Art. 51
Extension of authorisation for minor uses

REGISTRATION REPORT
Part A

Risk Management

Product code: ASKON

Active Substances:

Azoxystrobin 200 g/L and Difenoconazole 125 g/L

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen

Date: 15/02/2013

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of ASKON containing Azoxystrobin and Difenoconazole in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

- Section 3
- Section 4

Assessments for the safe use of ASKON have been made using endpoints agreed in the EU reviews of Azoxystrobin and Difenoconazole.

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

1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.
The application is intended for use in Germany only.

1.1 Application background

Details on applicant and application

Plant protection product	**ASKON**
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	006902-00/06
Applicant	Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen, Siebengebirgsstraße 200, 53229 Bonn, Germany
Authorisation holder	Syngenta Agro GmbH, Am Technologiepark 1-5, 63477 Maintal, Germany
Function	Fungicide
Type of formulation	Suspension concentrate
Expiration of authorisation	2021-12-31

1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

Azoxystrobin (0902)	
Content in PPP	200 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EU) 703/2011
Expiration of approval	31/12/2021
Difenoconazole (0865)	
Content in PPP	125 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/12/2018

1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI. Therefore the evaluation of the actual application is limited to the points not covered by the existing registration.

1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/ object	Harmful organism/ purpose	decision
001	cucumber, pumpkin, giant pumpkin, musky gourd, patisson, zucchini	Fungal leaf spot diseases	New MRL necessary before authorisation (0232000 Cucurbits - edible peel: 0.3 mg/kg)

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.
In Germany cultivated area of cucumber and cucurbits (edible peel) is about 266 ha (cucumber: 216 ha), therefrom worth to treat are 106 ha. Calculation shows that authorisation holder will not profit from authorisation in that use.
Upon this calculation and the examination of available alternative measures for the applied use(s) it can be stated that the applied use(s) is minor in nature and the authorisation is in the public interest.

1.4 Data protection claims

The authorisation holder is owner of the new studies submitted and claims data protection

1.5 Letters of Access

The authorisation holder is owner of the new studies submitted.
Authorisation holder agrees to the actual application to extend the authorisation.

2 Details of the authorisation

2.1 Product identity

Product name	ASKON
Authorisation number	006902-00
Composition	Azoxystrobin 200 g/L; Difenoconazole 125 g/L
Type of formulation	Suspension concentrate (SC)
Function	Fungicide
Authorisation holder	Syngenta Agro GmbH, Am Technologiepark 1-5, 63477 Maintal, Germany

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008

N	Dangerous for the environment
Xn	Harmful
RK051	R 51: Toxic to aquatic organisms
RX020	R 20: Harmful by inhalation
RX043	R 43: May cause sensitisation by skin contact
SK012	S 36/37: Wear suitable protective clothing and gloves.
SX002	S 12: Do not keep the container sealed.
SX013	S 13: Keep away from food, drink and animal feeding stuffs
SX024	S 24: Avoid contact with skin
SX035	S 35: This material and its container must be disposed of in a safe way.
SX046	S 46: If swallowed, seek medical advice immediately and show this container or label
SX057	S 57: Use appropriate container to avoid environmental contamination.
SP001	To avoid risk to man and the environment, comply with the instructions for use.

2.2.2 R and S phrases under Regulation (EC) No 547/2011

None

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

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

Operator protection

SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.

SB110 The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.

SE110 Wear tight fitting eye protection when handling the undiluted product.

SF245-01 Treated areas/crops may not be entered until the spray coating has dried.

SS110 Wear standard protective gloves (plant protection) when handling the undiluted product.

SS2101 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

SS610 Wear a rubber apron when handling the undiluted product.

Ecosystem protection

NW262 The product is toxic for algae.

NW264 The product is toxic for fish and aquatic invertebrates.

NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Integrated Pest Management (IPM)

NN2001 The product is classified as slightly harmful for populations of relevant beneficial insects

NN3002 The product is classified as harmful for populations of relevant predatory mites and spiders

Active substance

VH619 The content of toluene and Z-isomer in the technical active substance Azoxystrobin may not exceed 2 g/kg respectively 25 g/kg.

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

Honeybee

NB6641 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 authorisation is applied. (B4)

Integrated Pest Management (IPM)

2.2.3.2 Specific restrictions linked to the intended uses

Some of the authorized uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Operator protection

SS2202 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.

2.3 Product uses

PPP (product name/code) **ASKON (006902-00/06)**
active substance 1 **Azoxystrobin**
active substance 2 **Difenoconazole**
Applicant:
Zone(s): **central EU**

Formulation type: **SC**
Conc. of as 1: **200 g/L**
Conc. of as 2: **125 g/L**
professional use ☒
non professional use ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
01-001	DE	cucumber (CUMSA), pumpkin (CUUPE) giant pumpkin (CUUMX), musky gourd (CUUMO), patisson (CUUPM), zucchini (CUUPG) (vegetable, with edible peel)	G	fungal leaf spot diseases	spraying	from BBCH 19, at the beginning of infestation and/or when first symptoms become visible	a) 2 (10 to 14 days) b) 2	a) 0,75 – 1,0 L/ha b) 1,50 – 2,0 L/ha up to the height of plants, till 50 cm and till1 125 cm, respectively	as1: a) 0,094 – 0,125 kg/ha b) 0,18 – 0,25 kg/ha as2: a) 0,15 - 0,2 kg/ha b) 0,3 – 0,4 kg/ha	600 - 900	3	Restrictions (see 2.2.3.2) SS2202

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Analytical methods for commodities of high water content such as cucurbits are available and acceptable for enforcing Azoxystrobin.
Analytical methods for commodities of high water content such as cucurbits are available and acceptable for enforcing Difenoconazole.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected. A special risk assessment for the intended use of ASKON in greenhouse is reported in Part B, Section 3 of this dRR. On this basis a special restriction for applicants (SS2202 - " Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.") is necessary which is not included in the existing registration in Germany

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substances Azoxystrobin and Difenoconazole has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended use in cucurbits.

3.1.4.1 Residues

The available residue information is sufficient to perform an adequate assessment. Residues that are expected from the intended use of the plant protection product will not exceed the MRL set in Regulation (EC) No 396/2005 for Azoxystrobin.
For Difenoconazole a new MRL is necessary (0.3 mg/kg Cucurbits - edible peel) which is covered by a MRL proposal by Germany (EFSA Question Number EFSA-Q- 2011-051).

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumptions:
Azoxystrobin (0.2 mg/kg bw/d) – 53 % (DE children)
Difenoconazole (0.01 mg/kg bw/d) – 183 % (WHO cluster diet B)
Refinement: IEDI (EFSA PRIMo) - 91.5 % ((WHO cluster diet B)

Long-term dietary intake of residues of Azoxystrobin and Difenoconazole is unlikely to present a public health concern for European consumers.
No acute risk is expected from the consumption of radishes treated according to the intended use.

3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006902-00/00 according the uniform principles of directive 91/414/EEC.

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006902-00/00 according the uniform principles of directive 91/414/EEC.

The PPP ASKON and the active substances Azoxystrobin and Difenoconazole are toxic to the aquatic environment (azoxystrobine: *Mysidopsis bahia*: EC_{50}: 55 µg a.i./L; *O. mykiss*: LC_{50} 470 µg a.i./L; difenoconazole: *P. promelas*: NOEC: 3,6 µg a.i./L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW262, NW264 and NW468 are assigned, see also 2.2.3.1

The honeybee risk assessment for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

-The classification of effects on beneficial arthropods for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009.

-The categories and labelling for mode of action for the main application covers the use(s) in accordance with Article 51 of regulation (EC) No 1107/2009.

According to Article 51 of the regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products have not to be met.

3.2 Conclusions

PPP ASKON is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.
The intended use is minor in nature and the extension of authorisation is in public interest. Effects on bees and other beneficials were evaluated in the frame of the already authorised uses. No additional effects are anticipated because of the extension of uses(s).
The intended use in cucurbits edible peel will not result in residues above the MRLs set in or proposed for (Difenoconazole) Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues of Azoxystrobin and Difenoconazole is not expected.
Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

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

None

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

Appendix 3 – Letter of Access

No letter of access necessary. The authorisation holder is owner of the new studies submitted. The authorisation holder agrees to the actual application to extend the authorisation.

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Verbraucherschutz und
Lebensmittelsicherheit

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Mit Zustellungsurkunde

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.006902-00/06.53973
(bitte bei Antwort angeben)

DATUM 12. Februar 2013

GV1 006902-00/06

ASKON

Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG) Nr. 1107/2009

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit den Wirkstoffen:	200 g/l	Azoxystrobin
	125 g/l	Difenoconazol
Zulassungsnummer:	006902-00	
Versuchsbezeichnung:	SYD-21680-F-0-SC	
Antrag vom:	5. Juli 2011	

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006902-00/06-001	Pilzliche Blattfle-ckenerreger	Gurke, Garten-Kürbis, Riesenkürbis, Moschus-Kürbis, Patisson, Zuc-chini	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBI. I S. 148, 1281) festgesetzt:

- keine -

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Hans-Gerd Nolting
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 006902-00/06-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Pilzliche Blattfleckenerreger
Pflanzen/-erzeugnisse/Objekte:	Gurke, Garten-Kürbis, Riesenkürbis, Moschus-Kürbis, Patisson, Zucchini
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Gemüsebau
Anwendungsbereich:	Gewächshaus
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	Mit genießbarer Schale
Stadium der Kultur:	ab 19
- Erläuterungen:	
Anwendungszeitpunkt:	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Abstand:	10 bis 14 Tage
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
- Pflanzengröße bis 50 cm	0,75 l/ha in 600 l Wasser/ha
- Pflanzengröße 50 bis 125 cm	1 l/ha in 900 l Wasser/ha

- Erläuterungen:	Die Höhenstaffelung gilt nur für aufgeleitete Kulturen. Für nicht aufgeleitete Kulturen kann die in der Anwendung höchst angegebene Aufwandmenge zur Erzielung der hinreichenden Wirksamkeit erforderlich werden

Sonstige Ergänzungen und Hinweise: - keine -

2.2 Sonstige Kennzeichnungsauflagen

(SS2202)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

2.3 Wartezeiten

3 Tage	Gewächshaus: Gurke, Garten-Kürbis, Zucchini, Moschus-Kürbis, Patisson, Riesenkürbis

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology

Detailed summary of the risk assessment

Product code: **Askon**

Active Substances: **Azoxystrobin, 200 g/L and Difenoconazole, 125 g/L**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Pflanzenschutzdienst der Landwirtschaftskammer NRW

Date: 11/01/2012

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IIIA 7 Mammalian Toxicology

IIIA 7.1 Toxicological Evaluation of Active Substances

IIIA 7.1.1 Azoxystrobin

The following toxicological reference values in accordance with the EFSA Conclusion for the active substance azoxystrobin (EFSA Journal 2010; 8(4):1542, ASB2012-750) were applied:

Table 7.1.1-1 Agreed EU endpoints

	Value
ADI	0.2 mg/kg bw
AOEL systemic	0.2 mg/kg bw/d *
ARfD (acute reference dose)	Not allocated

IIIA 7.1.2 Difenoconazole

The following toxicological reference values in accordance with the EFSA Conclusion for the active substance difenoconazole (EFSA Journal 2011;9(1) :1967, ASB2012-749) were applied:

Table 7.1.2-1 Agreed EU endpoints

	Value
ADI	0.01 mg/kg bw
AOEL systemic	0.16 mg/kg bw/d *
ARfD (acute reference dose)	0.16 mg/kg bw/d

IIIA 7.2 Toxicological Evaluation of Pesticide

Table 7.2-1 General information on Askon

Product name and code	Askon (SYD-21680-F-0-SC)
Formulation type	SC
Active substances (incl. content)	Azoxystrobin; 200 g/L and difenoconazole; 125 g/L
Category	Fungicide
Statement as to whether the product was already evaluated as the 'representative formulation' during the Annex I inclusion or has been previously evaluated in an other MS according to Uniform Principles	No Askon is registered in DE until 31.12.2021 (authorisation no. 006902-00, cf. https://portal.bvl.bund.de/psm/jsp/index.jsp)

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

An overview on the classification and labelling of the preparation is given in paragraph 7.5.

