Art. 51
Extension of authorisation for minor uses

REGISTRATION REPORT
Part A

Risk Management

Product code: ASKON

Active Substances:

Difenoconazole 125 g/L and Azoxystrobin 200 g/L

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Pflanzenschutzdienst der Landwirtschaftskammer Nordrhein-Westfalen

Date: 19/07/2012

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PART A – Risk Management

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

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	006902-00/07
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

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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)

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
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

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	Aubergine, Tomato	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 cultivated area of aubergine and tomato is about 324 ha, there from worth to treat are 130 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 current application to extend the authorisation.

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2 Details of the authorisation

2.1 Product identity

Product name	ASKON
Authorisation number	006902-00
Composition	Difenoconazole 125 g/L; Azoxystrobin 200 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 51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
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

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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)

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

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.

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2.3 Product uses

PPP (product name/code) **ASKON**
active substance 1 **Difenconazol**
active substance 2 **Azoxystrobin**
Zone(s): **northern/central/southern/EU**

Formulation type: **SC**
Conc. of as 1: **125 g/L**
Conc. of as 2: **200 g/L**
professional use **x**
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		
001	DE	aubergine (SOLME) tomato (LYPES)	G	Fungal leaf spot diseases (FXBFXX)	spraying	from BBCH-Code 19 at beginning of infestation and/or when first symptoms become visible	2 2 (10 to 14 days)	a) 1 L/ha b) 2 L/ha	a.s.1 a) 125 g/L b) 200 g/L a.s.2 a) 250 g/L b) 400 g/L	600 - 900	3	plant height < 50 cm: 0.75 L/ha in 600 L/ha water plant height 50 - 125 cm: 1 L/ha in 900 L/ha water Restrictions (see 2.2.3.2) SS2202

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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 tomatoes and aubergine are available and acceptable for enforcing Azoxystrobin.

Analytical methods for commodities of high water content such as tomatoes or aubergines 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 a previous dRR (006902-00/06). 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 tomatoes and aubergine.

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 (3 mg/kg tomatoes and aubergine) and Difenoconazole (2 mg/kg tomatoes and 0.4 mg/kg aubergine).

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)

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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 tomatoes or aubergines 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 (Azoxystrobin: *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 tomatoes or aubergines 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.
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.

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

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Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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IHR ZEICHEN
IHRE NACHRICHT VOM
AKTENZEICHEN 200.22200.006902-00/07.53975
(bitte bei Antwort angeben)

DATUM 17. Juli 2012

GV1 006902-00/07

ASKON

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

mit den Wirkstoffen:	200 g/l Azoxystrobin; 125 g/l Difenoconazol
Zulassungsnummer	006902-00
Versuchsbezeichnung:	SYD-21680-F-0-SC
Genehmigung	GV1 006902-00 vom 05. Juli 2011 in der Fassung der Änderungsbescheide vom 26. März 2012, 20. Juni 2012
Ihr Antrag vom	27. Juni 2011

Die Zulassung des oben genannten Pflanzenschutzmittels wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 um folgende Anwendungsgebiete erweitert:

Schadorganismus/ Zweckbestimmung	Pflanzen/ -erzeugnisse/Objekte	Anwendungsnummer
Pilzliche Blattfleckenerreger	Aubergine, Tomate	006902-00/07-001

Folgende Auflagen werden gemäß § 36 Abs. 3 S. 1 PflSchG erteilt:

Siehe anwendungsbezogene Auflage in Anlage 1, unter 3.

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.

Im Auftrag

gez.

Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

Anlage

Dieses Schreiben ist maschinell gefertigt und daher ohne Unterschrift gültig.

Anlage 1 genehmigte Anwendung: 006902-00/07-001

1 Anwendungsgebiet:

Schadorganismus/Zweckbestimmung	Pilzliche Blattfleckenerreger
Pflanzen/-erzeugnisse/Objekte	Aubergine, Tomate

2 Einsatzgebiet: Gemüsebau

3 Kennzeichnungsauflagen:

3.1 Angaben zur sachgerechten Anwendung:

Anwendungsbereich	Gewächshaus
Stadium der Kultur	ab 19
Anwendungszeitpunkt	Bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung	2
- für die Kultur bzw. je Jahr	2
- Abstand	10 bis 14 Tage
Anwendungstechnik	spritzen
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

3.2 Sonstige Kennzeichnungsauflagen:

- keine -

3.3 Wartezeiten:

3 Tage	Gewächshaus: Aubergine, Tomate

4 Anwendungsbezogene Anwendungsbestimmungen:

- keine -

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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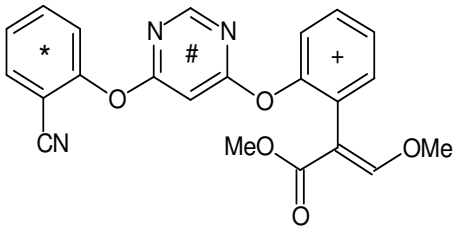
IIIA 8 METABOLISM AND RESIDUES DATA

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

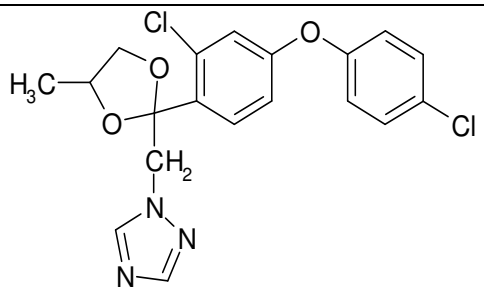
* based on EU evaluation (AIR-DAR and Addendum, May/September 2009, RMS UK)

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 8.1.2-1: 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 tomato and aubergine 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 8.2-1: 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)**	**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	Aubergine, Tomato	G	Fungal 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)	Difenoconazole (kg as/ha)	Azoxystrobin (kg as/ha)	Water (l/ha)	Difenoconazole (kg as/hl)	Azoxystrobin (kg as/hl)
up to 50 cm	0.75	0.094	0.15	600	0.014-0.016	0.022-0.025
50 cm up to 125 cm	1.0	0.125	0.2	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 Aubergine, Tomatoe

