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: 06/12/2012

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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 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	006902-00/11
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) No 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 current 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	Blanched celery (APUGD)	fungal leaf spot diseases	Authorise after change of MRL
002	Sweet fennel (FOEVA)	fungal leaf spot diseases	Authorise

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 the cultivated area of blanched celery (001) and sweet fennel (002) is about 50 ha, of which approx. 20 ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested use(s). All data are valid for open field.
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 applicant is owner of the new studies submitted and claims data protection

1.5 Letters of Access

The applicant is owner of the new studies submitted
Authorisation holder agrees to the current 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.

Mode of action (FRAC/HRAC/IRAC-Group): Difenoconazole G1, Azoxystrobin C3

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)

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)

Ecosystem protection

none

2.3 Product uses

PPP (product name/code) **ASKON (006902-00)** **Formulation type:** **SC**
active substance 1 **Difenconazol** **Conc. of as 1:** **125 g/L**
active substance 2 **Azoxystrobin** **Conc. of as 2:** **200 g/L**

Applicant: **Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen** **professional use** ☒ **non professional use** ☐

Zone(s): **central EU**

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		
001	DE	Blanched celery (APUGD)	F	Fungal leaf spot diseases	spraying	From BBCH 41 at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1 L/ha b) 1 L/ha	as1: a) 0.125 kg as/ha b) 0.125 kg/ha as2: a) 200 kg as/ha b) 200 kg as/ha	400-600	14	Restrictions (see 2.2.3.2) Registration possible after change of MRL. MRL application for 7 mg/kg is in progress. (EFSA-Q-2012-00677)

002	DE	Sweet fennel (FOEVA)	F	Fungal leaf spot diseases	spraying	From BBCH 41 at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 1 L/ha b) 1 L/ha	as1: a) 0.125 kg as/ha b) 0.125 kg/ha as2: a) 200 kg as/ha b) 200 kg as/ha	400-600	14	

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 fennel and celery are available and acceptable for enforcing residues of Azoxystrobin and 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.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substances Azoxystrobin and Difenoconazole have been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended uses in fennel and celery.

3.1.4.1 Residues

For fennel 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 and Difenoconazole.
For celery residue data do not match the GAP. The overdosed (2 applications instead of 1) trials show residues of Azoxystrobin (HR: 5.3 mg/kg) higher than the current MRL of 5 mg/kg.
A MRL application for 7 mg/kg proposed by France on basis of a more critical GAP with two applications matching the residue trials submitted with this application is in progress (November 2012) EFSA-Q-2012-00677.
Therefore a registration of this use will be possible after change of MRL.

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers results in the following maximum ADI consumptions:
TMDI calculation, EFSA PRIMo
Azoxystrobin (0.2 mg/kg bw/d) – 52,7 % (DE children)
Refined NEDI calculation, EFSA PRIMo
Difenoconazole (0.01 mg/kg bw/d) – 96,7 % (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 fennel and celery treated according to the intended uses.

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 Difenoconazol are toxic to the aquatic environment (Azoxystrobin: *Mysidopsis bahia*: EC50: 55 µg a.i./L; *O. mykiss*: LC50 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, NW468 are assigned.

Risk Assessment for Honeybees

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) applied for under the terms of Article 51 of regulation (EC) No 1107/2009.
-The categories and labelling for mode of action for the main application cover the use(s) applied for under the terms of 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 not need to be checked.

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 fennel will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues of Azoxystrobin and Difenoconazole is not expected. There is no special risk mitigation necessary which deviate from the existing registration.
For celery a registration is possible after change of MRL of Azoxystrobin to 7 mg/kg as proposed by France (EFSA-Q-2012-00677).
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

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 applicant is owner of the new studies submitted. Authorisation holder agrees to the current application to extend the authorisation.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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Mit Zustellungsurkunde

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.006902-00/11.66574
(bitte bei Antwort angeben)

DATUM 9. Januar 2013

GV1 006902-00/11

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:	16. April 2012	

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:

Dienstsitz Braunschweig
Bundesallee 50, Geb. 247
38116 Braunschweig
Tel: +49 (0)531 21497-0
Fax: +49 (0)531 21497-299

Abt. Pflanzenschutzmittel
Messeweg 11/12
38104 Braunschweig
Tel: +49 (0)531 299-5
Fax: +49 (0)531 299-3002

Dienststelle Berlin
Mauerstraße 39-42
10117 Berlin
Tel: +49 (0)30 18444-000
Fax: +49 (0)30 18444-89999

Referatsgr. Untersuchungen
Diedersdorfer Weg 1
12277 Berlin
Tel: +49 (0)30 18412-0
Fax: +49 (0)30 18412-2955

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006902-00/11-002	Pilzliche Blattfle-ckenerreger	Gemüsefenchel	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. 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):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006902-00/11-001	Pilzliche Blattfle-ckenerreger	Bleichsellerie	