IIIA 7.3 Dermal absorption

IIIA 7.3.1 Azoxystrobin

The evaluation for azoxystrobin is based on the dermal absorption of 0.3% for the concentrate and 0.5% for the dilution which was derived during the EU evaluation process (EFSA Journal 2010; 8(4):1542, ASB2012-750) for a 250 g/L SC formulation. For more detailed information see also Table 7.4-1.

IIIA 7.3.2 Difenoconazole

The evaluation for difenoconazole is based on a default value for the dermal absorption of 100% for the concentrate and the dilution, since no appropriate data for deriving a lower dermal absorption were available (see also Table 7.4-1).

IIIA 7.4 Safety Assessment of Pesticide Application

Table 7.4-1 Product information and toxicological reference values used for safety assessment of pesticide application

Product name and code	Askon (SYD-21680-F-0-SC, A13703 G)
Formulation type	SC
Active substances (incl. content)	Azoxystrobin; 200 g/L and difenoconazole; 125 g/L
Category	Fungicide
Container sizes, short description	1 L HDPE bottle, 5 L HDPE bottle 20 L HDPE can
Statement as to whether the product was already evaluated as the 'representative formulation' during the Annex I inclusion	The safety of the application of Askon was not evaluated as part of the EU review of azoxystrobin or difenoconazole.
AOEL systemic	Azoxystrobin: 0.2 mg/kg bw/d Difenoconazole: 0.16 mg/kg bw/d
Oral absorption	Azoxystrobin and difenoconazole: 100 %
Inhalative absorption	Azoxystrobin and difenoconazole: 100 %
Dermal absorption	Azoxystrobin: Concentrate: 0.3 %, Dilution: 0.5 % (based on an SC-formulation containing 250 g/L azoxystrobin, Ortiva) Difenoconazole: Concentrate: 100 %, Dilution: 100 % (default- value) *

* Data determined using an EC-formulation cannot be applied here since it contains organic solvent (> 60 % w/w) which is not present in Askon.

IIIA 7.4.1 Selection of critical use and justification

The critical GAP used for the safety assessment of the pesticide application within the scope of this application is presented in Table 7.4.1-1.

Table 7.4.1-1 Critical use according to Art. 51 VO 1107/2009 (worst case) for safety assessment of pesticide application

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F, G or I (b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications) a) per use b) per crop/ season (h)**	**L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **max**		
1	DE	Cucumber, Pumpkin, Giant pumpkin, Musky gourd, Pumpkin, bush, Zucchini	G	Fungal leaf spot diseases	spray application, hand-held spray equipment	BBCH 19 At beginning of infestation and/or when first symptoms become visible	b) 2 (10 days)	a) 1 b) 2	a) 0.2 azoxystrobin, 0.125 difenoconazole b) 0.4 azoxystrobin, 0.25 difenoconazole	900	3	

*Critical GAP for Operator Exposure and Worker Exposure (since this GV1 application comprises greenhouse applications exclusively, bystander and resident exposure is considered negligible)

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

IIIA 7.4.2 Evaluation

IIIA 7.4.2.1 Operator Exposure and Risk Assessment

IIIA 7.4.2.1.1 Estimation of Operator Exposure and Risk Assessment

Neither the German Model nor the UK POEM provides relevant data to assess the exposure of operators during greenhouse applications.

IIIA 7.4.2.1.2 Measurement of Operator Exposure and Risk Assessment

Operator exposure was estimated using a GLP study performed for the generic assessment of products applied in greenhouses. Detailed considerations and calculations as well as a summary of the greenhouse study are presented below.

Reference: KIIIA1 7.3.1 /01

Report: Mich, G.; 1996; Operator exposure in greenhouses during practical use of plant protection products. Report No. EF 94-02-03, Doc. No. M-024096-01, June 6, 1996; ECON GmbH Ingelheim, conducted in Germany, Dates of work July, 1994 – June, 1996, TOX2000-2081

Guidelines: Following the OECD guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application, Series on Testing and Assessment No. 9, 1997

GLP: Yes (certified laboratory)

Acceptability: The study is considered to be acceptable.

Material and methods

To elucidate the potential of operator's exposure by application of plant protection products in greenhouses an exposure study was performed. Dermal and inhalation exposure were measured using the patch technique (passive dosimetry technique), by analysis of whole body underwear, glove and hand rinsing and absorbent air filters during mixing/loading. The following plant protection products were applied on ornamentals at 2 sites in Germany: the wettable powder fungicide Euparen® WP 50 (a.s. dichlofluanid), the insecticide Rody® (a.s. fenpropathrin) and the fungicide Saprol® Neu (a.s. triforine) (both emulsifiable concentrates). Twelve experienced operators were monitored. The products were applied with conventionally used knapsack sprayers at recommended rates. All analytical methods were validated for the various matrixes in a wide range of concentrations.

Samples were extracted for analysis followed by gas chromatographic determination. The results of the measurements are reported as determined (i.e. µg active substance per sample) and as specific exposure values, i.e. as mg of exposure per kg of active substance handled. The latter facilitates the use of the data for generic purposes. Samples were analysed for each of the 3 active substances.

The following scenarios were investigated:
a) mixing and loading Euparen WP 50 for hydraulic knapsack sprayers,
b) application using knapsack sprayers to low cultures on tables,

c) application using knapsack sprayers to high cultures,
d) airborne concentrations after application.

The test substances Euparen® WP 50, Rody® and Saprol® Neu were applied in 4 greenhouses in the low crop scenario. 4 trials were performed in each house. The treated plants (hibiscus, cyclamen, anturium and scutelarium) had a height of 10-25 cm (+ 1.15 m table height). In the high crop scenario the test substances Euparen® WP 50, Rody® and Saprol® Neu were applied in 3 greenhouses. Again 4 trials were performed in each house. In this scenario roses were treated. They covered a height from 1.2-1.75 metres.

Results and discussion

All data were evaluated according to Lundehn et al., 1992 (TOX2003-430, German Model). For the calculation of exposure recorded values below limit of quantification were calculated as half the limit of quantification. Results of geometric mean exposure during application for the three scenarios are given below.

Table 7.4.2.1.1-1 Specific exposure during knapsack application in greenhouse low crops

Route of exposure during application in low crops	Exposure [mg/kg a.s. handled]	
	Actual	**Potential**
Dermal (head)	0.43926	0.43926
Dermal (hands)	0.00894	0.7357
Dermal (body)	0.22265	6.31994
Inhalation	0.39849	0.39849

Table 7.4.2.1.1-2 Specific exposure during knapsack application in greenhouse high crops

Route of exposure during application in high crops	Exposure (mg/kg a.s. handled)	
	Actual	**Potential**
Dermal (head)	1.56194	1.56194
Dermal (hands)	0.00746	13.1884
Dermal (body)	0.22789	82.47509
Inhalation	0.10841	0.10841

Conclusion

The study provides appropriate data for hand held scenarios in greenhouses. Application data may be used for generic purposes. Mixing/loading data are available for one wettable powder preparation (WP) only. However, it should be considered that the process of mixing/loading for both indoor and outdoor applications is comparable. Therefore, generic exposure estimates for mixing/loading can be taken from other models.

Estimation of operator exposure towards Askon in greenhouses

Generic exposure estimates for mixing/loading were taken from the EU wide accepted German Model. These data represent geometric means. Therefore, the application data taken from the greenhouse study are also calculated as geometric means.

The risk assessment was performed based upon the following assumptions:

Spray equipment: knapsack sprayer
Work rate/day: 1 ha
Dose rate: 0.2 kg a.s./ha of azoxystrobin and 0.125 kg a.s./ha of difenoconazole (1 L/ha product) for low crops (cucumbers or punpkins not tied up) and high crops (plants tied up)

Using the input parameters and the scheme of the calculation model, the estimated operator exposure can be calculated for mixing/loading and application (cf. appendix 2.1.1 und 2.1.2). The results for the estimated dermal and inhalation exposure for azoxystrobin are summarised in Table 7.4.2.1.1-3 and those for difenoconazole are summerised in Table 7.4.2.1.1-4.

Table 7.4.2.1.1-3 Estimated operator exposure towards azoxystrobin in greenhouses

Exposure route and type of work	**Estimated operator exposure [mg/person/d]**			
	German Model / Exposure study (HHS * – low level target)		**German Model / Exposure study (HHS * – high level target)**	
Dermal exposure	Without PPE	With PPE **	Without PPE	With PPE **
Mixing/loading	41.00	0.410	41.00	0.410
Application	1.50	0.298	19.44	3.775
Total, dermal	42.50	0.708	60.44	4.185
[mg/kg bw/d]	0.6071	0.010	0.8634	0.0598
Inhalation exposure				
Mixing/loading	0.010	0.010	0.010	0.010
Application	0.08	0.08	0.022	0.022
Total, inhalation	0.09	0.09	0.032	0.032
[mg/kg bw/d]	0.0013	0.0013	0.0004	0.0004
Total exposure				
Dermal + Inhalation	42.59	0.7979	60.47	4.217
Systemic exposure (absorbed dose)	0.2202	0.0924	0.2519	0.0518
[mg/kg bw/d]	0.0031	0.0013	0.0036	0.0007

* hand-held spray application
** PPE: gloves during mixing/loading and coverall during application

Table 7.4.2.1.1-4 Estimated operator exposure towards difenoconazole in greenhouses

Exposure route and type of work	Estimated operator exposure [mg/person/d]			
	German Model / Exposure study (HHS * – low level target)		German Model / Exposure study (HHS * – high level target)	
Dermal exposure	Without PPE	With PPE **	Without PPE	With PPE **
Mixing/loading	25.625	0.256	25.625	0.256
Application	0.937	0.186	12.153	2.359
Total, dermal	26.562	0.442	37.778	2.615
[mg/kg bw/d]	0.379	0.006	0.539	0.037
Inhalation exposure				
Mixing/loading	0.0062	0.0062	0.0062	0.0062
Application	0.0498	0.0498	0.0135	0.0135
Total, inhalation	0.0560	0.0560	0.0198	0.0198
[mg/kg bw/d]	0.0008	0.0008	0.0003	0.0003
Total exposure:				
Dermal + Inhalation	26.618	0.498	37.798	2.635
Systemic exposure (absorbed dose)	26.618	0.498	37.798	2.635
[mg/kg bw/d]	0.380	0.007	0.540	0.037

* hand-held spray application
** PPE: gloves during mixing/loading and coverall during application

Summary and conclusion

The estimated systemic exposure is compared with the proposed systemic AOEL-S values. Results are summarised in 7.4.2.1.1-5 and in Table 7.4.2.1.1-6.

Table 7.4.2.1.1-5 Estimated operator exposure towards azoxystrobin and comparison with the proposed AOEL

Exposure route and type of work	German Model / exposure study (HHS *– low level target)		German Model / exposure study (HHS *– high level target)	
	Without PPE	**With PPE ** **	**Without PPE**	**With PPE ** **
Systemic exposure (absorbed dose) [mg/person/d]	0.2202	0.0924	0.2519	0.0518
[mg/kg bw/d]	0.0031	0.0013	0.0036	0.0007
Amount of systemic AOEL [%]	**1.6**	**0.7**	**1.8**	**0.4**

* hand-held spray application
** PPE: gloves during mixing/loading and coverall during application

For azoxystrobin the corresponding systemic exposure estimate will account for up to 1.8 % of the systemic AOEL if the product is applied with knapsack sprayers. Operator exposure towards

azoxystrobin during mixing, loading and spraying will not exceed the AOEL, even if no protective clothing is used.

