|  |
| --- |
| REGISTRATION REPORT  Part A  Risk Management |
| Product code: -  Product name(s): ULTRACENT 460 EC  Chemical active substance(s):  Prothioconazole, 160 g/L Spiroxamine, 300 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| NATIONAL ASSESSMENT Poland  (authorization) |
| Applicant: XXXX  Submission date: August 2023  update December 2023  Evaluation date: October 2024  MS Finalisation date: February 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| August 2023 | First submission – application according to Article 33 in connection with Article 34 of Regulation (EC) No. 1107/2009 with reference to unprotected data of the product INPUT 460 EC authorized in Poland |
| December 2023 | The dossier was updated to include available information on the unprotected data of the reference product INPUT 460 EC (R-61/2011). |
| October 2024 | Version evaluated by zRMS PL |
| February 2025 | Final RR in the residues context (the B7 revision) |

Table of Contents

[1 Details of the application 5](#_Toc190249556)

[1.1 Application background 5](#_Toc190249557)

[1.2 Letters of Access 5](#_Toc190249558)

[1.3 Justification for submission of tests and studies 5](#_Toc190249559)

[1.4 Data protection claims 6](#_Toc190249560)

[2 Details of the authorization decision 6](#_Toc190249561)

[2.1 Product identity 6](#_Toc190249562)

[2.2 Conclusion 6](#_Toc190249563)

[2.3 Substances of concern for national monitoring 6](#_Toc190249564)

[2.4 Classification and labelling 7](#_Toc190249565)

[2.4.1 Classification and labelling under Regulation (EC) No 1272/2008 7](#_Toc190249566)

[2.4.2 Standard phrases under Regulation (EU) No 547/2011 8](#_Toc190249567)

[2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) 8](#_Toc190249568)

[2.5 Risk management 8](#_Toc190249569)

[2.5.1 Restrictions linked to the PPP 8](#_Toc190249570)

[2.5.2 Specific restrictions linked to the intended uses 8](#_Toc190249571)

[2.6 Intended uses (only NATIONAL GAP) 9](#_Toc190249572)

[3 Background of authorization decision and risk management 12](#_Toc190249573)

[3.1 Physical and chemical properties (Part B, Section 2) 12](#_Toc190249574)

[3.2 Efficacy (Part B, Section 3) 12](#_Toc190249575)

[3.3 Efficacy data 12](#_Toc190249576)

[3.3.1 Information on the occurrence or possible occurrence of the development of resistance 13](#_Toc190249577)

[3.3.2 Adverse effects on treated crops 13](#_Toc190249578)

[3.3.3 Observations on other undesirable or unintended side-effects 14](#_Toc190249579)

[3.4 Methods of analysis (Part B, Section 5) 14](#_Toc190249580)

[3.4.1 Analytical method for the formulation 14](#_Toc190249581)

[3.4.2 Analytical methods for residues 14](#_Toc190249582)

[3.5 Mammalian toxicology (Part B, Section 6) 15](#_Toc190249583)

[3.5.1 Acute toxicity 15](#_Toc190249584)

[3.5.2 Operator exposure 16](#_Toc190249585)

[3.5.3 Worker exposure 16](#_Toc190249586)

[3.5.4 Bystander and resident exposure 17](#_Toc190249587)

[3.6 Residues and consumer exposure (Part B, Section 7) 17](#_Toc190249588)

[3.6.1 Residues 17](#_Toc190249589)

[3.6.2 Consumer exposure 18](#_Toc190249590)

[3.7 Environmental fate and behaviour (Part B, Section 8) 18](#_Toc190249591)

[3.7.1 Predicted environmental concentrations in soil (PECsoil) 18](#_Toc190249592)

[3.7.2 Predicted environmental concentrations in groundwater (PECgw) 19](#_Toc190249593)

[3.7.3 Predicted environmental concentrations in surface water (PECsw) 20](#_Toc190249594)

[3.7.4 Predicted environmental concentrations in air (PECair) 20](#_Toc190249595)

[3.8 Ecotoxicology (Part B, Section 9) 21](#_Toc190249596)

[3.8.1 Effects on terrestrial vertebrates 21](#_Toc190249597)

[3.8.2 Effects on aquatic species 21](#_Toc190249598)

[3.8.3 Effects on bees 22](#_Toc190249599)

[3.8.4 Effects on other arthropod species other than bees 22](#_Toc190249600)

[3.8.5 Effects on soil organisms 23](#_Toc190249601)

[3.8.6 Effects on non-target terrestrial plants 23](#_Toc190249602)

[3.8.7 Effects on other terrestrial organisms (Flora and Fauna) 23](#_Toc190249603)

