

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: FF-075**

**Product name(s): EUSKATEL PRO**

**Chemical active substances:**

**Prothioconazole, 200 g/L**

**Azoxystrobin 150 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT - Poland**

**(New Product Authorization)**

**Applicant: Rotam Agrochemical Europe Limited**

**Submission date: June 2021**

**MS Finalisation date: April 2022; 08/2022**

FF-075 / EUSKATEL PRO  
Part A - National Assessment  
Applicant version

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## Version history

When	What
June 2021	New product application in accordance with Article 33 of Regulation (EC) No. 1107/2009.
April 2022	zRMS evaluation
August 2022	Final version after commenting period

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

This document describes the acceptable use conditions required for the authorisation of the formulated product ‘EUSKATEL PRO’(code: FF-075) a suspension concentrate (SC) formulation containing 200 g/L prothioconazole and 150 g/L azoxystrobin. The application is made in the central zone in accordance with Article 33 of Regulation (EC) No. 1107/2009.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C and where appropriate, specific national addendum. The information, data and assessments provided in the Registration Report, includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to ‘EUSKATEL PRO’ where those data have not been considered previously or as part of an EU review.

Otherwise assessments for the safe use of ‘EUSKATEL PRO’ have been made using existing endpoints agreed in the EU review of prothioconazole (EFSA Journal 10.2903/j.efsa.2007.106r) and azoxystrobin (EFSA Journal 2010; 8(4):1542).

This document also describes the specific conditions of use and labelling required for the authorization of ‘EUSKATEL PRO’.

Appendix 1 of this document provides a copy of the final product authorisation.

Appendix 2 of this document is a copy of the approved product label.

#### **1.1 Application background**

This application is submitted by Rotam Agrochemical Europe Limited in support of the authorisation of ‘EUSKATEL PRO’ a new suspension concentrate (SC) formulation containing 200 g/L prothioconazole and 150 g/L azoxystrobin, intended for use as an agricultural fungicide for the control of various fungal diseases in a variety of winter and spring cereals and winter oilseed rape.

This application requests authorisation of ‘EUSKATEL PRO’ in Poland and in accordance with Article 33 of Regulation (EC) No. 1107/2009. Poland has agreed to the role of the zonal Rapporteur Member State (zRMS) for the central zone evaluating the core dossier.

Prothioconazole was considered as a new active substance under the provisions of Directive 91/414/EEC. It was included in Annex 1 on 1 August 2008 under Inclusion Directive 2008/44/EC. The date of expiration of approval was 31 July 2018. As part of the ongoing AIR III renewal of approval evaluation (RMS Poland) the expiry date was extended until 31 July 2021 (COMMISSION IMPLEMENTING REGULATION (EU) 2020/869). As part of the Standing Committee on Plants, Animals, Food and Feed Section meeting (25 March 2021) the expiry is to be further extended to 31 July 2022. The EFSA conclusion available from the original evaluation (dated 12 July 2007) is cited in support of this application.

Azoxystrobin was renewed on 1 January 2012 under Commission Implementing Regulation (EU) No

703/2011. The date of expiration of approval was originally 31 December 2021. On 19 February 2019 the molecule was further extended until 31 December 2024 in accordance with Commission Implementing Regulation (EU) 2019/291. There is an EFSA conclusion available from the original evaluation (EFSA Journal 2010; 8(4):1542, dated 12 March 2010) and which is cited in support of this application.

Azoxystrobin is scheduled for review under the AIR IV renewal of approval programme. Austria is confirmed as the evaluating RMS.

On the advice of the zRMS, the application has been prepared in accordance with endpoints in force at the date of submission. In general terms the Article 33 dossier submitted in support of the registration in Poland utilises and relies upon unprotected active substance data and existing agreed EU endpoints for both molecules. All third-party data relied upon in support of this application and which are specific to the approvals for both prothioconazole and azoxystrobin are considered to be in the public domain and available in support of the evaluation.

Stand-alone formulation data are submitted to address formulation data points as appropriate and are considered to be compliant with Commission Regulation (EU) No. 284/2013. Data protection is claimed for all new data submitted in support of the request for authorisation.

This document is a summary of the data submitted to support the registration of 'EUSKATEL PRO'.

Details of the GAP intended are presented in section 2.6 of this document.

## **1.2 Letters of Access**

Rotam has access to all data generated by the Triazole Derived Metabolite (TDM) Task Force.

Letters of supply for prothioconazole and azoxystrobin technical are provided as part of the request for authorisation – see Appendix 3.

All other data cited and relied as part of the application request, are considered to be unprotected and available in support of the risk assessment.

## **1.3 Justification for submission of tests and studies**

The studies submitted are necessary for authorisation of 'EUSKATEL PRO' are in accordance with Reg. (EU) No. 284/2013.

## **1.4 Data protection claims**

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.

# **2 Details of the authorization decision**

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## 2.1 Product identity

Product code	FF-075
Product name in MS	EUSKATEL PRO
Authorization number	-
Function	Fungicide
Applicant	Rotam Agrochemical Europe Limited
Active substance(s) (incl. content)	Prothioconazole 200 g/L Azoxystrobin 150 g/L
Formulation type	Suspension Concentrate [Code: SC]
Packaging	0.03 to 1 litre high density polyethylene (HDPE) bottle 1.2 to 1000 litre HDPE drum 0.1 to 1 litre fluorinated HDPE bottle 1.2 to 25 litre fluorinated HDPE drum
Coformulants of concern for national authorizations	n/a
Restrictions related to identity	n/a
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

The evaluation of the application for EUSKATEL PRO resulted in the decision to grant the authorization.

### Efficacy section:

According to limited number of trials we can accept in the GAP table and label project only: in winter oilseed rape use against SCLESC, in winter wheat use against SEPTTR and PUCCRT, winter barley against PYRNTE (this use was not included in GAP and label for PL by Applicant), winter triticale against SEPTTR and PYRNTE, and spring barley against PYRNTE. Winter rye, spelt and durum wheat should be excluded due to lack of trials.

## 2.3 Substances of concern for national monitoring

n/a

## 2.4 Classification and labelling



### 2.4.1 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:	Skin Sens. 1
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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 GHS09
Signal word:	Warning
Hazard statement(s):	H317: May cause an allergic skin reaction H410 – Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	<p><b>WARNING SECTION OF THE LABEL (first page):</b>  P261: Avoid breathing spray.  P280: Wear protective gloves.  P302+P352: IF ON SKIN: Wash with plenty of water.  P391 - Collect spillage.</p> <p>Contains 1,2-Benzisothiazolin-3-one and reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)).  May produce an allergic reaction.</p> <p><u>Other section of the label:</u>  P261: Avoid breathing vapours/ spray.  P270: Do not eat, drink or smoke when using this product.  P272: Contaminated work clothing should not be allowed out of the workplace  P362+P364: Take off contaminated clothing and wash it before reuse.  P501: Dispose of contents and/or their container according to the separated collection system used in your municipality.</p> <p>And P280 as follows:  <u>Operator:</u>  <i>“Stosować rękawice ochronne i odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w czasie zabiegu.”</i>  “Use protective gloves and work wear during mixing and loading and application”</p> <p><u>Section First aid:</u>  P302+P352: IF ON SKIN: Wash with plenty of water.  P333+P313: If skin irritation or rash occurs: Get medical advice/attention</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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:	



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

## 2.4.2 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).
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## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

SPe3	20 m vegetative strip and 20 m no spray buffer was applied for uses in winter oilseed rape winter and spring cereals to surface water bodies
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:	
respective code if available	Classification: protective gloves. Exposure: None
Worker protection:	
respective code if available	No PPE Work wear and protective gloves are recommended
Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
respective code if available	20 m vegetative strip and 20 m no spray buffer was applied for uses in winter oilseed rape , winter and spring cereals to surface water bodies
Other specific restrictions	
respective code if available	

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

Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

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## 2.5.2 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	e.g. The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
respective code if available	e.g. The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	use number from GAP table in 2.6

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## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1.0, date: 2021-05-01

PPP (product name/code): EUSKATEL PRO / FF-075  
Active substance 1: Prothioconazole  
Active substance 2: Azoxystrobin  
Active substance.....: N/A  
Safener: N/A  
Synergist: N/A  
Applicant: Rotam Agrochem International Company Ltd  
Zone(s): central  
Verified by MS: yes/no

Formulation type: Suspension Concentrate  
Conc. of as 1: 200 g/L  
Conc. of as 2: 150 g/L  
Conc. of as ....: N/A  
Conc. of safener: N/A  
Conc. of synergist: N/A  
Professional use: ☐  
Non professional use: ☐

Field of use: fungicide

Use no.	Crop and/or situation (a)	Member state or Country	Product name	F / G / I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)	zRMS Conclusion (efficacy)
						Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	min interval between application (days)	kg as/hL min max	water L/ha min max	kg as/ha min max			
1	OSR, winter (BRSNW)	PL	FF-075	F	<i>Sclerotinia sclerotiorum</i> White mould (SCLESC)	SC	350	Foliar Spray	BBCH 55-69 BBCH 55 59	1-2	14	Prothio 0,040-0,160; azoxy 0,030-0,120	100 - 400	Prothio 0,040-0,160; Azoxystrobin 0,030-0,120	35-56	Max. individual dose 0.8 l per ha. Max. total dose per season 4.6 l per ha	<b>Efficacy section:</b> In Poland only 1 application can be accepted <b>Metabolism and residues:</b> Acceptable to BBCH 59 phase PHI of 56 is proposed by zRMS

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Use no.	Crop and/or situation (a)	Member state or Country	Product name	F / G / I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)	zRMS Conclusion (efficacy)
						Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	min interval between application (days)	kg as/hL min max	water L/ha min max	kg as/ha min max			
2	OSR, winter (BRSNW)	PL	FF-075	F	<i>Alternaria brassicae</i> Dark leaf spot (ALTEBA)	SC	350	Foliar Spray	BBCH 55-69	1-2	14	Prothio 0,040-0,160; azoxy 0,030-0,120	100 - 400	Prothio 0,160; Azoxy 0,120	35	Max. individual dose 0,8 l per ha Max. total dose per season 1,6 l per ha	Efficacy section: not accepted this use
3	wheat, winter and durum, spelt, triticale	PL	FF-075	F	<i>Septoria tritici</i> (SEPTTR)	SC	350	Foliar Spray	BBCH 30-59	1 - 2	14	Prothio 0,05-0,20; azoxy 0,375-0,150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: durum wheat and spelt is not accepted.
4	wheat, winter and durum, spelt, triticale	PL	FF-075		<i>Puccinia striiformis</i> Yellow Rust (PUCST)	SC	350	Foliar Spray	BBCH 30-59 Up to GS69	1-2	14	Prothio 0,05-0,20; azoxy 0,375-0,150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
5	wheat, winter and durum, spelt, triticale	PL	FF-075		<i>Puccinia recondita</i> Brown rust (PUCRT)	SC	350	Foliar Spray	BBCH 30-69	1 - 2	14	Prothio 0,05-0,20; azoxy 0,375-0,150	100 - 400	Prothio 0,05 0,20; azoxy 0,375 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: durum wheat, triticale and spelt is not accepted. Only 4-2 applications per season is accepted.
6	barley, spring	PL	FF-075	F	<i>Rhynchosporium secalis</i> Leaf blotch (RHYNSE)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 - 200; Azoxy 37,5 - 150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
7	barley, spring	PL	FF-075	F	<i>Pyrenophora teres</i> Net blotch (PYRNTE)	SC	350	Foliar Spray	BBCH 30-49 69	1 - 2	14	Prothio 50 - 200; Azoxy 37,5 - 150	100 - 400	Prothio 0,05 0,20; azoxy 0,375 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha Need to	Efficacy: only 1 application is accepted at BBCH 30-49

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Use no.	Crop and/or situation (a)	Member state or Country	Product name	F / G / I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)	zRMS Conclusion (efficacy)
						Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	min interval between application (days)	kg as/hL min max	water L/ha min max	kg as/ha min max			
8	Rye, winter	PL	FF-075	F	<i>Puccinia striiformis</i> Yellow Rust (PUCGST)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxystrobin 37,5-150	100 - 400	Prothio 0,20; azoxystrobin 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
9	Rye, spring	PL	FF-075	F	<i>Puccinia striiformis</i> Yellow Rust (PUCGST)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxystrobin 37,5-150	100 - 400	Prothio 0,20; azoxystrobin 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
10	Rye, winter	PL	FF-075	F	<i>Puccinia recondita</i> Brown rust (PUCCRT)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxystrobin 37,5-150	100 - 400	Prothio 0,20; azoxystrobin 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
11	Rye, spring	PL	FF-075	F	<i>Puccinia recondita</i> Brown rust (PUCCRT)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxystrobin 37,5-150	100 - 400	Prothio 0,20; azoxystrobin 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
12	Oats, winter	PL	FF-075	F	<i>Puccinia coronata</i> Crown rust (PUCCCA)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxystrobin 37,5-150	100 - 400	Prothio 0,20; azoxystrobin 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use

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						Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	min interval between application (days)	kg as/hL min max	water L/ha min max	kg as/ha min max			
13	Oats; spring	PL	FF-075		<i>Puccinia coronata</i> Crown-rust (PUCCCA)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxy 37,5-150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
14	Triticale; winter	PL	FF-075		<i>Puccinia coronata</i> Crown-rust (PUCCCA)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxy 37,5-150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use
15	Triticale; spring	PL	FF-075		<i>Puccinia coronata</i> Crown-rust (PUCCCA)	SC	350	Foliar Spray	BBCH 30-69	1-2	14	Prothio 50 -200; Azoxy 37,5-150	100 - 400	Prothio 0,20; azoxy 0,150	35	Max. individual dose 1,0 l per ha Max. total dose per season 2,0 l per ha	Efficacy section: not accepted this use

The calculations PEC were based on the critical GAP in B8 section

**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.

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<b>Remarks</b>	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
<b>columns:</b>	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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

### **3 Background of authorization decision and risk management**

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

All 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 thick off-white liquid, with a mild characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable and has no flash point below its decomposition temperature of 97.5 °C. It is not self-heating. In aqueous solution, it has a pH value of 6.64 at 20°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 significantly changed. The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in white HDPE bottles with white, plastic, screw-top lids. Its technical characteristics are acceptable for a Suspension concentrate formulation.

The intended concentration of use is 0.2 – 2% v/v

No tank mixes recommended

#### **3.2 Efficacy (Part B, Section 3)**

##### Introduction

The corresponding dRR, Part B, Section 3 summarises the information related to the efficacy of the plant protection product FF-075 (soluble concentrate) containing the active substances prothioconazole and azoxystrobin, which were included into Annex I of Directive 91/414/EEC under EU Regulations ((EU) 2019/150 and (EU) No 703/2011). The SANCO reports for prothioconazole (SANCO/3923/07 – 10/12/2007) and azoxystrobin (SANCO/11027/2011 – 20/03/2015)) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive(s) for prothioconazole (2019/150/EC) and azoxystrobin (703/2011/EC)) provide specific provisions under Part A and Part B, which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

Only uses as fungicide may be authorised.

##### Description of the plant protection product

FF-075 is a soluble concentrate (SC) containing 200 g/L prothioconazole and 150 g/L azoxystrobin for control of white mould, dark leaf spot, net blotch, yellow rust, brown rust, crown rust, leaf blotch and head blight complex with a post-emergence application of 0.8 – 1.0 L/ha on oilseed rape and cereals (professional use).

FF-075 is currently not registered. The application will be submitted based on Article 33 of EU 1107/2009 in the following member states of the Central regulatory zone: the Czech Republic, Germany, Ireland, and Poland.

##### Information on trials submitted



The corresponding dRR, Part B, Section 3 summarises 66 effectiveness trials against different fungicidal diseases performed during the period of 2019 and 2020 across a number of European countries (Czech Republic, Denmark, France, Germany, Ireland, Poland, Sweden and the United Kingdom) in a variety of crops (winter and spring wheat, winter and spring barley, winter rye, winter triticale, oats and winter oilseed rape).

### 3.3 Efficacy data

#### Preliminary tests

No preliminary range finding tests were conducted. The active substances included in the product FF-075 are available for long time on the market and are used for fungicides over several years. The mode of action and the effectiveness is well known of these substances.

Applicant did not submit any justification of the mixture. However, in efficacy trials different standard reference were used – comparing azoxystrobin or prothioconazole. Euskatel Pro applied at recommended dose achieved consistently similar or higher levels of control than obtained with the prothioconazole containing reference products as well as the azoxystrobin-containing reference products. Combining two actives in Euskatel Pro has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management in the opinion of Evaluator. In the world are already known fungicides with prothioconazole and azoxystrobin in one plant protection products, for example: Maxentis is a unique co-formulation of two of the world's most effective fungicides, prothioconazole and azoxystrobin. As a Group 3 and 11, dual mode of action fungicide, it provides improved disease control spectrum, efficacy, and resistance management, as well as an important rotation option following commonly used in-furrow and seed treatment fungicides. It is registered and used in Australia.

#### Minimum effective dose tests

The evaluation was carried out in accordance with the Uniform Principles. To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect, in accordance with EPPO 1/225 (2).

Applicant submitted in total 30 trials in which MED dose was studied. In the Maritime EPPO zone 15 trials was performed: 14 on winter cereals (13 winter wheat and 1 winter barley in CZ-2; DE-5; FR-3, IE-1 and UK-3) and 1 trial on spring cereals (spring wheat) in UK. In the N-E EPPO zone: 10 trials were performed on winter cereals (winter wheat-4; winter barley-3; winter rye-1 and winter triticale -2), 3 trials on spring cereals (spring barley) and 2 trials on winter oilseed rape. From N-E EPPO zone only Poland was represented by trials.

#### Following fungal diseases were studied during MED trials:

- *winter cereals:*
  - ✓ Maritime EPPO zone: ERYSGR-2 trials, FUSASP-2 trials, LEPTNO-1 trial, PUCCHD-1 trial, PUCCRE-2 trials, PUCCRT-5 trials, PUCGST-1 trial, PYRNTR-1 trial, SEPTTR-11 trials
  - ✓ N-E EPPO zone: ERYSGR-1 trial, PUCCHD-1 trial, PUCCRE-2 trials, PUCCR-1 trial, PYRNTE-4 trials, RAMUCC-1 trial, RHYNSE-1 trial, SEPTTR-5 trials.
- *spring cereals:*
  - ✓ Maritime EPPO zone: ERYSYGR – 1 trial
  - ✓ N-E EPPO zone: ERYSYGR – 1 trial, PYRNTE-2 trials, RHYNSE-1 trial

- *winter oilseed rape:*
  - ✓ Maritime EPPO zone: lack of trials
  - ✓ N-E EPPO zone: SCLESC-2 trials

Each cMS should decide if documentation presented by Applicant to support MED dose is sufficient. In the opinion of ZRMs registration in ~~S-E~~ and MED EPPO zone is not possible due to lack of trials. Also, cMS from Maritime and N-E should decide if limited number of trials for most fungal diseases can be accepted. **However, final decision about acceptance or not MED trials is left to cMS.**

The proposed rate of 1.0 L/ha should be considered the minimum effective dose to deliver broad spectrum control of the target diseases on winter and spring cereals and dose 0.8 L/ha for winter oilseed rape under a wide range of environmental conditions in the context of “bridging data” or existing knowledge on the active substances and other relevant formulations with prothioconazole and azoxystrobin on the market (EPPO standard PP 1/307).

According to the presented results for winter cereals and spring cereals the dose of 1.0 l/ha and for winter oilseed rape the dose of 0.8 L/ha of FF-075 applied once or twice on the crops provided the optimum overall control and should be considered as the minimum effective dose against all mentioned pests.

### **Efficacy tests**

All details about efficacy methodology used during efficacy trials are presented above by Applicant. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards.

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by enough field efficacy tests (at least 6 for major pest and at least 3 for minor pest). However, in Poland (ZRMs) lack of registered fungicides with azoxystrobin and prothioconazole in one plant protection product. So, Applicant should present for major crop at least 6 trials (optimally 10) and for minor crops – at least 6 trials carried out during two growing seasons. **Each cMS should decide if documentation can be acceptable, according to their national rules.**

Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

Applicant correctly presented results separately for Maritime and N-E EPPO zone. Lack of trials for MED and ~~S-E~~ EPPO zone. Also, Applicant correctly present results separately for winter and spring cereals. **However, within winter and spring cereals, the results of each cereal for each disease unit should be presented separately. Such a presentation of the results would make it easier for the cMS to make a final decision.**

### **MARITIME EPPO ZONE:**

#### **✓ WINTER CEREALS:**

Applicant submitted in total 39 field trials showing the results in research into product efficacy carried out on winter cereals (winter wheat at BBCH 30-65 – 29 trials; winter barley at BBCH 31-49 – 9 trials; winter triticale at BBCH 31-39 – 1 trial).

Following fungal diseases were studied during trials: ERYSGH (1 trial), ERYSGT (2 trials), FUSASP (2

trials), LEPTNO (2 trials), PUCCSI (1 trial), PUCGST (2 trials), PYRNTE (2 trials), PYRNTR (1 trial), RHYNSE (4 trials), PUCCHD (6 trials), PUCCRE (5 trials), PUCCRT (7 trials) and SEPTTR (26 trials).

In the opinion of ZRMS for most fungal diseases Applicant submitted not enough trials (at least 6 should be presented). Following diseases from winter cereals were not assessed by ZRMS due to not acceptable number of trials: ERYSGH, ERYSGT, FUSASP, LEPTNO, PUCGST, PUCCSI, PYRNTE, PYRNTR. Those pests should be deleted from GAP table and label project. However, final decision is left to cMS.

Following fungal diseases, the cMS from Maritime EPPO zone can consider as acceptable in GAP table and label project: RHYNSE (4 trials on winter barley), PUCCHD (6 trials on winter barley), PUCCRE (5 trials: 4 trials on winter barley, 1 on winter triticale), PUCCRT (7 trials on winter wheat) and SEPTTR (26 trials on winter wheat).

- **One application on winter cereals (A)** After the use of FF-075 as a preventative fungicide treatment in winter cereals (HORVW, TRZAW and TTLWI) in one application.