Table 7.4.2.1.1-6 Estimated operator exposure towards difenoconazole and comparison with the proposed AOEL

Exposure route and type of work	German Model / exposure study (HHS *– low level target)		German Model / exposure study (HHS *– high level target)	
	Without PPE	**With PPE ****	**Without PPE**	**With PPE ****
Systemic exposure (absorbed dose) [mg/person/d]	26.618	0.498	37.798	2.635
[mg/kg bw/d]	0.380	0.007	0.540	0.037
Amount of systemic AOEL [%]	**237**	**4.4**	**337**	**23.5**

* hand-held spray application
** PPE: gloves during mixing/loading and coverall during application

For difenoconazole the corresponding systemic exposure estimates will account for up to 337 % of the systemic AOEL if the product is applied with knapsack sprayers without PPE. Operator exposure towards difenoconazole will not exceed the AOEL, if respective protective equipment, i.e. gloves during mixing/loading and coverall during application, is used.

Taken together, exposure estimations within the scope of this application predict no unacceptable risk for the intended use of Askon both in low crops as well as in high crops provided that PPE as mentioned above is used by the operator. Intended uses in the greenhouse will be acceptable under these conditions based on the German Model and the exposure study.

IIIA 7.4.2.2 Worker Exposure and Risk Assessment

IIIA 7.4.2.2.1 Estimation of Worker Exposure and Risk Assessment

Table 7.4.2.2.1-1 Exposure models for intended uses

Critical use	Various vegetables in the greenhouse (max. 2 x 1 L Askon/ha)
Model	e.g. German re-entry model, Krebs et al. (2000) (available on http://www.bfr.bund.de/cm/343/schutz_von_personen_bei_nachfolgearbeiten_v1.xls) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienstes, 52(1), p. 5-9]

Table 7.4.2.2.1-2 Estimated worker exposure towards azoxystrobin

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate: 2 x 0.2 kg a.s./ha			
8 hours/day [1], TC: 2500 cm^2/person/h [2] Body weight: 60 kg	no PPE [3]	0.00057	0.3

[1] e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc.
[2] e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or
[3] no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

Table 7.4.2.2.1-3 Estimated worker exposure towards difenoconazole

Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Number of applications and application rate: 2 x 0.125 kg a.s./ha			
8 hours/day [1], TC: 2500 cm^2/person/h [2] Body weight: 60 kg	no PPE [3]	0.07143	44.6

[1] e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc.
[2] e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or
[3] no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

For the detailed calculations it is referred to Appendix 2.2.

IIIA 7.4.2.2.2 Measurement of Worker Exposure and Risk Assessment

Since the exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

IIIA 7.4.2.3 Bystander and Resident Exposure and Risk Assessment

Since within the scope of this application intended uses are restricted to greenhouse applications bystander and resident exposure is considered negligible.

IIIA 7.4.3 Conclusion of Exposure Estimation and Risk Assessment

The risk assessment has shown that the estimated exposure towards azoxystrobin and difenoconazole in Askon will not exceed the systemic AOEL for operators and workers, if specific PPE is worn by operators. Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

IIIA 7.5 Justified Proposals for Classification and Labelling and Safety Instructions

Justified Proposals for Classification and Labelling

In accordance with Directives 67/548/EEC and 1999/45/EC the following classification and labelling with regard to toxicological data has already been realised within the main application/authorisation for the preparation:

Table 7.5-1 Classification and labelling according to Directives 67/548/EEC and 1999/45/EC

Hazard symbol:	Xn
Indication of danger:	Harmful
Risk phrases:	20-43
Safety phrases:	2-13-24-36-37-46
Labelling texts and restrictions:	To avoid risks to man and the environment, comply with the instructions for use.

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification for toxicological hazards of the preparation according to GHS would be proposed:

Table 7.5-2 Classification and labelling according to Regulation (EC) No 1272/2008

Hazard classes, categories:	Acute tox. 4, sens. skin 1
Signal word:	Warning
Hazard statements:	H317-332
Labelling texts and restrictions:	To avoid risks to man and the environment, comply with the instructions for use.

Safety Instructions

Table 7.5-3 Safety phrases for use instructions

Safety instructions (codes according to BVL [1])		**Justification [2]**
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.	1
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.	1
SE110	Wear tight fitting eye protection when handling the undiluted product.	3
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.	2
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.	3,4
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.	3
SS2202	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying the diluted product.	4
SS610	Wear a rubber apron when handling the undiluted product.	3

[1] http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/eAntrag-Codelisten-EN.pdf?__blob=publicationFile&v=6
[2] Justification:
1 Mandatory for plant protection products
2 With regard to preventive health protection and good agricultural practice
3 Based on BBA-Guideline Teil I, 3-3 (1993)[1] with regard to the dangerous substance directive
4 Based on the exposure estimation according to the German model in combination with the greenhouse application data by Mich (1996) for the operator and the uniform principles for the protection of workers

[1] Biologische Bundesanstalt für Land- und Forstwirtschaft, Richtlinen für die Prüfung von Pflanzenschutzmitteln – Kennzeichnung von Pflanzenschutzmitteln (Gesundheitsschutz) (Federal Biological Research Centre for Agriculture and Forestry, Guidelines for Evaluation of Plant Protection Products – Labelling of Plant Protection Products (Human Health))

Appendix 1: List of data submitted in support of the evaluation

Table A.1-1 List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR
KIIIA1 7.3.1 /01	Mich, G.	1996	Operator exposure in greenhouses during practical use of plant protection products. Report No. EF 94-02-03, Doc. No. M-024096-01, June 6, 1996; ECON GmbH Ingelheim, conducted in Germany, Dates of work July, 1994 – June, 1996, TOX2000-2081			used

Appendix 2: Exposure calculations

A 2.1.1 Operator exposure calculations for azoxystrobin

Table A 2.1.1-1 Input parameters considered for the estimation of operator exposure (low target)

Formulation type:		Liquid	**Application technique:**	Spraying	
Application rate (AR):	0.2	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	0.3	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.7357	mg/person/kg a.s.
	0.5	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	6.31994	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.43926	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.2	mg/kg bw/d	**Inhalation appl. (I_A):**	0.39849	mg/person/kg a.s.

Table A 2.1.1-2 Estimation of operator exposure towards azoxystrobin using the German model and the data by Mich, G. (1996) for low targets

Operator exposure towards azoxystrobin					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in various vegetables, greenhouse, low crop					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(205 x 0.2 x 1 x 0.3%) / 70			(205 x 0.2 x 1 x 0.01 x 0.3%) / 70		
External dermal exposure	41	mg/person	External dermal exposure	0.41	mg/person
External dermal exposure	0.585714	mg/kg bw/d	External dermal exposure	0.005857	mg/kg bw/d
Systemic dermal exposure	**0.001757**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000018**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.7357 x 0.2 x 1 x 0.5%) / 70			(0.7357 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	0.14714	mg/person	External dermal exposure	0.14714	mg/person
External dermal exposure	0.002102	mg/kg bw/d	External dermal exposure	0.002102	mg/kg bw/d
Systemic dermal exposure	**0.000011**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000011**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(6.31994 x 0.2 x 1 x 0.5%) / 70			(6.31994 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	1.263988	mg/person	External dermal exposure	1.263988	mg/person
External dermal exposure	0.018057	mg/kg bw/d	External dermal exposure	0.018057	mg/kg bw/d
Systemic dermal exposure	**0.00009**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00009**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.43926 x 0.2 x 1 x 0.5%) / 70			(0.43926 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	0.087852	mg/person	External dermal exposure	0.087852	mg/person
External dermal exposure	0.001255	mg/kg bw/d	External dermal exposure	0.001255	mg/kg bw/d
Systemic dermal exposure	**0.000006**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000006**	**mg/kg bw/d**

Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	42.49898	mg/person	Total external dermal exposure	1.90898	mg/person
Total external dermal exposure	0.607128	mg/kg bw/d	Total external dermal exposure	0.027271	mg/kg bw/d
Total systemic dermal exposure	**0.001864**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.000125**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in Vegetables, greenhouse, low crop					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.05 x 0.2 x 1 x 100%) / 70			(0.05 x 0.2 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.01	mg/person	External inhalation exposure	0.01	mg/person
External inhalation exposure	0.000143	mg/kg bw/d	External inhalation exposure	0.000143	mg/kg bw/d
Systemic inhalation exposure	**0.000143**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000143**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.39849 x 0.2 x 1 x 100%) / 70			(0.39849 x 0.2 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.079698	mg/person	External inhalation exposure	0.079698	mg/person
External inhalation exposure	0.001139	mg/kg bw/d	External inhalation exposure	0.001139	mg/kg bw/d
Systemic inhalation exposure	**0.001139**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.001139**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.089698	mg/person	Total external inhalation exposure	0.089698	mg/person
Total external inhalation exposure	0.001281	mg/kg bw/d	Total external inhalation exposure	0.001281	mg/kg bw/d
Total systemic inhalation exposure	**0.001281**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.001281**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.220193	mg/person	Total systemic exposure	0.098423	mg/person
Total systemic exposure	0.003146	**mg/kg bw/d**	**Total systemic exposure**	0.001406	**mg/kg bw/d**
% of AOEL	**1.6**	**%**	**% of AOEL**	**0.7**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 2.1.1-3 Input parameters considered for the estimation of operator exposure (high target)

Formulation type:		Liquid	**Application technique:**	Spraying	
Application rate (AR):	0.2	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	0.3	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	13.1884	mg/person/kg a.s.
	0.5	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	82.47509	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	1.56194	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.2	mg/kg bw/d	**Inhalation appl. (I_A):**	0.10841	mg/person/kg a.s.

Table A 2.1.1-4 Estimation of operator exposure towards azoxystrobin using the German model and the data by Mich, G. (1996) for high targets

Operator exposure towards azoxystrobin					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in various vegetables, greenhouse, high crop					
Dermal exposure during mixing/loading			-		
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(205 x 0.2 x 1 x 0.3%) / 70			(205 x 0.2 x 1 x 0.01 x 0.3%) / 70		
External dermal exposure	41	mg/person	External dermal exposure	0.41	mg/person
External dermal exposure	0.585714	mg/kg bw/d	External dermal exposure	0.005857	mg/kg bw/d
Systemic dermal exposure	**0.001757**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000018**	**mg/kg bw/d**
Dermal exposure during application			-		
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(13.1884 x 0.2 x 1 x 0.5%) / 70			(13.1884 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	2.63768	mg/person	External dermal exposure	2.63768	mg/person
External dermal exposure	0.037681	mg/kg bw/d	External dermal exposure	0.037681	mg/kg bw/d
Systemic dermal exposure	**0.000188**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000188**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(82.47509 x 0.2 x 1 x 0.5%) / 70			(82.47509 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	16.495018	mg/person	External dermal exposure	16.495018	mg/person
External dermal exposure	0.235643	mg/kg bw/d	External dermal exposure	0.235643	mg/kg bw/d
Systemic dermal exposure	**0.001178**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001178**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(1.56194 x 0.2 x 1 x 0.5%) / 70			(1.56194 x 0.2 x 1 x 1 x 0.5%) / 70		
External dermal exposure	0.312388	mg/person	External dermal exposure	0.312388	mg/person
External dermal exposure	0.004463	mg/kg bw/d	External dermal exposure	0.004463	mg/kg bw/d
Systemic dermal exposure	**0.000022**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000022**	**mg/kg bw/d**

Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	60.445086	mg/person	Total external dermal exposure	19.855086	mg/person
Total external dermal exposure	0.863501	mg/kg bw/d	Total external dermal exposure	0.283644	mg/kg bw/d
Total systemic dermal exposure	**0.003146**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.001407**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in various vegetables					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.05 x 0.2 x 1 x 100%) / 70			(0.05 x 0.2 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.01	mg/person	External inhalation exposure	0.01	mg/person
External inhalation exposure	0.000143	mg/kg bw/d	External inhalation exposure	0.000143	mg/kg bw/d
Systemic inhalation exposure	**0.000143**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000143**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.10841 x 0.2 x 1 x 100%) / 70			(0.10841 x 0.2 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.021682	mg/person	External inhalation exposure	0.021682	mg/person
External inhalation exposure	0.00031	mg/kg bw/d	External inhalation exposure	0.00031	mg/kg bw/d
Systemic inhalation exposure	**0.00031**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.00031**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.031682	mg/person	Total external inhalation exposure	0.031682	mg/person
Total external inhalation exposure	0.000453	mg/kg bw/d	Total external inhalation exposure	0.000453	mg/kg bw/d
Total systemic inhalation exposure	**0.000453**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000453**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.251907	mg/person	Total systemic exposure	0.130137	mg/person
Total systemic exposure	0.003599	**mg/kg bw/d**	**Total systemic exposure**	0.001859	**mg/kg bw/d**
% of AOEL	**1.8**	**%**	**% of AOEL**	**0.9**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

A 2.1.2 Operator exposure calculations for difenoconazole

Table A 2.1.2-1 Input parameters considered for the estimation of operator exposure (low target)

Formulation type:	Liquid		**Application technique:**	Spraying	
Application rate (AR):	0.125	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	100	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.7357	mg/person/kg a.s.
	100	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	6.31994	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.43926	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.16	mg/kg bw/d	**Inhalation appl. (I_A):**	0.39849	mg/person/kg a.s.