[3.9 Relevance of metabolites (Part B, Section 10) 24](#_Toc190249604)

[4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) 24](#_Toc190249605)

[5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization 24](#_Toc190249606)

[Appendix 1 Copy of the product authorization 25](#_Toc190249607)

[Appendix 2 Copy of the product label 26](#_Toc190249608)

[Appendix 3 Letter of Access 27](#_Toc190249609)

[Appendix 4 Lists of data considered for national authorization 29](#_Toc190249610)

PART A

RISK MANAGEMENT

# Details of the application

## Application background

This application is submitted by XXXX to Poland for the first authorization of ULTRACENT 460 EC. ULTRACENT 460 EC is an emulsifiable concentrate containing 160 g/L prothioconazole and 300 g/L spiroxamine and is used as a fungicide in cereals. This application is based on the comparability with the reference product INPUT 460 EC of the authorization holder Bayer AG.

The application submitted herewith also relies on Article 34, in the form of an article 33 application. In the authorization procedure applied for herewith, Poland acts as zonal rapporteur member state (zRMS). There are no other concerned member states. Reference is made to the unprotected data and dossier submitted for INPUT 460 EC (R-61/2011, authorization holder Bayer AG) in Poland. Hence, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009. Additionally, data demonstrating the efficacy of the product as well as new studies on its physical-chemical properties is submitted in support of the application for authorization of ULTRACENT 460 EC.

The requested uses for ULTRACENT 460 EC are covered by those of the Polish reference product INPUT 460 EC. Formulation related data requirements are met by access to data previously submitted to the ministry for the identical and similar product INPUT 460 EC, reference to published data, and citing access to both Polish and EU review data now out of protection. The formulation of ULTRACENT 460 EC is supposed to be identical to that previously approved for INPUT 460 EC. For this reason, all formulation related data submitted by the original authorization holder for INUT 460 EC and held by the Polish ministry are cited as unprotected data in support of this current application. Therefore, except for the additionally submitted studies performed with ULTRACENT 460 EC, no new data nor risk assessment are required and thus are not presented in the current dossier.

This application refers to data and risk assessments performed in accordance with the Uniform Principles of Regulation (EC) No. 1107/2009 provided for the product INPUT 460 EC.

## Letters of Access

Letters of Access for the data packages of both active substances are provided with this application.

## Justification for submission of tests and studies

With this application, bridging field trials will be submitted to demonstrate efficacy of the plant protection product ULTRACENT 460 EC for the GAP applied for.

Additionally, new studies on its physical-chemical properties are submitted in support of the application for authorization of ULTRACENT 460 EC.

Otherwise, no data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Data protection claims

For the newly submitted data regarding physical-chemical properties of the plant protection product ULTRACENT 460 EC and efficacy field trials data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

Otherwise, reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC.

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | - |
| Product name in MS | ULTRACENT 460 EC |
| Authorization number | Not yet registered |
| Function | fungicide |
| Applicant | XXXX |
| Active substance(s)  (incl. content) | prothioconazole; 160 g/L  spiroxamine; 300 g/L |
| Formulation type | Emulsifiable concentrate [Code: EC] |
| Packaging | 1 L bottle, 3 L - 15 L jerry can, HDPE/PA & HDPE/EVOH Co-EX, professional user |
| Coformulants of concern for national authorizations | None |
| Restrictions related to identiy | Not applicable |
| Mandatory tank mixtures | Not applicable |
| Recommended tank mixtures | Not applicable |

## Conclusion

The evaluation of the application for **ULTRACENT 460 EC** resulted in the decision to grant the authorization. The reasons for the refusal are: insufficient data provided and the inconsistency of spiroxamine MRL for the barley.

## Substances of concern for national monitoring

None.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class(es), categories: | Acute Tox. 4, H302+H332  Skin Irrit. 2, H315  Eye Irrit. 2, H319  STOT SE 3, H335  Repr. 2, H361d  STOT RE 2, H373  Aquatic Acute 1, H400  Aquatic Chronic 1, H410 |

zRMS:

As it have been demonstrated in confidential part C of this report the composition of ULTRACENT 460 EC is comparable with composition of the product INPUT 460 EC, for which toxicological data are no longer protected, therefore in line with article 34 of Regulation (EC) No 1107/2009: “Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and …that any data protection period has expired.” Based on these data it is confirmed that ULTRACENT 460 EC should be classified as:

Acute tox. 4, H302+H332

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

Repr. 2, H361d

STOT RE 2, H373

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

EUH208 - Contains spiroxamine. May produce an allergic reaction.