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 indoor grown tomatoes. All supervised field trials available are overdosed by the number of applications and in some cases conducted with higher application rates as intended. However, resulting residues in mature fruits are all below the established MRLs for azoxystrobin in tomato and aubergine, allowing an assessment of the MRL compliance and a calculation of the dietary intake.
According to the current guidance for extrapolation (SANCO 9525/VI/95 rev.9) supervised field trial data on tomatoes may be used for the evaluation of aubergines. 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 tomatoes

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)			
Tomato	DE	Indoor	0.08; 0.14; 0.21(2); 0.28; 0.33(2); 0.36; 0.42; 0.47; 0.49; 0.54(2); 0.69(2); 0.84; 1.2 mg/kg	0.08; 0.14; 0.21(2); 0.28; 0.33(2); 0.36; 0.42; 0.47; 0.49; 0.54(2); 0.69(2); 0.84; 1.2 mg/kg	0.42	1.2	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 tomatoes and aubergine 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 indoor grown tomatoes. All supervised field trials available are overdosed by the number of applications.
According to the current guidance for extrapolation (SANCO 9525/VI/95 rev.9) supervised field trial data on tomatoes may be used for the evaluation of aubergines. 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 tomatoes

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*)			
Tomato	DE	Indoor	0.04; 0.07; 0.08(2); 0.1(3); 0.12, 0.46 mg/kg	0.04; 0.07; 0.08(2); 0.1(3); 0.12, 0.46 mg/kg	0.1	0.46	1

* 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 enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement 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 tomatoes or aubergines are available and acceptable for enforcing difenoconazole.

IIIA 8.2.2.2 Residues in processed commodities

Azoxystrobin

The following table gives a brief overview of the results of processing studies for azoxystrobin in tomato. For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

Table IIIA 8.2.2.2-1: Overview of the available processing studies for azoxystrobin in tomato

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF [(a)]	Median CF [(b)]	Comments
Fruit, washed	2	0.64, 0.71	0.675	1	
Juice	2	0.29, 0.36	0.325	1	
Puree	2	0.55, 1.4	0.975	1	
Preserves	2	<0.09, <0.14	<0.115	1	
Ketchup	2	0.36, 0.57	0.465	1	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Difenoconazole

The following table gives a brief overview of the results of processing studies for difenoconazole in tomato. For the detailed evaluation of new/additional residue trials it is referred to Appendix 2.

Table IIIA 8.2.2.2-2: Overview of the available processing studies for difenoconazole in tomato

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF [(a)]	Median CF [(b)]	Comments
Fruit, washed	1	0.5, 0.68, 0.72, 0.81	0.7	1	
Juice, pasteurized	4	0.18, 0.18, 0.23, 0.27	0.205	1	
Puree, sterilized	4	0.64, 0.68, 0.68, 0.81	0.68	1	
Preserves, sterilized	4	0.045, 0.045, 0.09, 0.09	0.0675	1	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

IIIA 8.2.2.3 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 8.3.1-1 and the toxicological reference values stated in Table IIIA 8.3.1-2. For the detailed calculation results it is referred to Appendix 3.
Processing factors were not included in the dietary intake assessment, since no concentration of residues was observed in processed commodities.

Table IIIA 8.3.1-1: 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	n.n.	not ARfD necessary

Table IIIA 8.3.1-2: 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 8.3.2-1 and the toxicological reference values stated in Table IIIA 8.3.2-2. For the detailed calculation results it is referred to Appendix 3.
Processing factors were not included in the dietary intake assessment, since no concentration of residues was observed in processed commodities.

Table IIIA 8.3.2-1: 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
Tomato	0.1	STMR	0.46	HR
Aubergine	0.1	STMR	0.46	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
Cucurbits with edible peel	0.01	STMR		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 8.3.2-2: 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)	Tomato: 72.7 % (based on BE child) Aubergine: 7.2 % (based on UK children, 4-6 years)
NESTI (NVS II model) (% ARfD)	Tomato: 14 % (based on 2- <5 year old DE children) Aubergine: 6 % (based on DE General population)
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: Tomato (0231010), Aubergine (0231030)	3	n.n.	n.n.	Existing MRL sufficient, HR: 1.2 mg/kg
Difenoconazole: Tomato (0231010)	2	n.n.	n.n.	Existing MRL sufficient, HR: 0.46 mg/kg
Difenoconazole: Aubergine (0231030)	0.4	n.n.	n.n.	Existing MRL sufficient, HR: 0.46 mg/kg Supervised trials were over-dosed (higher number of applications). Since only one single value was above the MRL and the rest far below (0.04-0.12 mg/kg), compliance with the existing MRL is assumed.

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 of 3 mg/kg for tomato and aubergine.
For difenoconazole, one single residue value (0.46 mg/kg) slightly exceeded the MRL of 0.4 mg/kg for aubergine. However, since the corresponding field trial was conducted with a higher number of applications, MRL compliance at cGAP conditions is assumed. For difenoconazole in tomatoes the MRL of 2 mg/kg is also considered sufficient.
The use of azoxystrobin and difenoconazole on tomatoes and aubergines 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 intended uses comply with existing EU MRLs for azoxystrobin and difenoconazole. 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	Sapiets, A.; Clarke, D.; Barnard, C.	1997	Residue levels in tomatoes from trials conducted in France during 1996 Syngenta RJ2294B RIP9800951		SYD	Used
OECD: KIIA 6.3	Clarke, D. M.; Bonfanti, F.	1998	Residue levels in tomatoes and process fractions from trials carried out in Italy Syngenta RJ2488B RIP9800954		SYD	Used
OECD: KIIA 6.3	Clarke, D. M.; Gallardo, E.	1998	Residue levels in tomatoes from trials carried out in Spain during 1997 Syngenta RJ2490B RIP9800957		SYD	Used
OECD: KIIA 6.3	Clarke, D. M.; Renard, C.	1998	Residue levels in glasshouse tomatoes from trials carried out in France during 1997 Syngenta RJ2489B RIP9800958		SYD	Used
OECD: KIIA 6.3	Gill, J. P.; Chamier, O. D.	1998	Residue levels in indoor tomatoes from a study carried out in Germany during 1997 Syngenta RJ2478B RIP9800959		SYD	Used
OECD: KIIA 6.3	Clarke, D. M.; Bouwman, J. J.	1998	Residue levels in glasshouse tomatoes from a trial carried out in the Netherlands during 1997 Syngenta RJ2552B RIP9800961		SYD	Used
OECD: KIIA 6.3	Clarke, D. M.; Bouwman, J. J.	1998	Residue levels in glasshouse tomatoes from glasshouse trials carried out in the Netherlands during 1997 Syngenta RJ2559B RIP9800963		SYD	Used
OECD: KIIA 6.3	Solé, C.	2002	Residue study with Difenoconazole (CGA169374) in or on tomatoes in Greece ; Amendment to the final report of study 2021/01, Amendment No. 1 Syngenta		SYD	Used