Table A 2.1.2-2 Estimation of operator exposure towards difenoconazole using the German model and the data by Mich, G. (1996) for low targets

Operator exposure towards					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in					
Dermal exposure during mixing/loading			-		
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(205 x 0.125 x 1 x 100%) / 70			(205 x 0.125 x 1 x 0.01 x 100%) / 70		
External dermal exposure	25.625	mg/person	External dermal exposure	0.25625	mg/person
External dermal exposure	0.366071	mg/kg bw/d	External dermal exposure	0.003661	mg/kg bw/d
Systemic dermal exposure	**0.366071**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003661**	**mg/kg bw/d**
Dermal exposure during application			-		
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.7357 x 0.125 x 1 x 100%) / 70			(0.7357 x 0.125 x 1 x 1 x 100%) / 70		
External dermal exposure	0.091963	mg/person	External dermal exposure	0.091963	mg/person
External dermal exposure	0.001314	mg/kg bw/d	External dermal exposure	0.001314	mg/kg bw/d
Systemic dermal exposure	**0.001314**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001314**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(6.31994 x 0.125 x 1 x 100%) / 70			(6.31994 x 0.125 x 1 x 1 x 100%) / 70		
External dermal exposure	0.789993	mg/person	External dermal exposure	0.789993	mg/person
External dermal exposure	0.011286	mg/kg bw/d	External dermal exposure	0.011286	mg/kg bw/d
Systemic dermal exposure	**0.011286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.011286**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.43926 x 0.125 x 1 x 100%) / 70			(0.43926 x 0.125 x 1 x 1 x 100%) / 70		
External dermal exposure	0.054908	mg/person	External dermal exposure	0.054908	mg/person
External dermal exposure	0.000784	mg/kg bw/d	External dermal exposure	0.000784	mg/kg bw/d
Systemic dermal exposure	**0.000784**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000784**	**mg/kg bw/d**

Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	26.561863	mg/person	Total external dermal exposure	1.193113	mg/person
Total external dermal exposure	0.379455	mg/kg bw/d	Total external dermal exposure	0.017044	mg/kg bw/d
Total systemic dermal exposure	**0.379455**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.017044**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.05 x 0.125 x 1 x 100%) / 70			(0.05 x 0.125 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.00625	mg/person	External inhalation exposure	0.00625	mg/person
External inhalation exposure	0.000089	mg/kg bw/d	External inhalation exposure	0.000089	mg/kg bw/d
Systemic inhalation exposure	**0.000089**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000089**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.39849 x 0.125 x 1 x 100%) / 70			(0.39849 x 0.125 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.049811	mg/person	External inhalation exposure	0.049811	mg/person
External inhalation exposure	0.000712	mg/kg bw/d	External inhalation exposure	0.000712	mg/kg bw/d
Systemic inhalation exposure	**0.000712**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000712**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.056061	mg/person	Total external inhalation exposure	0.056061	mg/person
Total external inhalation exposure	0.000801	mg/kg bw/d	Total external inhalation exposure	0.000801	mg/kg bw/d
Total systemic inhalation exposure	**0.000801**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000801**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	26.617924	mg/person	Total systemic exposure	1.249174	mg/person
Total systemic exposure	0.380256	**mg/kg bw/d**	**Total systemic exposure**	0.017845	**mg/kg bw/d**
% of AOEL	**237.7**	**%**	**% of AOEL**	**11.2**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 2.1.2-3 Input parameters considered for the estimation of operator exposure (high target)

Formulation type:	Liquid		**Application technique:**	Spraying	
Application rate (AR):	0.125	kg a.s./ha			
Area treated per day (A):	1	ha	**Dermal hands m/l ($D_{M(H)}$):**	205	mg/person/kg a.s.
Dermal absorption (DA):	100	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	13.1884	mg/person/kg a.s.
	100	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	82.47509	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	1.56194	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.05	mg/person/kg a.s.
AOEL	0.16	mg/kg bw/d	**Inhalation appl. (I_A):**	0.10841	mg/person/kg a.s.

Table A 2.1.2-4 Estimation of operator exposure towards difenoconazole using the German model and the data by Mich, G. (1996) for high targets

Operator exposure towards difenoconazole					
Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in					
Dermal exposure during mixing/loading			-		
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(205 x 0.125 x 1 x 100%) / 70			(205 x 0.125 x 1 x 0.01 x 100%) / 70		
External dermal exposure	25.625	mg/person	External dermal exposure	0.25625	mg/person
External dermal exposure	0.366071	mg/kg bw/d	External dermal exposure	0.003661	mg/kg bw/d
Systemic dermal exposure	**0.366071**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003661**	**mg/kg bw/d**
Dermal exposure during application			-		
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(13.1884 x 0.125 x 1 x 100%) / 70			(13.1884 x 0.125 x 1 x 1 x 100%) / 70		
External dermal exposure	1.64855	mg/person	External dermal exposure	1.64855	mg/person
External dermal exposure	0.023551	mg/kg bw/d	External dermal exposure	0.023551	mg/kg bw/d
Systemic dermal exposure	**0.023551**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.023551**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE$ [2)] $\times DA) / BW$		
(82.47509 x 0.125 x 1 x 100%) / 70			(82.47509 x 0.125 x 1 x 0.05 x 100%) / 70		
External dermal exposure	10.309386	mg/person	External dermal exposure	0.515469	mg/person
External dermal exposure	0.147277	mg/kg bw/d	External dermal exposure	0.007364	mg/kg bw/d
Systemic dermal exposure	**0.147277**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.007364**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(1.56194 x 0.125 x 1 x 100%) / 70			(1.56194 x 0.125 x 1 x 1 x 100%) / 70		
External dermal exposure	0.195243	mg/person	External dermal exposure	0.195243	mg/person
External dermal exposure	0.002789	mg/kg bw/d	External dermal exposure	0.002789	mg/kg bw/d
Systemic dermal exposure	**0.002789**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002789**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	37.778179	mg/person	Total external dermal exposure	2.615512	mg/person
Total external dermal exposure	0.539688	mg/kg bw/d	Total external dermal exposure	0.037364	mg/kg bw/d
Total systemic dermal exposure	**0.539688**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.037364**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.05 x 0.125 x 1 x 100%) / 70			(0.05 x 0.125 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.00625	mg/person	External inhalation exposure	0.00625	mg/person
External inhalation exposure	0.000089	mg/kg bw/d	External inhalation exposure	0.000089	mg/kg bw/d
Systemic inhalation exposure	**0.000089**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000089**	**mg/kg bw/d**

Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.10841 x 0.125 x 1 x 100%) / 70			(0.10841 x 0.125 x 1 x 1 x 100%) / 70		
External inhalation exposure	0.013551	mg/person	External inhalation exposure	0.013551	mg/person
External inhalation exposure	0.000194	mg/kg bw/d	External inhalation exposure	0.000194	mg/kg bw/d
Systemic inhalation exposure	**0.000194**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000194**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.019801	mg/person	Total external inhalation exposure	0.019801	mg/person
Total external inhalation exposure	0.000283	mg/kg bw/d	Total external inhalation exposure	0.000283	mg/kg bw/d
Total systemic inhalation exposure	**0.000283**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000283**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	37.79798	mg/person	Total systemic exposure	2.635313	mg/person
Total systemic exposure	0.539971	**mg/kg bw/d**	**Total systemic exposure**	0.037647	**mg/kg bw/d**
% of AOEL	**337.5**	**%**	**% of AOEL**	**23.5**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)
[2)] reduction factor for protective garment is 0.05 (professional appl.)

A 2.2 Worker exposure calculations

Table A 2.2-1 Input parameters considered for the estimation of worker exposure towards azoxystrobin

Intended use:	various vegetables		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.2	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	0.5	% (worst case)			
AOEL	0.2	mg/kg bw/d			

Table A 2.2-2 Estimation of worker exposure towards azoxystrobin using the German re-entry model

Without PPE			**With PPE**		
Worker (re-entry): Systemic dermal exposure after application in					
$SDE_W = (DFR \times TC \times WR \times AR \times NA \times DA) / BW$			$SDE_W = (DFR \times TC \times WR \times AR \times NA \times PPE \times DA) / BW$		
(1 x 2500 x 8 x 0.2 x 2 x 0.5%) / 70			(1 x 2500 x 8 x 0.2 x 2 x 5% x 0.5%) / 70		
External dermal exposure	8	mg/person	External dermal exposure	0.4	mg/person
External dermal exposure	0.114286	mg/kg bw/d	External dermal exposure	0.005714	mg/kg bw/d
Total systemic exposure	0.04	mg/person	Total systemic exposure	0.002	mg/person
Total systemic exposure	**0.000571**	**mg/kg bw/d**	**Total systemic exposure**	**0.000029**	**mg/kg bw/d**
% of AOEL	**0.29**	**%**	**% of AOEL**	**0.01**	**%**

[1)] acceptable without PPE: allocation of BVL code SF245-01 for spray applications

Table A 2.2-3 Input parameters considered for the estimation of worker exposure towards difenoconazole

Intended use:	various vegetables		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.125	kg a.s./ha	**Transfer coefficient (TC):**	2500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	8	h/d
Body weight (BW):	70	kg/person	**PPE**	5	%
Dermal absorption (DA):	100	% (worst case)			
AOEL	0.16	mg/kg bw/d			

Table A 2.2-4 Estimation of worker exposure towards difenoconazole using the German re-entry model

Without PPE			**With PPE**		
Worker (re-entry): Systemic dermal exposure after application in					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 2500 x 8 x 0.125 x 2 x 100%) / 70			(1 x 2500 x 8 x 0.125 x 2 x 5% x 100%) / 70		
External dermal exposure	5	mg/person	External dermal exposure	0.25	mg/person
External dermal exposure	0.071429	mg/kg bw/d	External dermal exposure	0.003571	mg/kg bw/d
Total systemic exposure	5	mg/person	Total systemic exposure	0.25	mg/person
Total systemic exposure	**0.071429**	**mg/kg bw/d**	**Total systemic exposure**	**0.003571**	**mg/kg bw/d**
% of AOEL	**44.6**	**%**	**% of AOEL**	**2.2**	**%**

[1)] acceptable without PPE: allocation of BVL code SF245-01 for spray applications

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: ASKON

Active Substance: 200 g/L Azoxystrobin and 125 g/L Difenoconazole

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Pflanzenschutzdienst der Landwirtschaftskammer NRW

Date: 23/12/2011

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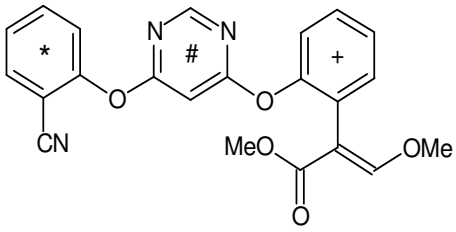
IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substances

IIIA 8.1.1 Azoxystrobin

Table IIIA 8.1.1-1: Information on the active substance azoxystrobin

Structural formula	
Common Name	azoxystrobin

IIIA 8.1.1.1 Storage stability

A brief summary of the storage stability data on azoxystrobin is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the Draft Re-Assessment Report prepared by UK (ASB2010-10494).