**RHYNSE** – The leaf pathogen RHYNSE resulted moderately susceptible (L3 in the first and second assessments) to susceptible (L1-L2, second assessment) to FF-075 applied at 1.0 l/ha on the winter cereals. Furthermore, the test product displayed comparable control as the observed after the application of the reference product (Curbatur/Proline) in all leaves and assessments after the application (for all the considered trials).

**PUCCHD** – The leaf pathogen PUCCHD was susceptible to FF-075 applied once at a rate of 1.00 l/ha on the winter cereals. The effect was observed either at the first or second assessment in all assessed leaves (L1 to L3). Its effect was comparable (in most of the trials) or even superior to the control performed by the reference product tested (Curbatur/Proline).

**PUCCRE** - The leaf pathogen PUCCRE resulted susceptible to FF-075 applied at a rate of 1.00 l/ha on the winter cereals in the EPPO Maritime zone. The effect was observed for the shown assessment in every leaf considered for disease assessment. The effect of the test product was either comparable (as compared with Curabatur/ Proline) or superior (as compared with the application of Amistar) to the control performed by the reference products tested the latter was true for all the assessed leaves and in all trials considered for the comparison.

**PUCCRT** – The leaf pathogen PUCCRT resulted susceptible to FF-075 applied at a rate of 1.00 l/ha on the winter cereals. The effect was observed when considering L1 for disease assessment. The effect of the test product was comparable (considering all trials) as the control performed by the treatment of Curbatur/Proline (reference product tested).

**SEPTTR** – The leaf pathogen SEPTTR resulted moderate tolerant (L2- 2<sup>nd</sup> assessment) to moderate susceptible (L3-1<sup>st</sup> assessment, L1 and L3-2<sup>nd</sup> assessment) to FF-075 applied at 1.0 l/ha on the winter cereals. This, was comparable with the control observed after the application of Curbatur/Proline for most of leaves in most of considered trials, but significant superior as compared with the application of Amistar for all leaves assessed and trials considered.

- **One application on winter cereals (B)** After the use of FF-075 as a preventative fungicide treatment in winter cereals (HORVW, TRZAW and TTLWI) in one application.

**RHYNSE** – The pathogen was moderately susceptible (L3 in the first assessment) to susceptible (L1-L3, second assessment) to FF-075 when applied once on the crop at 1.0 l/ha). Its use was comparable to the commercial treatment (Amistar and Curbatur/Proline).

**PUCCHD** – The leaf pathogen PUCCHD resulted moderate susceptible (L3 in the second assessment) to susceptible (L1 to L3 in the first assessment and L1 to L2 in second assessment) to FF-075 after its use when applied once on the winter cereals at a rate of 1.00 l/ha. Its effect was comparable to the to the control performed by the commercial treatment tested (Curbatur/Proline) for all assessed leaves and in all presented trials.

**PUCCRE** – The pathogen was susceptible to FF-075 after the use (L1-L3 overall the time assessed) when applied once on the crop at 1.0 l/ha. Its use was comparable (Curbatur/Proline) or superior (Amistar) to the commercial treatments

**PUCCRT** – The leaf pathogen PUCCRT resulted susceptible to FF-075 after the use (L1 in the assessment shown) when applied at a rate of 1.00 l/ha. The effect of the test product was comparable (considering both trials) as the control performed by the Curbatur/Proline, the commercial treatment.

**SEPTTR** – The pathogen was moderately tolerant (L1-L3 overall the time assessed) to FF-075 when applied once on the crop at 1.0 l/ha. Its use was comparable to the commercial treatment (Amistar and Curbatur/Proline).

- **Two applications on winter cereals (AB)** After the use of FF-075 as a preventative fungicide treatment in winter cereals after two stepwise applications

**RHYNSE** – two applications were not studied

**PUCCHD** – two applications were not studied

**PUCCRE** – two applications were not studied

**PUCCRT** – The leaf pathogen PUCCRT resulted to be moderately susceptible (all leaves assessed 26-41 DA-B) to susceptible (in leaves assessed in the first assessments and 12-25 DA-B) to FF-075 applied at 1.0 l/ha twice. The effect of the use FF-075 was statistically comparable to superior as compared with the control observed after the application of Curbatur/Proline and Amistar overall the evaluation (all assessed leaves in all assessments).

**SEPTTR** – The pathogen resulted moderately susceptible (L1-1<sup>st</sup> assessment, L2 and L3-2<sup>nd</sup> assessment) to susceptible (L3-1<sup>st</sup> assessment and L1-2<sup>nd</sup> assessment) to FF-075 when applied twice on the crop at 1.0 l/ha in the EPPO Maritime zone. Its use was comparable to the commercial treatment (Amistar. Curbatur/Proline and Torero).

#### ✓ **SPRING CEREALS:**

Applicant submitted in total 2 field trials showing the results in research into product efficacy carried out on spring cereals (spring wheat at BBCH 31-43 and spring barley at BBCH 31-51).

Following fungal diseases were studied during trials: ERYSGH (1), ERSGR (1), PUCCHD (1), PYRNTE (1) and RHYNSE (1). In the opinion of ZRMS for all fungal diseases Applicant submitted not enough trials (at least 6 should be presented). Also, for spring cereals not acceptable number of trials was presented. Only 2 trials carried out on different cereals is not accepted. At least 6 trials should be presented. cMS can consider extrapolating results from winter cereals. However, even then the number of trials is very limited for most fungal diseases. In our opinion, only for PUCCHD such extrapolation could be possible. However, final decision is left to cMS.

- **One application on spring cereals (A)** After the use of FF-075 as a preventative fungicide treatment in spring cereals (HORVS and TRZAS) after one application.

**PUCCHD** The leaf pathogen PUCCHD resulted susceptible to FF-075 applied at a rate of 1.00 l/ha in the EPPO Maritime zone when considering % of severity as the parameter of comparison. Furthermore, the test product displayed equivalent (as compared with Amistar and Proline) control as the observed after the application of the reference products.

- **One application on spring cereals (B)** After the use of FF-075 as a preventative fungicide treatment in spring cereals (HORVS and TRZAS) after one application

**PUCCHD** The leaf pathogen PUCCHD resulted susceptible to FF-075 applied at a rate of 1.00 l/ha in the EPPO Maritime zone when considering % of severity as the parameter of comparison. Furthermore, the test product displayed equivalent (as compared with Amistar and proline) control as the observed after the

application of the reference products.

- **Two applications on winter cereals (AB)** – was not studied.

✓ **WINTER OILSEED RAPE:**

Four field trials were carried out in Germany (2), United Kingdom (1) and Ireland (1) during 2020 (4), to assess the efficacy of FF-075 against SCLESC (4 trials) in winter oilseed rape (BRSNW).

In the opinion of ZRMs only 4 trials on winter oilseed rape are not accepted (it is a major crop, so at least 6 trials should be presented). Also, against SLESC the number of trials is not sufficient. However, final decision about acceptance or not the winter oilseed rape in GAP table and label project is left to cMS.

- **One application on oilseed rape** After the use of FF-075 as a preventative fungicide treatment in oilseed rape (BRSNW) after one application

**SCLESC** The pathogen resulted moderately susceptible (after assessment of stems) to FF-075 when applied once on the crop at 0.8 l/ha in the EPPO Maritime zone. Its use was comparable to the commercial treatment (Proline).

- **Two applications on winter cereals (AB)** – was not studied.

***North-East EPPO zone:***

✓ **WINTER CEREALS:**

Applicant submitted in total 18 field trials showing the results in research into product efficacy carried out on winter cereals (winter wheat at BBCH 31-43 – 8 trials; winter barley at BBCH 31-45 – 6 trials; winter triticale at BBCH 30-41 – 3 trials and winter rye at BBCH 31-43 – 1 trial).

Following fungal diseases were studied during trials: ERYSGH (2 trial), Puccr (1), Puccst (1), PYRNTR (1), RAMUCC (2), RHYNSE (2), PUCCHD (3), PUCCRE (3), PYRNTE (7) and SEPTTR (10).

In the opinion of ZRMS for most fungal diseases Applicant submitted not enough trials (at least 6 should be presented for major and 3 for minor). Following diseases from winter cereals were not assessed by ZRMS due to not acceptable number of trials: ERYSGH, Puccr, Puccst, PYRNTR, RAMUCC, RHYNSE. Those pests should be deleted from GAP table and label project. However, final decision is left to cMS.

Following fungal diseases cMS should consider as acceptable in GAP table and label project by cMS from N-E EPPO zone: PUCCHD (3 trials **on winter barley**), PUCCRE (3 trials **on winter wheat**), PYRNTE (7 trials **on winter barley**) and SEPTTR (10 trials: **8 trials on winter wheat and 2 trials on winter triticale**).

- **One application on winter cereals (A)** After the use of FF-075 as a preventative fungicide treatment in winter cereals ((HORVW, SECCW, TRZAW and TTLWI) in one application (A).

**PUCCHD** – The pathogen was moderately tolerant (L3, 2nd assessment) or susceptible (L3, 1st assessment and L1-L2, 2nd assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was in all cases, comparable to the commercial treatments (Amistar, Proline and Tazer 250 SC).

**PUCCRE** – not studied at this application

**PYRNTE** - The pathogen was moderately tolerant (L1-L2, 2nd assessment) or moderately (L3, 2nd assessment) to susceptible (L3, 1st assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was in all cases comparable or superior to the commercial treatments (Amistar, Proline and Tazer 250 SC).

**SEPTTR** – The pathogen was susceptible (L2-L3) to FF-075 when applied once on the crop at 1.0 l/ha in

the EPPO North-east zone. Its use was in all cases comparable or superior to the commercial treatments (Amistar, Proline and Tazer 250 SC).

- **One application on winter cereals (B)** After the use of FF-075 as a preventative fungicide treatment in winter cereals ((HORVW, SECCW, TRZAW and TTLWI) in one application (B).

**PUCCHD** – The pathogen was susceptible (L1-L3, 1st assessment and L1-L2, 2nd assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was in all cases, comparable or superior to the commercial treatments (Amistar, Proline and Tazer 250 SC).

**PUCCRE** –The pathogen was susceptible (L1-L3 overall the evaluation) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was in all cases, comparable to the commercial treatments (Proline and Tazer 250 SC).

**PYRNTE** -The pathogen was moderately susceptible (L3, 2nd assessment) to susceptible (L1-L3, 1st assessment and L1-L2, 2nd assessment; most of the trials) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was superior to comparable to the commercial treatments in most trials (Proline and Tazer 250 SC).

**SEPTTR** – The pathogen was moderately tolerant (for assessed L3, 2nd assessment) to susceptible (for all rest of leaves in both assessments) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable (Amistar and Proline) or superior (Tazer 250 SC) to the commercial treatment.

- **Two applications on winter cereals (AB)** After the use of FF-075 as a preventative fungicide treatment in winter cereals after two step-wise applications it

**PUCCHD** – two applications were not studied.

**PUCCRE** – The pathogen resulted susceptible (L1-L3) to FF-075 when applied twice on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable to the commercial treatment (Amistar and Proline).

**PYRNTE** -two applications were not studied.

**SEPTTR** – The pathogen resulted susceptible (L1-L3 overall the evaluation) to FF-075 when applied twice on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable to the commercial treatment (Amistar and Proline).

#### ✓ **SPRING CEREALS:**

In total, six field trials were carried out in Poland during 2020 (6), to assess the efficacy of the foliar preventative fungicide FF-075 against ERYSGR (1 trial), PUCCCA (1 trial), PYRNTE (4 trials) and RHYNSE (1 trial) in cereals planted in spring (AVESS and HORVS).

In the opinion of ZRMS for all fungal diseases Applicant submitted not enough trials (at least 6 should be presented). Also, for spring cereals not acceptable number of trials was presented. At least 6 trials should be presented for representative crop, ex. spring wheat or spring barley. Only, if we assessed spring cereals as one group number of trials seems to be acceptable. cMS from N-E EPPO zone can also consider extrapolating results from winter cereals. However, even then the number of trials is very limited for most fungal diseases. In our opinion, only for RHYNSE such extrapolation could be possible. However, final decision is left to cMS. Below we presented results from RHYNSE (in the case of extrapolation) and PYRNTE (in the case of acceptance limited number of trials by cMS).

- **One application on spring cereals (A)** After the use of FF-075 as a preventative fungicide treatment in spring cereals (AVESS and HORVS) after one application.

**RHYNSE** The pathogen was susceptible (L1-L3) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable or superior to the commercial treatment (Tazer 250 SC).

**PYRNTE** The pathogen was moderately tolerant (L1, 2nd assessment), moderately (L2-L3, 2nd assessment) or susceptible (L2-L3, 1st assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable or superior to the commercial treatment (Amistar, Proline and Tazer 250 SC).

- **One application on spring cereals (B)** After the use of FF-075 as a preventative fungicide treatment in spring cereals (AVESS and HORVS) after one application

**RHYNSE** The pathogen was moderately susceptible (L2, 2nd assessment) to susceptible (L1-L3, 1st assessment and L1, 2nd assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable to superior to the commercial treatment (Tazer 250 SC)

**PYRNTE** The pathogen was moderately susceptible (L2-L3, 1st assessment and L1, 2nd assessment) to susceptible (L1, 1st assessment and L2, 2nd assessment) to FF-075 when applied once on the crop at 1.0 l/ha in the EPPO North-east zone. Its use was comparable to superior to the commercial treatment (Amistar and Proline and Tazer 250 SC).

- **Two applications on winter cereals (AB)** – was not studied.

✓ **WINTER OILSEED RAPE:**

In total, four field trials were carried out in Poland during 2019 (2) and 2020 (2), to assess the efficacy of the foliar preventative fungicide FF-075 against ALTEBA (1 trial) and SCLESC (4 trials) in winter oilseed rape (BRSNW).

In the opinion of ZRMs only 4 trials on winter oilseed rape are not accepted (it is a major crop, so at least 6 trials should be presented). Also, against SLESC (4) and ALTEBA (1) the number of trials is not sufficient. However, final decision about acceptance or not the winter oilseed rape in GAP table and label project is left to cMS. Below, we present results for SCLESC. Only SCLESC should be consider by cMS in our opinion.

- **One application on oilseed rape** After the use of FF-075 as a preventative fungicide treatment in oilseed rape (BRSNW) after one application

**SCLESC** The pathogen was moderately tolerant (after assessment of stems) to FF-075 when applied once on the crop at 0.8 l/ha in the EPPO North-east zone. Its use was comparable to the commercial treatment (Proline). Additionally, after classifying the stems using a scale of damage (classes 0-4= no disease, 4 death), after the treatment with FF-075, high efficacy for classes 1-3 was observed. Furthermore, the effect was statistically comparable with the commercial treatment (Proline).

- **Two applications on winter cereals (AB)** – was not studied.

**Summary the assessment for cMS:** The relevance of extrapolations between crops should be confirmed at the national level with respect to national conventions and importance of pest and crop. Trials were carried out in the Maritime and North-East EPPO zone. Individual Member States should consider whether the results from other EPPO zones are also relevant to their area.

The number of submitted trials for most diseases does not meet EPPO PP 1/226 in all EPPO zones, however reduced number of trials is possible according to EPPO standard PP 1/307 with reference to the product. Concerned Member States will need to consider the current authorized uses for the reference product in their own Member State. However, the reference products based on the same active ingredients (similar formulation) were not used in the trials to prove the comparability with the test product. Therefore, such a cohesiveness seems impossible in the opinion of the ZRMs.

cMS need to consider whether the proposed provisions in the GAP or label design are appropriate, the application window and number of applications. Not all diseases have been studied to demonstrate the efficacy of one and two doses, and for some only one application per season has been studied. It is the



opinion of the ZRMs that the approved applications should be consistent with the overdose studies performed by the Applicant. Alternatively, if cMS already has a registered product of identical formulation, they may consider accepting certain records based on already registered labels if internal regulations permit.

## ASSESSMENT FOR POLAND

In Poland (N-E EPPO zone) we can use for assessment also results from neighboring countries from other EPPO zone (ex. CZ, DE).

No plant protection product with both active substances – prothioconazole and azoxystrobin is registered in Poland, so we need at least 6 valid trials for major and minor crops.

Poland has own extrapolation results. The extrapolation results from winter cereals to spring cereals is possible when Applicant submitted enough number of trials for representative crop (ex. winter wheat) and at least 1-2 efficacy trials against each disease for each species of spring cereals.

It is not acceptable to sum/combine different species of cereals as a group (ex. winter cereals) and then extrapolate results from other group (ex. spring cereals). Always for a representative plant (e.g., winter wheat) there should be a set of results and for extrapolated cereals - at least 1-2 studies confirming the community should be presented.

### ✓ **WINTER CEREALS:**

In Poland we can accept in the label project following fungal diseases:

**PUCCHD** (rdza jęczmienia) – Applicant submitted trials carried out on winter barley in DE (4 trials), CZ (1 trial) and PL (3 trials). On the basis on 8 valid trials PUCCHD can be included in Polish label. Two applications were not studied during trials, so only one application per season can be accepted. PUCCHD was not included in GAP table and label project for registration. So, that is why the ZRMs are only indicating that this application could be accepted.

**PYRNTE** (plamistość siatkowa jęczmienia) – Applicant submitted trials carried out in Poland on winter barley (7 trials). Submitted number of trials are sufficient for including control PYRNTE by FF-075 in winter barley. However, Applicant included only PYRNTE for spring barley, in the opinion of ZRMs also winter barley should be included for this disease in label and GAP project. Two applications were not studied during trials, so only one application per season can be accepted.

**SEPTTR** (septorioza paskowana liści pszenicy) - Applicant submitted trials carried out **in Poland** on winter wheat (17 trials: DE-8, CZ-1, PL-8) and winter triticale (2 trials: PL). Submitted number of trials are sufficient for including control SEPTTR by FF-075 in winter wheat and winter triticale. Two applications and proposed window Application (BBCH 30-69) can be accepted. Applicant also submitted 2 trials for winter triticale against SEPTTR, on the basis on extrapolating results from wheat, this crop can be also included in GAP table. Winter durum and spelt should be deleted from GAP table and label project due to lack of trials.

**PUCCRT** (rdza brunatna pszenicy) - Applicant submitted trials carried out on winter wheat in DE (5 trials), CZ (1 trial) and PL (1 trial). On the basis on 7 valid trials PUCCRT can be included in Polish label. Two applications and proposed window Application (BBCH 30-69) can be accepted. Winter triticale spelt and durum should be deleted from GAP table and label project due to lack of trials.

**Due to not enough number of trials following fungal diseases should be deleted from GAP table and Polish label project: ERYSGH, ERYSGT, FUSASP, LEPTNO, PUCCSI, PUC CST, PYRNTR, RHYNSE, RAMUCC.**

### ✓ **SPRING CEREALS:**

Limited number of trials, only 5 carried out on spring cereals (spring barley-5 trials, oat-1 trial) was presented by Applicant.



Only **PYRNTE** (plamistość siatkowa jęczmienia) can be accepted on spring barley (on the basis on extrapolating results from winter barley, because on spring barley only 4 valid trials were presented for the assessment). Two applications were not studied during trials, so only one application per season can be accepted. However, narrow application window was studied during trials in the opinion of ZRMs and on the basis on submitted trials we can accepted: BBCH 30-49.

**RHYNSE, ERYSGR, PUCCCA should be deleted from GAP table and Polish label project** due to not enough of number of trials and lack of possibility for extrapolating results.

✓ **WINTER OILSEED RAPE:**

Applicant submitted in total 6 valid trials carried out on winter oilseed rape in Poland (4 trials) and DE (2 trials). Only, **SCLESC** can be accepted in GAP table and Polish label project. **ALTEBA should be deleted from GAP table and label project** due to not enough of number trials (only 1 trial was presented by Applicant).

Application window for winter oilseed rape to control **SCLESC** (zgnilizna twardzikowa) **can be accepted**. However, only one application per season can be accepted. Two doses were not studied during trials..

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

Prothioconazole is a fungicide, which belongs to FRAC group 3, G1 respectively, called DMI-fungicides (DeMethylation Inhibitors). Based on the current evidence the resistance risk assessment for DMI, SBI-Class I, Triazoles will be medium. It is known a cross resistance between DMI fungicide active against the same fungus. DMI fungicides show no cross resistance to other SBI classes. The published use pattern for all SBI classes covered by the FRAC SBI Working Group guidelines for management strategy reflects the resistance risk assessment. The active ingredient has systemic properties, is very rapidly absorbed into the plant and akropetal distributed in the transpiration stream. This results in both a protective and curative action. The result of the effect of prothioconazole is the abnormal formation of fungal infection structures and a strong inhibition of mycelial growth and spore germination. A penetration of the plant or the seed is thus prevented. The active ingredient is selective on a wide range of dicotyledonous and monocotyledonous crop species. Resistance is known in various fungal species. Several resistance mechanisms are known including a number of target site mutations on the cyp51 gene (cytochrome p450), overexpression of the cyp51 gene and effects on ABC transporters.

It is a systemic fungicide that interferes with fungal sterol biosynthesis resulting in the impairment of membrane function and limitation of fungal growth.

DMI fungicides act by inhibiting the Cytochrome P450-dependent C-14 demethylase reaction in fungal sterol biosynthesis. Blockage of the sterol biosynthesis leads to a reduction in the normal sterol pathway end products and an accumulation of other abnormal sterols.

Azoxystrobin is a fungicide, which belongs to FRAC group 11, C3 respectively, called QoI-fungicides (Quinone outside Inhibitors). All of the resistance pathogens bear a single site mutation at position 143 in the *cyt b* gene at the G143A site. In many cases, the presence of the mutated allele was associated with a decrease in / loss of disease control. Increasing the dose of a QoI compound is therefore not expected to be effective in controlling QoI resistant strains. However, rust pathogens (*Puccinia* spp, *Phakopsora*, *Hemileia*) have not developed resistance to QoI fungicides up to date. Recently, it has been shown that the G143A amino acid substitution most likely does not occur, when there is an intron after the nucleotide triplet coding for the glycine (G) at position 143 (Grasso *et al.*, 2006). The self-splicing process requires a specific and conserved recognition sequence 4 to 6 bases upstream from the splicing site and therefore a mutation in the

triplet coding for G143 resulting in cytochrome b deficiency that is lethal. This gene structure is present in all rust species studied so far as well as in *Alternaria solani* (Grasso *et al.*, 2006) and *Pyrenophora teres* (Sierotzki *et al.*, 2007). In addition, a second mutation, F129L, has been detected in *Pythium aphanidermatum*, *Pyricularia grisea*, *Alternaria solani*, *Plasmopara viticola*, *Pyrenophora teres* and *Pyrenophora tritici-repentis*. The F129L resistance factors are significantly lower in comparison with the G143A mutation and field performance of QoI containing mixtures remains good. In the latter two pathogens additionally also the G137R mutation has been found, however, at very low frequency and with small resistance factors.