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
			2021/01 ASB2011-12607			
OECD: KIIA 6.3	Bour, D.	2006	Difenoconazole (CGA169374): Residue study on protected tomatoes in Northern France and the United Kingdom Syngenta 05-0414 ASB2011-12608		SYD	Used
OECD: KIIA 6.3	Bour, D.	2006	Difenoconazole (CGA169374): Residue study on protected tomatoes in Southern France and Spain Syngenta 05-0413 ASB2011-12609		SYD	Used
OECD: KIIA 6.3	Royer, A.	2007	Difenoconazole (CGA169374): Residue study on protected tomatoes in Switzerland in 2006 Syngenta T000699-06 ASB2011-12610		SYD	Used
OECD: KIIA 6.3	Royer, A.	2007	Difenoconazole (CGA169374): Residue study on protected tomatoes in Spain in 2006 Syngenta T000698-06 ASB2011-12611		SYD	Used
OECD: KIIA 6.5	Clarke, D. M.; Bonfanti, F.	1998	Residue levels in tomatoes and process fractions from trials carried out in Italy Syngenta RJ2488B RIP9800954		SYD	Used
OECD: KIIA 6.5	Ryan, J.	2006	Difenoconazole (CGA169374): Residue study in or on outdoor tomatoes and processed fraction in France (South) Syngenta 04-6049 ASB2011-12612		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 in tomatoes

Reference:	RIP9800951, RIP9800959, RIP9800954, RIP9800958, RIP9800957, RIP9800961, RIP9800963
Report	Residue studies with Azoxystrobin in or on indoor grown tomatoes
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) : SC
Commercial product (name) : Ortiva **004560-00**
Applicant : Syngenta Agro GmbH

Active ingredient : Azoxystrobin
Crop / crop group : Tomato

Submission date : 1998-08-17

Indoors / outdoors : Indoors
Other a. i. in formulation (common name and content) :
Residues calculated as : 8.1 Azoxystrobin
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)
RJ2294B, S213.96	Ondina	1) 1996-05-10 (planting)	0.13 0.13	520 520	0.025 0.025	1996-06-14 1996-06-21	BBCH 71-75	fruit green	0.10 0.12	<0.01 <0.01	0 1	analytical method: SOP RAM

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 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)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
FR-27800 Brionne, Haute-Nomandie 1997-05-19		2) 1996-06-14 - 1996-07-12 3) 1996-07-29	0.13 0.13 0.13 0.13 0.13	520 520 520 520 520	0.025 0.025 0.025 0.025 0.025	1996-06-28 1996-07-05 1996-07-12 1996-07-19 1996-07-26		fruit, ripe	0.08 0.06 0.06	<0.01 <0.01 <0.01	3 7 10	243/04 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800951
RJ2478B, RS-9702-G1 D-84030 Landshut, Bavaria 1998-05-06	Matador	1) 1997-04-28 (planting) 2) -- 3) --	0.50 0.50 0.50 0.50	2500 2500 2500 2500	0.020 0.020 0.020 0.020	1997-07-02 1997-07-10 1997-07-18 1997-07-28	BBCH 81	fruit	1.2 1.2 1.3 0.95 1.2	0.01 0.01 0.02 0.01 0.02	0 1 2 3 5	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP9800959
RJ2478B, RS-9702-K1 D-03058 Groß Gaglow Brandbg. 1998-05-06	Pannory	1) 1997-03-13 (planting) 2) -- 3) --	0.50 0.50 0.50 0.50	2500 2500 2500 2500	0.020 0.020 0.020 0.020	1997-05-13 1997-05-21 1997-05-30 1997-06-09	BBCH 73	fruit	0.38 0.38 0.41 0.33 0.33	<0.01 <0.01 <0.01 <0.01 <0.01	0 1 2 3 5	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP9800959
RJ2488B, IT51-97-P319 IT-71043 Manfredonia Puglia 1998-06-02	Galaxy	1) 1997-02-04 (planting) 2) -- 3) --	0.25 0.35 0.40 0.40 0.45 0.45	1000 1400 1600 1600 1800 1800	0.025 0.025 0.025 0.025 0.025 0.025	1997-03-20 1997-03-28 1997-04-05 1997-04-14 1997-04-23 1997-05-02	BBCH 74	fruit	0.33 0.32 0.27	0.01 <0.01 <0.01	3 7 10	analytical method: SOP RAM 243/04 and /05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP9800954

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)
RJ2489B, S215.97 FR-27800 Brionne, Normandie 1998-06-02	Tradiro	1) 1997-05-13 (planting) 2) -- 3) --	0.25 0.25 0.25 0.25 0.25 0.25	1000 1000 1000 1000 1000 1000	0.025 0.025 0.025 0.025 0.025 0.025	1997-06-23 1997-06-30 1997-07-08 1997-07-16 1997-07-24 1997-08-01	BBCH 75	fruit	0.21 0.19	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958
RJ2489B, S215.97 Part:2 FR-27800 Brionne, Normandie 1998-06-02	Tradiro	1) 1997-05-13 (planting) 2) -- 3) --	0.28 0.28 0.30 0.30 0.33 0.33	1100 1100 1200 1200 1300 1300	0.025 0.025 0.025 0.025 0.025 0.025	1997-06-23 1997-06-30 1997-07-08 1997-07-16 1997-07-24 1997-08-01	BBCH 75	fruit	0.54 0.33	0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958
RJ2489B, S622.97 FR-37510 Saint Genouph Loire-Valley 1998-06-02	Paola	1) 1997-03-27 (planting) 2) -- 3) --	0.25 0.25 0.25 0.25 0.25 0.25	1000 1000 1000 1000 1000 1000	0.025 0.025 0.025 0.025 0.025 0.025	1997-05-20 1997-05-28 1997-06-04 1997-06-11 1997-06-19 1997-06-27	BBCH 75	fruit	0.14 0.08	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958
RJ2489B, S622.97 Part:2 FR-37510 Saint Genouph Loire-Valley 1998-06-02	Paola	1) 1997-03-27 (planting) 2) -- 3) --	0.30 0.31 0.33 0.34 0.35 0.38	1200 1250 1300 1350 1400 1500	0.025 0.025 0.025 0.025 0.025 0.025	1997-05-20 1997-05-28 1997-06-04 1997-06-11 1997-06-19 1997-06-27	BBCH 75	fruit	0.21 0.15	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958