Table IIIA 8.1.1.1-1: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of azoxystrobin	Azoxystrobin and R230310 are stable for up to 24 months when stored at approximately –18°C in the following matrices: grapes, wine, apples, orange oil, orange juice, orange pulp, bananas, peaches, tomatoes (juice and paste), cucumbers, lettuce, carrot root, cereal straw, cereal grain, soybean meal, oilseed rape, pecans and peanut (oil and nut meat). Azoxystrobin is stable for up to 10 months in animal tissues, eggs and milk when stored at approximately –18°C.

IIIA 8.1.1.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of azoxystrobin in plants is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the Draft Re-Assessment Report prepared by UK (ASB2010-10494).

Table IIIA 8.1.1.2-1: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (wheat), fruit crops (grapes), oilseeds/pulses (peanuts) The metabolism of azoxystrobin in all plant matrices investigated proceeds along the following degradation and biotransformation steps: • Cleavage of the ether linkage between the phenylacrylate ring and the pyrimidinyl ring gives metabolite M 28 [R401553], and cleavage of the ether linkage between the cyanophenyl ring and the pyrimidinyl ring gives M 13. • Complex photochemical rearrangement leads to M U13. • The Z-isomer M 09 [R230310] of azoxystrobin is formed by photoisomerisation. • Oxidative cleavage of the acrylic bond leads to M 24 and M 19, further oxidation to M 30. • M 02 [R234886] is obtained by ester hydrolysis or oxidative o-dealkylation. Hydroxylation of the acrylic bond in M 02 [R234886] gives metabolite M U6. • Reduction of the acrylic bond of M 02 [R234886] gives M U5. • Azoxystrobin and its metabolites are incorporated naturally into sugars such as glucose. This is indicative of the mineralisation of azoxystrobin in soil (forming CO_2, which is subsequently assimilated and converted to simple sugars via photochemical reactions). • N-glucosylation of M 28 [R401553] forms M 42 [R405287]. However, despite formation of several metabolites the unchanged parent substance was identified as major residue in all matrices investigated.
Rotational crops	Wheat, radish, lettuce The metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The metabolism of azoxystrobin in rotational crops is more extensive with more metabolites being formed than in the primary crops but the metabolites in succeeding crops are produced in low concentrations. Metabolism in succeeding crops proceeded by four major routes: • Hydrolysis of the ester to give the free acid (M 02 *[R234886]*), followed by conjugation to glucose (N2) and malonylglucose (O3). • Reduction of the double bond of acid M 02 *[R234886]*, followed by conjugation to glucose (N1) and malonylglucose (O2 and M2).

	• Cleavage of the ether linkage into two ring compounds, followed by further conjugation to glucose. • Mineralisation and subsequent incorporation of ^{14}C-CO_2 into natural products.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	no data
Processed commodities (nature of residue)	No significant degradation of azoxystrobin observed under standard hydrolysis conditions (pH 4, 90°C, 20 minutes, pH 5, 100°C, 60 minutes, pH 6, 120°C, 20 minutes – in aqueous solution).
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Azoxystrobin
Plant residue definition for risk assessment	Azoxystrobin
Conversion factor(s) (monitoring to risk assessment)	none

IIIA 8.1.1.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of azoxystrobin in livestock is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the Draft Re-Assessment Report prepared by UK (ASB2010-10494).

Table IIIA 8.1.1.3.-1: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats, laying hens; pyrimidinyl, phenylacrylate and cyanophenyl label Goats: 25 mg/kg feed DM, 7 days. TRR up to 1.2 mg/kg in liver (0.02 mg/kg azoxystrobin), 0.25 mg/kg in kidney (0.008 mg/kg azoxystrobin), 0.06 mg/kg in muscle, 0.025 mg/kg in fat and 0.01 mg/kg in milk. A couple of metabolites was identified, with largest contributions by M 13, M 20 and M 28 [R401553]. Laying hens: 11 mg/kg feed DM, 10 days. Azoxystrobin and metabolite R401553 were the only identified residues. Transfer of TRR into tissues and eggs was very low (liver: 0.111 mg/kg; muscle: up to 0.018 mg/kg; skin+fat: up to 0.039 mg/kg; eggs: up to 0.059 mg/kg). Based on azoxystrobin levels in animal feed as calculated (see below), residues are expected to be significantly below 0.01 mg/kg in tissues and eggs.
Time needed to reach a plateau concentration in milk and eggs	Eggs: egg yolk 6-8 days, egg white 3-4 days (metabolism study) Milk: 3-5 days (feeding study)
Animal residue definition for monitoring	Azoxystrobin
Animal residue definition for risk assessment	Azoxystrobin
Conversion factor(s) (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

IIIA 8.1.1.4 Residues in rotational crops

A brief summary of the field rotational crop studies on azoxystrobin is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the Draft Re-Assessment Report prepared by UK (ASB2010-10494).

Table IIIA 8.1.1.4-1: Residues in rotational crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Field studies	Field trials on wheat, millet, radish, turnip, beetroot, mustard greens and leaf lettuce Residues were <0.01 mg/kg (LOQ) in edible parts. In non-edible commodities (animal feed), the highest residues were seen in cereals: up to 0.05 mg/kg in forage, 0.03 mg/kg in hay and 0.04 mg/kg in straw.

IIIA 8.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses according to national authorizations in DE) is provided in the following table.

Table IIIA 8.1.1.5-1: Calculation of the dietary burden (according to nationally authorized uses in DE)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Sugar beet leaves	16.0	0.000	30.000	20.000	25.000	0.380[a]	0.000	0.713	0.475	0.594
Fruit pomace	23.0	0.000	10.000	30.000	0.000	0.630 [b]	0.000	0.274	0.822	0.000
Cereal grain	86.0	70.000	10.000	0.000	15.000	0.015 [c]	0.012	0.002	0.000	0.003
Cereal straw	86.0	0.000	20.000	50.000	0.000	5.300 [d]	0.000	1.233	3.081	0.000
Pulses	86.0	10.000	0.000	0.000	0.000	0.010 [e]	0.001	0.000	0.000	0.000
Sugar beet root	20.0	20.000	30.000	0.000	60.000	0.010 [f]	0.010	0.015	0.000	0.030
Intake (mg/kg dry weight feed)							**0.023**	**2.236**	**4.378**	**0.626**
Intake (mg/kg feed as received)							**0.012**	**0.538**	**1.396**	**0.132**
Intake (mg/kg bw/d)							**0.001**	**0.081**	**0.188**	**0.025**
Intake (mg/animal/d)							**0.003**	**44.714**	**65.672**	**1.879**

[a] HR, based on cGAP: 2 x 0,25 kg as/ha, PHI: 36-43 d, BBCH 39-49
[b] STMR, based on cGAP: 3 x (0,075-0,3) kg as/ha, PHI: 35 d (partly overdosed trials, 3-8 x 0,25-0,4 kg as/ha, PHI 26-28 d), no processing factor for pomace available
[c] STMR, based on cGAP: barley, 2 x 0,2 kg as/ha, BBCH 31-61, PHI: 34-43 d
[d] HR, based on cGAP: barley, 2 x 0,2 kg as/ha, BBCH 31-61, PHI: 34-50 d
[e] STMR, based on cGAP: pea seed, dry, 2 x 0,2 kg as/ha, PHI: 42-45 d
[f] HR, based on cGAP: 2 x 0,25 kg as/ha, PHI: 36-43 d, BBCH 39-49

A brief summary of the available livestock feeding study/studies is given in the following table. Data, which has previously been evaluated at EU level is described in detail in the Draft Re-Assessment Report prepared by UK (ASB2010-10494). The dietary burden calculated at EU level is worst case as compared to the dietary burden based on nationally authorized uses in DE.

Table IIIA 8.1.1.5-2: Conditions of requirement of livestock feeding studies on azoxystrobin based on EU evaluation (AIR-DAR and Addendum, May/September 2009, RMS UK)

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	10.39 (dairy)* 12.43 (beef)*	1.6 *	4.15 *
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	no	no	no

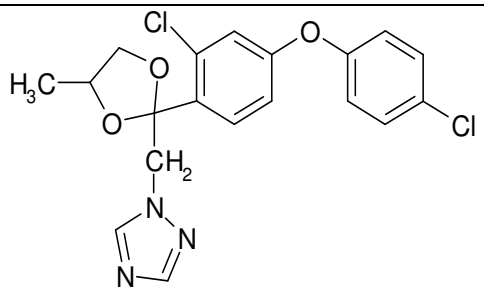
* based on EU evaluation (AIR-DAR and Addendum, May/September 2009, RMS UK)

Table IIIA 8.1.1.5-3: Results of livestock feeding studies on azoxystrobin

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cattle: 5, 25, 75 and 250	Laying hens (metab. study): 11	See ruminant
	Relevant dosing levels in feeding study: dairy cows: 25 mg/kg feed DM (2N) poultry: 11 mg/kg feed DM (7 N, from metab. study) Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	Not addressed
Liver	0.01 (25 mg/kg feed DM) <0.01 (5 mg/kg feed DM)	<0.01	Not addressed
Kidney	<0.01	<0.01	Not addressed
Fat	<0.01	<0.01	Not addressed
Milk	<0.01		Not addressed
Eggs		<0.01	

IIIA 8.1.2 Difenoconazole

Table IIIA 8.1.2-2: Information on the active substance difenoconazole

Structural formula	
Common Name	difenoconazole

IIIA 8.1.2.1 Storage stability

A brief summary of the storage stability data on difenoconazole is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the DAR for difenoconazole (ASB2010-10465) and the corresponding EFSA conclusion (ASB2012-749).

Table IIIA 8.1.2.1-1: Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Stability of difenoconazole and CGA 205375	Studies demonstrated the storage stability of difenoconazole under deep frozen conditions for at least 24 months in commodities with high water content (tomatoes, potatoes, wheat forage), high oil content (cottonseed oil, meal and seeds) and in dry commodities (wheat grain, straw). In lettuce, soybeans, bananas, eggs, milk, poultry breast, beef liver, fat, milk and tissues from dairy cattle, the storage stability of difenoconazole was demonstrated for at least 10 to 12 months. Metabolite CGA 205375 was shown to be stable in animal commodities for at least 10 months upon storage at <-18°C.

IIIA 8.1.2.2 Metabolism in plants and plant residue definition(s)

A brief summary of the metabolism of difenoconazole in plants is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the DAR for difenoconazole (ASB2010-10465) and the corresponding EFSA conclusion (ASB2012-749).