In different *Puccinia* species, the presence of an intron has been observed directly after the triplet GGT that encodes for glycine at position 143. In all rust species included in this study, as well as in *Alternaria solani* and *Pyrenophora teres*, the codon GGT at position 143 is located exactly at the exon/intron boundary and is likely part of the signal sequences essential for the recognition of the intronic RNA to be excised. The authors predict that a nucleotide substitution in codon 143 (GGT → GCT), which is two nucleotides upstream from the exon/intron junction, will strongly affect the splicing process, leading to a deficient cytochrome b. The substitution of guanine to cytosine obviously does not allow a proper pairing of the exonic nucleotides with the intronic IGS sequence in the pre-mRNA molecule. Therefore, this substitution will be lethal, and individuals carrying this mutation will not survive. This mechanism has been recently confirmed to have a strong effect on the availability of cyt b transcripts in yeast (Vallières *et al.* 2012). As a consequence, it is concluded that resistance to QoI fungicides based on the G143A mutation is not likely to evolve in species such as rusts (*Puccinia* spp, *U. appendiculatus*, *P. pachyrhizi*, *H. vastatrix*), *P. teres* and *A. solani*. The presence of such an intron has also been reported in *Monilinia laxa*, *Monilinia fructicola* (Miessner and Stammler, 2010, Luo *et al.*, 2010) and *Guignardia bidwellii* (Miessner *et al.*, 2011) In the fungal species investigated so far, the presence of an intron was conserved over all investigated isolates within a species, even after many years of high selection pressure by QoIs. There is only one exception, *Botrytis cinerea*, where two forms of the cytochrome b gene have been reported (Banno *et al.*, 2009). However, it cannot be excluded that mutations other than G143A conferring resistance may arise in upcoming populations selected by the use of QoI fungicides. For *A. solani* and *P. teres* the mutations F129L and/or G137R have been reported (Sierotzki *et al.* 2007, www.frac.info) as a mechanism for QoI tolerance. Both mutations are of minor importance, however, because they generally lead to lower resistance factors (www.frac.info) than the G143A mutation and it has been found that these two mutations have no, or only limited impact on the field efficacy of QoIs (Semar *et al.* 2007). The results give some confidence around the continued sustainability of disease control with QoI fungicides in pathogens containing an intron after codon 143 in the cytochrome b gene providing responsible resistance management practices are implemented.

The Qo fungicides inhibit plant pathogens by blocking the pathogens ability to produce energy. They do this by blocking the transfer of electrons at the Quinone "outside" site of the bc1 complex (complex III in the electron transport chain).

Prothioconazole, as a DMI fungicide, is classified by the FRAC (2020) as medium risk of resistance.

Azoxystrobin, as a QoI-fungicide, is classified by the FRAC (2021) as a high risk of resistance.

**As a summary, the risk of resistance to FF-075 is considered acceptable when the product is used according to the GAPs and taking into account the proposed management strategies.**

Without any precautions the resistance risk is unacceptable. The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

**Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.**

### **3.3.2 Adverse effects on treated crops**

The adverse effects of FF-075 on a variety of crops (winter and spring wheat, winter and spring barley, winter rye, winter triticale, oats and winter oilseed rape) in the EPPO Maritime and EPPO North-east zones of the Central, Southern and Northern regulatory zone were tested in a series of trials.

In total, in all 66 efficacy trials the evaluation of selectivity of FF-075 was included. All trials were conducted according to GEP and followed the appropriate EPPO standards by officially recognised testing organisations.

#### **Phytotoxicity to host crop**

##### EPPO Maritime zone

No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 1.0 L/ha (corresponding to 200 g/L prothioconazole and 150 g/L azoxystrobin) were observed in any trials conducted in winter cereals, except in one.

The symptoms observed in one trial were only minor and had no influence on the health of the plants. No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 1.0 L/ha (corresponding to 200 g/L prothioconazole and 150 g/L azoxystrobin) were observed in any trials conducted in spring cereals.

No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 0.8 L/ha (corresponding to 160 g/L prothioconazole and 120 g/L azoxystrobin) were observed in any trials conducted in winter oilseed rape.

##### EPPO North-east zone

No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 1.0 L/ha (corresponding to 200 g/L prothioconazole and 150 g/L azoxystrobin) were observed in any trials conducted in winter cereals, except in six.

The symptoms observed in these trials were only minor and had no influence on the health of the plants.

No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 1.0 L/ha (corresponding to 200 g/L prothioconazole and 150 g/L azoxystrobin) were observed in any trials conducted in spring cereals.

No phytotoxicity symptoms caused by FF-075 at the proposed use rate of 0.8 L/ha (corresponding to 160 g/L prothioconazole and 120 g/L azoxystrobin) were observed in any trials conducted in winter oilseed rape.

#### **Effects on the yield of treated plants or plant products**

##### EPPO Maritime zone

FF-075 at the proposed label rate of 1.0 L/ha (corresponding to 200 g/l of prothioconazole and 150 g/l of azoxystrobin) had no negative effect on the yield of winter cereals in the presence of disease.

FF-075 at the proposed label rate of 0.8 L/ha (corresponding to 160 g/l of prothioconazole and 120 g/l of azoxystrobin) had no negative effect on the yield of oilseed rape in the presence of disease.

##### EPPO North-east zone

FF-075 at the proposed label rate of 1.0 L/ha (corresponding to 200 g/l of prothioconazole and 150 g/l of azoxystrobin) had no negative effect on the yield of winter wheat in the presence of disease.

FF-075 at the proposed label rate of 1.0 L/ha (corresponding to 200 g/l of prothioconazole and 150 g/l of azoxystrobin) had no negative effect on the yield of winter wheat in the presence of disease.

FF-075 at the proposed label rate of 0.8 L/ha (corresponding to 160 g/l of prothioconazole and 120 g/l of azoxystrobin) had no negative effect on the yield of oilseed rape in the presence of disease.

### **Effects on the quality of plants or plant products**

#### EPPO Maritime zone

Results show that sole treatments with FF-075 at the dose rates of 1.0 L/ha do not have any negative impact on the quality of winter cereals tested in these trials.

Results show that sole treatments with FF-075 at the dose rates of 0.8 L/ha do not have any negative impact on the quality of oil seed rape tested in these trials.

#### EPPO North-east zone

Results show that sole treatments with FF-075 at the dose rates of 1.0 L/ha do not have any negative impact on the quality of winter cereals tested in these trials.

Results show that sole treatments with FF-075 at the dose rates of 1.0 L/ha do not have any negative impact on the quality of winter cereals tested in these trials.

Results show that sole treatments with FF-075 at the dose rate of 0.8 L/ha do not have any negative impact on the quality of oilseed rape tested in these trials.

### **Effects on the transformation processes**

Since applications of FF-075 are made at an early stage of the crop's development, it is unlikely that prothioconazole and azoxystrobin have a negative effect on the crop products after a biological transformation process like brewing.

However, ZRMs do not agree that FF-075 are made at an early stage of the crop's development. Application window for winter cereals is 30-59 BBCH or 30-69 (depending on pest), spring cereals – BBCH 30-69 and winter oilseed rape – BBCH 55-69. In the absence of studies, in the opinion of ZRMs – cMS should consider following entry in the label: *We cannot exclude the possibility of an impact on transformation processes.* Both active substances are well known for many years. Thus, no special studies regarding the transformation process are included in this document.

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

The only way of propagation, which is applicable for the relevant crops included in the GAP of FF-075, is via plant seeds. Therefore, any effect of FF-075 on seed germination would be expected to have a potential effect on the suitability of seeds from treated plants to be used for propagation purposes. It is generally assumed that, if no residues are present in the plant at normal harvest time, no effects are expected on plant parts for propagation.

The above depicted results of phytotoxicity, yield and quality aspects after an application of FF-075 show that the application has mostly no negative effect on the crops and crop products.

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

#### Impact on succeeding crops

Neither positive nor adverse effects on other plants including succeeding crops were detected while carrying out the above-mentioned efficacy trials with an application of FF-075.

Both active substances are well known for many years. Thus, no special studies regarding succeeding crops are included in this document.

The applicant did not perform trials for this annex point. The requirements of the EPPO Standard PP 1/207 (Effects on succeeding crops) are therefore not fulfilled. However, both active substances are well known for many years. Azoxystrobin and prothioconazole are not persistent in soil. The half-life is approx: 80 days and 3 days. There are no known effects on plant growth and development or soil activity; it is reasonable to consider that the application of Euskatel Pro (product code: FF-075) according to label recommendations has no adverse effects on succeeding crops. So, statement was accepted: *There are no known effects on plant growth and development or soil activity; it is reasonable to consider that the application of Euskatel Pro (product code: FF-075) according to label recommendations has no adverse effects on succeeding crops.*

#### Impact on other plants including adjacent crops

Neither positive nor adverse effects on other plants including adjacent crops were detected while carrying out the above-mentioned efficacy trials with an application of FF-075.

Both active substances are well known for many years. Thus, no special studies regarding adjacent crops are included in this document.

#### Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the conducted effectiveness trials.

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

#### **OTHER/SPECIAL STUDIES**

No other studies available.

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

#### 3.4.1 Analytical method for the formulation

A method is available for the determination of the active substances prothioconazole and azoxystrobin in the plant protection product 'EUSKATEL PRO' that relies on HPLC-UV at 254 nm using a TC-C18 column (250 x 4.6 mm, 5 µm).

Further methods are available for the determination of the relevant impurities (prothioconazole-desthio, prothioconazole-deschloro, and toluene) in the plant protection product FF-075 that rely on HPLC-UV at 220 nm using an EC-C18 column (150 x 4.6 mm, 2.7 µm). The LOQs of the methods are appropriate for the maximum allowed concentrations of the relevant impurities in plant protection products (i.e., prothioconazole-desthio and prothioconazole-deschloro: <0.125 g/kg; toluene: <1.25 g/kg).

Analytical methods are fully validated in accordance with SANCO/3030/99 rev.5.

**zRMS comment:** analytical methods proposed for the determination of the active substances – **prothioconazole** and **azoxystrobin** and relevant impurities – **prothioconazole-desthio** and **toluene** in the formulation FF-075 (EUSKATEL PRO) are specific, sensitive, precise, and accurate according to SANCO/3030/99 rev.5 guideline. Validated analytical method for the determination of **prothioconazole-deschloro** was also submitted. According to the current consolidated version of the Reg. (EU) No 540/2011, prothioconazole-deschloro is not considered as a significant or relevant impurity. According to the revision of SANCO/3923/07 from January 2021, prothioconazole-deschloro was indicated as the relevant impurity, with no maximum acceptable limit agreed. Still, it was not included in Appendix I, where information on prothioconazole and its impurities is summarised. zRMS conclusion: at the time of the evaluation the analytical method for prothioconazole-deschloro is not required and was not evaluated.

### 3.4.2 Analytical methods for residues

The data packages already agreed at EU level for the Annex I listings of prothioconazole and azoxystrobin are considered acceptable to support the authorisation of ‘EUSKATEL PRO’.

In addition new data have been generated in support of ecotoxicology studies for ‘EUSKATEL PRO’, these are summarised in part B5 of the dRR. ~~No further data are considered necessary.~~

#### **Noticed data gaps are:**

##### **Prothioconazole:**

- monitoring methods for body fluids and tissues (post-registration requirement)
- an independent laboratory validation (ILV) for drinking water (post-registration requirement)

##### **Azoxystrobin**

- monitoring methods for body fluids and tissues (post-registration requirement)

#### Foodstuff of plant origin

The proposed GAP includes application to cereals (wheat, barley, triticale, rye, oat) and oilseed rape. Validated analytical methods are available to monitor all components of the monitoring residue definition for both prothioconazole and azoxystrobin in high protein/starch (dry) and high oil commodities to at least the lowest MRLs in these groups (i.e. 0.01 mg/kg), covering the crop groups applied for. See part B5 of the dRR for full details of the analytical methods.

#### Foodstuff of animal origin

A LC-MS/MS method (00655 and 00655/M001) is available for the enforcement of prothioconazole-desthio in milk, meat, liver, kidney and fat to a LOQ of 0.01 mg/kg (meat, liver, kidney, fat) and 0.004 mg/kg (milk). The primary method is highly specific therefore negating the need for a confirmatory method. The method was independently validated in all five matrices. The method and ILV were fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

In the EFSA Conclusion, it is stated that “*a method is not available to monitor the glucuronide conjugate in products of animal origin*”. The need for including the glucuronide conjugate in the residue definition stemmed from the fact that the free metabolite was not found in milk. However, in the Art. 12 MRL Review for the active, actual residue levels of the glucuronide in milk were expected at a trace level at the calculated

dietary burden (<0.01 mg/kg) and so analysing the conjugates of prothioconazole-desthio would have negligible impact on the residue levels enforced in milk. No further data are necessary on this topic.

A GC-NPD method (RAM 255/03), that was fully accepted in the DAR and EFSA Conclusion, is acceptable to monitor azoxystrobin in animal commodities to a LOQ of 0.01 mg/kg (meat, liver, kidney, fat) and 0.001 mg/kg (milk). The data package already agreed at EU level for Annex I listing is therefore acceptable to support the authorisation of 'EUSKATEL PRO'. No additional data are considered necessary.

It is noted that in the Article 12 review (EFSA Journal 2013;11(12):3497), it was stated that a second fully validated analytical method (RAM 399), based on LC-MS/MS, and its ILV, were evaluated in the 2008 JMPR evaluation with a LOQ of 0.01 mg/kg in muscle, milk, kidney, liver and egg.

### Soil

A LC-MS/MS method (00610) is available to monitor prothioconazole and prothioconazole-desthio in soil to a LOQ of 0.006 mg/kg. The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

A further multi-residue DFG S19 GC-MS method (00086/M038) is available to monitor prothioconazole-desthio in soil to a LOQ of 0.01 mg/kg. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

A LC-MS/MS method (RAM 269/03) is available to monitor azoxystrobin in soil to a LOQ of 0.02 mg/kg. The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes. The data package already agreed at EU level for Annex I listing is therefore acceptable to support the authorisation of 'EUSKATEL PRO'. No additional information is necessary.

### Water

A LC-MS/MS method (00684) is available to monitor prothioconazole and prothioconazole-desthio in surface and drinking water to a LOQ of 0.1 µg/L (prothioconazole) and 0.05 µg/L (prothioconazole-desthio). The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

A further HPLC-UV method (00586) is available to monitor prothioconazole and prothioconazole-desthio in surface water to a LOQ of 6 µg/L. The analytical method was fully accepted in the DAR for monitoring purposes.

A GC-MSD method (RAM 358/01) is available to monitor azoxystrobin in surface and drinking water to a LOQ of 0.1 µg/L. The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

### Air

A LC-MS/MS method (00724) is available to monitor prothioconazole and prothioconazole-desthio in air to a LOQ of 0.015 mg/m<sup>3</sup> (prothioconazole) and 0.0006 mg/m<sup>3</sup> (prothioconazole-desthio). The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes.

A GC-MSD method (RAM 376/01) is available to monitor azoxystrobin in air to a LOQ of 0.003 mg/m<sup>3</sup>. The primary method is highly specific therefore negating the need for a confirmatory method. The analytical method was fully accepted in the DAR and EFSA Conclusion for monitoring purposes. The data



package already agreed at EU level for Annex I listing is therefore acceptable to support the authorisation of 'EUSKATEL PRO'. No additional information is necessary.

### Body fluids and tissues

Not required for prothioconazole - the active substance is not classified as toxic nor highly toxic and no residue definition has been set in this matrix.

A GC-NPD method (RAM 255/03), that was fully accepted in the DAR and EFSA Conclusion, is acceptable to monitor azoxystrobin in animal tissues to a LOQ of 0.01 mg/kg (meat, liver, kidney, fat). It is noted that in the Article 12 review (EFSA Journal 2013;11(12):3497), it was stated that a second fully validated analytical method (RAM 399), based on LC-MS/MS, and its ILV, were evaluated in the 2008 JMPR evaluation with a LOQ of 0.01 mg/kg in muscle, milk, kidney, liver and egg. A LC-MS/MS method (CTL/R/1401), that was fully accepted in the DAR and EFSA Conclusion, is acceptable to monitor azoxystrobin in body fluids to a LOQ of 0.05 µg/mL (plasma). The data package already agreed at EU level for Annex I listing is therefore acceptable to support the authorisation of 'EUSKATEL PRO'.

## **3.5 Mammalian toxicology (Part B, Section 6)**

To minimise the use of vertebrates in hazard identification, the calculation method according to Reg. No. (EC) 1272/2008 and the ECHA Guidance Document on the Application on the CLP Criteria (Version 5, 2017) have been applied to determine the classification and labelling requirements for 'EUSKATEL PRO' (see Part C for details).

### **3.5.1 Acute toxicity**

The following table summarises the outcome of the CLP calculation conducted according to Reg. No. (EC) 1272/2008 and the consequential H Phrases.

<b>Endpoint</b>	<b>Outcome</b>	<b>H-Phrase Following Calculation Method</b>
Acute Oral Tox	> 2000 mg/kg	None
Acute Dermal Tox	> 2000 mg/kg	None
Acute Inhalation Tox	5.47 mg/L air	None
Skin Irritation	Non-irritant	None
Eye Irritation	Non-irritant	None
Skin Sensitisation	Skin sensitizer	H317
Others	Not required	None

### **3.5.2 Operator exposure**

The results of the estimations indicate that the exposure of an unprotected operator (no PPE, wearing work wear) to prothioconazole (200 g/L) and azoxystrobin (150 g/L) remains on the acceptable level, i.e. below the value of AOEL. The exposure of an unprotected operator to prothioconazole-desthio exceeds the AOEL value for this metabolite. The use of EUSKATEL PRO (FF-075) causes no risk for operator using appropriate PPE (protective gloves) during mixing and loading.

Taking into account the classification of the product (Skin Sens.1, H317) and the results of exposure estimations, the following sentence is recommended by the evaluator to be placed in the warning section of the



**label:**

*“Stosować rękawice ochronne i odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w czasie zabiegu.”*

“Use protective gloves and work wear during mixing and loading and application”

Combined exposure is also within acceptable limits **with the use of PPE (protective gloves).**

### **3.5.3 Worker exposure**

The results of the estimation indicate that the exposure of an unprotected worker (no PPE, wearing work wear) to prothioconazole (200 g/L) prothioconazole-desthio and azoxystrobin (150 g/L) remains on **an acceptable level**, i.e. below the value of AOEL for the active substances (and highlighted metabolite).

Nevertheless, it is forbidden to re-enter area treated with Euskatel Pro/FF-075 until spray deposit on plant surfaces has dried.

Bearing in minds the hygienic rules, the use of work wear (coverall) and protective gloves is recommended by the evaluator during inspection of the treated area.

Combined exposure is also within acceptable limits without the use of PPE.

### **3.5.4 Bystander and resident exposure**

Systemic exposure to prothioconazole, prothioconazole-desthio and azoxystrobin is predicted to be within acceptable for bystanders and residents without the use of risk mitigation measures. The reference values acutely toxic active substance (RVAAS) for prothioconazole (and its metabolite – prothioconazole-desthio) and azoxystrobin are not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards these substances.

According to the estimation based on AOEM, the use of Euskatel Pro / FF-075 does not cause unacceptable health risk for bystander and resident (both adult and child): the zexpo-sure values are significantly below the AOEL for active substances.

The incidental short-time exposure of bystander and resident (children and adult) to prothioconazole (and its metabolite – prothioconazole-desthio) and azoxystrobin causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.

Combined exposure is also within acceptable limits without the use of risk mitigation measures.

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

### **3.6.1 Residues**

#### **Prothioconazole**

##### Storage stability

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), cereal grain and straw and for 24 months in high oil content.

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376. Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA.

Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA.

Residues of 1,2,4-Triazole and TA are not stable in oilseed rape (seed).

Residues of TAA are stable for 53 month and TLA are stable for 48 month in oilseed rape (seed).

#### Metabolism in plants and animals

Plant residue definition for monitoring (RD-Mo): Prothioconazole: Prothioconazole-desthio (sum of isomers)

Plant residue definition for risk assessment (RD-RA):

a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

b) TDMs (EFSA, 2018, SANCO/3923 /07 – final 10 December 2007, 26 January 2021), with separate assessment of:

- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

#### Magnitude of residues in plants

Wheat, durum, spelt, triticale, rye, oats, barley (spring and winter)

Proposed GAPs:

1-2 Applications (14 days interval), BBCH 30-69, 0.20 kg as/ha, PHI: 35 days

EU GAPs:

Wheat, rye, triticale

The intended GAP of prothioconazole in FF-075 is less critical than the EU-GAP:

3 x 0.2 kg a.s./ha, BBCH 69, PHI 35 d, int. 14-21 d

Barley, oat

The intended GAP of prothioconazole in FF-075 is the same than the EU-GAP:

2 x 0.2 kg a.s./ha, BBCH 69, PHI 35 d, int. 14-21 d

Prothioconazole

No new data are submitted in the framework of this application. The residue data on cereals were evaluated during the EU review of prothioconazole.

Sufficient EU trials on wheat, barley are available to support the proposed uses. The residue data are valid with regard to storage stability. The residues arising from the proposed uses will not exceed the MRLs for Prothioconazole established for cereals (0.1 (wheat, triticale, durum, spelt), 0.2 (barley) mg/kg, 0.05 (oat, rye); Reg. (EU) 2019/552).

Residues were measured according to the current enforcement residue definition - prothioconazole-desthio (sum of isomers).