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)
RJ2489B, S623.97 FR-37700 St. Pierre des Corps Loire-Valley 1998-06-02	Sweet Cherry	1) 1997-06-07 (planting) 2) -- 3) --	0.25 0.25 0.25 0.25 0.25 0.25	1000 1000 1000 1000 1000 1000	0.025 0.025 0.025 0.025 0.025 0.025	1997-07-12 1997-07-21 1997-07-29 1997-08-06 1997-08-14 1997-08-22	BBCH 77-78	fruit	0.49 0.43	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958
RJ2489B, S623.97 Part:2 FR-37700 St. Pierre des Corps Loire-Valley 1998-06-02	Sweet Cherry	1) 1997-06-07 (planting) 2) -- 3) --	0.30 0.31 0.34 0.36 0.40 0.43	1200 1250 1350 1450 1600 1700	0.025 0.025 0.025 0.025 0.025 0.025	1997-07-12 1997-07-21 1997-07-29 1997-08-06 1997-08-14 1997-08-22	BBCH 77-78	fruit	0.84 0.73	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months RIP9800958
RJ2490B, ES10-97SP001 ES-04113 Nijar, Almeria 1998-06-02	Gabriela	1) 1996-10-24 (planting) 2) -- 3) 1997-04-25	0.17 0.26 0.24 0.29 0.32 0.32	688 1047 953 1172 1275 1300	0.025 0.025 0.025 0.025 0.025 0.025	1997-03-18 1997-03-25 1997-04-02 1997-04-11 1997-04-18 1997-04-25	BBCH 87-89	fruit	0.51 0.69 0.35 0.51	0.02 0.02 0.01 0.01	0 3 7 10	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 9 months RIP9800957
RJ2490B, ES10-97SP001 Part:2 ES-04113 Nijar, Almeria 1998-06-02	Gabriela	1) 1996-10-24 (planting) 2) -- 3) 1997-04-25	0.17 0.21 0.21 0.21 0.27 0.26	688 828 844 853 1078 1044	0.025 0.025 0.025 0.025 0.025 0.025	1997-03-18 1997-03-25 1997-04-02 1997-04-11 1997-04-18 1997-04-25	BBCH 87-89	fruit	0.39 0.40 0.32 0.42	<0.01 0.01 <0.01 0.01	0 3 7 10	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 9 months RIP9800957

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)
RJ2490B, ES10-97SP101 ES-04113 Nijar, Almeria 1998-06-02	Gabriela	1) 1996-10-24 (planting) 2) -- 3) 1997-04-25	0.17 0.21 0.25 0.30 0.33 0.32	672 859 997 1201 1319 1291	0.025 0.025 0.025 0.025 0.025 0.025	1997-03-18 1997-03-25 1997-04-02 1997-04-11 1997-04-18 1997-04-25	BBCH 87-89	fruit,	0.42 <u>0.54</u> 0.41 0.43	<0.01 0.01 0.01 0.01	0 3 7 10	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 9 months <u>RIP9800957</u>
RJ2490B, ES1097SP101 Part:2 ES-04113 Nijar, Almeria 1998-06-02	Gabriela	1) 1996-10-24 (planting) 2) -- 3) 1997-04-25	0.17 0.22 0.19 0.21 0.27 0.23	688 884 754 853 1088 903	0.025 0.025 0.025 0.025 0.025 0.025	1997-03-18 1997-03-25 1997-04-02 1997-04-11 1997-04-18 1997-04-25	BBCH 87-89	fruit	0.48 <u>0.36</u> 0.34 0.32	<0.01 0.01 <0.01 <0.01	0 3 7 10	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 9 months <u>RIP9800957</u>
RJ2552B, NL10-97-P519 NL-Bospolder 39 Honselersdijk 1998-05-28	Favorita (cherry tomato)	1) 1996-12-01 (planting) 2) -- 3) --	0.42 0.49 0.52 0.45 0.44 0.47	1661 1939 2082 1796 1754 1896	0.025 0.025 0.025 0.025 0.025 0.025	1997-07-01 1997-07-09 1997-07-17 1997-07-25 1997-08-02 1997-08-11	BBCH 80-81	fruit	0.24 <u>0.28</u>	<0.01 <0.01	3 7	analytical method: SOP RAM 243/05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 3 months <u>RIP9800961</u>
RJ2559B, NL10-97-P127 NL-1695 GK Blokker, West of The Netherlands 1998-06-05	Aromata	1) 1996-12-10 (planting) 2) -- 3) 1997-05-16	0.70 0.93 0.58 0.87 0.83 0.77	2862 3805 2385 3538 3400 3149	0.025 0.025 0.024 0.025 0.025 0.025	1997-05-01 1997-05-09 1997-05-16 1997-05-24 1997-06-02 1997-06-09	BBCH 81-83	fruit	0.65 0.57 <u>0.69</u> 0.55 0.49	0.02 <0.01 0.03 <0.01 <0.01	0 1 3 7 9	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months <u>RIP9800963</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)
RJ2559B, NL10-97-P128 NL-1852 RH Heiloo, West of The Netherlands 1998-06-05	Cheetah	1) 1997-03-27 (planting) 2) -- 3) 1997-05-24	0.54 0.47 0.65 0.56 0.55 0.51	1991 1731 2389 2065 2037 1875	0.027 0.027 0.027 0.027 0.027 0.027	1997-05-09 1997-05-16 1997-05-24 1997-06-02 1997-06-09 1997-06-17	BBCH 81-83	fruit	0.37 0.42 0.43 <u>0.47</u> 0.32	0.01 <0.01 <0.01 <0.01 <0.01	0 1 3 7 10	 analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 4 months <u>RIP9800963</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 in tomatoes