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

|  |  |
| --- | --- |
| Hazard pictograms: | **GHS07,** **GHS08, GHS 09** |
| Signal word: | **Warning** |
| Hazard statement(s): | **H302+H332, H315, H319, H335, H361d, H373,** H400**, H410** |
| Precautionary statement(s): | **P260, P280, P304+P340, P305+P351+P338, P308+P311, P391, P410, P501** |
| Additional labelling phrases: | **To avoid risks to man and the environment, comply with the instructions for use. [EUH401]** |
|  | **Contains spiroxamine. May produce an allergic reaction. [EUH208]** |

|  |  |
| --- | --- |
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| EUH 208 | Contains spiroxamine. May produce an allergic reaction. |

**See Part C for justifications of the classification and labelling proposals.**

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe 3 | To protect aquatic organisms respect 20 m unsprayed, vegetated buffer zone to surface water bodies. |

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

There are no other phrases to be included according to Article 65 (3) of the Regulation (EU) No 1107/2009.

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
| - | - |
| Worker protection: |  |
| - | - |
| Integrated pest management (IPM)/sustainable use: | |
| - | - |
| Environmental protection | |
| - | - |
| Other specific restrictions | |
| - | - |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
| - | - |

### Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

|  |  |  |
| --- | --- | --- |
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
| respective code if available | - | - |
| Environmental protection: | | Relevant for use no. |
| respective code if available | - | - |

## Intended uses (only NATIONAL GAP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | |  | | | | | | |  | | GAP rev.0, date: 2023-08 | | | | |
| PPP (product name/code): | | | | ULTRACENT 460 EC | | | | | | | Formulation type: | | EC | | | | |
| Active substance 1: | | | | prothioconazole | | | | | | | Conc. of as 1: | | 160 g/L | | | | |
| Active substance 2: | | | | spiroxamine | | | | | | | Conc. of as 2: | | 300 g/L | | | | |
| Safener: | | | | - | | | | | | | Conc. of safener: | | - | | | | |
| Synergist: | | | | - | | | | | | | Conc. of synergist: | | - | | | | |
| Applicant: | | | | XXXX | | | | | | | Professional use: | |  | | | | |
| Zone(s): | | | | central | | | | | | | Non professional use: | |  | | | | |
| Verified by MS: | | | | no | | | | | | |  | |  | | | | |
| Field of use: | | | | fungicide | | | | | | |  | |  | | | | |
| 1 | 2 | 3 | | 4 | 5 | 6 | 7 | 8 | 9 | | 10 | | 11 | 12 | 13 | 14 | |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | | **Application rate** | | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) | |
|  |  |  | |  |  | Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |  |  | |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | |
| 1 | PL | Wheat (winter) | | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), powdery mildew (ERYSGR) | Foliar spray | BBCH 30-31 | 1. 1 2. 1 | - | | 1. 0.75 2. 0.75 | | 1. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha 2. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha | 200-400 | 35 |  | |
| 2 | PL | Wheat (winter) | | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), powdery mildew (ERYSGR) | Foliar spray | BBCH 31-37 | 1. 1 2. 1 | - | | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |
| 3 | PL | Wheat (winter and spring) | | F | Rust species (PUCCSP),  Brown rust (PUCCRE)  Powdery mildew (ERYSGR)  Septoria leaf spot(SEPTTR)  Glume blotch (LEPTNO)  Tan spot(PYRNTR) | Foliar spray | BBCH 30-59 | 1. 1 2. 1 | - | | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |
| 4 | PL | Barley (winter and spring) | | F | Eyespot (PSDCHE)  Brown rust (PUCCHD)  Powdery mildew (ERYSGR)  Rhynchosporium (RHYNSE)  Net blotch (PYRNTE)  Fusarium stem blight(FUSASP*)* | Foliar spray | BBCH 30-51 | 1. 1 2. 1 | - | | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |
| 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) | | | | | | | | | | | | | | | | | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | | | | | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |
| Minor uses according to Article 51 (interzonal uses) | | | | | | | | | | | | | | | | | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |
|  |  |  | |  |  |  |  |  |  | |  | |  |  |  |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| Remarks  table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  4 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  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

# Background of authorization decision and risk management

## Physical and chemical properties (Part B, Section 2)

For the support of the application for authorization of ULTRACENT 460 EC, reference is made to the unprotected data and dossier of the reference product INPUT 460 EC (R-61/2011). Additional studies on physical-chemical properties conducted for ULTRACENT 460 EC are submitted in Poland to support the application and are submitted here as well for reasons of completeness.

All additional studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a yellowish brown liquid, with a mild aromatic odour. In aqueous solution, it has a pH value around 7.08 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA containers. Its technical characteristics are acceptable for an EC formulation.