#### TDMs

Applicant refers to data presented in the EFSA Journal 2018;16(7):5376.

However, data gaps relevant for the risk assessment to cover the complete group of triazole derivate metabolites were found.

EFSA 2018: *Residue trials analysing for all TDMs and compliant with the representative uses on cereals (wheat, rye, barley, oats, triticale) and on rapeseeds together with rotational crops residue field trials were submitted in the framework of this confirmatory data assessment but were not supported by acceptable storage stability data for 1,2,4-T in cereal grain, straw and rapeseeds and for TLA in straw.*

Nevertheless, no chronic or acute intake concerns were identified.

*A 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted and it was demonstrated that the risk for the consumers is unlikely. The overall consumer exposure assessment for the TDMs could, however, not be finalised in view of the identified data gaps for additional storage stability data for the TDMs in several crop commodities and missing data to finalise the livestock exposure assessment.*

No critical areas of concern have been identified.

Therefore, supplementing the above-mentioned deficiencies can be considered as a post-registration requirement. Uses are accepted.

#### Oilseed Rape

##### Proposed GAPs:

1-2 Applications (14 days interval), BBCH 55 69, 0.16 kg as/ha, PHI: 35 days

##### EU-GAP:

1-2 Applications (14 – 28 days interval), start BBCH 53, 0.175 kg as/ha, PHI: 56 days

Applicant refers to the unprotected EU data compliant with EU GAP.

#### Prothioconazole

Residues Seed (n = 8, E): 5 x <0.01, 0.01, 2 x 0.02 mg/kg

Sufficient EU trials on oilseed Rape are available to support the proposed uses. The residue data are valid with regard to storage stability. The residues arising from the proposed uses will not exceed the MRLs for Prothioconazole established for oilseed Rape (0.15 mg/kg, Reg. (EU) 2019/552).

Residues were measured according to the current enforcement residue definition - prothioconazole-desthio (sum of isomers).

PHI of 56 is proposed by z zRMS as in EU GAP.

#### TDMs

Data gap: Residue trials analysing for all TDMs supported by acceptable storage stability data for 1,2,4-T in rapeseeds - post-registration requirement

#### Livestock Feeding Studies:

The calculated dietary burdens were found to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of residues in livestock is required. Applicant refers to out of protection EU data.

No exceedances of the existing EU MRLs for prothioconazole in animal commodities are anticipated as a result of the proposed uses of FF-075

#### TDMs

Applicant refers to data presented in the EFSA Journal 2018;16(7):5376.

The livestock exposure assessment cannot be finalised with regard to the outstanding data for acceptable residue trials in primary and rotational crops.

#### Data gap:

*Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.*

The above mentioned data gap should be addressed as part of the next renewal of approval of the active substance prothioconazole, or for the triazole fungicides as a whole.

#### Industrial Processing and/or Household Preparation:

As the proposed uses are supported by EU agreed data previously considered for Annex I approval, no further investigation into the magnitude of residues in processed commodities is considered necessary. No data gaps were found.

The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.

#### Residues in Representative Succeeding Crops:

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed

#### TDMs

Data gap: Rotational crops field residue trials supported by acceptable storage stability data on TDMs.

zRMS considers that the missing data can be provided when the product is reassessed.

#### The consumer risk assessment

Chronic and acute exposure calculations were performed using EFSA PRIMo revision 3.1 and calculated exposures were compared with the established toxicological reference values. The proposed uses of prothioconazole in the formulation FF-075 do not represent unacceptable acute and chronic risks for the consumer.

#### TDMs

Applicant refers to data presented in the EFSA Journal 2018;16(7):5376.

EFSA Journal 2018;16(7):5376:

*The 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 is not applicable in the framework of confirmatory data assessed here.*

*The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (STMR values and the HR values), derived for each TDM for each crop groups and each product of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA. Using the EFSA PRIMo rev.2A, the IEDI accounted for 60% of the ADI (FR toddler) for 1,2,4-T, 5% of the ADI (WHO Cluster diet B) for TA, 1% of the ADI (WHO Cluster diet B) for TAA and < 1% of the ADI (FR toddler) for TLA. The acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 6.7% of the ARfD (potatoes) for TLA. Since the toxicological reference values for TLA were derived by bridging with the reference values of TA, a combined dietary risk assessment for TA and TLA was performed. No chronic or acute intake concerns were identified with up to 6% ADI (WHO Cluster diet B), and 34% and 8% ARfD (watermelons) respectively for children and adults.*

SANCO/3923 /07 – final 10 December 2007, 26 January 2021: *A ‘worst-case’ consumer dietary intake assessment with regard to the TDMs for the group of triazole active substances that were assessed in the framework of the confirmatory data submitted for several triazole active substances was conducted by the RMS. This assessment concluded that an unacceptable risk for consumers is unlikely. The proposed uses of prothioconazole in the formulation FF-075 do not represent unacceptable acute and chronic risks for the consumer. Therefore, no changes to the existing provisions of the approval of prothioconazole are required.*

#### Other / special studies

Since the intended uses are performed during flowering in a honey-relevant crop (oilseed rape), information on potential residues of prothioconazole and azoxystrobin in honey is required in case of use on oilseed rape. No new data are submitted in the framework of this application. Study to investigate residues in honey resulting from the use of FF-075 has recently been initiated.

Therefore, currently use after BBCH 59 is not accepted. Data gap should be supplemented.

#### **Azoxystrobin**

##### Storage stability

In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in:

dry/starch commodities (cereal grain, straw, carrot)

high water content (apple, peach, tomato, cucumber, lettuce, banana)

high acid content (grape, orange)

high oil content (soybean meal, oilseed rape, pecans, peanut, orange oil)

Azoxystrobin was shown to be stable in freezer storage at approximately -18°C in animal tissues, eggs and milk after storage for up to ten months.

No new data submitted in the framework of this application. No further information is required.

### Metabolism in plants and animals

All metabolism data are active substance data and were evaluated in the EU review of azoxystrobin.

Plant and animal residue definition for monitoring and risk assessment: azoxystrobin. No further evaluation is required.

### Magnitude of residues in plants

Wheat, durum, spelt, triticale, rye, oats, barley (spring and winter)

Proposed GAPs:

1-2 Applications (14 days interval), BBCH 30 69, 0.15 kg as/ha, PHI: 35 days

Applicant refers to the unprotected EU data compliant with EU GAP.

Trials GAP: 2 x 0.25 kg as/ha (14 days interval), BBCH 31-59 and 31-69, PHI 35d (DAR 2009).

Proposed GAP is less critical than EU GAP. The number of trials is sufficient as to support the use of azoxystrobin in wheat and barley according to the proposed GAP in Central Zone. 35 days is proposed for PHI.

The residues arising from the proposed uses will not exceed the MRLs for wheat and barley (set at 1.5 for barley, oats and 0.5 mg/kg for wheat, durum, spelt, triticale, rye - Reg. (EU) 2021/1807, SANTE/11280/2021).

### Oilseed Rape

Proposed GAPs:

1-2 Applications (14 days interval), BBCH 55 69, 0.12 kg as/ha, PHI: 35 days

This application relies upon the now-unprotected trials previously evaluated at EU level.

EU-GAP: : 2 x 0.25 kg a.s./ha (foliar), BBCH 55, PHI 21 d, int. not stated

Sufficient EU trials on oilseed Rape are available to support the proposed uses. The residue data are valid with regard to storage stability. The residues arising from the proposed uses will not exceed the MRLs for Azoxystrobin established for oilseed Rape (0.5 mg/kg, Reg. (EU) 2021/1807, SANTE/11280/2021).

### Livestock Feeding Studies:

The calculated dietary burdens were found to exceed the trigger value of 0.004 mg/kg bw/day (2017 Animal Model, OECD methodology). Further investigation of residues in livestock is required.

No new data are submitted in the framework of this application.

The available unprotected data are considered sufficient to support the intended product uses of FF-075 on wheat (incl. triticale, durum, spelt), rye, barley, oat and rapeseed when evaluating against existing EU-agreed endpoints. No exceedances of the existing EU MRLs for azoxystrobin in animal commodities are anticipated as a result of the proposed uses of FF-075.

### Industrial Processing and/or Household Preparation:

The available unprotected data are considered sufficient to support the intended product uses of FF-075 on wheat (incl. triticale, durum, spelt), rye, barley, oat and rapeseed when evaluating against existing EU-agreed endpoints.

#### Residues in Representative Succeeding Crops:

No new data are submitted in the framework of this application.

Rotational crop field trials were evaluated in the framework of the EU peer review (EFSA, 2010).

Residues in rotational crops will have no impact on the MRLs in plants and livestock products, provided that azoxystrobin is applied in compliance with the EU cGAPs.

#### The consumer risk assessment

Chronic and acute exposure calculations were performed using EFSA PRIMo revision 3.1 and calculated exposures were compared with the established toxicological reference values. The proposed uses of azoxystrobin in the formulation FF-075 do not represent unacceptable chronic risks for the consumer.

#### Other / special studies

Since the intended uses are performed during flowering in a honey-relevant crop (oilseed rape), information on potential residues of prothioconazole and azoxystrobin in honey is required in case of use on oilseed rape. No new data are submitted in the framework of this application. Study to investigate residues in honey resulting from the use of FF-075 has recently been initiated.

Therefore, currently use after BBCH 59 is not accepted. Data gap should be supplemented.

#### Noticed data gaps are:

##### TDMs:

- Residue trials analysing for all TDMs supported by acceptable storage stability data for 1,2,4-T in cereal grain, straw and rapeseeds and for TLA in straw - post-registration requirement
- Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin - post-registration requirement.

This data gap should be addressed as part of the next renewal of approval of the active substance prothioconazole, or for the triazole fungicides as a whole.

- Rotational crops field residue trials supported by acceptable storage stability data on TDMs - post-registration requirement

zRMS considers that the missing data can be provided when the product is reassessed.

##### Other/special studies:

- Since the intended uses are performed during flowering (BBCH 55 69) in a honey-relevant crop (oilseed rape), information on potential residues of prothioconazole and azoxystrobin in honey is required in case of use on oilseed rape after BBCH 59 phase.

### **3.6.2 Consumer exposure**

#### **Prothioconazole**

TMDI (% ADI) according to EFSA PRIMo rev3.1	35 % (based on NL toddler)
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FF-075 / EUSKATEL PRO  
Part A - National Assessment  
Applicant version

IEDI (% ADI) according to EFSA PRIMo rev3.1	n/a
IESTI (% ARfD) according to EFSA PRIMo rev3.1*	Wheat: 29 % (children) Barley: 22 % (children) Rye: 6 % (children) Rapeseeds/canola seeds: 4 % (children) Oat: 1 % (children)
NTMDI (% ADI) **	n/a
NEDI (% ADI)**	n/a
NESTI (% ARfD) **	n/a

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

MRLs in all commodities were used as inputs for the chronic consumer risk assessments resulting in a maximum chronic intake (TMDI) of 35 % (NL toddler) of the ADI for prothioconazole.

Acute exposure assessments were conducted only for the commodities under consideration, again using current EU MRLs, and resulted in a maximum acute intake (IESTI) of 29 % (wheat, children) of the ARfD.

Based on the ‘worst-case’ TMDI and IESTI calculations performed with MRL inputs, no further refinement of the consumer risk assessment is considered necessary. The proposed uses of prothioconazole in the formulation FF-075 do not represent unacceptable acute and chronic risks for the consumer.

## TDMs

Applicant refers to data presented in the EFSA Journal 2018;16(7):5376.

EFSA Journal 2018;16(7):5376:

*The ‘worst-case’ consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 is not applicable in the framework of confirmatory data assessed here.*

*The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (STMR values and the HR values), derived for each TDM for each crop groups and each product of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA. Using the EFSA PRIMo rev.2A, the IEDI accounted for 60% of the ADI (FR toddler) for 1,2,4-T, 5% of the ADI (WHO Cluster diet B) for TA, 1% of the ADI (WHO Cluster diet B) for TAA and < 1% of the ADI (FR toddler) for TLA. The acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 6.7% of the ARfD (potatoes) for TLA. Since the toxicological reference values for TLA were derived by bridging with the reference values of TA, a combined dietary risk assessment for TA and TLA was performed. No chronic or acute intake concerns were identified with up to 6% ADI (WHO Cluster diet B), and 34% and 8% ARfD (watermelons) respectively for children and adults.*



SANCO/3923 /07 – final 10 December 2007, 26 January 2021: *A ‘worst-case’ consumer dietary intake assessment with regard to the TDMs for the group of triazole active substances that were assessed in the framework of the confirmatory data submitted for several triazole active substances was conducted by the RMS. This assessment concluded that an unacceptable risk for consumers is unlikely. The proposed uses of prothioconazole in the formulation FF-075 do not represent unacceptable acute and chronic risks for the consumer. Therefore, no changes to the existing provisions of the approval of prothioconazole are required.*

### Azoxystrobin

TMDI (% ADI) according to EFSA PRIMo rev3.1	82% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev3.1	n/a
IENTI (% ARfD) according to EFSA PRIMo rev3.1	n/a
NTMDI (% ADI) *	n/a
NEDI (% ADI)*	n/a
NESTI (% ARfD) *	n/a

\* if national model is available

MRLs in all commodities were used (Reg. (EU) 2021/1807) as inputs for the chronic consumer risk assessments resulting in a maximum chronic intake (TMDI) of 82 % (NL toddler) of the ADI for azoxystrobin.

Based on the ‘worst-case’ TMDI calculation performed with MRL inputs, no further refinement of the consumer risk assessment is considered necessary. The proposed uses of azoxystrobin in the formulation FF-075 do not represent unacceptable chronic risks for the consumer.

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

The fate and behaviour of the active substance prothioconazole in the environment has been evaluated at EU level according to Commission Regulation (EU) No. 1107/2009, full details are provided in the EU Draft Assessment Report and related documents and are summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

The fate and behaviour of the active substance azoxystrobin in the environment has been evaluated at EU level according to Commission Regulation (EU) No. 1107/2009, full details are provided in the EU Draft Assessment Report and related documents and are summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542).

The formulated product ‘EUSKATEL PRO’ is a mixture containing the active substances prothioconazole (200 g/L) and azoxystrobin (150 g/L). Concentrations of the active substances in various environmental compartments are predicted following use of ‘EUSKATEL PRO’ in accordance with the critical GAP for central Europe. Based on data evaluated in the EU reviews for prothioconazole and azoxystrobin, appropriate endpoints were used to calculate PEC values for the formulated product and the active substances and their respective metabolites in soil, groundwater and surface water for the intended use patterns.

### 3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

Predicted environmental concentrations of each active substance and its metabolites in soil (PEC<sub>soil</sub>) were calculated based on a first-tier approach using a Microsoft® Excel spreadsheet. The calculations were based

on the critical GAP for the 'EUSKATEL PRO' formulation in central Europe assuming a soil mixing depth of 5 cm and a soil bulk density of 1.5 g/cm<sup>3</sup>. Crop interception was accounted for as appropriate.

The results for PEC<sub>soil</sub> for the active substances and metabolites were used for the ecotoxicological risk assessment.

#### Prothioconazole

Based on the maximum proposed use rates for 'EUSKATEL PRO' in central Europe, the maximum initial predicted environmental concentration in soil (PEC<sub>soil</sub>) of prothioconazole will be 0.0550 mg/kg.

For the prothioconazole metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04), the maximum initial predicted environmental concentrations in soil (PEC<sub>soil</sub>) will be 0.0162 and 0.0552 mg/kg, respectively. When repeated applications over multiple years are taken into account, the resulting maximum accumulated predicted environmental concentrations in soil (PEC<sub>accumulation</sub>) will be 0.0163 mg/kg and 0.0569 mg/kg for prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04), respectively.

#### Azoxystrobin

Based on the maximum proposed use rates for 'EUSKATEL PRO' in central Europe, the maximum initial predicted environmental concentration in soil (PEC<sub>soil</sub>) of azoxystrobin will be 0.0785 mg/kg. When repeated applications over multiple years are taken into account, the resulting maximum accumulated predicted environmental concentration in soil (PEC<sub>accumulation</sub>) will be 0.1292 mg/kg.

For the azoxystrobin metabolites R234886, R401553 and R402173, the maximum initial predicted environmental concentrations in soil (PEC<sub>soil</sub>) will be 0.0222, 0.0072 and 0.0112 mg/kg, respectively.

#### Formulation 'EUSKATEL PRO'

Based on the maximum proposed use rate for 'EUSKATEL PRO' in central Europe, the maximum predicted environmental concentration in soil (PEC<sub>soil</sub>) of the formulated product will be 0.2933 mg/kg.

### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

Predicted environmental concentrations of each active substance and its metabolites in groundwater (PEC<sub>gw</sub>) were calculated using the relevant FOCUS groundwater scenarios and the FOCUS groundwater models, PEARL (version 4.4.4), PELMO (version 5.5.3) and MACRO (version 5.5.4). The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the 'EUSKATEL PRO' formulation in Europe. The FOCUS crop scenarios 'winter oilseed rape', 'winter cereals' and 'spring cereals' were selected for the simulations. As the formulation is foliar applied, crop interception was accounted for in the simulations in accordance with FOCUS guidance. No calculations were performed for the formulated product 'EUSKATEL PRO', since its components, other than the active substances, will dissipate rapidly after application.

#### Prothioconazole

In all cases, PEC<sub>gw</sub> for prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) were <0.001 µg/L. Based on this assessment, the 'EUSKATEL PRO' formulation can be used as proposed throughout central Europe, without risk of prothioconazole or its soil metabolites exceeding acceptable levels in groundwater.

### Azoxystrobin

In all cases,  $PEC_{gw}$  for azoxystrobin and its metabolites R401553 and R402173 were  $<0.001 \mu\text{g/L}$ . For metabolite R234886,  $PEC_{gw}$  were  $>0.1 \mu\text{g/L}$  in four of the six scenarios for winter oilseed rape (max.  $PEC_{gw}$   $4.742 \mu\text{g/L}$ ), in six of the nine scenarios for winter cereals (max.  $PEC_{gw}$   $4.901 \mu\text{g/L}$ ) and in three of the six scenarios for spring cereals (max.  $PEC_{gw}$   $4.515 \mu\text{g/L}$ ). Based on this assessment, the 'EUSKATEL PRO' formulation can be used as proposed throughout central Europe, without risk of azoxystrobin or its metabolites R401553 and R402173 exceeding acceptable levels in groundwater. However, a groundwater relevance assessment is required for metabolite R234886. The relevance assessment for R234886 is presented in Document Part B Section 10 of this submission and summarised in Point 3.9.

### **Toxicological evaluation of the metabolites**

The metabolites of prothioconazole are predicted to occur in groundwater at concentrations below  $0.001 \mu\text{g/L}$ . Thus, the assessment of the relevance of its metabolites according to the stepwise procedure (acc. to SANCO/221/2000 –rev.10) is not required.

In case of azoxystrobin: Taking into account all toxicological data, the metabolite R234886 is considered toxicologically non-relevant. The results of the consumer risk calculations indicate that the use of FF-075/EUSKATEL PRO according to the list of intended uses presented in GAP Table, causes no risk for health for the adults, toddlers and infants.

### **3.7.3 Predicted environmental concentrations in surface water ( $PEC_{sw}$ )**

Predicted environmental concentrations of each active substance and its soil and / or aquatic metabolites in surface water and sediment ( $PEC_{sw}$  and  $PEC_{sed}$ ) were calculated using the FOCUS surface water models and scenarios. The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the 'EUSKATEL PRO' formulation in Europe. The FOCUS crop scenarios 'winter oilseed rape', 'winter cereals' and 'spring cereals' were selected for the simulations. Predicted environmental concentrations in surface water ( $PEC_{sw}$ ) for the formulated product 'EUSKATEL PRO' were calculated using the FOCUS spray drift calculator.

The results for  $PEC_{sw}$  for the active substances and metabolites were used for the ecotoxicological risk assessment.

### Prothioconazole

Predicted environmental concentrations of prothioconazole and its soil and / or aquatic metabolites prothioconazole-S-methyl (M01), prothioconazole-desthio (M04), 1,2,4-triazole (M13) and prothioconazole-triazolylketone (M42), in surface water and sediment were calculated at FOCUS Steps 1 and 2. FOCUS Step 3 calculations were also conducted for prothioconazole and its metabolite prothioconazole-desthio (M04). Step 4 calculations were triggered for prothioconazole-desthio (M04) and additional calculations were therefore performed at FOCUS Step 4 by reducing spray drift and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips).

### Azoxystrobin

Predicted environmental concentrations of azoxystrobin and its soil and aquatic metabolites R234886, R401553 and R402173, in surface water and sediment were calculated at FOCUS Steps 1 and 2. FOCUS Steps 3 and 4 calculations were also conducted for azoxystrobin. Step 4 calculations were performed by reducing spray drift and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction

buffer zones (vegetated filter strips).

#### Formulation 'EUSKATEL PRO'

Predicted environmental concentrations of the formulated product 'EUSKATEL PRO' in surface water due to spray drift were calculated using the FOCUS spray drift calculator. The maximum PEC<sub>sw</sub> values for 'EUSKATEL PRO' were 7.0671 µg/L considering a FOCUS default buffer, 2.2987 µg/L considering a 5 metre no-spray buffer zone, 1.2191 µg/L considering a 10 metre no-spray buffer zone and 0.6335 µg/L considering a 20 metre no-spray buffer zone.

### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

#### Prothioconazole

The vapour pressure at 20°C of the active substance prothioconazole is  $< 10^{-5}$  Pa. Hence the active substance prothioconazole is regarded as non-volatile. In addition, the laboratory soil metabolism and degradation studies indicate that significant volatilisation of prothioconazole and its metabolite prothioconazole-desthio (M04) is unlikely to occur as no volatiles were detected at levels above 0.1% AR. Therefore, consideration of exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilisation with subsequent deposition is not required.

#### Azoxystrobin

The vapour pressure at 20°C of the active substance azoxystrobin is  $< 10^{-5}$  Pa. Hence the active substance azoxystrobin is regarded as non-volatile. Therefore consideration of exposure of adjacent surface waters and terrestrial ecosystems by the active substance azoxystrobin due to volatilisation with subsequent deposition is not required.