Reference:	ASB2011-12607, ASB2011-12608, ASB2011-12609, ASB2011-12610, ASB2011-12611
Report	Residue studies with Difenoconazole (CGA169374) in or on indoor grown tomatoes
Guideline(s):	Yes (EU Guidance for 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) : A7402T, EC (submitted to *GV1* **006902-00/07**) treated with formulation A7402T, EC 250
Applicant : Syngenta Agro GmbH

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

Submission date : 2011-10-28

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)
T000698-06-REG, study T000698-06, trial ES-FR-06-0100 Spain 04745 Almeria 2007-10-26	Tibet	1) 2006-01-26 (planting) 2) 3) 2006-04	0.12 0.13 0.12	1134 1231 1194	0.010 0.010 0.010	2006-05-26 2006-06-02 2006-06-09[4)]	BBCH 88	fruit	0.070	3	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months ASB2011-12611

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)
T000698-06-REG, study T000698-06, trial ES-FR-06-0101 Spain 41720 Sevilla 2007-10-26	Bond	1) 2006-02-03 (planting) 2) 2006-03-10 3) 2006-06	0.13 0.12 0.13	1004 960 1064	0.012 0.013 0.012	2006-05-25 2006-06-01 2006-06-09[4)]	BBCH 81	fruit	0.10	3	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months ASB2011-12611
T000699-06-REG, study T000699-06, trial CH-FR-06-0218 Switzerland 1926 Fully / VS 2007-11-21	Migello	1) 2006-03-14 (planting) 2) 3) 2006-07	0.14 0.12 0.14	1090 960 1070	0.013 0.013 0.013	2006-05-24 2006-06-01 2006-06-09[4)]	BBCH 74-82	fruit	0.080	3	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 4 months ASB2011-12610
T000699-06-REG, study T000699-06, trial CH-FR-06-0219 Switzerland 1926 Fully / VS 2007-11-21	Petula	1) 2006-04-01 (planting) 2) 3) 2006-07	0.13 0.13 0.13	1240 1210 1220	0.010 0.010 0.010	2006-06-14 2006-06-22 2006-06-30[4)]	BBCH 69-85	fruit	0.080	3	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months ASB2011-12610
05-0413, study 05-0413, trial AF/8578/SY1 France 82370 Orgueil 2006-05-11	Brenda	1) 2005-06-15 (planting) 2) 3) 2005-09	0.13 0.13 0.13	1000 1067 981	0.013 0.012 0.013	2005-08-11 2005-08-19 2005-08-29[4)]	BBCH 79	fruit	0.050 0.040 0.060 0.10 0.050	0[5)] 0 1 3 7	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 2 months ASB2011-12609

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)
05-0413, study 05-0413, trial AF/8578/SY2 Spain 41920 Los Palacios 2006-05-11	Dici	1) 2005-02-10 (planting) 2) 3) 2005-06	0.13 0.13 0.13	1000 988 973	0.013 0.013 0.013	2005-05-24 2005-06-03 2005-06-13[4)]	BBCH 75	fruit	0.070 0.16 0.16 0.12 0.12	0[5)] 0 1 3 7	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months ASB2011-12609
05-0414, study 05-0414, trial AF/8577/SY1 United Kingdom TF6 5EW Charlton, Shropshire 2006-05-15	Espiro	1) 2005-05-01 (planting) 2) 3) 2005-08	0.13 0.13 0.13	1025 1038 1038	0.012 0.012 0.012	2005-07-15 2005-07-23 2005-08-01[4)]	BBCH 81-85	fruit	0.11 0.11 0.13 0.090 0.10	0[5)] 0 1 3 7	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 2 months ASB2011-12608
05-0414, study 05-0414, trial AF/8577/SY2 France 49650 Allonnes 2006-05-15	Belle	1) 2005-04-05 (planting) 2) 3) 2005-07	0.13 0.13 0.13	1000 1016 1011	0.013 0.012 0.012	2005-06-20 2005-06-28 2005-07-06[4)]	BBCH 81-82	fruit	0.030 0.040 0.080 0.030 0.040	0[5)] 0 1 3 7	4) spraying 5) before last treatment analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 3 months ASB2011-12608

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)
2021/01, study 2021/01, trial AF/8570/SY2 Greece 35009 Kenourgio Locridos 2002-06-11	Noa	1) 2001-03-20 (planting) 2) 3) 2001-06-10 2001-07-30	0.12 0.12 0.12 0.12	1240 1243 1240 1238	0.010 0.010 0.010 0.010	2001-05-28 2001-06-04 2001-06-11 2001-06-18[4)]	BBCH 89	fruit	0.20 0.51 0.24 0.16 <u>0.46</u> 0.26 0.19 0.26	0[5)] 0 1 3 7 7 14 14	4) spraying 5) before last treatment use formulation: A-7402 G (250 g/l Difenoconazole), analytical method: AG 575 A modified (ECD), LOQ: 0.01mg/kg, max. sample storage: 10 months, replicate field samples <u>ASB2011-12607</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

A 2.3.1 Magnitude of residues for azoxystrobin

Reference:	RIP9800954
Report	Residue levels in tomatoes and process fractions from trials carried out in Italy, Clarke, D. M.; Bonfanti, F., 1998, RJ2488B
Guideline(s):	Yes (Guidance according to Dir. 91/414/EEC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

In two supervised field trials involving treatment of outdoor grown tomatoes with azoxystrobin the fruits were processed into washed fruits, peeled, fruits, puree, ketchup, juice and preserves. Processing was conducted following common commercial practice using fruits samples three days after the final application.
Analysis of all samples was performed with Method SOP RAM 243 Ver. 04 and 05, involving extraction with acetonitrile:water, partitioning into dichloromethane, clean-up by adsorption chromatography on silica and finally GC-NPD detection (LOQ: 0.01 mg/kg, Recoveries 99-107%, RSD: 3-7%).