Table IIIA 8.1.2.2-1: Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruits and fruiting vegetables (grapes, tomatoes), root vegetables (potatoes), cereals (wheat) and pulses and oilseeds (oilseed rape) were covered, all as foliar application using [phenyl-^{14}C] or [triazole-^{14}C] labelled difenoconazole. The metabolism was also investigated in wheat following seed treatment with difenoconazole (phenyl and triazole label). Difenoconazole was extensively degraded in crops investigated, with very similar metabolic pathways in all four crop categories. In tomatoes (fruits, foliage), potatoes (tubers, foliage) and oilseed rape (seed, pods) parent difenoconazole and its metabolite triazole alanine were identified as major constituents of the TRR (except for mature potato tubers: in the phenyl study the main component of the TRR was CGA 205375). In wheat straw and grain 1,2,4-triazole, triazole acetic acid and triazole alanine were dominating after treatment with [triazole-^{14}C] labelled difenoconazole. In the phenyl study the majority of the TRR in straw was parent difenoconazole along with its metabolite CGA 2053755 while in grain the conjugates of metabolite CGA 1891386 accounted for up to 35% of the TRR. Studies on grapes showed that the essential part of the TRR in mature plant parts (foliage and fruits) was difenoconazole. The available studies with wheat, potatoes and oilseed rape indicated translocation of triazole related residues to tubers, grain and seed.

Rotational crops	Leafy vegetables (lettuce, spinach), root vegetables (carrot, sugar beet and turnip), cereals (spring and winter wheat, maize), Soil treatment, phenyl and/or triazole labelled difenoconazole. Residues of triazole alanine (10 - 66 %), triazole lactic acid (9.7 – 54 %) and triazole acetic acid (2.7 – 39 %) were identified as major components of the TRR after application of [triazole-^{14}C] difenoconazole. Results from the confined study with [phenyl-^{14}C] labelled active substance indicated that the TRR was very low. Therefore no characterization of the TRR was attempted.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	no data
Processed commodities (nature of residue)	Difenoconazole is stable under standard conditions representing pasteurisation, boiling and sterilisation.
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Difenoconazole
Plant residue definition for risk assessment	Two separate residue definitions (provisional): 1) Difenoconazole 2) Triazole derivative metabolites (TDM) pending the definition of a common and harmonised approach for all active substances of the triazole chemical class
Conversion factor(s) (monitoring to risk assessment)	not applicable

IIIA 8.1.2.3 Metabolism in livestock and animal residue definition(s)

A brief summary of the metabolism of difenoconazole in livestock is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the DAR for difenoconazole (ASB2010-10465) and the corresponding EFSA conclusion (ASB2012-749).

Table IIIA 8.1.2.3-1: Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.Nr and 8.6)

Animals covered	Lactating goats and laying hens were investigated using [phenyl-^{14}C] and [triazole-^{14}C] labelled difenoconazole. Difenoconazole was rapidly metabolised, with the majority of the administered radioactivity being excreted via urine and faeces (up to 97 % in hens and up to 88% in goats). Transfer of radioactivity into milk, eggs and edible tissues was low, thus demonstrating that neither difenoconazole nor its metabolites accumulate. Difenoconazole was identified in all investigated matrices, but the main component of the residues was metabolite CGA 205375 which is regarded as less toxic than the parent compound. As the metabolic pattern in ruminants does not significantly differ from that in rats, a pig study was not required.
Time needed to reach a plateau concentration in milk and eggs	Milk = 2 - 6 days Eggs = 5 - 7 days

Animal residue definition for monitoring	Reg. (EC) 396/2005: Difenoconazole Proposal from EFSA Conclusion: Difenoconazole alcohol (CGA-205375), expressed as difenoconazole
Animal residue definition for risk assessment	Proposal from EFSA Conclusion: Two separate residue definitions (provisional): 1) Difenoconazole alcohol (CGA-205375), expressed as difenoconazole 2) Triazole derivative metabolites pending information on metabolism of TDM in animals and pending the definition of a common and harmonised approach for all active substances of the triazole chemical class.
Conversion factor(s) (monitoring to risk assessment)	not concluded
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	yes, log Pow is 4.4 at pH 8 (though results from metabolism and feeding studies do not indicate high fat solubility)

IIIA 8.1.2.4 Residues in rotational crops

A brief summary of the field rotational crop studies on difenoconazole is given in the following table. Data, which has been previously evaluated at EU level, is described in detail in the DAR for difenoconazole (ASB2010-10465) and the corresponding EFSA conclusion (ASB2012-749).

Table IIIA 8.1.2.4-1: Residues in rotational crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Field studies	In confined rotational crop studies the uptake of radioactive residues by succeeding crops was investigated following application to bare soil. The uptake was generally low, but higher with the [triazole-^{14}C] label than with the [phenyl-^{14}C] label. Field studies showed that residues of difenoconazole and triazole alanine did not occur in carrots and spinach planted 30 days after application of difenoconazole to bare ground.

IIIA 8.1.2.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses according to national authorizations in DE) is provided in the following table.

Table IIIA 8.1.2.5-1: Calculation of the dietary burden (according to nationally authorized uses in DE)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Sugar Beet leaves	16	--	30	30	25	0.62 [a]	--	1.163	1.163	0.969
Apple Pomace	23	--	10	-	--	0.28 [b]	--	0.122	--	--
Cereal (grain)	86	70	10	--	15	0.02 [c]	0.016	0.002	--	0.003

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1.9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Cereals (straw)	86	--	20	50	--	1.3 [c]	--	0.302	0.756	--
Fodder beet	10	20	30	20	60	0.1 [a]	0.200	0.300	0.200	0.600
Rape seed	86	10	--	10	--	0.02 [e]	0.002	0.007	0.002	0.005
Intake (mg/kg dry weight feed)							0.219	1.899	2.118	1.572
Intake (mg/kg feed as received)							0.077	0.344	0.475	0.203
Intake (mg/kg bw/d)							0.014	0.069	0.091	0.063
Intake (mg/animal/d)							0.026	37.778	31.775	4.717

[a] HR, based on the following cGAP: 2 x 0.1 kg as/ha, PHI: 28 d
[b] STMR-P, based on the following cGAP: 4 x 0.019 kg as/ha, 4 x 0.004 kg as/hl, PHI: 28 d, PF = 4 for pomace
[c] HR (straw) STMR (grain), based on the following cGAP: 2 x 0.125 kg as/ha, PHI: 35 d
[d] STMR, based on the following cGAP: 2 x 0.125 kg as/ha, PHI: F not specified, covered by vegetation period

A brief summary of the available livestock feeding study/studies is given in the following table. Data, which has previously been evaluated at EU level, is described in detail in the DAR for difenoconazole (ASB2010-10465) and the corresponding EFSA conclusion (ASB2012-749).

Table IIIA 8.1.2.5-2: Conditions of requirement of livestock feeding studies on difenoconazole

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	yes 1.9 (cow) 2.1 (beef)	yes 0.22	yes 1.6
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	yes	yes	yes

Table IIIA 8.1.2.5-3: Results of livestock feeding studies on difenoconazole

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Several cow feeding studies with following dosing levels: 1, 3, 5, 15, 50 mg/kg feed DM	Hen feeding study with 4 dosing levels: 0.3, 1, 3, 10 mg/kg feed DM	See ruminant
	Relevant dosing levels in feeding study: 1 and 3 mg/kg feed for cows, beef and pigs and 0.3 mg/kg feed for poultry Expected difenoconazole residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	<0.01	<0.01	<0.01
Kidney	<0.01	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	<0.01		<0.01
Eggs		<0.01	

IIIA 8.2 Evaluation of the intended use(s)

IIIA 8.2.1 Selection of critical use and justification

The critical GAP for indoor grown cucumbers and other cucurbits with edible peel which is used for the consumer intake and risk assessment is presented in Table IIIA 8.2-1.
Under consideration of a variable application rate in dependence of the plant height, the cGAP was defined as 2 x 1 L formulation per ha (2 x 0.2 kg azoxystrobin and 2 x 0.125 kg difenoconazole per ha).

Table IIIA 8.2-2: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days)** **(i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season** **(h)**	**kg, L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	Cucumber (incl. gherkins), Pumpkins, Patisson, Zucchini with edible peel	G	Fungual leaf spot diseases	spraying	from BBCH 19 onwards	a) 2 b) 2 (10 – 14 days)	0.75 – 1 l/ha (see below)	see below	600-900	3	

Height of plant	Application rate				Application concentration	
	Formulation (kg/ha)	Azoxystrobin (kg as/ha)	Difenoconazole (kg as/ha)	Water (l/ha)	Azoxystrobin (kg as/hl)	Difenoconazole
up to 50 cm	0.75	0.15	0.094	600	0.022 – 0.025	0.014-0.016
50 cm up to 125 cm	1.0	0.2	0.125	900		

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

IIIA 8.2.2 Cucumber (incl. gherkins), Pumpkins, Patisson, Zucchini

IIIA 8.2.2.1 Residues in primary crops

Azoxystrobin

The following table gives a brief overview of the supervised residue trials selected for the assessment of azoxystrobin in cucumbers grown in glasshouse. The data from cucumbers can be extrapolated to the whole group of cucurbits with edible peel. The available residue trials involve 3-4 instead of the intended two treatments. Nevertheless they are considered appropriate for evaluation. For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

Table IIIA 8.2.2.1-1: Overview of the selected supervised residue trials for azoxystrobin in cucumber

Commo-dity	Region [(a)]	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (azoxystrobin)	Risk assessment (azoxystrobin)			
Cucumber	DE	Indoor	0.02, 0.03, 0.04, 0.04, 0.05, 0.07, 0.13, 0.4 mg/kg	0.02, 0.03, 0.04, 0.04, 0.05, 0.07, 0.13, 0.4 mg/kg	0.045	0.4	1

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Analytical methods for commodities of high water content such as cucurbits are available and acceptable for enforcing azoxystrobin.

Difenoconazole

The following table gives a brief overview of the supervised residue trials selected for the assessment of difenoconazole in cucumbers grown in glasshouse. The data from cucumbers can be extrapolated to the whole group of cucurbits with edible peel. The available residue trials involve 3-4 instead of the intended two treatments. Nevertheless they are considered appropriate for evaluation. For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

Table IIIA 8.2.2.1-2: Overview of the selected supervised residue trials for difenoconazole in cucumber

Commo-dity	Region [(a)]	Outdoor / Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (difenoconazole)	Risk assessment (difenoconazole*)			
Cucumber	DE	Indoor	<0.01(2), 0.01(4), 0.02, 0.03, 0.06, 0.18 mg/kg	<0.01(2), 0.01(4), 0.02, 0.03, 0.06, 0.18 mg/kg	0.01 mg/kg	0.18	not applicable

* the second part of the residue definition as proposed by EFSA (1. difenoconazole; 2. TDM) is currently not considered since a harmonized EU approach is not yet available.
(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Analytical methods for commodities of high water content such as cucurbits are available and acceptable for enforcing difenoconazole.

IIIA 8.2.2.2 Proposed Pre-Harvest Intervals, Withholding Periods

The critical GAP includes a PHI of 3 days.

IIIA 8.3 Consumer intake and risk assessment

IIIA 8.3.1 Azoxystrobin

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-1) and the toxicological reference values stated in Table IIIA 8.3-2. For the detailed calculation results it is referred to Appendix 3.

Table IIIA 8.3-1: Residue input values for the consumer risk assessment

Commodity	**Chronic risk assessment**		**Acute risk assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
all	variable	MRL	n.n.	no ARfD necessary

Table IIIA 8.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.2 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	52.7 % (based on 2- <5 year old DE children)*
NTMDI (% ADI) according to NVS II-model	67.5 % (based on 2- <5 year old DE children)*
IEDI (EFSA PRIMo) (% ADI)	not required
NEDI (% ADI)	not required
Factors included in IEDI and NEDI	not applicable
ARfD	not allocated
IESTI (EFSA PRIMo) (% ARfD)	not necessary
NESTI (% ARfD)	not necessary
Factors included in IESTI and NESTI	not applicable

* both calculations are based on the same underlying consumption data, but due to differences in the models calculation results differ

IIIA 8.3.2 Difenoconazole

The consumer intake and risk assessment is based on the appropriate input values given in Table IIIA 8.3-3) and the toxicological reference values stated in Table IIIA 8.3-4. For the detailed calculation results it is referred to Appendix 3.