## **3.8 Ecotoxicology (Part B, Section 9)**

The ecotoxicology assessment of risk to non-target organisms from exposure to azoxystrobin, prothioconazole and its metabolites has been evaluated at EU level according to Commission Regulation (EU) No. 1107/2009, full details are provided in the EU Draft Assessment Report and related documents and are summarised in the EFSA Conclusion for each respective active substance

The formulated product EUSKATEL PRO, contains the active substances prothioconazole (200 g/L) and azoxystrobin (150 g/L). The risk to non-target organisms was evaluated in accordance with the critical GAP for central Europe and the calculated PEC values for the formulated product, the active substances and its metabolites in soil and surface water for the intended use patterns.

Refinement of the risk assessment and the levels of mitigation applied to the assessments are in-line with the permissible zonal and Member States refinement options.

### 3.8.1 Effects on terrestrial vertebrates

Regulatory testing with birds has been conducted with prothioconazole, azoxystrobin and the relevant metabolite, prothioconazole-desthio (M04) in accordance with EU requirements for quail (*Colinus virginianus*) and the mallard duck (*Anas platyrhynchos*). Results from these studies, summarised in the EFSA Review Reports for prothioconazole and azoxystrobin show that the active substances and prothioconazole-desthio (M04) have low toxicity to birds.

The estimated toxicity for EUSKATEL PRO, derived from the combined assessment of the active ingredients, demonstrates low risk to birds from applications of the formulated product.

The assessment of risk from secondary poisoning of earthworm-eating birds and fish-eating birds via exposure to prothioconazole, prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01) via bioaccumulation in earthworms and fish indicates low risk to birds following applications of EUSKATEL PRO in accordance with the proposed GAP.

An acceptable acute and long-term risk to birds is expected from the proposed uses of EUSKATEL PRO in winter oilseed rape (BBCH 55-69) and winter and spring cereals (BBCH 30-69).

Regulatory testing with mammals has been conducted with azoxystrobin, prothioconazole and the relevant metabolite, prothioconazole-desthio (M04), in accordance with EU requirements for rat and mouse. Results from these studies, summarised in the EFSA Review Reports for azoxystrobin and prothioconazole, show that the active substances and metabolite, prothioconazole-desthio (M04), have low toxicity to mammals.

The TER<sub>it</sub> values do not exceed the Annex VI trigger of 5 for prothioconazole-desthio (M04) when considering both relevant mammalian species in winter and spring cereals and winter oilseed rape, and when deposition factors in cereals are refined, according to the guidance in EFSA, (2009).

The estimated toxicity for EUSKATEL PRO, derived from the combined assessment of the active ingredients, demonstrates low risk to mammals from applications of the formulated product in accordance with the GAP.

The assessment of risk from secondary poisoning of earthworm-eating mammals and fish-eating mammals via exposure to prothioconazole, prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01) via bioaccumulation in earthworms and fish indicates low risk to mammals following applications of EUSKATEL PRO in accordance with the proposed GAP.

Low risk to mammalian species is expected from applications of EUSKATEL PRO in accordance with the GAP.

No data on reptiles and terrestrial amphibians are available for EUSKATEL PRO. In the absence of a specific framework, the data and risk assessment for birds and mammals are considered an adequate surrogate for other terrestrial vertebrates. No overt toxicity has been observed in any of the avian and mammalian studies relevant for the ecotoxicological risk assessment. In addition, low acute and long-term risks were concluded for birds and mammals. Since terrestrial amphibians and reptiles' diets have generally a lower vegetation content than those of the focal bird and mammal species considered in the previous risk assessment, it is expected that exposure to feed items possibly contaminated with EUSKATEL PRO will be lower for terrestrial amphibians and reptiles than birds and mammals. As such, no adverse effects or risks are expected for reptiles and terrestrial amphibians exposed to prothioconazole or prothioconazole-desthio (M04) following applications of EUSKATEL PRO.

### 3.8.2 Effects on aquatic species

Regulatory testing with fish, aquatic invertebrates, algae and aquatic macrophytes has been conducted with prothioconazole, azoxystrobin, the relevant metabolites and EUSKATEL PRO in accordance with EU requirements.

Based on the risk assessment for aquatic organism with consideration PEC<sub>sw</sub> values relevant for scenarios D3, D4 and R1 calculated by FOCIS STEP1-4 program the following risk mitigation measures should be applied to surface water bodies:

- **20 m vegetative strip and 20 m no spray buffer was applied for uses in winter oilseed rape, winter and spring cereals.**

### 3.8.3 Effects on bees

Regulatory testing with honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) has been conducted with prothioconazole, azoxystrobin and the formulated product, EUSKATEL PRO, in accordance with EU requirements for bees. An acceptable acute and long-term risk to bees is expected from the proposed uses of EUSKATEL PRO in winter and spring cereals, and winter oilseed rape in accordance with the proposed GAP.

### 3.8.4 Effects on other arthropod species other than bees

Regulatory testing with the non-target arthropod indicator species *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Coccinella septempunctata* and *Chrysoperla carnea* has been conducted with EUSKATEL PRO in accordance with EU requirements. Results from these studies, show that EUSKATEL PRO has low toxicity to non-target arthropods. At Tier II the PER in-field or off-field values for both GAP scenarios are below the 50% effect rate for all species, indicating a low risk to non-target arthropods within the treated fields, and adjacent untreated habitat.

### 3.8.5 Effects on soil organisms

Regulatory testing with *Folsomia candida* and *Hypoaspis aculeifer* has been conducted with azoxystrobin, prothioconazole and the relevant soil metabolites. Regulatory testing with earthworms (*Eisenia fetida*), has been conducted with azoxystrobin, the relevant metabolites of azoxystrobin, and the relevant metabolites of prothioconazole, prothioconazole-desthio (M04) and prothioconazole-S-methyl (M01) in accordance with EU requirements for soil macrofauna. Results from the studies with prothioconazole, azoxystrobin and the relevant metabolites, summarised in the EFSA Review Reports, show that the active substance and the studies with the relevant metabolites have low toxicity to soil macrofauna. Regulatory testing with earthworms, *Folsomia candida* and *Hypoaspis aculeifer* has also been conducted with EUSKATEL PRO. Results from these studies show that EUSKATEL PRO has low toxicity to non-target soil organism.

All acute and long-term TER values were calculated to be in excess of the accepted trigger values and a low risk for non-target soil organisms was concluded.

Regulatory testing with soil microorganisms has been conducted with EUSKATEL PRO, prothioconazole, azoxystrobin and the relevant metabolites in accordance with EU requirements. Results from these studies,

summarised in the EFSA Review Reports for prothioconazole, and Appendix 2 (FF-075), show that the formulated product, active substance and relevant metabolites have low toxicity to soil microorganisms.

### **3.8.6 Effects on non-target terrestrial plants**

The TER values considering the data gathered from the seedling emergence and vegetative vigour studies for EUSKATEL PRO are greater than the predicted exposure rates derived from the treatment of winter oilseed rape (BBCH 55-69) and winter and spring cereals (BBCH 30-69) at a distance of 1m from the treated field. Acceptable risk to non-target higher plants is concluded from uses of EUSKATEL PRO in accordance with the GAP.

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

An assessment of the effects of prothioconazole and azoxystrobin on the inhibition of the respiration rate of aerobic wastewater micro-organisms resulted in EC<sub>50</sub> values of >10,000 mg a.s./L and >3.2 mg a.s./L, respectively. Therefore, it can be assumed that adverse effects on methods of sewage treatment are unlikely when EUSKATEL PRO is applied according to GAP.

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

The azoxystrobin metabolite R234886 is predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required. The relevance assessment confirms that because the structure of R234886 is very similar to azoxystrobin, the overt toxicity for R234886 will have been adequately evaluated in the studies with the parent compound. The oral LD<sub>50</sub> for R234886 was >5000 mg/kg and it was negative in an Ames test. Based on the weight of evidence R234886 is not considered relevant.

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

Neither prothioconazole nor azoxystrobin are considered to be candidates for substitution.

## **5 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.





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## **Appendix 1   Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.
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## Appendix 2 Copy of the product label

### Metabolizm i pozostałości:

Akceptowalne zastosowanie w ochronie rzepaku: do fazy BBCH 59

Akceptowalny okres karencji w ochronie rzepaku: 56 dni

Błąd w etykiecie – prośba o wyjaśnienie:

protiokonazol (związek z grupy triazoli) – ~~250 g/l~~, 200 g/l

azoksystrobina (związek z grupy strobiluryn) – ~~125 g/l~~, 150 g/l

### **Skuteczność:**

Ze względu na ograniczoną liczbę badań możemy zaakceptować w projekcie etykiety stosowanie na rzepaku ozimym przeciwko SCLESC (max 1 aplikacja na sezon), pszenicy ozimej przeciwko SEPTTR (max 2 aplikacje na sezon) i PUCCRT (max 2 aplikacje na sezon), w jęczmieniu jarym przeciwko PYRNTE (max 1 aplikacja na sezon) oraz w pszenżycie ozimym przeciwko SEPTTR (max 2 aplikacje na sezon). Pozostałe zastosowania zostały wykreślone z powodu niewystarczającej liczby badań. Dodano także informację, iż nie można wykluczyć możliwości negatywnego wpływu na produkty roślinne po procesie transformacji biologicznej, takim jak warzenie piwa.

**Posiadacz zezwolenia:** Rotam Agrochemical Europe Ltd., Hamilton House, Mabledon Place, Londyn, WC1H9BB, Zjednoczone Królestwo Wielkiej Brytanii i Irlandii Północnej, tel.: +44 2079 53 04 47, e-mail: contacteu@rotam.com

## Euskatel Pro



Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

protiokonazol (związek z grupy triazoli) – ~~250~~ 200 g/l,

azoksystrobina (związek z grupy strobiluryn) – ~~125~~ 150 g/l.

**Zezwolenie MRiRW nr R -      z dnia      r.**

 	
<b>Uwaga</b>	
H317	Może powodować reakcję alergiczną skóry
H315	Działa drażniąco na skórę.
H319	Działa drażniąco na oczy.
H335	Może powodować podrażnienie dróg oddechowych.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować

EUH401	zgodnie z instrukcją użycia. Zawiera 1,2-Benzisothiazolin-3-one oraz mieszaninę reakcyjną of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)). Może powodować reakcję alergiczną.
P261 P264 P273 P280 P302+P352 P305+P351+P338 P337 + P313 P403+P233 P391	Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy. Dokładnie umyć ręce po użyciu. Unikać uwalniania do środowiska. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody W przypadku dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Przechowywać w dobrze wentylowanym miejscu. Przechowywać pojemnik szczelnie zamknięty. Zebrać wyciek.

## OPIS DZIAŁANIA

FUNGICYD, koncentrat w postaci stężonej zawiesiny do rozcieńczania wodą (SC) o działaniu układowym, do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego.

Środek zawiera substancję czynną protiokonazol – związek z grupy inhibitorów biosyntezy steroli – inhibitorów demetylacji (SBI-DMI) (grupa FRAC 3) i substancję czynną azoksystrobina zaliczaną do grupy strobiluryn – fungicydy QoI, inhibitory oddychania na poziomie komórkowym (grupa FRAC 11).

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

### Rzepak ozimy

Zgnilizna twardzikowa ~~czarna krzyżownic~~

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 0,8 l/ha.

Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy gdy widoczne są pojedyncze pąki kwiatowe (główny kwiatostan), nadal zamknięte do końca fazy kwitnienia (BBCH 55-69 BBCH 55-59).

Liczba zabiegów: ~~2~~ 1.

~~Odstęp między zabiegami: co najmniej 14 dni.~~

Zalecana ilość wody: 100-400 l/ha.

Większą ilość wody stosować w przypadku mocno zagęszczonego ładu, celem dobrego pokrycia roślin cieczą użytkową.

Zalecane opryskiwanie: drobnokropliste.

**Pszemica ozima, pszenica durum, pszenica orkisz, pszenżyto ozime**

*Septorioza paskowana liści*

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: W celu uzyskania najlepszych efektów środek należy stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy początku wzrostu źdźbła do końca fazy kłoszenia (BBCH 30-59).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 100-400 l/ha.

Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.

Zalecane opryskiwanie: drobnokropliste.

#### ~~Rdza żółta~~

~~Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.~~

~~Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, do końca fazy kwitnienia (BBCH 69).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.~~

~~Odstęp między zabiegami: co najmniej 14 dni.~~

~~Zalecana ilość wody: 100-400 l/ha.~~

~~Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

#### **Pszenica ozima**

##### *Rdza brunatna*

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy początku wzrostu źdźbła do końca fazy kwitnienia (BBCH 30-69).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~2~~ 2.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 100-400 l/ha.

Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.

Zalecane opryskiwanie: drobnokropliste.

~~Maksymalna łączna liczba zabiegów w sezonie wegetacyjnym: 2.~~

#### **Jęczmień jary**

##### ~~Rynchosporioza zbóż~~, plamistość siatkowa jęczmienia

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy początku wzrostu źdźbła do ~~końca fazy kwitnienia~~ całkowitego rozwinięcia liścia flagowego (BBCH 30-49 ~~69~~).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~2~~ 1

~~Odstęp między zabiegami: co najmniej 14 dni.~~

Zalecana ilość wody: 100-400 l/ha.

Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.

Zalecane opryskiwanie: drobnokropliste.

#### **~~Żyto ozime, żyto jare~~**

##### **~~Rdza żółta, rdza brunatna~~**

~~Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.~~

~~Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy początku wzrostu źdźbła do końca fazy kwitnienia (BBCH 30-69).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.~~

~~Odstęp między zabiegami: co najmniej 14 dni.~~

~~Zalecana ilość wody: 100-400 l/ha.~~

~~Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

#### **~~Owies ozimy, owies jary, pszenżyto ozime, pszenżyto jare~~**

##### **~~Rdza koronowa~~**

~~Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.~~

~~Termin stosowania: W celu uzyskania najlepszych efektów środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów chorób, od fazy początku wzrostu źdźbła do końca fazy kwitnienia (BBCH 30-69).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.~~

~~Odstęp między zabiegami: co najmniej 14 dni.~~

~~Zalecana ilość wody: 100-400 l/ha.~~

~~Większą ilość wody stosować w przypadku mocno zagęszczonego łanu, celem dobrego pokrycia roślin cieczą użytkową.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

### **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

~~rzepak ozimy, pszenica ozima, pszenica durum, pszenica orkisz, pszenżyto ozime, jęczmień jary, żyto ozime, żyto jare, owies ozimy, owies jary, pszenżyto jare~~ - 35 dni.

~~rzepak ozimy~~: 56 dni

1. Warunkiem skuteczności zabiegu jest dokładne pokrycie roślin cieczą użytkową.
2. Podczas stosowania środka nie dopuścić do:
  - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
  - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
3. Środek zawiera substancję czynną substancję czynną protiokonazol – związek z grupy inhibitorów biosyntezy steroli – inhibitorów demetylacji (SBI-DMI) (grupa FRAC 3) i substancję czynną azoksysstrobina zaliczaną do grupy strobiluryn – fungicydy QoI, inhibitory oddychania na poziomie komórkowym (grupa FRAC 11). W ramach strategii przeciwdziałania odporności sprawców chorób zaleca się m. in. stosowanie środka maksymalnie 2 razy w sezonie wegetacyjnym.
4. Nie możemy wykluczyć możliwości negatywnego wpływu na produkty roślinne po procesie transformacji biologicznej, takim jak warzenie piwa.

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Nosić rękawice ochronne.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Zawartością opakowania przed użyciem wstrząsnąć. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową i uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wleciu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Bezpośrednio po pracy aparaturę dokładnie wymyć oraz przepłukać ~~co najmniej dwukrotnie~~ trzykrotnie wodą.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Unikać wdychania rozpylonej cieczy.

Stosować rękawice ochronne i odzież roboczą ~~odzież ochronną i ochronę oczu/ochronę twarzy zabezpieczającą przed oddziaływaniem środków ochrony roślin~~ w trakcie przygotowywania cieczy użytkowej oraz ~~rękawice ochronne i odzież roboczą~~ w trakcie wykonywania zabiegu i wkraczania na obszar poddany zabiegowi.

Zanieczyszczoną odzież ochronną nie wносить poza miejsce pracy.

Zdjąć zanieczyszczoną odzież i wyprać przed ponownym użyciem.

## **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych należy zastosować 20 metrową zadarnioną strefę od zbiorników i cieków wodnych

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą**

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**wejść ludzie oraz zostać wprowadzone zwierzęta:**

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin (~~przez 7 dni no-  
sić rękawice ochronne i kalosze~~).

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**

xxxxxxx / Nie dotyczy

**Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwie-  
rzęta mogą być karmione tymi roślinami (okres karencji dla pasz):**

xxxxxxx / Nie dotyczy

**Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić ro-  
śliny uprawiane następnie:**

xxxxxxx / Nie dotyczy

**WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY  
ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C, z dala od źródeł ciepła i światła słonecznego.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.  
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpa-  
dów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami  
niebezpiecznymi.

**PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

**W PRZYPADKU KONTAKTU ZE SKÓRĄ:** Umyć dużą ilością wody.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę leka-  
rza.

~~W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontak-  
towe, jeżeli są i można je łatwo usunąć. Nadal płukać.~~

~~W przypadku narażenia lub steczenia: Zasięgnąć porady/zgłosić się pod opiekę lekarza.~~

~~W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę le-  
karza.~~

Okres ważności – ~~2 lata~~ 1 rok

Data produkcji –

Zawartość netto -

Nr partii -

## **Appendix 3 Letter of Access**

### **3.1 Letter of Access – Triazole Derived Metabolite (TDM)**



### **3.2 Letter of supply – Prothioconazole**



**安徽久易农业股份有限公司**  
**ANHUI JIUYI AGRICULTURE CO., LTD.**

**CONFIDENTIAL**

Date 15 April 2019

**PROTHIOCONAZOLE – LETTER OF SUPPLY**

We, **Anhui JiuYi Agriculture Co., Ltd.**, located at Hefei Circulate Economy Zone, Hefei City, Anhui Province, P.R. China, hereby declare that we supply prothioconazole Technical to **Rotam Agrochemical Co., Ltd.**, located at Unit 6, 26/F Trend Centre, 29 Cheung Lee Street, Chai Wan, Hong Kong, China.

The sources of active substance prothioconazole produced by **Anhui JiuYi Agriculture Co., Ltd.**, has been assessed and approved by the Dutch authority as equivalent to the reference source evaluated by the European Commission and included in Annex I of Directive 91/414/EEC

The manufacturing sites of Anhui JiuYi Agriculture Co. for prothioconazole, are:

**Source 1**

Company: **Anhui JiuYi Agriculture Co., Ltd.**  
Hefei Circulate Economy Zone,  
Hefei City,  
Anhui Province,  
P. R. China

This letter is valid exclusively for the above mentioned applications and products.

Yours sincerely,

Done in Hefei, on the 15<sup>th</sup> April 2019

Name: Mr. Xiao Liyu

Position: General Manager

Anhui JiuYi Agriculture Co., Ltd.

Add: Hefei Circulate Economy Zone, Hefei City, Anhui Province, China  
Http://www.jnyongye.com Email: xly@jyukel-agrochem.com  
Tel: 0086 551 85389805 Fax: 0086 551 85386005

1/1

### **3.3 Letter of supply - Azoxystrobin**



**Hebei Veyong Bio-Chemical Co., Ltd.**

No. 6, Middle Huagong Road, Circulation Chemical Industry Park, Shijiazhuang City, Hebei, China  
Tel: +86 311 85915903 85910033 85916161 85918304 85915808  
Fax: +86 311 85938574 11/30/2020  
http://www.veyong.com

Date: 07 December 2020

**AZOXYSTROBIN- LETTER OF SUPPLY**

We, **Hebei Veyong Bio-Chemical Co., Ltd.**, located at No.6, Middle Huagong Road, Circulation Chemical Industry Park, Shijiazhuang City, Hebei, China, hereby declare that we supply Azoxystrobin Technical to **Rotam Agrochemical Co., Ltd.**, located at Unit 6, 26/F Trend Centre, 29 Cheung Lee Street, Chai Wan, Hong Kong, China.

The sources of active substance Azoxystrobin produced by **Hebei Veyong Bio-Chemical Co., Ltd.**, has been assessed and approved by the Netherlands authority as equivalent to the reference source evaluated by the European Commission and included in Annex I of Directive 91/414/EEC.

The manufacturing site of Hebei Veyong Bio-Chemical Co., Ltd for Azoxystrobin is:

Company : **Hebei Veyong Bio-Chemical Co., Ltd.**

No.6, Middle Huagong Road,  
Circulation Chemical Industry Park,  
Shijiazhuang City,  
Hebei, China

This letter is valid exclusively for the above mentioned application and product.

Yours sincerely,

Done in Shijiazhuang, on the 07th December 2020

A handwritten signature in black ink, appearing to read "Fan Zhaohui".

General manager: Fan Zhaohui  
Hebei Veyong Bio-Chemical Co., Ltd.