Results and discussions

The analytical method as well as the processing procedure itself is acceptable.

The results are summarized in the following tables.

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

Active ingredient : Azoxystrobin
Crop / crop group : Tomato

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 1998-08-17

Content of a.i. (g/kg or g/l) : 250 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : Ortiva **004560-00**
Applicant : Syngenta Agro GmbH

Indoors / outdoors : Outdoors (European South)
Other a. i. in formulation (common name and content) :
Residues calculated as : 8.1 Azoxystrobin
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)
RJ2488B IT33-97-P317	Ideal Peel	1)1997-04-13 (planting)	0.30	1200	0.025	1997-06-16	BBCH 87	fruit	0.15	<0.01	3	
			0.30	1200	0.025	1997-06-23			0.15	0.01	7	
		2) --	0.30	1200	0.025	1997-07-01			0.14	0.01	10	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 3 months
IT-29017		3) --	0.30	1200	0.025	1997-07-09						
Fiorenzuola d'			0.30	1200	0.025	1997-07-17		fruit, RAC	0.07	<0.01	3	
Arda, Emilia			0.30	1200	0.025	1997-07-25		fruit, washed	0.05	<0.01	3	
Romagna								fruit, peeled	<0.01	<0.01	3	
								juice	0.02	<0.01	3	
1998-06-02								peel	0.13	<0.01	3	
								purée	0.10	<0.01	3	
								preserves	<0.01	<0.01	3	RIP9800954
								ketchup	0.04	<0.01	3	

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 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)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)			(d)	(e)
RJ2488B IT42-97-P318 IT-41007 Borgo Sabotino Lazio 1998-06-02	Snob	1) 1997-04-17 (planting) 2) -- 3) --	0.20 0.20 0.25 0.25 0.25 0.25 0.25	800 800 1000 1000 1000 1000 1000	0.025 0.025 0.025 0.025 0.025 0.025 0.025	1997-06-04 1997-06-12 1997-06-20 1997-06-28 1997-07-07 1997-07-15 1997-07-22	BBCH 88-89	fruit fruit, RAC fruit, washed fruit, peeled juice peel purée preserves ketchup	0.16 0.09 0.06 0.11 0.07 <0.01 0.04 0.14 0.06 <0.01 0.04	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	3 7 10 3 3 3 3 3 3 3 3	analytical method: SOP RAM 243/04 and 05 (GC-N-TID), LOQ: 0.01 mg/kg, max. sample storage: 3 months RIP9800954

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

Table A 2: Residue data from tomato processing study with azoxystrobin

RAC	Residues in RAC (mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/ Reference
fruit	0.07 / 0.11	3	fruit, washed	0.05 / 0.07	0.71 / 0.64	RIP9800954
fruit	0.07/ 0.11	3	juice	0.02 / 0.04	0.29 / 0.36	RIP9800954
fruit	0.07/ 0.11	3	puree	0.10 / 0.06	1.4 / 0.55	RIP9800954
fruit	0.07/ 0.11	3	preserve	<0.01 / <0.01	0.14 / 0.09	RIP9800954
fruit	0.07/ 0.11	3	ketchup	0.04 / 0.04	0.57 / 0.36	RIP9800954

* processing factor

Conclusion

Based on the presented study, PFs for azoxystrobin in processed tomatoes can be derived (see summary).

Comments of zRMS:	Acceptable

A 2.3.2 Magnitude of residues for difenoconazole

Reference: ASB2011-12612

Report: Difenoconazole (CGA169374): Residue study in or on outdoor tomatoes and processed fraction in France (South), Ryan, J., 2006, 04-6049

Guideline(s): Yes (EU, Dir. 91/414/EEC)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

In the study submitted, one supervised field trial was conducted involving application of difenoconazole to tomatoes outdoors. From the treated field four replicate samples were collected and separately processed into washed tomatoes, tomato juice, tomato puree and tomato preserve. In addition to the balance part of the study, three follow-ups were conducted for the relevant processing products.
All residues were analysed with method REM 147.08. Extraction was achieved with methanol/ammonium hydroxide at reflux followed by SPE and determination using HPLC-MS/MS. The LOQ was validated at 0.01 mg/kg (Average recovery: 90%, RSD: 11%).

Results and discussions

The analytical method as well as the processing procedure itself is acceptable.

The results are summarized in the following tables.

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

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

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2011-10-28

Content of a.i. (g/kg or g/l) : 250 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : A7402T, EC (submitted to *GV1* **006902-00/07**) treated with formulation A7402T, EC 250
Applicant : Syngenta Agro GmbH

Indoors / outdoors : Outdoors (European South)
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)
04-6049, study 04-6049, trial AF/7870/SY/1, balance study, juice France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, crushed fruit, RAC juice, pasteurized juice, raw pomace, wet pomace, dry	0.24 0.22 0.050 0.070 0.39 5.1	7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months ASB2011-12612
04-6049, study 04-6049, trial AF/7870/SY/1, balance study, canned fruit France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, RAC fruit, peeled peel preserves, sterilized preserves, raw blanching water cooling water	0.22 <0.01 1.9 0.01 0.020 0.020 <0.01	7 7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months ASB2011-12612

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)
04-6049, study 04-6049, trial AF/7870/SY/1, balance study, puree France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, sieved fruit, crushed fruit, RAC pomace, wet puree, sterilized puree, raw paste	0.18 0.22 0.22 1.3 0.18 0.16 0.39	7 7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months ASB2011-12612
04-6049, study 04-6049, trial AF/7870/SY/1, balance study, washed fruit France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, RAC fruit, without calyx, sorted fruit, washed, without calyx calyx washing water	0.22 0.19 0.15 10.6 0.020	7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months ASB2011-12612
04-6049, study 04-6049, trial AF/7870/SY/1, follow up 1 France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, RAC fruit, washed juice, pasteurized pomace, wet pomace, dry puree, sterilized preserves, sterilized	0.22 0.11 0.040 0.54 5.2 0.15 0.020	7 7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months ASB2011-12612

