | 0.4081                             | 0.1852         | 0.09698         |

**Bold** = worst-case application pattern

**Table 8.9-52: FOCUS STEP 4 global maximum PEC<sub>sw</sub> values for prothioconazole-desthio, following application to Winter Cereals in Spring**

| Scenario                   | Winter Cereals<br>(two applications) |                |                 | Winter Cereals<br>(single application) |                |                 |
|----------------------------|--------------------------------------|----------------|-----------------|--|----------------|-----------------|
|                            | None                                 | 10             | 20              | None                                   | 10             | 20              |
| <b>Vegetated strip (m)</b> | <b>None</b>                          | <b>10</b>      | <b>20</b>       | <b>None</b>                            | <b>10</b>      | <b>20</b>       |
| <b>No spray buffer (m)</b> | <b>STEP 3</b>                        | <b>10</b>      | <b>20</b>       | <b>STEP 3</b>                          | <b>10</b>      | <b>20</b>       |
| D3 ditch                   | <b>0.1055</b>                        | <b>0.01417</b> | <b>0.007200</b> | 0.05982                                | 0.008583       | 0.004455        |
| D4 pond                    | <b>0.03537</b>                       | <b>0.02132</b> | <b>0.01388</b>  | 0.02054                                | 0.01264        | 0.008359        |
| D4 stream                  | 0.06452                              | 0.01183        | 0.00601         | <b>0.0721</b>                          | <b>0.01396</b> | <b>0.007247</b> |
| D5 pond                    | <b>0.04375</b>                       | <b>0.02642</b> | <b>0.01723</b>  | 0.02574                                | 0.01584        | 0.01048         |
| D5 stream                  | 0.1072                               | 0.01965        | 0.009985        | <b>0.1110</b>                          | <b>0.02149</b> | <b>0.01116</b>  |
| R1 pond                    | <b>0.1397</b>                        | <b>0.06437</b> | <b>0.03589</b>  | 0.05443                                | 0.02684        | 0.01570         |
| R1 stream                  | <b>1.058</b>                         | <b>0.4807</b>  | <b>0.2517</b>   | 0.3520                                 | 0.1599         | 0.08370         |
| R3 stream                  | <b>1.136</b>                         | <b>0.5185</b>  | <b>0.2720</b>   | 0.4567                                 | 0.2084         | 0.1093          |
| R4 stream                  | <b>0.7137</b>                        | <b>0.3220</b>  | <b>0.1681</b>   | 0.2455                                 | 0.1108         | 0.05780         |

**Bold** = worst-case application pattern

**Table 8.9-53: FOCUS STEP 4 global maximum PEC<sub>sw</sub> values for prothioconazole-desthio, following application to Spring Cereals**

| Scenario                   | Spring Cereals<br>(two applications) |                |                | Spring Cereals<br>(single application) |                |                 |
|----------------------------|--------------------------------------|----------------|----------------|--|----------------|-----------------|
|                            | None                                 | 10             | 20             | None                                   | 10             | 20              |
| <b>Vegetated strip (m)</b> | <b>None</b>                          | <b>10</b>      | <b>20</b>      | <b>None</b>                            | <b>10</b>      | <b>20</b>       |
| <b>No spray buffer (m)</b> | <b>STEP 3</b>                        | <b>10</b>      | <b>20</b>      | <b>STEP 3</b>                          | <b>10</b>      | <b>20</b>       |
| D3 ditch                   | 0.1103                               | 0.01482        | 0.00753        | <b>0.1218</b>                          | <b>0.01747</b> | <b>0.009069</b> |
| D4 pond                    | <b>0.04453</b>                       | <b>0.02690</b> | <b>0.01755</b> | 0.02803                                | 0.0173         | 0.01147         |
| D4 stream                  | 0.07733                              | 0.01417        | 0.007508       | <b>0.08232</b>                         | <b>0.01594</b> | <b>0.008275</b> |
| D5 pond                    | <b>0.04304</b>                       | <b>0.02598</b> | <b>0.01694</b> | 0.02639                                | 0.01626        | 0.01076         |
| D5 stream                  | 0.1054                               | 0.01932        | 0.00982        | <b>0.1169</b>                          | <b>0.02263</b> | <b>0.01175</b>  |
| R4 stream                  | <b>1.315</b>                         | <b>0.5917</b>  | <b>0.3087</b>  | 0.6792                                 | 0.3089         | 0.1618          |