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

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: 006902-00/11-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Pilzliche Blattfleckenerreger

Pflanzen/-erzeugnisse/Objekte: Gemüsefenchel

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:

Stadium der Kultur: ab 41

- Erläuterungen:

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

- Erläuterungen:

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1
- für die Kultur bzw. je Jahr: 1
- Abstand:
- Erläuterungen Anzahl Behandlungen:

Mischungspartner:

- Erläuterungen:

Anwendungstechnik: spritzen

- Erläuterungen:

Aufwand:

- 1 l/ha in 400 bis 600 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

14 Tage	Gewächshaus: Gemüsefenchel

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 2 nicht zugelassene Anwendung: 006902-00/11-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Pilzliche Blattfleckenerreger

Pflanzen/-erzeugnisse/Objekte: Bleichsellerie

Verwendungszweck:

2 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:

Stadium der Kultur: ab 41

- Erläuterungen:

Anwendungszeitpunkt: Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

- Erläuterungen:

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1
- für die Kultur bzw. je Jahr: 1
- Abstand:
- Erläuterungen Anzahl Behandlungen:

Mischungspartner:

- Erläuterungen:

Anwendungstechnik: spritzen

- Erläuterungen:

Aufwand:

- 1 l/ha in 400 bis 600 l Wasser/ha

- Erläuterungen:

Sonstige Ergänzungen und Hinweise: - keine -

3 Begründung

Rückstandsverhalten:
Die beantragte Anwendung führt im Erntegut zu Rückständen oberhalb des geltenden Rückstandshöchstgehalts für den Wirkstoff Azoxystrobin.

Ein Rückstandshöchstgehalt in ausreichender Höhe ist bei der EFSA zur Bewertung anhängig (EFSA-Q-2012-00677), so dass eine Zulassung zu einem späteren Zeitpunkt durchaus möglich erscheint. Um dann umgehend die Zulassung aussprechen zu können, empfehle ich Ihnen, termingerecht Widerspruch gegen diese Ablehnungsentscheidung einzulegen.

DRAFT 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

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Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Landwirtschaftskammer NRW - Pflanzenschutzdienst

Date: July 2012

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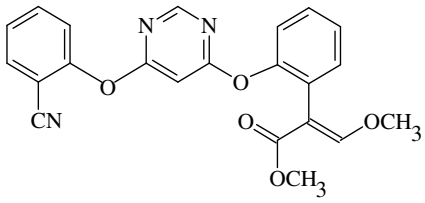
IIIA 8 METABOLISM AND RESIDUES DATA

IIIA 8.1 Evaluation of the active substances

IIIA 8.1.1 Azoxystrobin

Table IIIA 8.1-1: Information on the active substance azoxystrobin

Structural formula	
Common Name	Azoxystrobin
CAS number	131860-33-8

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) and the EFSA conclusion on the peer review (ASB2012-750).

Table IIIA 8.1-2: Stability of residues (Annex IIA, point 6.1)

Azoxystrobin and R230310	Azoxystrobin and its metabolite R230310 (Z-isomer) 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) and the EFSA conclusion on the peer review (ASB2012-750).

Table IIIA 8.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Cereals (wheat), fruit crops (grapes), oilseeds/pulses (peanuts), ^{14}C-cyanophenyl, ^{14}C-pyrimidinyl and ^{14}C-phenylacrylate labelled parent 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]. Despite of formation of several metabolites the unchanged parent substance was identified as major residue component in all matrices investigated.
Rotational crops	Wheat, radish, lettuce, application to bare soil at a rate of 2.1 kg as/ha, ^{14}C-cyanophenyl, ^{14}C-pyrimidinyl and ^{14}C-phenylacrylate labelled parent, PBI 30, 200 and 365 days The metabolism of azoxystrobin in succeeding crops is almost similar for all analysed crops and also similar to that observed in primary crops. The metabolism of azoxystrobin in rotational crops is more extensive with more metabolites being formed than in 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	Not applicable

Processed commodities (nature of residue)	No significant degradation of ^{14}C-phenylacrylate-azoxystrobin was 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) and the EFSA conclusion on the peer review (ASB2012-750).

Table IIIA 8.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

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 livestock animals 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) and the EFSA conclusion on the peer review (ASB2012-750).

Table IIIA 8.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	US field trials on wheat, millet, radish, turnip, beetroot, mustard greens and leaf lettuce, PBI 29 and 120 days, application rates 0.9-2.24 kg as/ha Residues were recalculated for EU application rates: <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). Existing MRLs for azoxystrobin (all crops) are 0.05 mg/kg or above. None of the MRLs will be exceeded as a result of the cultivation of rotational crops.