Table IIIA 8.3-3: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucurbits with edible peel	0.01	STMR	0.18	HR
Pome fruit	0.12	STMR, EC, 2008		not relevant for intended uses
Apricots	0.14	STMR, EC, 2008		not relevant for intended uses
Peaches	0.15	STMR, EC, 2008		not relevant for intended uses
Olives	0.47	STMR, EC, 2008		not relevant for intended uses
Beetroot, swedes, turnips	0.08	STMR, EC, 2008		not relevant for intended uses
Peppers	0.14	STMR, EFSA, 2010		not relevant for intended uses
Fresh herbs	4.65	STMR, EFSA, 2010		not relevant for intended uses
Celery	0.34	STMR, EC, 2007		not relevant for intended uses
Fennel	1.66	STMR, EFSA, 2009		not relevant for intended uses
all other commodities	variable	MRL		not relevant for intended uses

Table IIIA 8.3-4: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	182.9 % (based on WHO Cluster diet B)
NTMDI (% ADI) according to NVS II model	164.9 % (based on 2- <5 year old DE children)
IEDI (EFSA PRIMo) (% ADI)	91.5 % (based on WHO Cluster diet B)
NEDI (NVS II model) (% ADI)	92.9 % (based on 2- <5 year old DE children)
Factors included in IEDI and NEDI	STMR values as listed above
ARfD	0.16 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	Cucumber: 6.6 % (based on NL child)
NESTI (NVS II model) (% ARfD)	Cucumber: 5 % (based on 2- <5 year old DE children)
Factors included in IESTI and NESTI	none

IIIA 8.4 Proposed maximum residue levels (MRLs)

The existing EU MRLs and proposals for new MRLs (if required) for the crops applied for in this dossier are summarized in Table IIIA 8.4-1.

The intended uses are not relevant for livestock feeding.

Table IIIA 8.4-1: Overview of the existing EC MRL(s) and new MRL proposals (if required)

Commodity (Code)	**Existing EC MRL (mg/kg)**	**Proposed EC MRL (mg/kg)**	**Result of OECD calculator**	**Justification for the proposal/ Comments**
Azoxystrobin: Cucurbits with edible peel (0232000)	1	1	Not conducted	Existing MRL sufficient, HR: 0.4 mg/kg
Difenoconazole: Cucurbits with edible peel (0232000)	0.1	0.3	0.3	Current MRL is exceeded. OECD-Calculator suggests 0.3 mg/kg. No dietary intake concern identified. Extrapolation to the whole group of "cucurbits with edible peel", since all commodities within the group are covered by the GAP.

IIIA 8.5 Conclusion

The available data for azoxystrobin and difenoconazole is considered sufficient for evaluation. No chronic or acute intake concern was identified for any of the two substances.
Azoxystrobin residues were all below the established MRL for cucurbits with edible peel of 1 mg/kg.
For difenoconazole a higher MRL of at least 0.3 mg/kg is required for cucurbits with edible peel. A corresponding Evaluation report is prepared in parallel.

The use of azoxystrobin and difenoconazole on cucurbits with edible peel is not relevant for animal feeding purposes.
Indoor uses on fruiting vegetables are also not relevant concerning succeeding crops. Besides this fact, none of the two active substances shows a significant transfer via the roots. However, triazoles metabolites could occur following application of difenoconazole. An overall assessment of triazoles is currently prepared on European level and is not considered in the framework of the present dossier.

In summary it is concluded that the data submitted for azoxystrobin and difenoconazole is sufficient for evaluation and for a proposal of the new MRL required. No dietary intake concern was identified.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR
OECD: KIIA 6.3	Solé, C.	2002	Residue study with Difenoconazole (CGA 169374) in or on cucumbers in Italy (greenhouse) 2054/01 ASB2011-9977		SYD	Used
OECD: KIIA 6.3	Solé, C.	2002	Residue study with Difenoconazole (CGA 169374) in or on cucumbers in Italy (greenhouse) 2053/01 ASB2011-9978		SYD	Used
OECD: KIIA 6.3	Heillaut, C.	2008	Azoxystrobin (ICI5504) and Difenoconazole (CGA169374) - Residue study on protected cucumbers in France (South) and Spain in 2007 T011469-06 ASB2011-9982		SYD	Used
OECD: KIIA 6.3	Leak, J.	2009	Azoxystrobin and Difenoconazole- Residue study on protected cucumber in Spain in 2008 T009546-07 ASB2011-9983		SYD	Used
OECD: KIIA 6.3	Leak, J.	2009	Azoxystrobin and Difenoconazole - Residue study on protected cucumber in Northern France in 2008 T009551-07 ASB2011-9984		SYD	Used

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further data submitted.

A 2.2 Residues in primary crops

No further data submitted.

A 2.2.1 Nature of residues

No further data submitted.

A 2.2.2 Magnitude of residues for azoxystrobin

Reference:	ASB2011-9982, ASB2011-9983, ASB2011-9984
Report	Residue studies with difenoconazole in or on indoor grown sweet peppers
Guideline(s):	yes (EU Guidance to Dir. 91/414/EEC)
Deviations:	none
GLP:	yes
Acceptability:	yes

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 200 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : ASKON **006902-00** (submitted to RA 1 **006902-00/06**) treated with formulation A13703G 325 SC, (200 g/l Azoxystrobin ICI5504 + 125 g/l Difenoconazole CGA169374)
Applicant : Syngenta Agro GmbH

Active ingredient : Azoxystrobin (ICIA5504)
Crop / crop group : Cucumber

Submission date : 2011-08-29

Indoors / outdoors : Indoors
Other a.i. in formulation (content and common name) : 125 g/l Difenoconazole (CGA 169374)
Residues calculated as : 8.1 Azoxystrobin (ICIA5504)
8.2 R230310

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
T009546-07-REG, study FSGD-007, trial SRS08-150-37FR, plot 2 Spain 12580 Benicarlo, Comunidad Valenciana 2009-10-28	Darina	1) 2008-02-25 (planting) 2) 2008-03 - 2008-06 3) 2008-04 - 2008-06	0.20 0.20 0.18	996 1007 917	0.020 0.020 0.020	2008-06-10 2008-06-17 2008-06-26[4)]	BBCH 76	fruit	0.070 0.040 <u>0.050</u>	<0.01 <0.01 <0.01	0 1 3	4) spraying analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months <u>ASB2011-9983</u>
T009546-07-REG, study FSGD-007, trial SRS08-151-37FR, plot 2 Spain 46440 Almussafes 2009-10-28	R2 954	1) 2008-07-28 (planting) 2) 2008-08 - 2008-10 3) 2008-09	0.21 0.20 0.20	1047 997 992	0.020 0.020 0.020	2008-09-01 2008-09-08 2008-09-15[4)]	BBCH 74	fruit	0.070 0.070 <u>0.040</u>	<0.01 <0.01 <0.01	0 1 3	4) spraying analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months <u>ASB2011-9983</u>
T009551-07-REG, study FSGD-006, trial SRF08-001-37FR, plot 2 France 71570 La Chapelle de Guinchay 2009-09-01	Toril	1) 2008-07-01 (planting) 2) 3) 2008-08-20	0.20 0.21 0.21	1007 1027 1037	0.020 0.020 0.020	2008-08-01 2008-08-10 2008-08-17[4)]	BBCH 85-87	fruit	0.16 0.19 <u>0.13</u>	<0.01 <0.01 <0.01	0 1 3	4) spraying analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months <u>ASB2011-9984</u>

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
T009551-07-REG, study FSGD-006, trial SRF08-002-37FR, plot 2 France 71570 La Chapelle de Guinchay 2009-09-01	Serit	1) 2008-07-30 (planting) 2) 3) 2008-09-15	0.20 0.20 0.20	1013 999 1008	0.020 0.020 0.020	2008-08-28 2008-09-05 2008-09-12[4)]	BBCH 85-86	fruit	0.35 0.30 <u>0.40</u>	<0.01 <0.01 <0.01	0 1 3	4) spraying analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months <u>ASB2011-9984</u>
T011469-06-REG, study T011469-06, trial AF/11493/SY/1 Spain 50193 Peñaflor, Aragon 2008-07-10	Serena	1) 2007-05-07 (planting) 2) 3) 2007-09	0.21 0.20 0.21	1236 1220 1236	0.017 0.017 0.017	2007-08-27 2007-09-04 2007-09-12[4)]	BBCH 87	fruit	0.070 0.070 0.060 <u>0.070</u>	<0.01 <0.01 <0.01 <0.01	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 1 month <u>ASB2011-9982</u>

1	2	3	4			5	6	7	8.1	8.2	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl							
	(a)	(b)				(c)		(a)			(d)	(e)
T011469-06-REG, study T011469-06, trial AF/11493/SY/2 Spain 50014 Zaragoza, Cogullada 2008-07-10	Serena	1) 2007-05-21 (planting) 2) 3) 2007-09	0.20 0.20 0.21	1170 1203 1236	0.017 0.017 0.017	2007-08-27 2007-09-04 2007-09-12[4)]	BBCH 87	fruit	0.030 0.14 0.050 <u>0.040</u>	<0.01 <0.01 <0.01 <0.01	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg,max. sample storage: 1 month <u>ASB2011-9982</u>
T011469-06-REG, study T011469-06, trial FR-FR-07-0077 France 47320 Clairac, Aquitaine 2008-07-10	Gardon	1) 2007-04-12 (planting) 2) 3) 2007-05	0.20 0.21 0.22	819 843 897	0.025 0.025 0.025	2007-05-07 2007-05-14 2007-05-22[4)]	BBCH 86	fruit	0.020 0.040 0.030 <u>0.020</u>	<0.01 <0.01 <0.01 <0.01	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg,max. sample storage: 5 months <u>ASB2011-9982</u>
T011469-06-REG, study T011469-06, trial FR-FR-07-0148 France 13390 Aureille 2008-07-10	Airbus	1) 2007-05-31 (planting) 2) 3) 2007-07	0.20 0.20 0.20	997 991 1005	0.020 0.020 0.020	2007-07-09 2007-07-17 2007-07-24[4)]	BBCH 82	fruit	0.01 0.030 0.040 <u>0.030</u>	<0.01 <0.01 <0.01 <0.01	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: RAM 305/03, (HPLC-MS/MS), LOQ: 0.01 mg/kg,max. sample storage: 3 months <u>ASB2011-9982</u>

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.