## Efficacy (Part B, Section 3)

ULTRACENT 460 EC is a new fungicide product for use in wheat and barley. All field data from Poland are included. For submissions to Poland, these data are relevant, as disease levels in these trials were significant and indicate a good test for the product and the reference product.

The intention of this submission is to demonstrate the comparability of ULTRACENT 460 EC to Input 460 EC, as part of an Article 34 submission. It would then be appropriate to refer to the out-of-protection data for this product, for extrapolation to uses not included in this programme of trials.

## Efficacy data

Preliminary tests

The preliminary work on prothioconazole and spiroxamine is in the public domain; no further preliminary work was conducted by the applicant.

Minimum effective dose

The dose rates of prothioconazole and spiroxamine in the product ULTRACENT 460 EC are well established; the applicant does not propose to change these rates.

Efficacy tests

A total programme of eight replicated trials was conducted in Poland in 2022. This programme gives a very clear indication of the very high levels of control of key diseases which can be achieved by the use of ULTRACENT 460 EC.

The trials results indicate that the product can achieve high levels of control of a range of fungal diseases in wheat and barley. This performance is comparable to that of the reference product Input 460 EC.

In almost every case the performance of ULTRACENT 460 EC was equivalent to that of the reference products. It is submitted that based on the data presented in this dossier ULTRACENT 460 EC can be approved for use on wheat and barley.

It is reasonable to extrapolate from this range of trials on five diseases to the other diseases in the GAP table. This comparability means that it is reasonable to regard all out of protection data for Input 460 EC as being applicable to ULTRACENT 460 EC.

### Information on the occurrence or possible occurrence of the development of resistance

The active substances in the proposed product ULTRACENT 460 EC are prothioconazole and spiroxamine.

Prothioconazole is a triazole, DMI fungicide, FRAC Group 3, G1. Spiroxamine is a spiroketalamine compound, active by sterol biosynthesis inhibition; Δ14 reductase and Δ8 to Δ7 isomerase inhibition (SBII), in FRAC Group 5.

Triazole and other DMI (De-Methylation Inhibitor) fungicides have been available for many years and as a result resistance has developed in a wide range of pathogens. These include some major cereal diseases including *Zymoseptoria tritici*, powdery mildew, Rhynchosporium and possibly Net Blotch.

The use of this product without any restrictions or recommendations for risk mitigation is not acceptable.

The use pattern should therefore be modified by an appropriate resistance management strategy.

The risk of pathogens developing resistance to fungicides can be reduced by various means.

(1) Where available, make full use of disease-resistance varieties.

(2) Use crop rotation to avoid the build-up of soil-borne pathogens.

(3) Practise good crop hygiene by paying close attention to the disposal of plant debris and elimination of other primary sources or inoculum, *e.g.* self-sown plants, dumps *etc.*

(4) Use soil sterilisation, tool disinfection and general hygiene to reduce the incidence of disease.

(5) Minimise the use of fungicides by avoiding unnecessary prophylactic treatments and particularly repeated applications of fungicides of the same group.

(6) Alternate applications of fungicides from different groups, or use recommended formulated mixtures or tank-mixes designed to help combat resistance. Use at effective doses. Lists of popular fungicides approved for use on different crops ordered by fungicide group are available online at http://frag.csl.gov.uk.

(7) Make as full a use as possible of fungicides with a multi-site mode of action, which are less prone to fungicide resistance problems.

(8) In cereals, use can be made of varietal mixtures and other diversification strategies to decrease epidemic development.

The risk for the development of resistance of target species were analysed following EPPO guideline PP1/213(1). As resistance to this class of chemistry already exists in field populations of key pathogens, an anti-resistance strategy has been developed and described.

### Adverse effects on treated crops

Phytotoxicity to host crop

No symptoms of phytotoxicity were observed in any of the efficacy trials conducted, at any of the assessment timings.

Effect on the yield

A total of eight efficacy trials were carried out in 2022 in Poland. The objective was to confirm the yield response of product in the presence of disease.

ULTRACENT 460 EC at the proposed label rate of 1.0 L/ha had an overall positive effect on the yield of cereals in the presence of disease. In fact, there was a 11% increase in yield over the untreated.

Effect on the quality

No disease-free trials in this series were taken to yield. The reviewer is referred to the out-of protection data for Input 460 EC.

Effect on transformation processes

No transformation work was conducted in this series. The reviewer is referred to the out-of protection data for prothioconazole and spiroxamine

Impact on treated plants or plant products to be used for propagation

No disease-free trials in this series were taken to yield. The reviewer is referred to the out-of protection data for Input 460 EC.

### Observations on other undesirable or unintended side-effects

Impact on succeeding crops

Prothioconazole and spiroxamine are fungicides with no herbicidal activity. Consequently, the applicant proposes that no work is required to determine the safety to potential succeeding crops.