**Bold** = worst-case application pattern

#### PEC<sub>sw/sed</sub> of formulation

The formulated product contains prothioconazole as its only active substance and risk assessment should generally be based on the PEC<sub>sw</sub> and PEC<sub>sed</sub> values of the active substance and its metabolites. For completeness, the PEC<sub>sw</sub> values for the formulated product were calculated using the FOCUS drift calculator for a single application. Multiple applications, drainflow, runoff and sediment concentrations are not relevant for the formulation, as it dissociates into its component substances on contact with soil or water. The worst-case application rate of 0.8 L/ha (200 g as/ha) was used, with the nominal product density of 994.8 g/L (see KCP 2.6.1) to give an application rate of 795.8 g product/ha. The PEC<sub>sw</sub> values are summarised in Table 8.9-54.

**Table 8.9-54: Formulated product PEC<sub>sw</sub> values**

| STEP 3 FOCUS Drift Values       |        |
|---------------------------------|--------|
| Rate (g/ha) [worst-case use]    | 795.8  |
| Ditch spray drift (%)           | 1.9274 |
| Pond spray drift (%)            | 0.2191 |
| Stream spray drift (%)          | 1.4304 |
| PEC <sub>sw</sub> µg/L (ditch)  | 5.1127 |
| PEC <sub>sw</sub> µg/L (pond)   | 0.1743 |
| PEC <sub>sw</sub> µg/L (stream) | 3.7943 |

#### Relevant PEC<sub>sw</sub> for assessment in Poland

For all substances except the metabolite prothioconazole-desthio, all FOCUS scenarios will result in acceptable risks (please refer to Part B.9 for the full assessment). The assessment of prothioconazole-desthio requires consideration of appropriate exposure scenarios and mitigation measures. For approval in Poland, the D3, D4 and R1 scenarios are relevant for risk assessment. The following PEC<sub>sw</sub> values represent the worst-cases for each crop. These same scenarios are considered relevant in Belgium and Luxembourg. For other concerned member states, appropriate national addenda will be provided to summarise relevant models and scenarios.

**Table 8.9-55: Worst-case scenarios for Prothioconazole-desthio in Poland**

| Crop           | Applications | STEP 3   |                   | STEP 4   |                   |          |                   |
|----------------|--------------|----------|-------------------|----------|-------------------|----------|-------------------|
|                |              | Scenario | PEC <sub>sw</sub> | 10m VFS  |                   | 20m VFS  |                   |
|                |              |          |                   | Scenario | PEC <sub>sw</sub> | Scenario | PEC <sub>sw</sub> |
| Winter OSR     | 1(A)         | R1s      | 0.2701            | R1s      | 0.1184            | R1s      | 0.06116           |
|                | 1(S)         | R1s      | 0.2787            | R1s      | 0.1265            | R1s      | 0.0662            |
|                | 2(A+S)       | R1s      | 0.4671            | R1s      | 0.2123            | R1s      | 0.1111            |
|                | 2(S+S)       | R1s      | 0.5814            | R1s      | 0.2637            | R1s      | 0.1381            |
| Spring OSR     | 1            | R1s      | 0.4081            | R1s      | 0.1852            | R1s      | 0.09698           |
|                | 2            | R1s      | 1.073             | R1s      | 0.4871            | R1s      | 0.2550            |
| Winter cereals | 1            | R1s      | 0.3520            | R1s      | 0.1599            | R1s      | 0.0837            |
|                | 2            | R1s      | 1.058             | R1s      | 0.4807            | R1s      | 0.2517            |
| Spring cereals | 1            | D3d      | 0.1218            | D3d      | 0.01747           | D4p      | 0.01147           |
|                | 2            | D3d      | 0.1103*           | D3d      | 0.02690*          | D4p      | 0.01755           |

\* The single application value is higher than the 2-application value, and should be used for risk assessment.