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 8.1-6: 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	–	30	–	25	0.380[a]	–	0.713	–	0.594
Fruit pomace	23.0	–	–	30	–	0.630 [b]	–	–	0.822	–
Cereal grain	86.0	70	20	–	15	0.04 [c]	0.033	0.009	–	0.007
Cereal straw	86.0	–	20	50	–	5.300 [d]	–	1.233	3.081	–
Pulses	86.0	10	–	–	–	0.010 [e]	0.001	–	–	–
Sugar beet root	20.0	20	30	20	60	0.010 [f]	0.010	0.015	0.010	0.030
			Intake (mg/kg dry weight feed)				**0.044**	**1.969**	**3.913**	**0.631**
			Intake (mg/kg bw/d)				**0.003**	**0.072**	**0.168**	**0.025**
			Intake (mg/animal/d)				**0.005**	**39.387**	**58.697**	**1.892**

[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 0.25 kg as/ha, up to BBCH 59, PHI: 35 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) and the EFSA conclusion on the peer review (ASB2012-750).

Table IIIA 8.1-7: Conditions of requirement of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	1.97 (dairy)* 3.91 (beef)* 10.39 (dairy)** 12.43 (beef)**	0.04* 1.6 **	0.63* 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)	Yes (liver only)	No	No

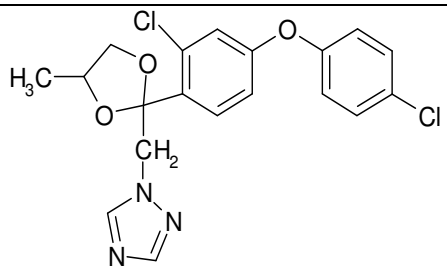
* based on nationally authorized uses in DE
** based on EU evaluation (AIR-DAR and Addendum, May/September 2009, RMS UK), worst case

Table IIIA 8.1-8: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cattle: 5, 25, 75, 250	Laying hens: 11 (from metab. study)	See ruminant
Relevant dosing levels in feeding studies (mg/kg feed dry matter)	5; 25	11	5 (ruminant)
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	0.01 (25 mg/kg feed DM) <0.01 (5 mg/kg feed DM)	<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 8.1.2 Difenoconazole

Table IIIA 8.1-9: Information on the active substance difenoconazole

Structural formula	
Common Name	Difenoconazole
CAS number	119446-68-3

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 8.1-10: Stability of residues (Annex IIA, point 6.1)

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 8.1-11: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

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	Not applicable
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 8.1-12: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

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 livestock animals 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 8.1-13: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	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 8.1-14: 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
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 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

Table IIIA 8.1-15: Conditions of requirement of livestock feeding studies (Annex IIA, point 6.4)

	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

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 8.1-16: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	1, 3, 5, 15, 50 (several cow studies)	Hen: 0.3, 1, 3, 10	See ruminant
	Relevant dosing levels in feeding study: 1 and 3 for cows, beef and pigs and 0.3 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 used for consumer intake and risk assessment is presented in Table IIIA 8.2-1.

Table IIIA 8.2-1: 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)**	**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** **min / max**		
1	DE	Celery	G	Fungal leaf spot diseases	spraying	from BBCH 41	a) 1 b) 1	a) 1.0 b) 1.0	a) 125 g as/ha difenoconazole 200 g as/ha azoxystrobin b)125 g as/ha difenoconazole 200 g as/ha azoxystrobin	400-600	14	
2	DE	Fennel	G	Fungal leaf spot diseases	spraying	from BBCH 41	a) 1 b) 1	a) 1.0 b) 1.0	a) 125 g as/ha difenoconazole 200 g as/ha azoxystrobin b)125 g as/ha difenoconazole 200 g as	400-600	14	

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 Celery/fennel

IIIA 8.2.2.1 Residues in primary crops

All supervised field trials involved two applications instead of a single treatment as envisaged. The following table gives a brief overview of the supervised residue trials in celery matching the intended PHI of 14 days and the intended amount of active substance applied per treatment (± 25%). The residue data can be extrapolated to fennel. For the detailed evaluation of new/additional residue trials, it is referred to Appendix 2.

Table IIIA 8.2-2: Overview of the selected supervised residue trials for azoxystrobin and difenoconazole in celery

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (DoR see below)	Risk assessment (DoR see below)			
celery ➔ fennel	NEU	Indoor	azoxystrobin: 0.11, 0.29, 0.63, 1.4, 1.5; 1.6, 1.9; 3.3, 5.3	azoxystrobin: 0.11, 0.29, 0.63, 1.4, 1.5; 1.6, 1.9; 3.3, 5.3	azoxystrobin: 1.5	azoxystrobin: 5.3	not applicable
celery ➔ fennel	NEU	Indoor	difenoconazole: 0.31, 0.52, 0.56, 0.83; 1.1, 1.6, 1.7, 3.2; 3.4	difenoconazole: 0.31, 0.52, 0.56, 0.83; 1.1, 1.6, 1.7, 3.2; 3.4	difenoconazole: 1.1	difenoconazole: 3.4	not applicable

Underline median value from trial results (based on DoR for risk assessment)

(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 fennel and celery are available and acceptable for enforcing residues of azoxystrobin and difenoconazole.