河北威远生物化工有限公司  
HEBEI VEYONG BIO-CHEMICAL CO., LTD

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF Prothioconazole 200 g/L + Azoxystrobin 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2950 RRL Global Services GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 2.2.1 KCP 2.2.2	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF Prothioconazole 200 g/L + Azoxystrobin 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2949 RRL Global Services	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 2.7.1/01	Jun Lu	2021	STUDY ON THE PHYSICO-CHEMICAL PROPERTIES OF PROTHIOCONAZOLE 200 G/L + AZOXYSTROBIN 150 G/L SUSPENSION CONCENTRATE AFTER ACCELERATED STORAGE AT 54°C FOR 14 DAYS Rotam Agrochem International Co., Ltd. Study No.: 2951 RRL Global Services GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 2.7.1/02	Jun Lu	2021	DETERMINATION OF RELEVANT IMPURITIES IN PROTHIOCONAZOLE 200 g/L + AZOXYSTROBIN 150 g/L SUSPENSION CONCENTRATE Rotam Agrochem International Co., Ltd. Study No.: 2952 RRL Global Services GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 5.2.1.1/01	Lu, J.	2020	Study on the method validation of prothioconazole 200 g/l + azoxystrobin 150 g/l suspension concentrate Study No.: 2878 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 5.2.1.2/01	Lu, J.	2020	Method validation of relevant impurities in prothioconazole 200 g/l + azoxystrobin 150 g/l suspension concentrate Study No.: 2959 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.1.2/02	Lu, J.	2021	Method validation for impurity-3 (prothioconazole deschloro) in prothioconazole 200 g/l + azoxystrobin 150 g/l suspension concentrate Study No.:3030 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 5.2.2/01	Bogner, F	2020	Analytical phase report. Prothioconazole 200 g/L+ Azoxystrobin 150 g/L SC (FF-075): Honey Bee ( <i>Apis mellifera</i> L.) Chronic Oral Toxicity Test (10-Day Feeding) under Laboratory Conditions Report no. S20-00395-L3 GLP Unpublished <i>Contained in Annex 2 of Lozano, J.; 2020, Report no. S20-00395 - see dRR B9]</i>	N	Y	Data/study report never submitted before	Rotam
KCP 5.2.2/02	Bogner, F	2020	Analytical phase report. Prothioconazole 200 g/L+ Azoxystrobin 150 g/L SC (FF-075): Honey Bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions Report no. S20-00396-L3 GLP Unpublished <i>Contained in Annex 2 of Lozano, J.; 2020, Report no. S20-00396 - see dRR B9]</i>	N	Y	Data/study report never submitted before	Rotam
KCP 5.2.2/03	Wendling, K.	2020	Final Report. Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC: Acute Oral and Contact Toxicity to the Bumble Bee, <i>Bombus terrestris</i> L. under Laboratory Conditions Report no. S19-03594 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.2/04	Yu, J.	2021	Method validation, solubility and stability of Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075) in aquatic test mediums Report no. 2856 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 5.3.2.2/01	Herrmann, S.S.	2014	Determination of pesticide residues in maize for livestock feed by GC-MS/MS and LC-MS/MS (QuEChERS method) Validation Report 17 EURL for Cereals and Feeding stuff, National Food Institute, Technical University of Denmark GLP status not specified Published	N	Y	Data/study report never submitted before	-
KCP 5.3.2.2/02	Poulsen, M.E.	2012	Determination of pesticide residues in wheat, oat, rye, rice and barley by LC-MS/MS (QuEChERS method) Validation Report 9 EURL for Cereals and Feeding stuff, National Food Institute, Technical University of Denmark GLP status not specified Published	N	Y	Data/study report never submitted before	-
KCP 7.3	W.J.M. Maas	2021	The In Vitro Percutaneous Absorption of Radiolabelled Prothioconazole-desthio n Two In-use Dilutions through Human Split- Thickness Skin Company Report No 20274709 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 9.2.4.1/01	Thomas, V.	2021	Predicted environmental concentrations of azoxystrobin and its metabolites in groundwater using the FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 groundwater models and scenarios	N	N	-	Rotam



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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Company Report No. 18-015-26-001 TSG Consulting Non GLP Unpublished				
KCP 10.2.1/01	Li, N	2021	<i>Daphnia</i> ( <i>Daphnia magna</i> ), acute immobilization test with prothioconazole 200 g/L + Azoxystrobin 150 g/L SC EC (FF-075) Rotam Research Laboratory (RRL), China Study report no.: 2859 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.2.1/02	Li, N	2021	Fresh water algae ( <i>Pseudokirchneriella subcapitata</i> ) growth inhibition test with prothioconazole 200 g/L + azoxystrobin 150 g/L EC (FF-075) Rotam Research Laboratory (RRL), China Study report no.: 2858 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.2.1/03	Li, N	2021	<i>Lemna minor</i> growth inhibition test with prothioconazole 200 g/L + azoxystrobin 150 g/L SC (FF-075). Rotam Research Laboratory (RRL), China Study report no.: 2867 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.1.1.1/01	Parker, T	2020	Honeybees ( <i>Apis mellifera</i> ), acute oral toxicity test with Prothioconazole 200 g/L +Azoxystrobin 150 g/L SC (FF 075) Rotam Research Laboratory (RRL), China Study report No.: 2862 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.1/02	Parker, T	2021	Honeybees ( <i>Apis mellifera</i> ), acute contact toxicity test with Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075) Rotam Research Laboratory (RRL), China Study report No.: 2863 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.1.1.1.3/01	Wendling, K.	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC: Acute Oral and Contact Toxicity to the Bumble Bee, <i>Bombus terrestris</i> L. under Laboratory Conditions. Eurofins Agrosience Services Ecotox GmbH Study report No.: S19-03594 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.1.2/01	Lozano, J.	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Honey Bee ( <i>Apis mellifera</i> L.) Chronic Oral Toxicity Test (10-Day Feeding) under laboratory conditions. Trialcamp S.L.U., Spain Study report No.: S20-00395 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.1.3/01	Lozano, J.	2020	Prothioconazole 200 g/L+ Azoxystrobin 150 g/L SC (FF-075): Honey Bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test following Repeated Exposure under laboratory conditions. Trialcamp S.L.U., Spain Study report No.: S20-00396 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1/01	Varela, S.	2021	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF075): Toxicity to the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under Standard Laboratory Conditions. Eurofins Agrosience Services Ecotox GmbH, Study report No.: S20-09657. GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.2.1/02	Walter, C., and Stäbler, P.	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Toxicity to the Aphid Parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under Laboratory Conditions. Eurofins Agrosience Services Ecotox GmbH Study report No.: S19-04385 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.2.1/03	Walter, C. and Stäbler, P.	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Toxicity to the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under Extended Laboratory Conditions. Eurofins MITOX FOPSE Sarl, France Study report no. S19-04389 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.2.1/04	Walter, C. and Stäbler, P.	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Toxicity to the Aphid Parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under Extended Laboratory Conditions. Eurofins Agrosience Services Ecotox GmbH	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study report No.: S19-04386 GLP Unpublished				
KCP 10.3.2.1/05	Luna, F	2020	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Toxicity to the Ladybird, <i>Coccinella septempunctata</i> L. (Coleoptera: Coccinellidae) Using an Extended Laboratory Test with Freshly Applied Spray Deposits. TrialCamp S.L.U., Spain Study report No.: S19- 04397 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.3.2.1/06	Walter, C., and Stäbler, P.	2019	Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075): Toxicity to the Green Lacewing Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions. Eurofins Agrosience Services Ecotox GmbH Study report No.: S19-00968. GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.4.1.1/01	Parker, T	2021	Earthworm ( <i>Eisenia fetida</i> ), reproduction test with Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075) in artificial soil. Rotam Research Laboratory (RRL), China Study report no.: 2866 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.4.2.1/01	Senn, L	2021	Prothioconazole 200g/L + Azoxystrobin 150g/L SC (FF-075): Reproduction toxicity to the collembolan species <i>Folsomia candida</i> in artificial soil.	N	Y	Data/study report never submitted before	Rotam

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			ECT Oekotoxikologie GmbH, Germany Study report No.: 20AV6CR. GLP Unpublished				
KCP 10.4.2.1/02	Senn, L	2021	Prothioconazole 200g/L + Azoxystrobin 150g/L SC (FF-075): Reproduction toxicity to the predaceous mite <i>Hypoaspis</i> (Geolaelaps) aculeifer in artificial soil. ECT Oekotoxikologie GmbH, Germany; Study report No.: 20AV3HR. GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.5/01	Li, N	2021	Effects of Prothioconazole 200 g/L + Azoxystrobin 150 g/L EC (FF-075) on soil microorganisms: Nitrogen transformation test Rotam Research Laboratory (RRL), China Study report No.: 2864 GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.6/01	Förster, B	2021	Prothioconazole 200 g/L + azoxystrobin 150 g/L SC (FF-075): Terrestrial plant seedling emergence and seedling growth test. Study report No.: 20AV6PA GLP Unpublished	N	Y	Data/study report never submitted before	Rotam
KCP 10.6/02	Förster, B	2021	Prothioconazole 200 g/L + azoxystrobin 150 g/L SC (FF-075): Terrestrial Vegetative Vigour Test. Study report No.: 20AV6PB	N	Y	Data/study report never submitted before	Rotam

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

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

Prothioconazole

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Data point	Author(s)	Year	Title Company, Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
IIA 4.1.2/23	Heinemann, O.	2000	Analytical determination of residues of JAU6476 and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001) Bayer AG, Report No.: 00598/M001	N	Bayer
KCA 6.1/03	Freitag, T.	2007	Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months MR-07/282	N	Bayer
IIA 6.0/01	Heinemann, O.	2001a	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices Bayer AG, Report No.: MR-282/00	N	Bayer
IIA 6.1.1/01	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer AG, Report No.: MR-198/99	N	Bayer
IIA 6.1.1/03	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer AG, Report No.: PF3906,	N	Bayer
IIA 6.1.1.1 /01	Haas, M.	2001b	Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues Bayer AG, Report No.: MR-084/01	N	Bayer
IIA 6.1.2/01	Haas, M.	2001d	Metabolism of [phenyl-UL- 14C]JAU6476 in peanuts Bayer AG, Report No.: MR-193/01	N	Bayer

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IIA 6.2.1/02	Duah, F. K.; Lopez, R. T.	2004	The metabolism of [triazole-3,5-14 C] JAU 6476 in wheat Bayer AG, Report No.: 200733	N	Bayer
IIA 6.2.1/06	Haas, M.	2000	Metabolism of [triazole-UL-14C]JAU6476 in peanuts Bayer AG, Report No.: MR-194/02	N	Bayer
IIA 6.2.1/07	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [phenyl-UL-14C]JAU6476 in sugar beets Bayer AG, Repot No.: 200466	N	Bayer
IIA 6.2.1/08	Beedle, E. C.; Ying, S. L.	2004	The metabolism of [triazole-UL-14C]JAU6476 in sugar beets Bayer AG, Repot No.: 200467	N	Bayer
IIA 6.2.2.1 /01	xxxxxxx	2001a	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat Bayer AG, Report No.: MR-092/01,	Y	Bayer
IIA 6.2.2.2 /01	xxxxxxx	2002a	[Phenyl-UL-14C]JAU6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Bayer AG, Report No.: MR-091/01	Y	Bayer
IIA 6.2.3/02	xxxxxxx	2004	[Triazole-UL-14C]JAU 6476: Absorption, distribution, excretion, and metabolism in the lactating goat Bayer AG, Report No.: MR-448/02	Y	Bayer
IIA 6.2.2.2.1 /01	xxxxxxx	2002b	Validation of the residue analytical method for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4- hydroxy-desthio residues in animal matrices using aged radioactive residues Bayer AG, Report No.: MR-091/01 Part 2	Y	Bayer
IIA 6.2.2.3 /01	xxxxxxx	2001b	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in laying hens Bayer AG, Report No.: MR-309/01	Y	Bayer
IIA 6.2.2.3 /02	xxxxxxx	2001c	[Triazole-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens Bayer AG, Report No.: MEF-005/03	Y	Bayer



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IIA 6.3.2.1.2 /02	Heinemann, O.	2001i	Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2104/00, Report includes Trial Nos.: R 2000 0454/0 R 2000 0457/5 R 2000 0474/5 R 2000 0475/3 R 2000 0476/1	N	Bayer
IIA 6.3.2.1.2 /04	Heinemann, O.	2001 l	Determination of residues of JAU 6476-desthio in/on wheat and triticale after spray application of JAU 6476 250 EC in Spain and France Bayer AG, Report No.: RA-2105/00, Report includes Trial Nos.: R 2000 0482/6 R 2000 0479/6 R 2000 0478/8 R 2000 0455/9	N	Bayer
KCA 6.3.2.1.3 /03	Heinemann, O.	2001j	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2101/00, Report includes Trial Nos.: R 2000 0452/4 R 2000 0456/7 R 2000 0462/1 R 2000 0464/8 R 2000 0465/6	N	Bayer
IIA 6.3.2.1.3 /05	Heinemann, O.; Elke, K.	2001b	Determination of residues of JAU 6476-desthio in/on winter barley after spray application of JAU 6476 250 EC in France, Italy and Portugal Bayer AG, Report No.: RA-2144/98, Report includes Trial Nos.: R 1998 1317/6 R 1998 1571/3 R 1998 1572/1	N	Bayer

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IIA 6.3.2.1.3 /06	Heinemann, O.	2001 k	Determination of residues of JAU 6476-desthio in/on spring barley after spray application of JAU 6476 250 EC in Spain, Italy and Southern France Bayer AG, Report No.: RA-2103/00, Report includes Trial Nos.: R 2000 0473/7 R 2000 0472/9 R 2000 0470/2 R 2000 0453/2	N	Bayer
KCA 6.3.2.2/01	Heinemann, O.	2002a	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Germany, Sweden, Northern France and Great Britain Bayer AG, Report No.: RA-2088/00, Report includes Trial Nos.: R 2000 0079/0 R 2000 0419/2 R 2000 0420/6 R 2000 0421/4	N	Bayer
IIA 6.3.2.2/02	Heinemann, O.	2001g	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Southern France Bayer AG, Report No.: RA-2089/00, Report includes Trial Nos.: R 2000 0422/2 R 2000 0080/4	N	Bayer
IIA 6.3.2.2/03	Heinemann, O.	2002c	Determination of residues of JAU 6476-desthio on rape spray application of JAU 6476 250 EC in Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2178/01, Report includes Trial Nos.: R 2001 0518/5 R 2001 0517/7 R 2001 0516/9 R 2001 0515/0	N	Bayer
IIA 6.3.2.2/04	Heinemann, O.	2002b	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in southern France Bayer AG, Report No.: RA-2179/01, Report includes Trial Nos.: R 2001 0519/3 R 2001 0520/7	N	Bayer

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IIA 6.4/01	xxxxxxxxx	2001	JAU 6476-desthio - Dairy cattle feeding study Bayer AG, Report No.: MR-535/00	Y	Bayer
IIA 6.5/01	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Bayer AG, Report No.: MR-166/00	N	Bayer
IIA 6.6/01	Haas, M.	2001c	Confined rotational crop study with JAU6476 Bayer AG, Report No.: MR-159/00	N	Bayer
IIA 6.6/02	Duah, F. K.; Kraai, M. J.	2004	The accumulation of [triazole-3,5-14C] JAU6476 in confined rotational crops Bayer AG, Report No.: 200623	N	Bayer
IIA 7/01	Borchers, H., Klein, O.	2002	JAU 6476: List of metabolites Bayer AG, Report No.: REG02-0014 Date: 2002-02-28 Non GLP Unpublished	N	BAY
IIA 7.1.1.1.1/01 IIA 7.1.1.2.1/01	Gilges, M.	2000	Aerobic degradation of JAU 6476 in two soils Bayer AG, Report No. MR-549/99 Date: 2000-01-27, amended: 2000-09-06 and 2001-12-05 GLP Unpublished	N	BAY
IIA 7.1.1.1.1/02 IIA 7.1.1.2.1/02	Hellpointner, E.	2001b	Degradation and metabolism of JAU6476 in aerobic soils Bayer AG, Report No. MR-104/01 Date: 2001-07-25 GLP Unpublished	N	BAY

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IIA 7.1.1.1.1/03 IIA 7.1.1.2.1/03	Gilges, M.	2001a	Degradation of JAU6476-S-methyl (WAK7861) in four soils under aerobic conditions Bayer AG, Report No. MR-340/00 Date: 2001-06-29, amended: 2001-07-31 GLP Unpublished	N	BAY
IIA 7.1.1.1.1/04 IIA 7.1.1.2.1/04	Gilges, M.	2001b	Degradation of JAU6476-desthio (SXX0665) in four soils under aerobic conditions Bayer AG, Report No. MR-327/00 Date: 2001-06-29, amended: 2001-07-31 GLP Unpublished	N	BAY
IIA 7.1.1.1.2/01 IIA 7.1.1.2.1/02	Gilges, M.	2001d	Photolysis of JAU6476 on soil surface Bayer AG, Report No. MR-242/00 Date: 2001-07-25, amended: 2002-01-23 GLP Unpublished	N	BAY
IIA 7.1.1.2.2/01	Schramel, O.	2001a	Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy) Bayer AG, Report No. RA-2152/98 Date: 2001-03-30 Report includes study nos.: R812587, R812595, R812609, R812617, R812625, R812633, R815667, R815675 GLP Unpublished	N	BAY
IIA 7.1.1.2.3/01	Schramel, O.	2001b	Determination of the storage stability of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S- methyl in soil Bayer AG, Report No. MR-644/99 Date: 2001-03-30 GLP Unpublished	N	BAY

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IIA 7.1.2/02	Briggs, G.G.	1973	A simple relationship between soil adsorption of organic chemicals and their octanol /water partition coefficients 7th British Insecticide and Fungicide Conference Proc., Nottingham/UK, 83-86, 1973 Report No. M9976 = MO-00-00125 Date: 1973 Non GLP Published	N	BAY
IIA 7.1.2/03	Fent, G.	1998	Adsorption/desorption of [phenyl- UL-14C]SXX 0665 on four different soils Generated by SLFA Neustadt, Bayer AG, Report No. FM768 Date: 1998-08-11 GLP Unpublished	N	BAY
IIA 7.1.3.1/01	Riegner, K.	1999	Leaching behaviour of JAU 6476 formulated as 250 EC in soil (parent leaching) Bayer AG, Report No.: MR-098/99 Date: 1999-04-20 GLP Unpublished	N	BAY
IIA 7.1.3.2/01	Babczinski, P.	2001	Aged soil column leaching of JAU6476 Bayer AG, Report No.: MR-364/00 Date: 2001-06-01, amended: 2001-07-04 GLP Unpublished	N	BAY

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IIA 7.1.3.4/01	Schad, T.	2001b	Calculation of degradation rates of JAU6476 based on aerobic soil degradation studies Bayer AG, Report No.: MR-383/01 Date: 2001-10-04 Non GLP (calculation) Unpublished	N	BAY
IIA 7.1.3.4/02	Schad, T.	2001c	Calculation of temperature referenced first order DT <sub>50</sub> of JAU6476 and its metabolite JAU6476-desthio based on field dissipation studies conducted in Europe Bayer AG, Report No.: MR-468/01 Date: 2001-10-04 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1/01	Schneider, J.	2001	Physical and chemical properties of JAU 6476 Bayer AG, Report No. 14 0120 0950 Date: 2001-08-08 GLP Unpublished	N	BAY
IIA 7.2.1.1/01	Riegner, K.	1998	Hydrolysis of [phenyl-UL-14C]JAU 6476 in sterile aqueous buffer solutions Bayer AG, Report No. MR-623/98 Date: 1998-11-16 GLP Unpublished	N	BAY
IIA 7.2.1.2/01	Hellpointner, E.	2001a	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water of JAU 6476 Bayer AG, Report No. MR-101/01 Date: 2001-04-10 GLP Unpublished	N	BAY

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IIA 7.2.1.2/03	Hellpointner, E.	1993a	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of SXX 0665 in water Bayer AG, Report No. PF3852 Date: 1993-03-25 GLP Unpublished	N	BAY
IIA 7.2.1.2/04	Schaefer, H.	2001h	Calculation of DT <sub>50</sub> values of JAU6476 metabolite thiazocine generated by photolysis in aqueous solution Bayer AG, Report No. MR-591/01 Date: 2001-12-04 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1.2/05	Schaefer, H.	2001i	Prediction of maximum amounts of JAU6476-thiazocine in surface water under natural conditions Bayer AG, Report No. MR-597/01 Date: 2001-12-07 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1.2/06	Oggenfuss, P.	2000	Spectra of CGA 71019 Source: Novartis Crop Protection, Report No. 83573 Date: 2000-04-13 GLP Unpublished	N	Triazole Alanine Group (TAG)

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IIA 7.2.1.3.2/02	Scholz, K.	2001	Anaerobic aquatic metabolism of JAU6476 Bayer AG, Report No.: MR-275/01 Date: 2001-07-31 Non GLP Unpublished	N	BAY
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IIA 7.2.2.2/02	Hellpointner, E.	2000	Calculation of the chemical lifetime of JAU 6476-DESTHIO in the troposphere Bayer AG, Report No. MR-323/00 Date: 2000-07-13 Non GLP Unpublished	N	BAY
II A, 8.1.1 /01	xxxxxxx	1999	JAU 6476 techn.ai.: Acute oral toxicity for bobwhite quail (Colinus virginianus) Bayer CropScience, Report No.: BAR/LD 028, Edition Number: M- 013030-01-1 Source: Redacted Date: 1999-06-17 GLP Unpublished	Y	Bayer CropScience AG



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II A, 8.1.1 /02	xxxxxxxxxxx	1990b	SXX 0665 (Technical Grade) acute oral LD50 to bobwhite quail Bayer CropScience, Report No.: VB-009, Edition Number: M- 013315-01-1 Date: 1990-11-30 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.1.2 /01	xxxxxxxxxxx	2001b	JAU 6476 techn.: 5-day dietary LC50 for bobwhite quail (Colinus virginianus) Bayer CropScience, Report No.: BAR/LC 005 Edition No.: M-054770-01-1 Source: Redacted GLP Unpublished	Y	Bayer CropScience AG
II A, 8.1.2 /03	xxxxxxxxxxx	2001c	JAU 6476-desthio.: 5-day dietary LC50 for bobwhite quail (Colinus virginianus) Bayer CropScience, Report No.: BAR/LC 011 Edition No.: M-056229-02-1 Source: Redacted GLP Unpublished	Y	Bayer CropScience AG
II A, 8.1.3 /02	xxxxxxxxxxx	2000b	Reproduction study in mallard duck with JAU 6476 (by dietary admixture) Bayer CropScience, Report No.: 259919, Edition Number: M- 035123-01-1 Date: 2000-11-07 Source: Redacted GLP Unpublished	Y	Bayer CropScience AG
II A, 8.1.3 /03	xxxxxxxxxxx	2002	JAU 6476-desthio techn. ai.: Effects of a subchronic dietary exposure to the northern bobwhite quail including effects on reproduction and behaviour Bayer CropScience, Report No.:BAR/REP 006, Edition Number: M090509-01-1 Date: 2002-01-07 Source: Redacted GLP Unpublished	Y	Bayer CropScience AG