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)
04-6049, study 04-6049, trial AF/7870/SY/1, follow up 2 France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, RAC fruit, washed juice, pasteurized pomace, wet pomace, dry puree, sterilized preserves, sterilized	0.22 0.18 0.060 0.58 5.7 0.14 <0.01	7 7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months <u>ASB2011-12612</u>
04-6049, study 04-6049, trial AF/7870/SY/1, follow up 3 France 82210 St. Nicolas de la Grave 2006-01-06	Netico	1) 2004-04-20 (planting) 2) 3) 2004-08	0.38 0.38 0.38	614 720 717	0.061 0.052 0.052	2004-08-10 2004-08-17 2004-08-24[4)]	BBCH 85-87	fruit, RAC fruit, washed juice, pasteurized pomace, wet pomace, dry puree, sterilized preserves, sterilized	0.22 0.16 0.040 0.47 4.8 0.15 0.020	7 7 7 7 7 7 7	4) spraying analytical method: REM 147.08 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 14 months <u>ASB2011-12612</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

Table A 3: Residue data from tomato processing study with difenoconazole

RAC	Residues in RAC (mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/ Reference
fruit	0.22	7	fruit, washed	0.11, 0.15, 0.16, 0.18	0.5, 0.68, 0.72, 0.81	ASB2011-12612
fruit	0.22	7	juice, pasteurized	0.04 (2), 0.05, 0.06	0.18, 0.18, 0.23, 0.27	ASB2011-12612
fruit	0.22	7	puree, sterilized	0.14, 0.15(2), 0.18	0.64, 0.68, 0.68, 0.81	ASB2011-12612
fruit	0.22	7	preserve, sterilized	<0.01, 0.01, 0.02 (2),	<0.045, 0.045, 0.09, 0.09	ASB2011-12612