IIIA 8.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

IIIA 8.2.2.3 Residues in processed commodities

Azoxystrobin

The effect of processing on the nature of residue was evaluated during the EU peer review based on studies representing pasteurization, baking/brewing/boiling and sterilization conditions. Azoxystrobin was hydrolytically stable under these conditions. Thus for processed commodities the same residue definition applies as for raw agricultural products.

Specific studies to assess the magnitude of residues during the processing of celery or fennel were not provided for azoxystrobin. A processing factor of <0.29 was derived by EFSA for cooked beans in the Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin (ASB2012-750). It is expected that a similar processing factor applies for other cooked vegetables.

Difenoconazole

The effect of processing on the nature of residue was evaluated during the EU peer review based on studies representing pasteurization, baking/brewing/boiling and sterilization conditions. Difenoconazole was hydrolytically stable under these conditions. Thus for processed commodities the same residue definition applies as for raw agricultural products.

Specific studies to assess the magnitude of residues during the processing of celery or fennel were not

provided for difenoconazole. A processing factor of 0.049 was derived by EFSA for cooked carrots in the Reasoned Opinion on the modification of the existing MRLs for difenoconazole in swedes and turnips (ASB2012-3441). It is expected that a similar processing factor applies for other cooked vegetables.

IIIA 8.2.2.4 Proposed pre-harvest intervals, withholding periods

The proposed PHI of 14 days is appropriate.

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 commodities	variable	MRL	--	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 2-4 years old DE children)*
NTMDI (% ADI) according to NVS II model	67.5 % (based on 2-4 years old DE children)*
IEDI (% ADI) according to EFSA PRIMo	not required
NEDI (% ADI) according to NVS II model	not required
Factors included in IEDI and NEDI	not applicable
ARfD	not allocated
IESTI (% ARfD) according to EFSA PRIMo	not necessary
NESTI (% ARfD) according to NVS II model	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 (refined) consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment

Pome fruit	0.12	STMR, EC, 2008	na	not relevant for intended uses
Apricots	0.14	STMR, EC, 2008	na	not relevant for intended uses
Peaches	0.15	STMR, EC, 2008	na	not relevant for intended uses
Strawberries	0.14	STMR	na	not relevant for intended uses
Olives	0.47	STMR, EC, 2008	na	not relevant for intended uses
Beetroot	0.05	STMR, EC, 2008	na	not relevant for intended uses
Swedes, turnips	0.08	STMR, EC, 2008	na	not relevant for intended uses
Tomatoes	0.72	STMR, EC, 2008	na	not relevant for intended uses
Peppers	0.14	STMR, EFSA, 2010	na	not relevant for intended uses
Aubergines	0.10	STMR, EFSA, 2010	na	not relevant for intended uses
Broccoli	0.13	STMR, EFSA, 2011	na	not relevant for intended uses
Water cress	0.07	STMR, EC, 2007	na	not relevant for intended uses
Parsley, celery leaves and chervil	4.65	STMR, EFSA, 2009	na	not relevant for intended uses
Beet leaves	0.04	STMR, EFSA, 2011	na	not relevant for intended uses
Cardoons	0.83	STMR, EFSA, 2011	na	not relevant for intended uses
Globe artichokes	0.06	STMR, EFSA, 2011	na	not relevant for intended uses
Celery	5	MRL, STMR not considered, since existing MRL is not sufficient	3.4	HR (for preliminary assessment only, from overdosed trials)
Fennel	1.1	STMR (intended use)	3.4	HR
all other commodities	variable	MRL	na	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	183.6 % (based on WHO Cluster diet B)
NTMDI (% ADI) according to NVS II model	152.3 % (based on 2-4 years old DE children)
IEDI (% ADI) according to EFSA PRIMo	96.7 % (based on WHO Cluster diet B)

NEDI (% ADI) according to NVS II model	81.3 % (based on 2-4 years old DE children)
Factors included in IEDI and NEDI	STMR values as listed above
ARfD	0.16 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo	celery: 97.6 % (based on NL children, 17.1kg bw) fennel: 55.6 (based on NL adults, 63 kg bw)
NESTI (% ARfD) according to NVS II model	celery: 31% (based on DE general population) fennel: 42 % (based on DE general population)
Factors included in IESTI and NESTI	none

IIIA 8.4 Proposed maximum residue levels (MRLs)

All supervised field trials involved two applications instead of a single treatment as envisaged.

For difenoconazole the existing MRL of 5 mg/kg for celery and fennel is sufficient to cover even residues arising after two treatments. No new MRL is required.