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II A, 8.2.1 /01	xxxxxx	1999a	JAU 6476- Acute toxicity (96 hours) to Rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a static test Bayer CropScience, Report No.: DOM 99076 Date: 1999-09-01 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.1 /04	xxxxxx	1990a	SXX 0665: Acute toxicity to rainbow trout in a static test Bayer CropScience, Report No.: FF-298 Date: 1990-10-26 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.1 /06	xxxxxx	2001d	JAU 6476-S-methyl- Acute toxicity (96 hours) to rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a semi-static test. Bayer CropScience, Report No.: DOM 21047 Date: 2001-09-25 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.1 /07	xxxxxx	1983a	Report for the test for cut of CGA 032 to rainbow trout Bayer CropScience, Report No.: 821418 Date: 1983-08-30 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.2.2 /01	xxxxxx	2001e	JAU 6476- Early life stage toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) under flow-through conditions Bayer CropScience, Report No.: DOM 20028 Date: 2001-12-11 GLP Unpublished	Y	Bayer CropScience AG

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II A, 8.2.2.2 /02	xxxxxx	2002	JAU 6476-desthio: Early life-stage toxicity test with rainbow trout ( <i>Oncorhynchus mykiss</i> ) under flow-through conditions Springborn Lab. AG, Horn Bayer CropScience, Report No.: 1022.013.321 Date: 2002-02-15 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.2.1 /01	xxxxxx	2002	1,2,4-Triazole- Juvenile growth test, fish ( <i>Oncorhynchus mykiss</i> ) Bayer CropScience, Report No.: DOM 21060 Date: 2002-01-14 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.3 /01	xxxxxx	2001	(14C)-JAU 6476- Bioconcentration and biotransformation in bluegill ( <i>Lepomis macrochirus</i> ) under flow-through conditions Bayer CropScience, Report No.: DOM 21003 Date: 2001-11-13 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.3 /02	xxxxxx	2001	(14C)-JAU 6476-desthio- Bioconcentration and biotransformation in bluegill ( <i>Lepomis macrochirus</i> ) under flow-through conditions Bayer CropScience, Report No.: DOM 20006 Date: 2001-06-21 GLP Unpublished	Y	Bayer CropScience AG
II A, 8.2.4 /01	Heimbach, F.	1999c	Acute toxicity of JAU 6476 (tech.) to water fleas ( <i>Daphnia magna</i> ) Bayer CropScience, Report No.: HBF/DM 212, Date: 1999-08-13 Unpublished	N	Bayer CropScience AG

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II A, 8.2.4 /03	Dorgerloh, M.; Sommer, H.	2001b	Acute toxicity of JAU 6476-S-methyl (tech.) to waterfleas ( <i>Daphnia magna</i> ) Bayer CropScience, Report No.: DOM 21055 Date: 2001-09-03 Unpublished	N	Bayer CropScience AG
II A, 8.2.4 /04	Rufli, H.	1983b	Report on the test for acute toxicity of CGA 98032 to <i>Daphnia magna</i> Bayer CropScience, Report No.: 821416 Date: 1983-08-05 Unpublished	N	Bayer CropScience AG
II A, 8.2.5 /01	Hendel, B.; Sommer, H.	2001	Influence of JAU 6476 (tech) on the reproduction rate of water fleas Bayer CropScience, Report No.: HBD/RDM Date: 2001-04-11 Unpublished	N	Bayer CropScience AG
II A, 8.2.5 /02	Dorgerloh, M.; Sommer, H.	2001c	Influence of JAU 6476-desthio on the reproduction rate of water fleas in a static renewal laboratory system Bayer CropScience, Report No.: DOM 21036 Date: 2001-09-10 Unpublished	N	Bayer CropScience AG
II A, 8.2.6 /01	Dorgerloh, M.	2000b	JAU-6476- Influence on the growth of green alga, <i>Selenastrum capricornutum</i> Bayer CropScience, Report No.: DOM 99107 Date: 2000-10-25 Unpublished	N	Bayer CropScience AG

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II A, 8.2.6 /02	Heimbach, F.	1990b	Growth inhibition of green algae ( <i>Scenedesmus subspicatus</i> ) by SXX 0665 (tech.) Bayer CropScience, Report No.: HBF/AL 78 Date: 1990-06-20 Unpublished	N	Bayer CropScience AG
II A, 8.2.6/03	Dorgerloh, M.; Sommer, H.	2001a	JAU 6476-S-methyl- Influence on the growth of the green alga, <i>Selenastrum capricornutum</i> Bayer CropScience, Report No.: DOM 21028 Date: 2001-07-20 Unpublished	N	Bayer CropScience AG
II A, 8.2.6 /04	Palmer, S. J.; Kendall, T. Z.; Krueger, H. O.	2001	1,2,4-Triazole: A 96-hour toxicity test with the freshwater alga ( <i>Selenastrum capricornutum</i> ) Wildlife International Ltd., Easton, MD, USA Bayer CropScience, Report No.: 528A-101 Date: 2001-08-31 Unpublished	N	Bayer CropScience AG
II A, 8.2.7 /01	Hendel, B.	2000a	Influence of JAU 6476 (tech.) on development and emergence of larve of <i>Chironomus riparius</i> in a water-sediment system Bayer CropScience, Report No.: HDB/CH 42 Date: 2000-09-14 Unpublished	N	Bayer CropScience AG
II A, 8.2.7 /02	Hendel, B.	2000b	Influence of SXX 0665 (tech.) on development and emergence of larve of <i>Chironomus riparius</i> in a water-sediment system Bayer CropScience, Report No.: HDB/CH 43 Date: 2000-10-19 Unpublished	N	Bayer CropScience AG

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II A, 8.3.1.1 /01	Wilhelmy, H.	1999	JAU 6476 a.9.- Acute effects on the honeybee <i>Apis mellifera</i> NOACK Laboratorium, Sarstedt, Germany Bayer CropScience, Report No.: IBA64051 Date: 1999-11-10 Unpublished	N	Bayer CropScience AG
II A, 8.4.2 /02	Meisner, P.	2000d	Influence of JAU 6476-desthio on the reproduction of earthworms ( <i>Eisenia fetida</i> ) Bayer CropScience, Report Number: MPE/RG 332/00 Edition: M-026193-01-2 GLP Unpublished	N	Bayer CropScience AG
II A, 8.4.2 /03	Heimbach, F.	2000b	Influence of JAU 6476-S-Methyl on the reproduction of earthworms ( <i>Eisenia fetida</i> ) Bayer CropScience, Report Number: HBF/RG 317 Edition: M-021370-01-1 GLP Unpublished	N	Bayer CropScience AG
II A, 8.5 /02	Anderson, J. P. E.	1999b	Influence of JAU 6476 technical substance on the microbial mineralization of nitrogen in soils Bayer CropScience, Report No.: AJO/203199 Edition Number: M-024673-01-1 Date: 1999-12-08 GLP Unpublished	N	Bayer CropScience AG
II A, 8.5 /03	Anderson, J. P. E.	2000	Influence of the metabolite JAU 6476-desthio on the microbial mineralization of nitrogen in soils Bayer AG, Leverkusen, Germany Report No.: AJO/219101, Edition Number: M- 057459-01-1Date: 2000-05-09 GLP Unpublished	N	Bayer CropScience AG

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II A, 8.6 /01	Meisner, P.; Kolb, U.	2000	Herbicidal screening data for JAU 6476 (tech.) Bayer AG, Leverkusen, Germany Report No.: MPE NTP 13/00 Date: 2000-07-07 GLP Unpublished	N	Bayer CropScience AG
II A, 8.6 /03	Nienstedt, K. M.	2002	Reproduction toxicity test exposing Folsomia candida (collembola) to JAU 6476 technical Bayer CropScience, Report Number: 1022.028.641 Edition: M-034235-01-1 GLP Unpublished	N	Bayer CropScience AG
II A, 8.6 /04	Hoogendoorn, G. M.	2000	An extended laboratory study to evaluate the effects of JAU 6476 on the predaceous mite Hypoaspis aculeifer canestrini (acari: Laelapidae) MITOX tichting Bevordering Duurzame Plagbestrijding, Amsterdam, Netherlands Bayer CropScience, Report No.: B060HAE, Edition Number: M- 037786-02-1 Date: 2000-05-29 GLP Unpublished	N	Bayer CropScience AG

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II A, 8.6 /05	Moser, T.; Roembke, J.	2001	Acute and reproduction toxicity of JAU 6476-Desthio to the collembolan species Folsomia candida according to the ISO Guideline 11267 Bayer CropScience, Report Number: P1CR Edition: M-035070-03-1 GLP Unpublished	N	Bayer CropScience AG
II A, 8.6 /07	Moser, T.; Scheffczyk, A.	2001	Acute and reproduction toxicity of JAU 6476-S-methyl to the collembolan species Folsomia candida Bayer CropScience, Report Number: P35CR Edition: M-087207-01-1 GLP Unpublished	N	Bayer CropScience AG
II A, 8.6 /08	Lechelt-Kuntze	2002	JAU 6476 EC 250: Effect on the earthworm fauna of a grassland area in one year Bayer CropScience, Report No.: LKC/RGF 58, Edition Number: M- 040814-03-1 Date: 2002-02-28 GLP Unpublished	N	Bayer CropScience AG
II A, 8.7 /01	Mueller, G	1999	Investigation of the ecological properties of JAU 6476 Bayer AG, Leverkusen, Germany Report No.: 839 N/99, Edition Number: M- 012578-01-1 Date: 1999-05-17 GLP Unpublished	N	Bayer CropScience AG
KCP 5.2.2/01	Heinemann, O.	2000a	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals by HPLC/MS/MS 00598 Bayer AG GLP Unpublished	N	Bayer AG



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KCP 5.2.2/02	Heinemann, O.	2000b	Analytical determination of residues of JAU6476 and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001) 00598/M001 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.2.2/03	Schramel, O.	2001	Determination of the storage stability of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil MR-644/99 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.2.2/04	Schramel, O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS 00610 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.2.2/05	Heinemann, O.	2001a	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS 00647 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.2.2/06	Heinemann, O.	2001b	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS 00655 Bayer AG GLP Unpublished	N	Bayer AG

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KCP 5.2.2/07	Heinemann, O.	2001c	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in milk by HPLC-MS/MS (00655/M001) 00655/M001 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.2/01	Weeren, R.D. and Pelz, S.	2000	Modification M033 of method 00086: Validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476-desthio in materials of plant and animal origin 00086/M033 Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany GLP Unpublished	N	Bayer AG
KCP 5.3.2.2/02	Class, Th.	2001	Independent laboratory validation of DFG method S19 (extended revision) for the determination of residues of JAU 6476-desthio (BAYER method 00086/M033) in plant materials P/B 484 G PTRL Europe, Ulm, Germany GLP Unpublished	N	Bayer AG
KCP 5.3.2.2/03	Heinemann, O.	2000a	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals by HPLC/MS/MS 00598 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.2/04	Heinemann, O.	2000b	Analytical determination of residues of JAU6476 and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001) 00598/M001 Bayer AG GLP Unpublished	N	Bayer AG

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KCP 5.3.2.2/05	Heinemann, O.	2001a	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-desthio in/on cereals and canola by HPLC-MS/MS 00647 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.3/01	Heinemann, O.	2001b	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS 00655 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.3/02	Heinemann, O.	2001c	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in milk by HPLC-MS/MS (00655/M001) 00655/M001 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.3/03	Dubey, L.	2001	Independent laboratory validation of Bayer methods 00655 and 00655/M001 for the determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS A-14-01-01 Battelle, Geneva Research Centres, Carouge/Geneva, Switzerland GLP Unpublished	N	Bayer AG
KCP 5.3.2.3/04	Weber, H., Weber, E. and Spiegel, K.	2002	Validation of the residue analytical method for the determination of JAU6476-desthio , JAU6476-3-hydroxy-desthio and JAU6476-4-hydroxy-desthio residues in animal matrices using aged radioactive residues MR-091-01 Bayer AG GLP Unpublished	N	Bayer AG

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KCP 5.3.2.4/01	Schramel, O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil by HPLC-MS/MS Report no. 00610 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.4/02	Steinhauer, S.	2001	Enforcement method 00086/M038 for the determination of the residues of JAU6476-desthio in soil – validation of DFG method S19 (extended revision) 00086/M038 Dr Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany GLP Unpublished	N	Bayer AG
KCP 5.3.2.5/01	Sommer, H.	1999	Method for the determination of JAU6476 and SXX0665 in test water from aquatic toxicity test by HPLC [Tox/Ecotox method] 00586 Bayer AG Non-GLP Unpublished	N	Bayer AG
KCP 5.3.2.5/02	Sommer, H.	2001	Enforcement method 00684 for determination of JAU6476 and JAU6476-desthio in drinking and surface water by HPLC-MS/MS 00684 Bayer AG GLP Unpublished	N	Bayer AG
KCP 5.3.2.6/01	Maasfeld, W.	2002a	Method for the determination of JAU6476 in air by HPLC-MS/MS 00724 Bayer AG GLP Unpublished	N	Bayer AG

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KCP 5.3.2.6/02	Maasfeld, W.	2002b	[The study was relied on in the DAR however reference details were not provided in the DAR. Reference details below are instead taken from the dRAR] Method for the determination of JAU6476-desthio (SXX0665) in air by HPLC-MS/MS 00731 Bayer AG, Leverkusen, Germany GLP Unpublished	N	Bayer AG
KCP 7	EFSA	2007	Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole EFSA Scientific Report (2007) 106, 1-98 EFSA Non GLP Published	N	EFSA
KCP 7	RAC	2019	Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Prothioconazole (ISO); 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione CLH-O-0000001412-86-269/F RAC Non GLP Published	N	RAC

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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 6.3	Burke, S.R.	1995	ICIA5504 and R23031: Validation of a method for the determination of residues in cereals and vines. Final report. Zeneca RJ 1729B RIP96-00474	N	Syngenta
IIA 6.3	Clarke, D.M.	1994	ICIA5504 and R230310: Validation of a method [RAM 243/02] for the determination of residues in cereals and vines Zeneca RJ 1557B RIP96-00475	N	Syngenta
IIA 6.1	Allin, R.	1995	ICIA5504: Metabolism in Winter Wheat RJ1888B RIP96-00104	N	Syngenta
IIA 6.1	Earl, V.A. and Hadfield, S.T	1994	ICI5504: Metabolism in Vines RJ1676B RIP96-00105	N	Syngenta
IIA 6.1	Webb, J.	1995	ICI5504: Metabolism in Peanuts RJ1807B RIP96-00106	N	Syngenta
IIA 6.1	Wilkinson, M.J.	1994	ICI5504: Metabolism in Winter Wheat RJ1682B RIP96-00103	N	Syngenta
IIA 6.1.2	Burke, S.R.	1997	Azoxystrobin and R230310: Storage stability in various crops stored deep frozen for up to two years. Final Report. ZENECA Agrochemicals Report RJ2352B	N	Syngenta

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IIA 6.1.2	Sapiets, A.	1997	Azoxystrobin: Storage stability of residues in eggs and tissues Study 95JH229 ZENECA Agrochemicals Report Series RJ2352B	N	Syngenta
IIA 6.2	xxxxxx	1994	The metabolism of 14C-Pyrimidinyl labelled ICIA5504 in the laying hen ISN331/942668 RIP96-00110	Y	Syngenta
IIA 6.2	xxxxxx	1995	The metabolism of 14C-Phenyl acrylate labelled ICIA5504 in the laying hen ISN333/950182 RIP96-00111	Y	Syngenta
IIA 6.2	xxxxxx	1995	The metabolism of 14C-Cyanophenyl labelled ICIA5504 in the laying hen ISN333/950918 RIP96-00109	Y	Syngenta
IIA 6.2	xxxxxx	1995	ICIA5504: Metabolism of orally administered multiple doses in the lactating goat RJ1805B RIP96-00107	Y	Syngenta
IIA 6.2	xxxxxx	1995	Further investigation of residues in liver following oral administration of multiple doses to the lactating goat RJ1957B RIP96-00108	Y	Syngenta
IIA 6.2.2/01	xxxxxx	1996	14A-ICIA5504: Metabolism of orally administered multiple doses in laying hens Report No. RJ2084B Syngenta File No. ICI5504/0738	Y	Syngenta
IIA 6.2.2/02	xxxxxxx	1996	ICIA5504: Metabolism of orally administered multiple doses in the lactating goat Report Number: RJ2083B Syngenta File No. ICI5504/0739	Y	Syngenta

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IIA 6.3	Burke, S.R.	1995	ICIA5504 + R23031: Storage stability in various crops stored deep frozen for up to two years. Interim report 3 (Straw, Grapes and Wine) RJ1961B RIP96-00198	N	Syngenta
IIA 6.3	Burke, S.R.	1995	ICIA5504 + R23031: Storage stability in various crops stored deep frozen for up to two years. Interim report 1 (Cereals, Grapes and Wine) RJ1858B RIP96-00140	N	Syngenta
IIA 6.3	Sapiets, A.	1996	ICIA5504: Residue levels in wheat grain and milled process fractions from a trial carried out in Germany during 1995 JR2065B RIP96-00191	N	Syngenta
IIA 6.4	xxxxxx	1995	ICIA5504: Residue transfer study in dairy cows fed on a diet containing ICIA5504 RJ1878B RIP96-00141	Y	Syngenta
IIA 6.4.1/01	xxxxxx.	1997	Azoxystrobin: Residue transfer in laying hens Report No. RJ2349B Syngenta File No. ICI5504/073	Y	Syngenta
IIA 6.5	Sapiets, A.	1997	ICIA5504: Residue levels in malting barley and process fractions from studies conducted in Germany during 1996 GLP Unpublished RJ2382B	N	Syngenta
IIA 6.5	Sapiets, A.	1998	ICIA5504: Residue levels in malting barley and brewing fractions from a trial conducted in the United Kingdom during 1996 GLP Unpublished RJ2452B	N	Syngenta



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IIA 6.5	Sapiets, A.	1996	Processing study: milling/baking of wheat RJ2065B ICI5504/0718	N	Syngenta
IIA 6.5	Clarke, D.M.	1997	Processing study: milling/baking of wheat RJ2297B	N	Syngenta
IIA 6.5.1/01	Grout, S.J.	2002	14C-Phenylacrylate Azoxystrobin: Aqueous hydrolysis at 90, 100 & 120°C Report Number: RJ3296B Syngenta File No. ICI5504/1393	N	Syngenta
IIA 6.3.5 / 02	Benazeraf L.	2004	Residue Study with Azoxystrobin (ICI5504) in or on Barley in UK Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0406 GLP, not published Syngenta File No ICI5504/2453	N	Syngenta
IIA 6.3.5 / 04	Benazeraf L.	2004b	Residue Study with Azoxystrobin (ICI5504) in or on Barley in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0408 GLP, not published Syngenta File No ICI5504/2724	N	Syngenta
IIA 6.3.5 / 05	Benazeraf L.	2004c	Residue Study with Azoxystrobin (ICI5504) in or on Barley in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0418 GLP, not published Syngenta File No ICI5504/2722	N	Syngenta
IIA 6.3.5 / 06	Benazeraf L.	2005b	Azoxystrobin (ICI5504): Residue Study in or on Winter Barley in the United Kingdom Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0403 GLP, not published Syngenta File No ICI5504/3004	N	Syngenta

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IIA 6.3.5 / 07 & IIA 6.5.3 / 03	Simon P.	2006	Azoxystrobin - Residue study in or on barley and processed barley products in Germany 2004 (Test product A12705B) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, gba210004 GLP, not published Syngenta File No ICI5504/3546	N	Syngenta
IIA 6.3.5 / 08	Sole C.	2004	Residue study with Azoxystrobin (ICI5504) in or on Barley in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0301 GLP, not published Syngenta File No ICI5504/2659	N	Syngenta
IIA 6.3.5 / 09	Sole C.	2004a	Residue study with Azoxystrobin (ICI5504) in or on Barley in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0302 GLP, not published Syngenta File No ICI5504/2660	N	Syngenta
IIA 6.3.5 / 10	Sole C.	2004b	Residue study with Azoxystrobin (ICI5504) in or on Barley in France (South) Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0303 GLP, not published Syngenta File No ICI5504/2661	N	Syngenta
IIA 6.3.5 / 11	Sole C.	2004c	Residue Study with Azoxystrobin (ICI5504) in or on Barley in France (South) Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0304 GLP, not published Syngenta File No ICI5504/2455	N	Syngenta

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IIA 6.3.5 / 12	Sole C.	2004d	Residue Study with Azoxystrobin (ICI5504) in or on Barley in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0305 GLP, not published Syngenta File No ICI5504/2454	N	Syngenta
IIA 6.3.5 / 13	Benazeraf L.	2005c	Azoxystrobin (ICI5504): Residue Study in or on Winter Barley in Southern France Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0304 GLP, not published Syngenta File No ICI5504/3000	N	Syngenta
IIA 6.3.5 / 14	Benazeraf L.	2005d	Azoxystrobin (ICI5504): Residue Study in or on Winter Barley in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0305 GLP, not published Syngenta File No ICI5504/3001	N	Syngenta
IIA 6.3.6 / 01	Sole C.	2004e	Residue Study with Azoxystrobin (ICI5504) in or on Winter Wheat in the UK Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0401 GLP, not published Syngenta File No ICI5504/2726	N	Syngenta
IIA 6.3.6 / 02	Sole C.	2004f	Residue Study with Azoxystrobin (ICI5504) in or on Winter Wheat in the UK Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0402 GLP, not published Syngenta File No ICI5504/2725	N	Syngenta
IIA 6.3.6 / 03	Sole C.	2004g	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in France (North) Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0403 GLP, not published Syngenta File No ICI5504/2449	N	Syngenta