Further information on the fate and behaviour of the active substances in ULTRACENT 460 EC in the soil can be found in the relevant section in the fate and behaviour dossiers submitted for this product.

It is submitted that there will be no unacceptable effects to succeeding crops from applications of ULTRACENT 460 EC to wheat and barley.

Impact on other plants including adjacent crops

Prothioconazole and spiroxamine are approved to be applied to a wide range of crops around the world; due to the activity and excellent selectivity of the product, it is unlikely that the product will cause damage to any neighboring crops. Nevertheless, it is of importance to limit the drift of the product onto non-target plants including adjacent crops.

Effects on beneficial and other non-target organisms

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

## Methods of analysis (Part B, Section 5)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Analytical method for the formulation

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

### Analytical methods for residues

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*The following information can be found in the evaluation reports that were compiled for the authorization of* *INPUT 460 EC (R-61/2011) in Poland:*

Validated analytical methods are provided for the determination of residues of Prothioconazole (JAU 6476) and Spiroxamine (KWG 4168) in material of agricultural and animal origin and in soil, water and air.

The limits of quantification (LOQ) of the included analytical methods are sufficient to verify compliance with the respective reference values for food of agricultural origin, material of animal origin, water, soil and air. Determinations were performed at different levels of fortification including the proposed limits of quantification of the analytical methods.

Conclusions:

1) Average recovery rates obtained: 70 to 110%.

2) Relative standard deviation obtained: <20%.

3) The proposed analytical methods are specific for the analytes determined.

4) No interfering compounds were found to be present in the matrices tested (< 30% quantification limit). limit of quantification).

5) Methods meet Sanco requirements: "Guidance document on residue analytical methods SANCO/825/00 rev.7 (17.03.04)' and 'Guidance document Quality control procedures for pesticide residues analysis SANCO/10232/2006 (24.03.06)'.

The adequate methods are available.

Not accepted as the unprotected data of the product *INPUT 460 EC (R-61/2011)* needed to the authorisation was not provided.

## Mammalian toxicology (Part B, Section 6)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

The applicant Bayer Sp. z o.o. has submitted the results of toxicological tests accepted for the preparation of an assessment and report on the toxicity to humans and animals of the product INPUT 460 EC.

The estimated exposure to the plant protection product for the operator, worker and bystanders does not indicate a health risk for these groups of workers.

### Acute toxicity

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

**zRMS**:

As it have been demonstrated in confidential part C of this report the composition of ULTRACENT 460 EC is comparable with composition of the product INPUT 460 EC, for which toxicological data are no longer protected, therefore in line with article 34 of Regulation (EC) No 1107/2009: “Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and …that any data protection period has expired.”Based on these data it is confirmed that ULTRACENT 460 EC should be classified as:

Acute tox. 4, H302+H332

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

Repr. 2, H361d

STOT RE 2, H373

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

EUH208 - Contains spiroxamine. May produce an allergic reaction.

### Operator exposure

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

**zRMS**:

***The assumption of 60% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio is acceptable.***

**Operators.** As a result of application product ULTRACENT 460 EC at dose of 1L/ha in line with GAP the exposure of operator wearing work wear covering body, arms and legs during M/L and A and protective gloves doing M/L calculated with the EFSA AOEM 2022 amounted for spiroxamine 55.3% of respective AOEL, to prothioconazole 4% of AOEL and to Prothioconazole-desthio 23.7% of respective AOEL. Combined Hazard index was below 1. Therefore, the application of a product ULTRACENT 460 EC does not pose an unacceptable risk to the health of operator using tractor-mounted/trailed boom sprayer without drift reduction technology for application of the product at dose of 1L/ha in line with its intended use within good agricultural practice providing that he is wearing a work wear (with arms, body and legs covered) during M/L and A, and protective gloves during M/L. It is noted that the product is classified as Skin Irrit. 2 and Eye Irrit 2 thus the operator should wear a work wear covering arms, body and legs during mixing/loading and application, protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

### Worker exposure

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

**zRMS**:

The estimation of exposure of worker wearing a work wear (with arms, body and legs covered) to both active substances of a product ULTRACENT 460 EC applied on a field of cereals at dose of 1.0 L product/ha, using tractor-mounted/trailed boom sprayer without drift reduction technology, calculated with the EFSA AOEM 2022 demonstrates that a potential exposure of worker and an exposure of worker wearing a work wear (with arms, body and legs covered) is equal respectively for spiroxamine 51.8 % of respective AOEL, to prothioconazole 3.4% of AOEL and to Prothioconazole-desthio 24.4% of respective AOEL.