A 2.2.3 Magnitude of residues for difenoconazole

Reference:	ASB2011-9977, ASB2011-9978, ASB2011-9982, ASB2011-9983, ASB2011-9984
Report	Residue studies with difenoconazole in or on indoor grown cucumbers
Guideline(s):	yes (EU Guidance to Dir. 91/414/EEC)
Deviations:	none
GLP:	yes
Acceptability:	yes

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 250 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : SCORE **024353-00** (submitted to RA1 **006902-00/06**) treated with formulation A-7402 G, EC 250
Applicant : Syngenta Agro GmbH

Active ingredient : Difenoconazole (CGA 169374)
Crop / crop group : Cucumber

Submission date : 2011-08-29

Indoors / outdoors : Indoors
Other a.i. in formulation (content and common name) :
Residues calculated as : Difenoconazole (CGA 169374)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
2053/01, study 2053/01, trial 1 Bagnarola di Budrio Italy 44050 Bologna 2002-06-03	Darina	1) 2001-03-18 (planting) 2) 3) 2001-05-15 - 2001-07-20	0.13 0.13 0.13 0.13	982 1015 1007 1007	0.013 0.012 0.012 0.012	2001-05-29 2001-06-07 2001-06-18 2001-06-29[4)]	BBCH 84-86	fruit	0.030 <u>0.01</u> <0.01 <0.01 <0.01	0 3 7 7 14	4) spraying analytical method: AG 575 A modified (GC-ECD), LOQ: 0.01 mg/kg, max. sample storage: 9 months <u>ASB2011-9978</u>
2054/01, study 2054/01, trial 1 Via Cadriano Italy 44057 Bologna 2002-06-03	Darina	1) 2001-02-15 (planting) 2) 3) 2001-05-15 - 2001-07-20	0.13 0.13 0.13 0.13	1013 967 983 1017	0.012 0.013 0.013 0.012	2001-05-29 2001-06-07 2001-06-18 2001-06-29[4)]	BBCH 84-86	fruit	0.090 <u>0.01</u> <0.01 <0.01 <0.01	0 3 7 7 14	4) spraying analytical method: AG 575 A modified (GC-ECD), LOQ: 0.01 mg/kg, max. sample storage: 9 months <u>ASB2011-9977</u>

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Note: All entries to be filled in as appropriate

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : ASKON **006902-00** (submitted to RA 1 **006902-00/06**) treated with formulation A13703G 325 SC, (200 g/l Azoxystrobin ICI5504 + 125 g/l Difenoconazole CGA169374)
Applicant : Syngenta Agro GmbH

Active ingredient : Difenoconazole (CGA 169374)
Crop / crop group : Cucumber

Submission date : 2011-08-29

Indoors / outdoors : Indoors
Other a.i. in formulation (content and common name) : 200 g/l Azoxystrobin (ICIA5504)

Residues calculated as : Difenoconazole (CGA 169374)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
T009546-07-REG, study FSGD-007, trial SRS08-150-37FR, plot 2 Spain 12580 Benicarlo, Comunidad Valenciana 2009-10-28	Darina	1) 2008-02-25 (planting) 2) 2008-03 - 2008-06 3) 2008-04 - 2008-06	0.12 0.13 0.11	996 1007 917	0.013 0.012 0.012	2008-06-10 2008-06-17 2008-06-26[4)]	BBCH 76	fruit	0.030 0.01 <u>0.020</u>	0 1 3	4) spraying analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months <u>ASB2011-9983</u>
T009546-07-REG, study FSGD-007, trial SRS08-151-37FR, plot 2 Spain 46440 Almussafes 2009-10-28	R2 954	1) 2008-07-28 (planting) 2) 2008-08 - 2008-10 3) 2008-09	0.13 0.12 0.12	1047 997 992	0.012 0.012 0.012	2008-09-01 2008-09-08 2008-09-15[4)]	BBCH 74	fruit	0.040 0.030 <u>0.01</u>	0 1 3	4) spraying analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months <u>ASB2011-9983</u>

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
T009551-07-REG, study FSGD-006, trial SRF08-001-37FR, plot 2 France 71570 La Chapelle de Guinchay 2009-09-01	Toril	1) 2008-07-01 (planting) 2) 3) 2008-08-20	0.13 0.13 0.13	1007 1027 1037	0.012 0.012 0.012	2008-08-01 2008-08-10 2008-08-17[4)]	BBCH 85-87	fruit	0.070 0.10 0.060	0 1 3	4) spraying analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months ASB2011-9984
T009551-07-REG, study FSGD-006, trial SRF08-002-37FR, plot 2 France 71570 La Chapelle de Guinchay 2009-09-01	Serit	1) 2008-07-30 (planting) 2) 3) 2008-09-15	0.13 0.12 0.13	1013 999 1008	0.013 0.012 0.012	2008-08-28 2008-09-05 2008-09-12[4)]	BBCH 85-86	fruit	0.17 0.17 0.18	0 1 3	4) spraying analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg,max. sample storage: 3 months ASB2011-9984
T011469-06-REG, study T011469-06, trial AF/11493/SY/1 Spain 50193 Peñaflor, Aragon 2008-07-10	Serena	1) 2007-05-07 (planting) 2) 3) 2007-09	0.13 0.13 0.13	1236 1220 1236	0.010 0.010 0.010	2007-08-27 2007-09-04 2007-09-12[4)]	BBCH 87	fruit	0.030 0.050 0.030 0.030	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 1 month ASB2011-9982

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
T011469-06-REG, study T011469-06, trial AF/11493/SY/2 Spain 50014 Zaragoza, Cogullada 2008-07-10	Serena	1) 2007-05-21 (planting) 2) 3) 2007-09	0.12 0.13 0.13	1170 1203 1236	0.010 0.010 0.010	2007-08-27 2007-09-04 2007-09-12[4)]	BBCH 87	fruit	0.01 0.090 0.030 <u>0.01</u>	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 1 month <u>ASB2011-9982</u>
T011469-06-REG, study T011469-06, trial FR-FR-07-0077 France 47320 Clairac, Aquitaine 2008-07-10	Gardon	1) 2007-04-12 (planting) 2) 3) 2007-05	0.13 0.13 0.14	819 843 897	0.016 0.016 0.016	2007-05-07 2007-05-14 2007-05-22[4)]	BBCH 86	fruit	<0.01 0.10 <0.01 <<u>0.01</u>	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 5 months <u>ASB2011-9982</u>
T011469-06-REG, study T011469-06, trial FR-FR-07-0148 France 13390 Aureille 2008-07-10	Airbus	1) 2007-05-31 (planting) 2) 3) 2007-07	0.12 0.12 0.13	997 991 1005	0.013 0.013 0.012	2007-07-09 2007-07-17 2007-07-24[4)]	BBCH 82	fruit	<0.01 0.01 0.01 <<u>0.01</u>	0[5)] 0 1 3	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS-MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months <u>ASB2011-9982</u>

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

Comments of zRMS:	Acceptable.

A 2.3 Residues in processed commodities

No further data submitted.

A 2.4 Residues in rotational crops

No further data submitted.

A 2.5 Residues in livestock

No further data submitted.

A 2.6 Other studies/information

No further data submitted.

Appendix 3 Pesticide Residue Intake Modell (PRIMo)

Azoxystrobin			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,2**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Prepare workbook for refined calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

	TMDI (range) in % of ADI minimum - maximum
	6 53
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
52,7	DE child	34,5	Citrus fruit	2,4	Strawberries	1,9	Solanacea
50,1	NL child	30,5	Citrus fruit	3,3	Root and tuber vegetables	3,2	Brassica vegetables
39,9	UK Toddler	17,3	Citrus fruit	11,4	Sugar beet (root)	2,0	Root and tuber vegetables
39,5	IE adult	20,0	Citrus fruit	2,2	Brassica vegetables	2,0	Root and tuber vegetables
39,2	WHO Cluster diet B	11,7	Citrus fruit	5,8	Solanacea	4,5	Bulb vegetables
38,3	FR toddler	17,5	Citrus fruit	4,0	Root and tuber vegetables	3,6	Leek
27,1	ES child	17,6	Citrus fruit	1,7	Solanacea	1,2	Rice
27,0	SE general population 90th percentile	10,4	Citrus fruit	2,8	Root and tuber vegetables	2,8	Brassica vegetables
26,8	UK Infant	10,1	Citrus fruit	5,0	Sugar beet (root)	2,4	Root and tuber vegetables
24,3	NL general	13,9	Citrus fruit	1,8	Brassica vegetables	1,5	Root and tuber vegetables
23,6	PT General population	6,5	Brassica vegetables	5,8	Citrus fruit	2,8	Table and wine grapes
23,6	WHO cluster diet E	6,3	Citrus fruit	2,6	Root and tuber vegetables	2,1	Brassica vegetables
21,3	FR infant	7,9	Citrus fruit	3,6	Root and tuber vegetables	2,4	Strawberries
21,3	WHO regional European diet	6,1	Citrus fruit	2,5	Bulb vegetables	2,3	Root and tuber vegetables
21,2	WHO cluster diet D	3,5	Citrus fruit	3,0	Brassica vegetables	2,9	Bulb vegetables
19,7	WHO Cluster diet F	8,5	Citrus fruit	2,2	Root and tuber vegetables	1,7	Brassica vegetables
18,7	ES adult	10,9	Citrus fruit	1,5	Solanacea	1,1	Bulb vegetables
18,0	UK vegetarian	7,9	Citrus fruit	1,9	Sugar beet (root)	1,3	Bulb vegetables
15,3	FR all population	4,9	Citrus fruit	4,1	Table and wine grapes	0,8	Root and tuber vegetables
15,2	IT kids/toddler	5,5	Citrus fruit	2,4	Solanacea	1,0	Wheat
14,1	UK Adult	5,2	Citrus fruit	2,0	Sugar beet (root)	1,1	Table and wine grapes
13,4	FI adult	8,5	Citrus fruit	0,7	Root and tuber vegetables	0,7	Solanacea
13,0	IT adult	4,3	Citrus fruit	2,0	Solanacea	0,8	Lettuce and other salad plants
12,6	DK child	2,3	Citrus fruit	1,9	Root and tuber vegetables	1,4	Bulb vegetables
9,2	PL general population	2,0	Root and tuber vegetables	1,6	Bulb vegetables	1,5	Solanacea
8,6	DK adult	1,9	Citrus fruit	1,5	Table and wine grapes	1,0	Root and tuber vegetables
6,3	LT adult	1,7	Root and tuber vegetables	1,0	Solanacea	1,0	Brassica vegetables

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Difenoconazole

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,16**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Prepare workbook for refine calculations

Undo refined calculations

Explain choice of toxicological reference values.

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	16 92
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
91,5	WHO Cluster diet B	22,2	Tomatoes	10,8	Lettuce	9,0	Olives for oil production
76,3	UK Toddler	45,7	Sugar beet (root)	4,2	Tomatoes	3,9	Wheat
72,6	FR toddler	14,2	Spinach	11,0	Beans (with pods)	7,3	Carrots
69,2	NL child	7,6	Apples	7,4	Spinach	5,9	Potatoes
68,0	DE child	14,5	Apples	7,0	Tomatoes	6,3	Table grapes
61,4	IE adult	6,3	Wine grapes	4,0	Other leafy brassica	3,5	Sweet potatoes
51,9	UK Infant	20,2	Sugar beet (root)	5,7	Peas (without pods)	4,0	Carrots
50,0	WHO cluster diet E	8,0	Wine grapes	3,9	Wheat	3,8	Potatoes
49,3	FR infant	8,9	Spinach	8,4	Beans (with pods)	7,9	Carrots
48,1	WHO regional European diet	11,3	Lettuce	7,9	Tomatoes	4,0	Potatoes
45,0	ES child	12,5	Lettuce	7,1	Tomatoes	4,4	Wheat
42,0	PT General population	12,4	Wine grapes	6,4	Tomatoes	5,3	Potatoes
40,8	ES adult	16,1	Lettuce	5,6	Tomatoes	2,3	Wheat
40,0	FR all population	20,0	Wine grapes	3,3	Wheat	3,1	Tomatoes
39,5	WHO cluster diet D	7,3	Tomatoes	6,5	Wheat	4,1	Potatoes
38,4	WHO Cluster diet F	9,0	Lettuce	4,9	Tomatoes	3,6	Wheat
38,4	IT kids/toddler	10,3	Tomatoes	8,7	Lettuce	6,6	Wheat
37,8	SE general population 90th percentile	5,5	Tomatoes	4,2	Potatoes	4,0	Chinese cabbage
37,3	IT adult	11,3	Lettuce	8,4	Tomatoes	4,1	Wheat
35,7	DK child	5,5	Wheat	4,4	Rye	4,2	Lettuce
35,2	NL general	3,6	Lettuce	3,1	Wine grapes	3,1	Tomatoes
32,7	UK vegetarian	7,6	Sugar beet (root)	4,5	Tomatoes	4,2	Lettuce
30,0	UK Adult	8,0	Sugar beet (root)	5,4	Wine grapes	3,5	Lettuce
21,8	DK adult	7,0	Wine grapes	3,0	Tomatoes	2,0	Wheat
21,1	PL general population	6,4	Tomatoes	3,4	Potatoes	2,5	Apples
17,6	LT adult	4,5	Tomatoes	3,2	Potatoes	2,2	Apples
15,7	FI adult	3,1	Tomatoes	2,3	Lettuce	1,5	Wine grapes