For azoxystrobin the existing MRL of 10 mg/kg for fennel is sufficient to cover even residues arising after two treatments, but this conclusion can not be drawn for celery, where the current MRL is established at 5 mg/kg. With a HR found at 5.3 mg/kg in the (overdosed) residue trials it is not clear if the MRL will get exceeded consequent to the intended application or not. On the other hand, the available data can not be used to propose a new (higher) MRL because they do not match the critical GAP. No MRL proposal can therefore be made.

IIIA 8.5 Conclusion

For difenoconazole supervised field trials on celery showed no residues above the existing MRL of 5 mg/kg difenoconazole, even following two treatments. The trials can be extrapolated to fennel. Therefore it can also be concluded that residues of difenoconazole in fennel also comply with the established MRL of 5 mg/kg. Hence no further action is needed.

For azoxystrobin all supervised field trials involved two applications instead of a single treatment as envisaged. Residues in celery were found between 0.11 and 5.3 mg/kg at a 14 day PHI. For fennel the established MRL of 10 mg/kg for azoxystrobin is sufficient to cover residues arising from the intended uses. For celery the MRL for azoxystrobin is currently set at the level of 5 mg/kg and would get exceeded by residues arising from the intended use. In the absence of supervised field trials matching the intended GAP, no new MRL can be derived.

The intended use of azoxystrobin and difenoconazole on fennel and celery is not relevant for animal feeding purposes.

Furthermore, none of the two active substances shows a significant transfer into succeeding/rotational crops. However, triazole derivative metabolites (TDMs) may be formed in soil, consequent to application of difenoconazole. An overall assessment of triazoles is currently prepared on European level and is not further considered in the framework of the present evaluation.

The chronic and the short-term intake of azoxystrobin and difenoconazole residues is unlikely to present a public health concern.
As far as consumer health protection is concerned, BfR agrees with the authorization of the intended use 11-002 on fennel. The use 11-001 on celery is not acceptable, as it appears likely from the available residue trials that the existing MRL for azoxystrobin in celery may be breached. On the other hand these residue trials are not suitable to derive a new MRL, which would accommodate the needs of the GAP.

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** Study-Status / Usage*
OECD: KIIA 6.3	Anon.	2012	Rückstände von Difenoconazol in/auf Sellerie(Bleich-) Gewächshaus ASB2012-8358		GO1	5
OECD: KIIA 6.3	Yozgatli, H.P., Amann, S.	2011	Yozgatli, H.P., Amann, S. Azoxystrobin, Difenoconazole – residue study on protected celery in Northern France and Germany in 2009 and 2010 Northern France and Germany in 2009 and 2010 28.07.2011 S09-01459 GLP: yes unpublished ASB2012-8359		SYN	1
OECD: KIIA 6.3	Yozgatli, H.P., Breyer, N., Amann, S.	2011	Azoxystrobin, Difenoconazole – Residue study on protected celery in Spain Southern France and Italy in 2009 and 2010 S09-01460 GLP: yes unpublished ASB2012-8360		SYN	1
All	Sweden	2006	Draft Assessment Report on difenoconazole ASB2010-10465			
All	EFSA	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole. EFSA Journal 2011;9(1):1967. [71 pp.].			
All	UK	2009	Draft Assessment Report on azoxystrobin ASB2010-10494			
All	EFSA	2010	Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin. EFSA Journal 2010; 8(4):15421542. [110 pp.]. ASB2012-750			
All	EFSA	2010	EFSA Modification of the existing MRLs for difenoconazole in swedes and turnips EFSA Journal 2010; 8(2):1510. ASB2012-3441			

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

A 2.2.2 Magnitude of residues in celery

Reference:	KIIA 6.3
Report	ASB2012-8359 (for details see reference list)
Guideline(s):	Yes
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Residues of azoxystrobin in celery

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

Active ingredient : Azoxystrobin (ICI5504)
Crop / crop group : Stick Celery

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2012-05-31

Content of a.i. (g/kg or g/l) : 200 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : A13703G (submitted to GV1 **006902-00/11**)
Applicant : Landwirtschaftskammer NRW - Pflanzenschutzdienst (GO1)

Indoors / outdoors : Indoors
Other a.i. in formulation (content and common name) : 125 g/l Difenoconazole
Residues calculated as : 8.1 Azoxystrobin (ICI5504)
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)
study S09-01459, trial S09-01459-03 Germany 27632 Mulsum 2011-07-28	Artur	1) 2010-06-03 (planting) 2) 3) 2010	0.21 0.20	313 298	0.066 0.066	2010-07-28 2010-08-11[4)]	BBCH 44-45	whole plant	5.3 4.6 3.7 3.3 2.2	0.01 0.020 0.01 0.01 <0.01	0 3 7 14 21	4) spraying analytical method: RAM 305/03, max. sample storage: 10 months ASB2012-8359