The sum of exposures of worker wearing a work wear (with arms, body and legs covered) to both active substances and to metabolite Prothioconazole-desthio expressed as percent-age of their AOELs (51.8 % + 3.4 % + 24.4%) is below 100%, therefore the application of product ULTRACENT 460 EC does not pose an unacceptable risk to the health of worker wearing a work wear (with arms, body and legs covered) entering for 2hrs inspection a field of cereals treated with a product ULTRACENT 460 EC according to its intended use on cereals within good agricultural practice.

### Bystander and resident exposure

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

**zRMS**:

The exposure estimation of resident (adult and child) to both active substances of a product ULTRACENT 460 EC applied on a field of cereals at dose of 1.0 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, and 10 m not spray buffer zone calculated with the EFSA AOEM 2022 demonstrates that such a exposure for child and adult resident is equal respectively for spiroxamine to 63.4% and to 31.1 % of AOEL, and for prothioconazole to 4.2 % and to 2.0 % of AOEL for Prothioconazole, and to Prothioconazole-desthio an environmental metabolite of Prothioconazole to 35.3 and 16.5 % of AOEL The combined exposures of adult or child resident to both active substances and to metabolite Prothioconazole-desthio expressed as hazard index equal respectively 1 for child resident and 0.5 for adult resident thus the application of product ULTRACENT 460 EC does not pose an unacceptable risk to the health of adult and child resident for its intended use on cereals within good agricultural practice under condition of using risk management measures such as drift reduction technology (50%) and 10 m buffer zone not spread with a product. It is highly probable that the exposures of residents have been considerably overestimated since a default dermal absorption values were used for Prothioconazole, while in fact its absorption could be at least two times smaller. Also the dermal absorption value of 20% for Prothioconazole-desthio has been used based on results of old study, and its real absorption is most probably lower.

No bystander acute exposure estimation for spiroxamine and for prothioconazole is required since no acute acceptable operator exposure value (AAOEL) has be set for any of these active substances nor for metabolite Prothioconazole-desthio. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to spiroxamine and to prothioconazole, and to metabolite prothioconazole-desthio as a result of application of a product ULTRACENT 460 EC with accordance with intended use within good agricultural practice.

## Residues and consumer exposure (Part B, Section 7)

See B7 for details of the evaluator decision justification.

Since the relevant registration report of INPUT 460 EC was not provided, the inconsistency of spiroxamine MRL for the barley was already identified within INPUT 460 EC residue data presented, and in the context of prothioconazole, the triazoles data submission requirement was not met, the authorization for UL-TRACENT 460 EC cannot be granted.

Note: the “List of data relied on and not submitted by the applicant but necessary for evaluation” in Appendix 4 is used by an evaluator to indicate the studies that should be asap submitted to allow the assessment. It is not clear what is the applicant’s intention here.

### Residues

**February 2025**: the applicant reconstructed the B7 clearly providing all required data consistently with the current requirements. The data available are now considered sufficient for risk assessment. An exceedance of the current MRLs is not expected to be exceeded. The chronic and the short-term intakes of the actives are unlikely to present a public health concern. The approval for the intended GAP of Ultracent 460 EC can be granted.

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

Stability studies of prothioconazole and prothioconazole-desthio (metabolite M04) residues were carried out on wheat samples (considering whole plant, straw and grain). The samples were analysed by HPLC-MS/MS. The method's limit of quantification was 0.05 mg/kg for straw and green material and 0.01 mg/kg for grain (Heinemann 2001). It was found that there was no decrease in prothioconazole residue levels for 180 days, when stored at -18 ºC. The stability of prothioconazole-desthio was also demonstrated for more than 540 days. The concentrations of both substances tested during storage were within the required limits (70 - 110% of initial concentrations). The results showed that the storage time of the samples to be analysed in field trials was acceptable.

Stability studies of spiroxamine and N-oxide metabolite (M3) residues were carried out on wheat samples (considering whole plant, straw and grain). Test samples were fortified at 0.5 mg/kg and stored at -20ºC for 434 days. No decrease in residue levels was observed during storage of the samples.

### Consumer exposure

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

TMDI (chronic) and IESTI (acute) were calculated with PRIMo revision 3.1 (2021/01/06). Taking into consideration the current MRLs. TMDI and IESTI values were all below the Trigger of 100 % of ADI and ARfD, respectively.

Extensive calculations sheets are presented in Appendix 3 of Part B Section 7 (A 3.1 TMDI calculations, A 3.3 IESTI calculations – Raw commodities and A 3.4 IESTI calculations – Processed commodities).