## 8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

### Review Comments:

The data on atmospheric degradation and behaviour in air for Prothioconazole provided by the Notifier are considered acceptable. The prothioconazole is regarded as non-volatile and, consequently, exposure of adjacent surface waters and terrestrial ecosystems by prothioconazole due to volatilization with subsequent deposition is not expected.

The endpoints for prothioconazole in the EFSA 2007 conclusion are sufficient to assess the risk from the product and are summarised below.

**Table 8.10-1 Summary of atmospheric degradation and behaviour**

|   |  |
|---|--|
| Compound                                    | Prothioconazole  |
| Direct photolysis in air                    | Not studied – no data requested  |
| Quantum yield of direct phototransformation | Not studied – no data requested  |
| Photochemical oxidative degradation in air  | Prothioconazole:<br>Half-life: 1.1 hours<br>Chemical lifetime: 1.6 hours<br>Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, $1.5 \times 10^6$ OH radicals/cm <sup>3</sup> )<br>prothioconazole-desthio (M04):<br>Half-life: 14.2 hours<br>Chemical lifetime: 20.5 hours<br>Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, $1.5 \times 10^6$ OH radicals/cm <sup>3</sup> ) |
| Volatilisation                              | Vapour pressure: $<4 \times 10^{-7}$ Pa<br>Henry's law constant : $3 \times 10^{-5}$ Pa.m <sup>3</sup> .mol <sup>-1</sup><br><br>Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (M04) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.   |
| Metabolites                                 | Not studied – no data requested  |

The vapour pressure at 20 °C of the active substance was  $<4 \times 10^{-7}$  Pa, below the minimum detectable level in the study. Hence the active substance is regarded as non-volatile. Therefore, exposure of adjacent surface

waters and terrestrial ecosystems by the active substance will be negligible. Any trace amounts reaching the air will quickly degrade in the atmosphere via reaction with OH radicals and there is no risk of long-range transport or atmospheric accumulation.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b>   | <b>Vertebrate study<br/>Y/N</b> | <b>Owner</b>     |
|-------------------|------------------|-------------|--|---------------------------------|------------------|
| K-CP<br>9.2.4/01  | Hale, M.         | 2021        | Prothioconazole: Predicted Environmental Concentrations in Groundwater Following Application to Cereals and Oilseed Rape, Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO<br>Staphyt Regulatory, Report No 21/122<br>Non-GLP<br>Unpublished | N                               | Nufarm<br>Europe |
| K-CP<br>9.2.5/01  | Hale, M.         | 2021        | Prothioconazole: Predicted Environmental Concentrations in Surface Water Following Application to Cereals and Oilseed Rape, Using FOCUS STEPS 1-4<br>Staphyt Regulatory, Report No 21/119<br>Non-GLP<br>Unpublished                        | N                               | Nufarm<br>Europe |

### List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b>   | <b>Vertebrate study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------|--------------|
|                   |                  |             | No previously-evaluated studies have been submitted. All endpoints were taken from EFSA conclusion (EFSA Scientific Report (2007) 106, 1-98) and associated DAR summaries. |                                 |              |

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|------------|-----------|------|---|-------------------------|-------|
| KCP XX     | Author    | YYYY | Title<br>Company Report N<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished                       | Y/N                     | Owner |
|            |           |      |   |                         |       |

**List of data relied on not submitted by the applicant but necessary for evaluation**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
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|            |           |      |   |                         |       |