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IIA 6.3.6 / 04	Sole C.	2004h	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0404 GLP, not published Syngenta File No ICI5504/2448	N	Syngenta
IIA 6.3.6 / 05	Sole C.	2004i	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0414 GLP, not published Syngenta File No ICI5504/2723	N	Syngenta
IIA 6.3.6 / 06	Benazeraf L.	2005e	Azoxystrobin (ICI5504): Residue Study in or on Winter Wheat in United Kingdom Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0308 GLP, not published Syngenta File No ICI5504/3003	N	Syngenta
IIA 6.3.6 / 07	Simon P.	2006a	Azoxystrobin: Residue study in or on wheat and processed wheat products in Germany 2004 (Test product: A12705B) Syngenta Agro GmbH, Maintal, Germany, gwh220004 GLP, not published Syngenta File No ICI5504/3323	N	Syngenta
IIA 6.3.6 / 08	Benazeraf L.	2004d	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0306 GLP, not published Syngenta File No ICI5504/2632	N	Syngenta
IIA 6.3.6 / 09	Benazeraf L.	2004e	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0307 GLP, not published Syngenta File No ICI5504/2633	N	Syngenta

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IIA 6.3.6 / 10	Benazeraf L.	2004f	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in France (South) Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0308 GLP, not published Syngenta File No ICI5504/2634	N	Syngenta
IIA 6.3.6 / 11	Benazeraf L.	2004g	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in France (South) Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0309 GLP, not published Syngenta File No ICI5504/2728	N	Syngenta
IIA 6.3.6 / 12	Benazeraf L.	2004h	Residue Study with Azoxystrobin (ICI5504) in or on Wheat in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 03-0310 GLP, not published Syngenta File No ICI5504/2727	N	Syngenta
IIA 6.3.6 / 13	Benazeraf L.	2005f	Azoxystrobin (ICI5504): Residue Study in or on Winter Wheat in Southern France Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0302 GLP, not published Syngenta File No ICI5504/3035	N	Syngenta
IIA 6.3.6 / 14	Benazeraf L.	2005g	Azoxystrobin (ICI5504): Residue Study in or on Winter Wheat in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, 04-0303 GLP, not published Syngenta File No ICI5504/3041	N	Syngenta
IIA 6.5.3/04	Heillaut, C.	2008	Azoxystrobin (ICI5504): Residue Study on Wheat and Processed Wheat Products from Switzerland in 2006 Report No. T000676-06-REG. ADME Bioanalyses, France Syngenta File No. ICI5504/3940	N	Syngenta

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IIA 7.1.1.1.1 IIA 7.1.1.1.2 IIA 7.1.1.2.1	Mason, R. Butters, C.A.	1994	Degradation in soil under aerobic and anaerobic conditions Company Report No.: RJ 1754B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.1	Tummon, O.J.	1995	Laboratory degradation in three selected soil types Company Report No.: RJ 1819B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.1	Warinton, J.S., Chalofti, I., Harvey, B.R.	1995	Degradation of 14C-labelled compound in soil under laboratory conditions Company Report No.: RJ 1801B GLP Unpublished	N	Syngenta
IIA 7.1.1.1.2	Winter, L., Joseph, R.S.	1995	Soil surface photolysis Company Report No.: RJ 1716B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995a	Field soil dissipation in a trial carried out in Germany during 1993/1994: Final report Company Report No.: RJ 1935B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995b	Field soil dissipation in a trial carried out in Germany during 1994/95 Company Report No.: RJ 1946B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Hall, G.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1993/1994: Final report Company Report No.: RJ 1940B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1993/1994 Company Report No.: RJ 1942B	N	Syngenta

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			GLP Unpublished		
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995a	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1938B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995b	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1928B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995c	Field soil dissipation in a trial carried out in France during 1994/1995 Company Report No.: RJ 1943B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1994/95 Company Report No.: RJ 1944B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Eschenbrenner, P.	1995	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1941B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Myles, P.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1994/95 Company Report No.: RJ 1945B GLP Unpublished	N	Syngenta
IIA 7.1.2	Rowe, D., Lane, M.C.G.	1994	Adsorption and desorption in soil Company Report No.: RJ 1541B GLP Unpublished	N	Syngenta

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IIA 7.1.3.1 IIA 7.1.3.2	Butters, C.A., Ma- son, R.	1994	Mobility of ICIA5504 and its degradation products in prepared soil columns Company Report No.: RJ 1694B GLP Unpublished	N	Syngenta
IIA 7.1.3.1	Hurt, A.D.	1994	Leaching of formulated material in soil columns Company Report No.: RJ 1777B GLP Unpublished	N	Syngenta
IIA 7.1.3.1	Hurt, A.D.	1995	Leaching of formulated material in soil columns Company Report No.: RJ 1852B GLP Unpublished	N	Syngenta
IIA 7.1.3.1	Hurt, A.D.	1995	Leaching of formulated material in soil columns Company Report No.: RJ 1874B GLP Unpublished	N	Syngenta
IIA 7.2.1.1	Tummon, O.J.	1995	Aqueous hydrolysis at pH 4, 7 and 9 at 50°C Company Report No.: RJ 1971B GLP Unpublished	N	Syngenta
IIA 7.2.1.3.2	Warinton, J.S.	1994	Degradation in water-sediment systems under laboratory conditions Company Report No.: RJ 1679B GLP Unpublished	N	Syngenta
IIA 7.2.2	Kuet, S.F.	1995	Volatilization from soil and leaf surfaces following application as a SC formulation Company Report No.: RJ 1885B GLP Unpublished	N	Syngenta
IIA 8.2.1.3/01	xxxxxx	2002	R401553 (azoxystrobin metabolite): Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) Syngenta Crop Protection AG, Basel, Switzerland 7252/B, 2013675	Y	Syngenta



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			No SYN501657/0002 GLP Unpublished		
IIA 8.2.1.3/02	xxxxxx	2002	R402173 (Azoxystrobin metabolite): Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) Syngenta Crop Protection AG, Basel, Switzerland No SYN511114/0001 7338/B, 2013671 GLP Unpublished	Y	Syngenta
IIA 8.3.1.1/01	Bowles AJ, Wallace SJ	2002a	R401553 (Azoxystrobin metabolite): Acute toxicity to <i>Daphnia magna</i> , Syngenta Crop Protection AG, Basel, Switzerland, Brixham Environmental Laboratory, Brixham United Kingdom, BL7253/B 2013672 No SYN5016579003 GLP Unpublished	N	Syngenta
IIA 8.3.1.1/02	Wallace SJ	2002a	R402173 (Azoxystrobin metabolite): Acute toxicity to <i>Daphnia magna</i> . Syngenta Crop Protection AG, Basel, Switzerland, Brixham Environmental Laboratory, Brixham United Kingdom, BL7339/B 2013670 No SYN11114/0002 GLP Unpublished	N	Syngenta
IIA 7.1.1.1.1 IIA 7.1.1.1.2 IIA 7.1.1.2.1	Mason, R. Butters, C.A.	1994	Degradation in soil under aerobic and anaerobic conditions Company Report No.: RJ 1754B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.1	Tummon, O.J.	1995	Laboratory degradation in three selected soil types Company Report No.: RJ 1819B GLP	N	Syngenta

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			Unpublished		
IIA 7.1.1.2.1	Warinton, J.S., Chalofiti, I., Harvey, B.R.	1995	Degradation of 14C-labelled compound in soil under laboratory conditions Company Report No.: RJ 1801B GLP Unpublished	N	Syngenta
IIA 7.1.1.1.2	Winter, L., Joseph, R.S.	1995	Soil surface photolysis Company Report No.: RJ 1716B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995a	Field soil dissipation in a trial carried out in Germany during 1993/1994: Final report Company Report No.: RJ 1935B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995b	Field soil dissipation in a trial carried out in Germany during 1994/95 Company Report No.: RJ 1946B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Hall, G.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1993/1994: Final report Company Report No.: RJ 1940B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1993/1994 Company Report No.: RJ 1942B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995a	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1938B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995b	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1928B	N	Syngenta

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			GLP Unpublished		
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995c	Field soil dissipation in a trial carried out in France during 1994/1995 Company Report No.: RJ 1943B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1994/95 Company Report No.: RJ 1944B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Eschenbrenner, P.	1995	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1941B GLP Unpublished	N	Syngenta
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Myles, P.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1994/95 Company Report No.: RJ 1945B GLP Unpublished	N	Syngenta
IIA 7.1.2	Rowe, D., Lane, M.C.G.	1994	Adsorption and desorption in soil Company Report No.: RJ 1541B GLP Unpublished	N	Syngenta
IIA 7.1.3.1 IIA 7.1.3.2	Butters, C.A., Mason, R.	1994	Mobility of ICIA5504 and its degradation products in prepared soil columns Company Report No.: RJ 1694B GLP Unpublished	N	Syngenta
IIA 7.1.3.1	Hurt, A.D.	1994	Leaching of formulated material in soil columns Company Report No.: RJ 1777B GLP Unpublished	N	Syngenta
IIA	Hurt, A.D.	1995	Leaching of formulated material in soil columns	N	Syngenta

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7.1.3.1			Company Report No.: RJ 1852B GLP Unpublished		
IIA 7.1.3.1	Hurt, A.D.	1995	Leaching of formulated material in soil columns Company Report No.: RJ 1874B GLP Unpublished	N	Syngenta
IIA 7.2.1.1	Tummon, O.J.	1995	Aqueous hydrolysis at pH 4, 7 and 9 at 50°C Company Report No.: RJ 1971B GLP Unpublished	N	Syngenta
IIA 7.2.1.3.2	Warinton, J.S.	1994	Degradation in water-sediment systems under laboratory conditions Company Report No.: RJ 1679B GLP Unpublished	N	Syngenta
IIA 7.2.2	Kuet, S.F.	1995	Volatilization from soil and leaf surfaces following application as a SC formulation Company Report No.: RJ 1885B GLP Unpublished	N	Syngenta
IIA 8.4/01	Smyth DV, Sankey SA, Kent SJ, Syntanley RD	1994	ICIA5504: Toxicity to the freshwater Diatom <i>Navicula pelliculosa</i> Zeneca Agrochemicals, Jealotts Hill, United Kingdom, BL5054/B  No ICI5504/0965 GLP Unpublished	N	Syngenta
IIA 8.4/02	Smyth DV, Kent SI Sankey SAShearing JM	1994	ICIA5504: Toxicity to the Blue Green Alga <i>Anabaena flos-aquae</i> Zeneca Agrochemicals, Jealotts Hill, United Kingdom, BL5054/B No ICI5504/0967 GLP Unpublished	N	Syngenta

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IIA 8.4 / 03	Bowler AJ, Wallace SJ	2002b	R401553 (Azoxystrobin metabolite): Toxicity to the green alga <i>Selenastrum capricornutum</i> Syngenta Crop Protection AG, Basel, Switzerland Brixham environmental Laboratory, Brixham, United Kingdom, BL7254/B. 2013669 No SYN501657/0004 GLP Unpublished	N	Syngenta
IIA 8.4 / 04	Wallace SJ, Woodyer JM	2002	R402173 (Azoxystrobin metabolite): Toxicity to the green alga <i>Selenastrum capricornutum</i> Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL7340/B, 2013668 No SYN511114/0003 GLP Unpublished	N	Syngenta
IIA 8.6	Smyth DV, Sankey SA, Kent SJ, Sytanley RD	1994a	ICIA5504: Toxicity to the Duckweed <i>Lemna gibba</i> Zeneca Agrochemicals, Jealotts Hill, United Kingdom, BL5000/B No ICI5504/0963 GLP Unpublished	N	Syngenta
IIA 8.9.1/01	Friedrich S.	2002	Acute toxicity of R234886 to the earthworm <i>Eisenia fetida</i> Syngenta Crop Protection AG, Basel, Switzerland BuioChem agrar, Gerichshain, Germany, 2013645, 0110 48 076 No R234886/0001 GLP Unpublished	N	Syngenta

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IIA 8.9.1 / 02	Friedrich S.	2008	SYN501657 - Acute toxicity to the earthworm <i>Eisenia fetida</i> Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 071048052S T003940-07 No SYN501657/0006 GLP Unpublished	N	Syngenta
IIA 8.9.1 / 03	Friedrich S.	2008a	SYN501114 - Acute toxicity to the earthworm <i>Eisenia Foetida</i> Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048051S T003941-07 No SYN501114/0001 GLP Unpublished	N	Syngenta
IIA 8.10/01	Lemnitzer B	2002	Effects of R234886 (metabolite of Azoxystrobin) on the activity of soil microflora. Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 071048052S T003940-07 No R234886/0002 GLP Unpublished	N	Syngenta
IIA 8.10 / 02	Schulz L.	2008	SYN501657 - Effects on the activity of soil microflora Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048046C/N T003946-07 No SYN501657/0007 GLP Unpublished	N	Syngenta
IIA 8.10 / 03	Schulz L.	2008a	SYN501114 - Effects on the activity of soil microflora Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048045C/N T003947-07 No SYN501114/0002 GLP Unpublished	N	Syngenta

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IIA 8.11.1/01	Kent SJ, Sankey SA, Grinnell AJ	1993	ICIA5504: Acute Toxicity to Mysid Shrimp ( <i>Mysidopsis bahia</i> ) Zeneca AgroChemicals, Jealotts Hill, United Kingdom, BL4785/B NO ICI5504/0925 GLP Unpublished	N	Syngenta
IIA 8.11.1/02	Kent SJ, Sankey SA, Grinnell AJ	1994	ICIA5504: Acute Toxicity to Larvae of the Pacific Oyster ( <i>Crassostrea gigas</i> ) Zeneca AgroChemicals, Jealotts Hill, United Kingdom, BL4842/B No ICI5504/0927 GLP Unpublished	N	Syngenta
IIA 8.11.1/03	Boeri RL, Magazu JP, Ward TJ	1997	Chronic Toxicity of Azoxystrobin to the Mysid <i>Mysidopsis bahia</i> Zeneca AgroChemicals, Jealotts Hill, United Kingdom, BL4842/B No ICI5504/0952 GLP Unpublished	N	Syngenta
IIA 8.11.1/04	Smyth DV, Kent SJ, Sankey SA, Johnson PA	1994	ICIA5504: Toxicity to the Marine Alga <i>Skeletonema costatum</i> Zeneca AgroChemicals, Jealotts Hill, United Kingdom, BL5053/B No ICI5504/0966 GLP Unpublished	N	Syngenta
IIA 8.12	Porch JR, Krueger H O	2002	A Toxicity Test to Determine the Effects of Azoxystrobin on Seedling Emergence and Growth of Terrestrial Plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd, Easton MD USA No ICI5504/1376 GLP Unpublished	N	Syngenta
KCP 5.2.2/12	Lister, N.	1999	Azoxystrobin: Validation of RAM 305/01 for the determination of azoxystrobin and R230310 in crops Report no. RJ2770B GLP Unpublished	N	Syngenta

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KCP 5.2.2/13	Sapiets, A.	1996	ICIA5504 and R230310: Validation of a method for the determination of residues in animal tissue, eggs and milk RAM 255/03 Report no. RJ1089B GLP Unpublished	N	Syngenta
KCP 5.2.2/14	Johnson, R.	2000	Residue analytical method for the analysis of azoxystrobin, R230310, R2334886, R401553 and R402173 in soil RAM 269/03 Syngenta File No. ICI5504/0751 Non-GLP Unpublished	N	Syngenta
KCP 5.2.2/15	Robinson, N.	2000	Analytical method for the determination of residues of azoxystrobin in water RAM 358/01 Syngenta File No. ICI5504/0758 Non-GLP Unpublished	N	Syngenta
KCP 5.2.2/16	Hurt, A.	1999	Residue analytical method for the analysis of azoxystrobin, R230310, R2334886, R401553 and R402173 in water RAM 292/02 Syngenta File No. ICI5504/0767 GLP Unpublished	N	Syngenta
KCP 5.3.3/01	Kang, J.	2003	Independent laboratory validation of SPO RAM 305/02 analytical method for the determination of residues of azoxystrobin and R2303010 in leafy crops, brassicae and root/tuber crops Report no. CEMR-1708 v3 GLP Unpublished	N	Syngenta
KCP 5.3.3/02	Croucher, A.	2002	Independent laboratory validation of SPO RAM 305/02 analytical method for the determination of residues in crops (brassicae, maize and root crops) Syngenta File No. ICI5504/1336 GLP Unpublished	N	Syngenta



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KCP 5.3.3/03	xxxxxx	1999	Method validation, solubility and stability of Prothioconazole 200 g/L + Azoxystrobin 150 g/L SC (FF-075) in aquatic test mediums Report no. CTL/R/1401 Non-GLP Unpublished	Y	Syngenta
IIIA 10.1.6	Pestana C.	2005	Avian Acute Oral Toxicity Test for ICI-A-5504 SC Syngenta Crop Protection AG, Basel, Switzerland RL143164-AVO-B No ICI5504/2949 GLP Unpublished	N	Syngenta
IIIA1 10.2.3	Cole JFH, Everett CJ, Gentle W	2000	Azoxystrobin: An outdoor Pond Microcosm Study. Zeneca AgroChemicals, Jealotts Hill, United Kingdom, RJ2857B SYNICI5504/0976 GLP Unpublished	N	Syngenta
IIIA1 10.3	Murfitt R.	2008	Review of effect of lower bodyweight upon wild mammal population dynamics Syngenta – Jealotts Hill International, Bracknell, Berkshire, United Kingdom TMJ5073 SYN N/1184 GLP Unpublished	N	Syngenta
IIIA1 10.5.1/01	Taruza S.	2001	Azoxystrobin: A rate-response laboratory Test to evaluate the effects of a 250 g/l SC formulation on the Predatory Mite. <i>Typhlodromus pyri</i> Syngenta Crop Protection AG, Basel, Switzerland Mabo-Tox Ltd Southampton, UK SYN-01-45 GLP Unpublished	N	Syngenta

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IIIA1 10.5.1/02	Stacey D.	2004	Azoxystrobin: A laboratory bioassay of the effects of fresh residues of a 250 g/L-1 SC formulation (A12705B) on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Syngenta – Jealotts Hill International, Bracknell, Berkshire, United Kingdom RJ3518B GLP Unpublished	N	Syngenta
IIIA1 10.5.2/01	Baxter I	2000	Azoxystrobin 250 g/l SC (YF10537): An Extended Laboratory Test to determine effects on the parasitoid, <i>Aphidius rhopalosiphi</i> Zeneca AgroChemicals, Jealotts Hill, United Kingdom, RJ2857B Agrochemical Evaluation Unit, The University of Southampton, United Kingdom ZEN-99-13/C No ICI5504/0880 GLP Unpublished	N	Syngenta
IIIA1 10.5.2/02	Austin M.	1998	A Laboratory Study to Evaluate the effects of Azoxystrobin 25SC on <i>Orius laevigatus</i> (Hemiptera: Anthocoridae). Zeneca AgroChemicals, Jealotts Hill, United Kingdom, ER-98-31 No ICI5504/0874 GLP Unpublished	N	Syngenta
IIIA1 10.5.2/03	Phillips D	2001	Azoxystrobin: A Tier II Extended Laboratory Test to Evaluate the Effects of an SC Formulation on the Foliar-Dwelling Predator <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Syngenta Crop Protection AG, Basel, Switzerland ZEN-00-12/C No ICI5504/1177 GLP Unpublished	N	Syngenta

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IIIA1 10.5.2/05	Travis A., Gill A.	1998	An Extended Laboratory Study to evaluate the Effects of Azoxystrobin 25SC on the Green Lacewing <i>Chrysoperla carnea</i> . Zeneca AgroChemicals, Jealotts Hill, United Kingdom, ER-97-50 GLP Unpublished	N	Syngenta
IIIA1 10.5.2/06	Kuhner C	1998	Azoxystrobin 250 g/l SC: Acute Toxicity to the Ladybird <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) Zeneca AgroChemicals, Jealotts Hill, United Kingdom, ER-97-50 97178/01-NECS/C No ICI5504/0877 GLP Unpublished	N	Syngenta
IIIA1 10.5.2/07	Baxter I	2001	Azoxystrobin: A Tier II Extended Laboratory Test to Evaluate the Effects of an SC Formulation on the Ground-Dwelling Predator <i>Poecilus cupreus</i> (Coleoptera, carabidae) Syngenta Crop Protection AG, Basel, Switzerland ZEN-00-13/C No ICI5504/1181 GLP Unpublished	N	Syngenta
IIIA1 10.5.2/08	Kling A	2000	Azoxystrobin: An extended Laboratory Test to Determine the Effects of a 250 g/l SC formulation, incorporated into soil on the Ground Beetle <i>Poecilus cupreus</i> (Coleoptera carabidae) Zeneca AgroChemicals, Jealotts Hill, United Kingdom, GAB Biotechnologie GmbH Niefern, Germany, 20001035/01 NEPC/C No ICI5504/0822 GLP Unpublished	N	Syngenta

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IIIA1 10.5.2/09	Austin H.	1998	A Laboratory Study to evaluate the Effects of Azoxystrobin 25SC on <i>Pardosa spp.</i> (Araneae: Lycosidae) Zeneca AgroChemicals, Jealotts Hill, United Kingdom ER-98-22 No ICI5504/0876 GLP Unpublished	N	Syngenta
IIIA1 10.6.3	Moser T, Rombke J	2000	Azoxystrobin: Reproduction Toxicity of a Azoxystrobin 250g/l SC to the earthworm <i>Eisenia Andrei</i> in an artificial soil test. Zeneca AgroChemicals, Jealotts Hill, United Kingdom ECT Oekotoxikologie GmbH, Bad Sodenam Ts., Germany, F10RR  No ICI5504/0903 GLP Unpublished	N	Syngenta
IIIA1 10.6.6	Barth M	2001	Azoxystrobin: Toxicity of a 250 g/l SC formulation (YF10537) on the reproduction of the Collembola <i>Folsomia candida</i> Syngenta Crop Protection AG, Basel, Switzerland. BioChem agrar, Gerichshain, Germany, 01 10 48 049, 2013722 No ICI5504/1319 GLP Unpublished	N	Syngenta
IIIA1 10.6.7	Kollmann S.	2004	A12705A: Litterbag test on decomposition of organic material in the field by soil macro and microorganisms. Syngenta Crop Protection AG, Basel, Switzerland. Springborn Smithers Laboratories (Europe) AG, Hom, Switzerland, 1047.124.797 2033547 No ICI5504/2319 GLP Unpublished	N	Syngenta

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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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS>  If previously submitted in <b>this</b> MS: Data protection started with: <insert authorization number of first authorization>	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS>  If previously submitted in <b>this</b> MS: Data protection started with: <insert authorization number of first authorization>	Owner