## Environmental fate and behaviour (Part B, Section 8)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

### Predicted environmental concentrations in soil (PECsoil)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~In soil, prothioconazole - JAU6476 degrades 49.9% to JAU6476-desthio(M04) (in field tests, the maximum conversion rate is 57.1%) and 14.6% to JAU6476-S-methyl (M01). The substance only slightly mineralises to CO2 - 0.9-10.7%, while the amount of non-extractable residues after 120 days reaches 35.6 - 48.3%.~~

~~Spiroxamine degrades slowly in soil to CO2 (30.7 - 44.7% after 100 days) and non-extractable residues (24.7 - 26.4% after 100 days). No significant degradation products were found.~~

~~For INPUT 460 EC formulation, calculated initial PECs = 0.66 mg/kg soil~~

The PECsoil calculations for Prothioconazole, Spiroxamide, their metabolites, and for formulation were provided by the Applicant and are considered acceptable. The risk envelope approach was used. The EU agreed endpoints were used for PECsoil calculations of Prothioconazole, Spiroxamide and their metabolites.

The PECsoil reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

### Predicted environmental concentrations in groundwater (PECgw)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization~~**~~of INPUT 460 EC (R-61/2011) in Poland:~~*

|  |  |
| --- | --- |
| ~~Assessment of risk to groundwater from the active substance (as a consequence of the calculation, respectively accurate concentrations)~~ | ~~Prothioconazole: The results of the assessment of the predicted environmental concentrations of prothioconazole in groundwater as submitted by the applicant show that with the proposed use of the plant protection product INPUT 460 EC for Poland, the concentration of this substance in groundwater is below the threshold value of 0,1 mg/l. Therefore, it can be concluded that the likelihood of prothioconazole contamination of groundwater resulting from the use of the plant protection product INPUT 460 EC is minimal.~~  ~~Spiroxamine: The results of the estimation of the predicted environmental concentrations of spiroxamine in groundwater submitted by the applicant show that with the proposed use of the plant protection product INPUT 460 EC for Poland, the concentration of this substance in groundwater is below the threshold value of 0.1 mg/l. Therefore, the likelihood of groundwater contamination by spiroxamine resulting from the use of the plant protection product INPUT 460 EC can be considered to be minimal.~~ |
| ~~Groundwater risk assessment by metabolites (as a consequence of the calculation, respectively accurate concentrations)~~ | ~~Prothiconazole: An assessment was carried out for two relevant degradation products of JAU6476 in soil - JAU6476-desthio and JAU6476-S-methyl. In both cases, the predicted environmental concentrations of these substances in groundwater were found to be below the threshold value of 0.1 µg/l with the use pattern of the plant protection product INPUT 460 EC proposed for Poland. For this reason, it can be concluded that the likelihood of groundwater contamination by JAU6476-desthio and JAU6476-S-methyl resulting from the use of the plant protection product INPUT 460 EC is minimal.~~  ~~Spiroxamine: no significant soil degradation products of spiroxamine were identified and therefore no further evaluation was carried out.~~ |
| ~~Assessment of the relevance of metabolites (structure, biological effectiveness, ecotoxicological relevance)~~ | ~~Prothiconazole: No risk of groundwater contamination by JAU6476 degradation products was identified and therefore no further assessment of their relevance was conducted.~~  ~~Spiroxamine: No assessment was required due to no significant soil degradation products of spiroxamine being detected.~~ |

The PECGW calculations for Prothioconazole and its metabolites: Prothioconazole-S-methyl, Prothioconazole-desthio), Spiroxamine and its metabolites: M01, M02, M03, were provided by the Applicant and are considered acceptable.

For active substances and their relevant metabolites PECGW calculations were performed with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4.

The PECGW of Prothioconazole and Spiroxamine (80th percentile), their metabolites, at 1 m depth following uses on cereals at the proposed maximum rates, were less than 0.001 μg/L in all scenarios of three models.

In conclusion, the results demonstrate that ULTRACENT 460 EC can be applied safely according to the recommended use patterns without risk of Prothioconazole, Prothioconazole-S-methyl and Prothioconazole-desthio, Spiroxamine, M01, M02 and M03 exceeding acceptable levels in groundwater.

### Predicted environmental concentrations in surface water (PECsw)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

The PECSSW/SED calculations for Prothioconazole and its metabolites (Prothioconazole-desthio, 1,2,4-Triazole) were provided by the Notifier and are considered acceptable.

For active substance and its relevant metabolites PECSW calculations were performed with FOCUS STEPS 1-2 (active substance and all its metabolites) and FOCUS STEP 3 (Prothioconazole-desthio) and FOCUS STEP 4 (Prothioconazole-desthio).

The additional calculation were performed by zRMS for Prothioconazole-S-methyl (Step 1).

The EU agreed endpoints were used.