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)
study S09-01459, trial S09-01459-04 France 67140 Stotzheim, Alsace 2011-07-28	Tall Utah 52/70 NT	1) 2010-06-25 (planting) 2) 3) 2010	0.20 0.23	296 342	0.066 0.067	2010-08-04 2010-08-18[4)]	BBCH 44-45	whole plant	3.7 5.3	0.13 0.22	7 14	4) spraying analytical method: RAM 305/03, max. sample storage: 10 months ASB2012-8359
study S09-01459, trial S09-01459-01 France 56860 Plouhinec 2011-07-28	Golden	1) 2009-06-24 (planting) 2) 3) 2009-10	0.21 0.19	310 283	0.066 0.067	2009-08-28 2009-09-11[4)]	BBCH 45	whole plant	1.8 2.7 1.6 0.63 0.21	0.01 0.050 0.050 0.030 0.01	0 3 7 14 21	4) spraying analytical method: RAM 305/03, max. sample storage: 21 months ASB2012-8359
study S09-01459, trial S09-01459-02 France 56860 Plouhinec 2011-07-28	Celebrity	1) 2009-06-24 (planting) 2) 3) 2009-10	0.19 0.22	283 330	0.067 0.066	2009-08-28 2009-09-11[4)]	BBCH 45	whole plant	2.4 1.3 2.3 0.29 0.040	0.030 0.030 0.070 0.020 <0.01	0 3 7 14 21	4) spraying analytical method: RAM 305/03, max. sample storage: 21 months ASB2012-8359
study S09-01459, trial S09-01459-05 France 56520 Guidel Plage 2011-07-28	Golden	1) 2010-06-29 (planting) 2) 3) 2010	0.22 0.22	223 220	0.10 0.10	2010-08-17 2010-08-31[4)]	BBCH 42-43	stalks	2.1 1.4	0.070 0.060	7 14	4) spraying analytical method: RAM 305/03, max. sample storage: 9 months ASB2012-8359

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.

Reference: KIIA 6.3

Report ASB2012-8359 (for details see reference list)

Guideline(s): Yes

Deviations: No

GLP: Yes

Acceptability: Yes

Table A 3: Residues of azoxystrobin in celery

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) : A13703G (submitted to GV1 **006902-00/11**)
Applicant : Syngenta Agro GmbH

Active ingredient : Azoxystrobin (ICI5504)
Crop / crop group : Stick Celery

Submission date : 2012-05-31

Indoors / outdoors : Indoors
Other a.i. in formulation
(content and common name) : 125 g/l Difenoconazole
Residues calculated as : 8.1 Azoxystrobin (ICI5504)
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)
study S09-01460, trial S09-01460-01 Spain 11149 Conil de la Frontera, Cadiz 2011-07-26	Imperial	1) 2009-09-14 (planting) 2) 3)	0.20 0.21	493 523	0.040 0.040	2009-11-13 2009-11-27[4)]	BBCH 45-46	whole plant	5.0 3.2 3.4 1.5 0.74	0.020 0.01 0.020 0.01 <0.01	0 3 7 14 21	4) spraying analytical method: RAM 305/03, (HPLC-MS-MS), max. sample storage: 19 months ASB2012-8360

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)
study S09-01460, trial S09-01460-02 Spain 11149 Conil de la Frontera, Cadiz 2011-07-26	Imperial	1) 2009-11-10 (planting) 2) 3)	0.19 0.20	387 497	0.050 0.040	2009-12-14 2009-12-28[4)]	BBCH 46-47	whole plant	8.5 6.0 4.5 1.4 1.9	0.030 0.030 0.040 0.020 0.030	0 3 7 14 21	4) spraying analytical method: RAM 305/03, (HPLC-MS-MS), max. sample storage: 18 months ASB2012-8360
study S09-01460, trial S09-01460-03 France 31 Haute Garonne, Midi Pyrénées 2011-07-26	Darklet	1) 2010-05-14 (planting) 2) 3)	0.19 0.21	281 314	0.066 0.066	2010-06-04 2010-06-18[4)]	BBCH 45-46	whole plant	0.28 0.11	<0.01 <0.01	7 14	4) spraying analytical methods: RAM 305/03, (HPLC-MS-MS), max. sample storage: 12 months ASB2012-8360
study S09-01460, trial S09-01460-04 Italy 4100 Latina, Lazio 2011-07-26	Octavius	1) 2010-10-01 (planting) 2) 3)	0.21 0.22	521 546	0.040 0.040	2010-12-27 2011-01-10[4)]	BBCH 45-46	whole plant	2.5 1.6	0.020 0.020	7 14	4) spraying analytical methods: RAM 305/03, (HPLC-MS-MS), max. sample storage: 5 months ASB2012-8360

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.