The PECSW/SED calculations for Spiroxamine and its metabolites (M01, M02, M03 and M06) were provided by the Applicant and are considered acceptable.

For active substance and its relevant metabolites PECSW calculations were performed with FOCUS STEPS 1-2 (active substance and all its metabolites) and FOCUS STEP 3-4 (Spiroxamine).

The EU agreed endpoints were used.

The PECsw reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~Based on the assessment carried out, it can be concluded that the product Input 460 EC does not pose a risk to surface water.~~

~~The assessment carried out with regard to the threat to surface water indicates that the product Input 460 EC meets the requirements set out in Part C of Annex 3 to the Ordinance of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

### Predicted environmental concentrations in air (PECair)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

*The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

Due to the low volatility of both spiroxamine and prothioconazole and their rapid degradation in the atmosphere, unacceptable air pollution and secondary atmospheric deposition resulting from the use of INPUT 460 EC is not expected.

The assessment carried out with regard to air pollution indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).

## Ecotoxicology (Part B, Section 9)

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

### Effects on terrestrial vertebrates

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment carried out for birds and other terrestrial vertebrates indicates that Input 460 EC meets the requirements set out in Part C of Annex 3 to the Ordinance of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

***Birds***

A risk assessment for birds was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for birds.

***Mammals***

A risk assessment for mammals was conducted according to the “Guidance Document on Risk Assessment for Birds and Mammals” (EFSA Journal 2009; 7(12):1438). In the tiered risk assessment, an acceptable risk from the use of ULTRACENT 460 EC according to the GAP was demonstrated for mammals.

### Effects on aquatic species

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~A risk assessment carried out assuming the maximum predicted environmental concentration in surface water showed that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839), provided that it is applied at a distance of 20 m from water bodies and watercourses.~~

The relevant predicted environmental concentrations in water (PECsw) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The initial risk assessment was based on the worst case PECsw values and the results of laboratory toxicity testing.

According to Polish national requirements, for each crop the appropriate for Poland scenarios must be included (for surface water: D3, D4, R1). Due to the lack of R1 scenarios for spring cereals, the winter cereals for this scenario are use as surrogate crop.

The calculated PEC/RAC ratios indicate an acceptable risk for all groups of aquatic organisms with following mitigation measures:

To protect aquatic organisms respect 20 m unsprayed, vegetated buffer zone to surface water bodies.

### Effects on bees

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment carried out showed that the use of Input 460 EC does not pose a risk to bees as the HQ risk factors are below the cut-off value of 50. The product can therefore be categorised as low risk to bees.~~

~~The risk assessment carried out indicates that the product will not cause unacceptable effects on bees and therefore meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839). No risk management measures are required in this respect.~~

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible risk associated with the exposure of beesto ULTRACENT 460 EC.

No studies on chronic effects of the formulation to adult bees or to larvae were provided in the risk assessment to bees, although this is a data requirement set by the Commission Regulation (EU) 284/2013. The deficiencies should be addressed before the new EFSA guidance becomes applicable.

### Effects on other arthropod species other than bees

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment for terrestrial arthropods other than bees indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

Based on the results of the conducted risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of ULTRACENT 460 EC according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

### Effects on soil organisms

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The risk assessment carried out for earthworms and other soil macro-organisms indicates that the product Input 460 EC meets the requirements given in Part C of Annex 3 to the Regulation of the Minister of Agriculture and Rural Development of 17 May 2005 (Journal of Laws No. 100, item 839).~~

Safe use of ULTRACENT 460 EC in cereals (worst case exposure scenario) were confirmed based on TERLT calculations for active substances, their metabolites and for formulation. Based on it, safe use of ULTRACENT 460 EC in cereals (worst case exposure scenario) was identified.

### Effects on non-target terrestrial plants

~~No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.~~

*~~The following information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:~~*

~~The results of the preliminary biological studies and the results of the studies conducted in accordance with OECD guidelines indicate that Input 460 EC will not cause unacceptable impacts on adjacent terrestrial plants.~~

Based on the results of studies for both active substances, no herbicidal of ULTRACENT 460 EC effect is expected.

### Effects on other terrestrial organisms (Flora and Fauna)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

## Relevance of metabolites (Part B, Section 10)

No data is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. ULTRACENT 460 EC does not contain a candidate for substitution.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

1. Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

1. Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

1. Letter of Access

XXXX

1. Lists of data considered for national authorization

No data other than the one cited below is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

|  |
| --- |
| The trials relating to the efficacy section "KCP 6.2, 6.4", in the table highlighted in gold (in total 8 trials), should be considered as protected data. |

List of data submitted by the applicant and relied on

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XXXX | XXXX |

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

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

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 Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

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

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XXXX | XXXX |