Reference:	KIIA 6.3
Report	ASB2012-8359 (for details see reference list)
Guideline(s):	Yes
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 4: Residues of difenoconazole in celery

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)	:	A13703G (submitted to GV1 **006902-00/11**)
Applicant		:	Landwirtschaftskammer NRW - Pflanzenschutzdienst

Active ingredient	:	Difenoconazole (CGA169374)
Crop / crop group	:	Stick Celery
Submission date	:	2012-05-31
Indoors / outdoors	:	Indoors
Other a.i. in formulation (content and common name)	:	200 g/l Azoxystrobin (ICI5504)
Residues calculated as	:	8.1 Difenoconazole (CGA169374) 8.2 Triazolyle-Alanine (TA) 8.3 Triazolyle-Acetic-Acid (TAA) 8.4 Triazole lactic acid (TLA) 8.5 1,2,4-triazole (1,2,4-T)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	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)	Residues (mg/kg)	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)
study S09-01459, trial S09-01459-03 Germany 27632 Mulsum 2011-07-28	Artur	1) 2010-06-03 (planting) 2) 3) 2010	0.13 0.12	313 298	0.041 0.042	2010-07-28 2010-08-11[4)]	BBCH 44-45	whole plant	3.9 3.1 2.5 1.7 1.3	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 0.01 0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 21	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 10 months ASB2012-8359
study S09-01459, trial S09-01459-04 France 67140 Stotzheim, Alsace 2011-07-28	Tall Utah 52/70 NT	1) 2010-06-25 (planting) 2) 3) 2010	0.12 0.14	296 342	0.041 0.042	2010-08-04 2010-08-18[4)]	BBCH 44-45	whole plant	2.6 3.4	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	7 14	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 10 months ASB2012-8359
study S09-01459, trial S09-01459-01 France 56860 Plouhinec 2011-07-28	Golden	1) 2009-06-24 (planting) 2) 3) 2009-10	0.13 0.12	310 283	0.042 0.042	2009-08-28 2009-09-11[4)]	BBCH 45	whole plant	1.2 1.9 1.4 0.52 0.35	0.030 0.01 0.020 0.030 0.030	<0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 0.020 0.020 0.030	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 21	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 21 months ASB2012-8359
study S09-01459, trial S09-01459-02 France 56860 Plouhinec 2011-07-28	Celebrity	1) 2009-06-24 (planting) 2) 3) 2009-10	0.12 0.14	283 330	0.042 0.042	2009-08-28 2009-09-11[4)]	BBCH 45	whole plant	2.2 0.95 1.8 0.56 0.070	<0.01 0.030 <0.01 <0.01 0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.020 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 21	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 21 months ASB2012-8359

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	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)	Residues (mg/kg)	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)
study S09-01459, trial S09-01459-05 France 56520 Guidel Plage 2011-07-28	Golden	1) 2010-06-29 (planting) 2) 3) 2010	0.14 0.14	223 220	0.062 0.062	2010-08-17 2010-08-31[4)]	BBCH 42-43	stalks	1.7 1.1	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	7 14	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 9 months ASB2012-8359

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.

Reference:	KIIA 6.3
Report	ASB2012-8360 (for details see reference list)
Guideline(s):	Yes
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 5: Residues of difenoconazole in celery

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)	:	A13703G (submitted to GV1 **006902-00/11**)
Applicant		:	Syngenta Agro GmbH

Active ingredient	:	Difenoconazole (CGA169374)
Crop / crop group	:	Stick Celery
Submission date	:	2012-05-31
Indoors / outdoors	:	Indoors
Other a.i. in formulation (content and common name)	:	200 g/l Azoxystrobin (ICI5504)
Residues calculated as	:	8.1 Difenoconazole (CGA169374) 8.2 Triazolyle-Alanine (TA) 8.3 Triazolyle-Acetic-Acid (TAA) 8.4 Triazole lactic acid (TLA) 8.5 1,2,4-triazole (1,2,4-T)

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	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)	Residues (mg/kg)	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)
study S09-01460, trial S09-01460-01 Spain 11149 Conil de la Frontera, Cadiz 2011-07-26	Imperial	1) 2009-09-14 (planting) 2) 3)	0.12 0.13	493 523	0.025 0.025	2009-11-13 2009-11-27[4)]	BBCH 45-46	whole plant	3.1 1.9 2.1 <u>0.83</u> 0.41	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 21	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 19 months ASB2012-8360
study S09-01460, trial S09-01460-02 Spain 11149 Conil de la Frontera, Cadiz 2011-07-26	Imperial	1) 2009-11-10 (planting) 2) 3)	0.12 0.12	387 497	0.031 0.025	2009-12-14 2009-12-28[4)]	BBCH 46-47	whole plant	5.8 3.6 3.0 <u>3.2</u> 1.0	0.020 0.01 0.01 0.020 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01	0 3 7 14 21	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 18 months ASB2012-8360
study S09-01460, trial S09-01460-03 France 31 Haute Garonne, Midi Pyrénées 2011-07-26	Darklet	1) 2010-05-14 (planting) 2) 3)	0.12 0.13	281 314	0.042 0.042	2010-06-04 2010-06-18[4)]	BBCH 45-46	whole plant	0.51 <u>0.31</u>	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	7 14	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), max. sample storage: 12 months ASB2012-8360

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	8.5	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)	Residues (mg/kg)	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)
study S09-01460, trial S09-01460-04 Italy 4100 Latina, Lazio 2011-07-26	Octavius	1) 2010-10-01 (planting) 2) 3)	0.13 0.14	521 546	0.025 0.025	2010-12-27 2011-01-10[4)]	BBCH 45-46	whole plant	2.5 1.6	0.01 0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	7 14	4) spraying analytical methods: REM 147.08 (HPLC-MS-MS), Triazole: GRM053.01A, (HPLC-HPLC-MS-MS), , blind value Triazole alanine 0.02 mg/kg, max. sample storage: 5 months ASB2012-8360

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 new study on residues in processed commodities has been submitted/(and) none is needed due to low residues at harvest.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (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:	**peer review**	Source of ARfD:	**peer review**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

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	pTMRLs at LOQ (in % of ADI)
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	WHO cluster diet E	6,3	Citrus fruit	2,6	Root and tuber vegetables	2,1	Brassica vegetables	
23,6	PT General population	6,5	Brassica vegetables	5,8	Citrus fruit	2,8	Table and wine grapes	
21,3	WHO regional European diet	6,1	Citrus fruit	2,5	Bulb vegetables	2,3	Root and tuber vegetables	
21,3	FR infant	7,9	Citrus fruit	3,6	Root and tuber vegetables	2,4	Strawberries	
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	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

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:	

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 97

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	pTMRLs at LOQ (in % of ADI)
96,7	WHO Cluster diet B	22,2	Tomatoes	10,8	Lettuce	9,0	Olives for oil production	
78,1	UK Toddler	45,7	Sugar beet (root)	4,2	Tomatoes	3,9	Wheat	
74,6	DE child	14,5	Apples	8,7	Herbal infusions (dried)	7,0	Tomatoes	
71,3	FR toddler	14,2	Spinach	11,0	Beans (with pods)	7,3	Carrots	
70,1	NL child	7,6	Apples	7,4	Spinach	5,9	Potatoes	
67,9	IE adult	6,4	Celery	6,3	Wine grapes	4,0	Other leafy brassica	
52,9	WHO cluster diet E	8,0	Wine grapes	3,9	Wheat	3,8	Potatoes	
52,4	UK Infant	20,2	Sugar beet (root)	5,7	Peas (without pods)	4,0	Carrots	
50,6	WHO regional European diet	11,3	Lettuce	7,9	Tomatoes	4,0	Potatoes	
48,7	FR infant	8,9	Spinach	8,4	Beans (with pods)	7,9	Carrots	
45,9	ES child	12,5	Lettuce	7,1	Tomatoes	4,4	Wheat	
43,4	PT General population	12,4	Wine grapes	6,4	Tomatoes	5,3	Potatoes	
42,8	WHO cluster diet D	7,3	Tomatoes	6,5	Wheat	4,1	Potatoes	
41,8	ES adult	16,1	Lettuce	5,6	Tomatoes	2,3	Wheat	
41,2	FR all population	20,0	Wine grapes	3,3	Wheat	3,1	Tomatoes	
40,0	IT kids/toddler	10,3	Tomatoes	8,7	Lettuce	6,6	Wheat	
40,0	WHO Cluster diet F	9,0	Lettuce	4,9	Tomatoes	3,6	Wheat	
38,3	SE general population 90th percentile	5,5	Tomatoes	4,2	Potatoes	4,0	Chinese cabbage	
38,1	IT adult	11,3	Lettuce	8,4	Tomatoes	4,1	Wheat	
37,6	DK child	5,5	Wheat	4,4	Rye	4,2	Lettuce	
36,5	NL general	3,6	Lettuce	3,1	Wine grapes	3,1	Tomatoes	
34,8	UK vegetarian	7,6	Sugar beet (root)	4,5	Tomatoes	4,2	Lettuce	
31,0	UK Adult	8,0	Sugar beet (root)	5,4	Wine grapes	3,5	Lettuce	
22,3	DK adult	7,0	Wine grapes	3,0	Tomatoes	2,0	Wheat	
21,4	PL general population	6,4	Tomatoes	3,4	Potatoes	2,5	Apples	
18,1	LT adult	4,5	Tomatoes	3,2	Potatoes	2,2	Apples	
15,9	FI adult	3,1	Tomatoes	2,3	Lettuce	1,5	Wine grapes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Difenoconazole is unlikely to present a public health concern.