* processing factor

Figure A 1: Processing flowchart for washed tomatoes

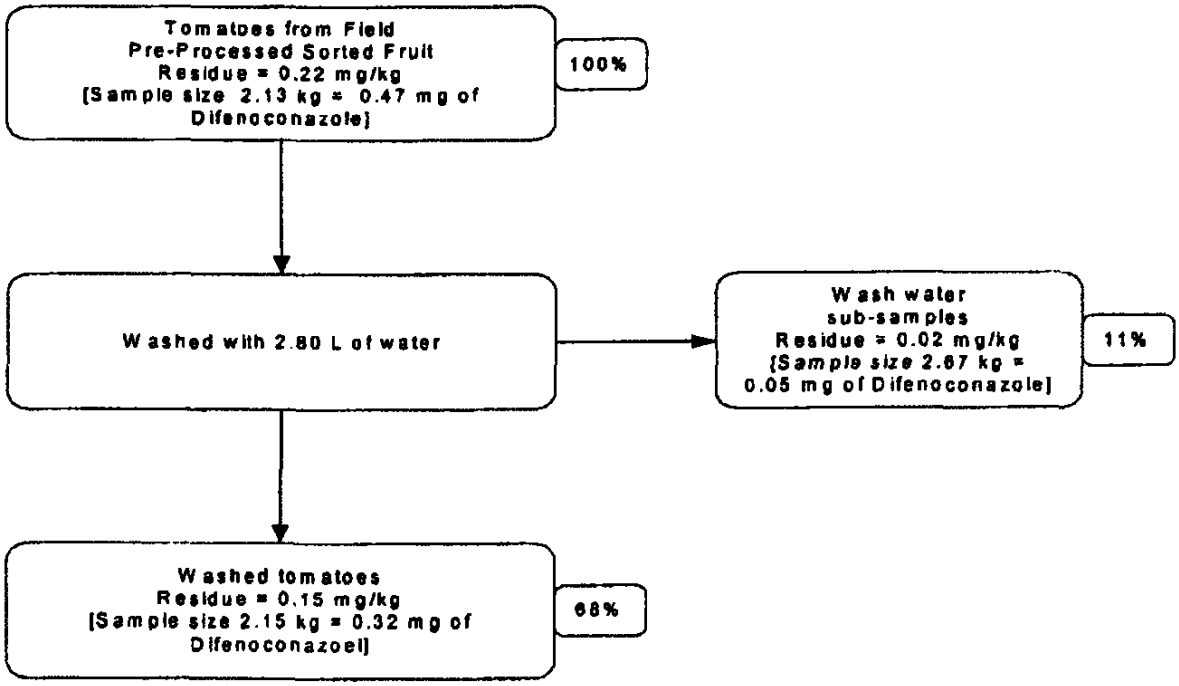


Figure A 2: Processing flowchart for tomato juice

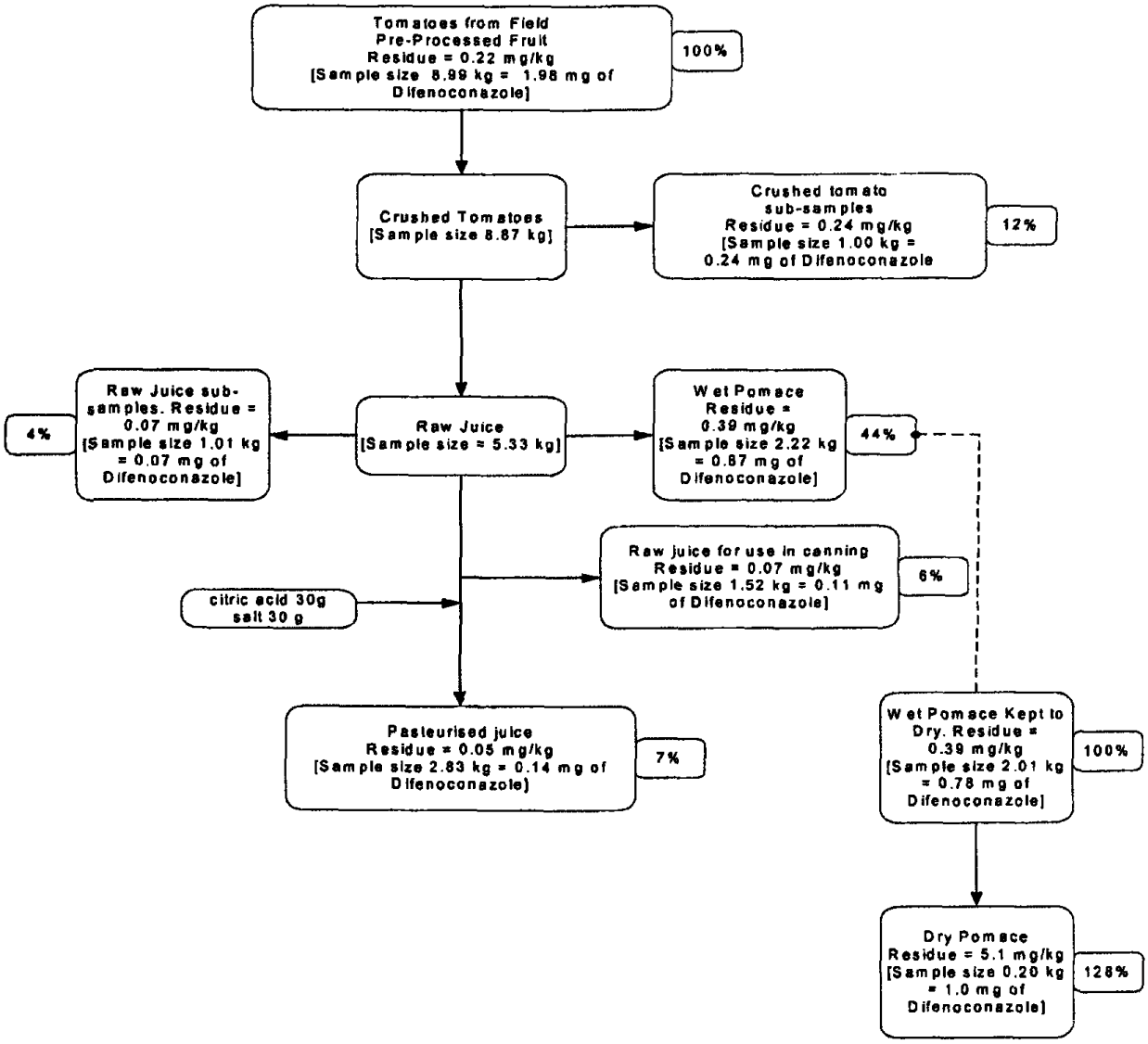


Figure A 3: Processing flowchart for tomato puree

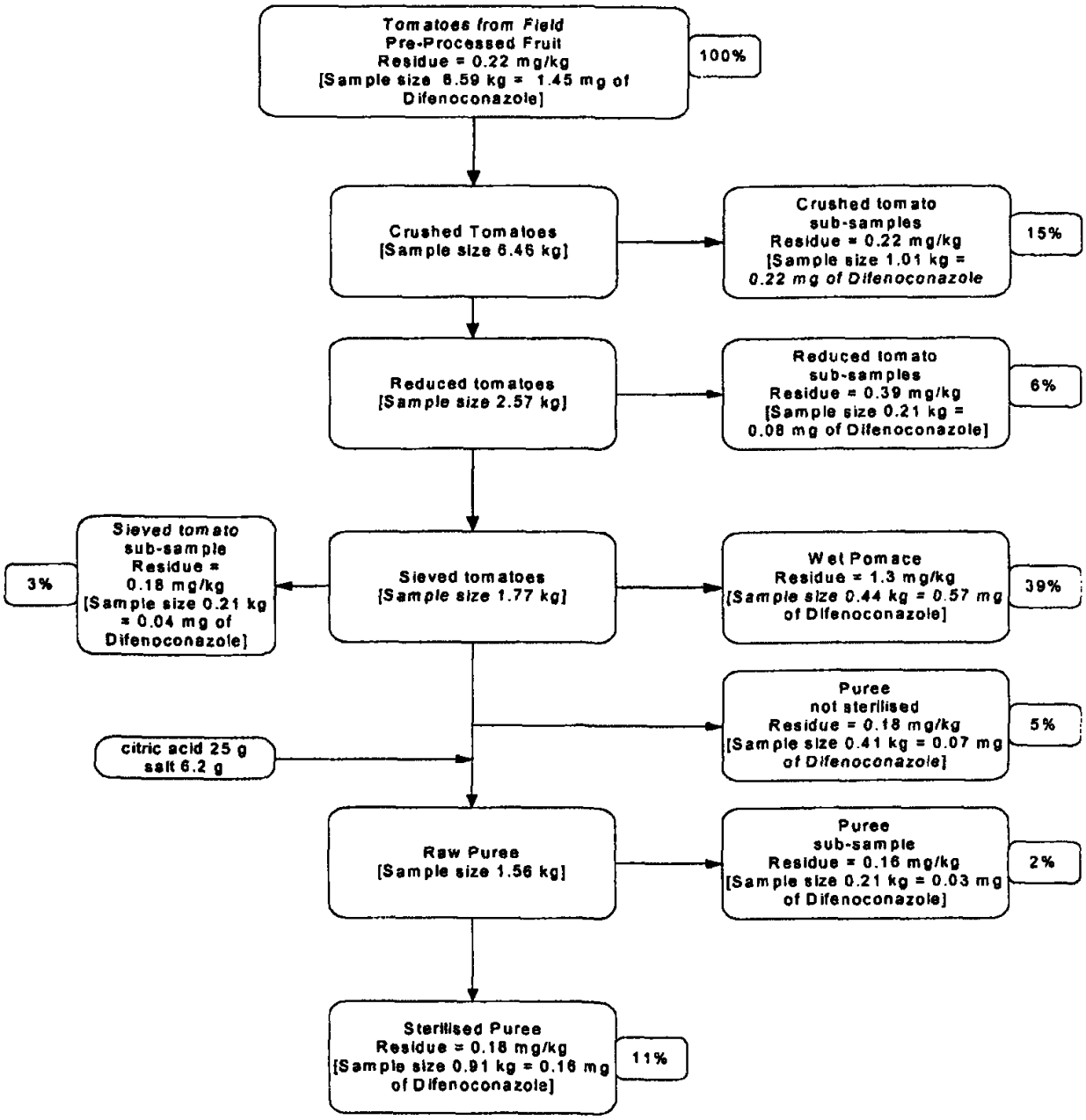
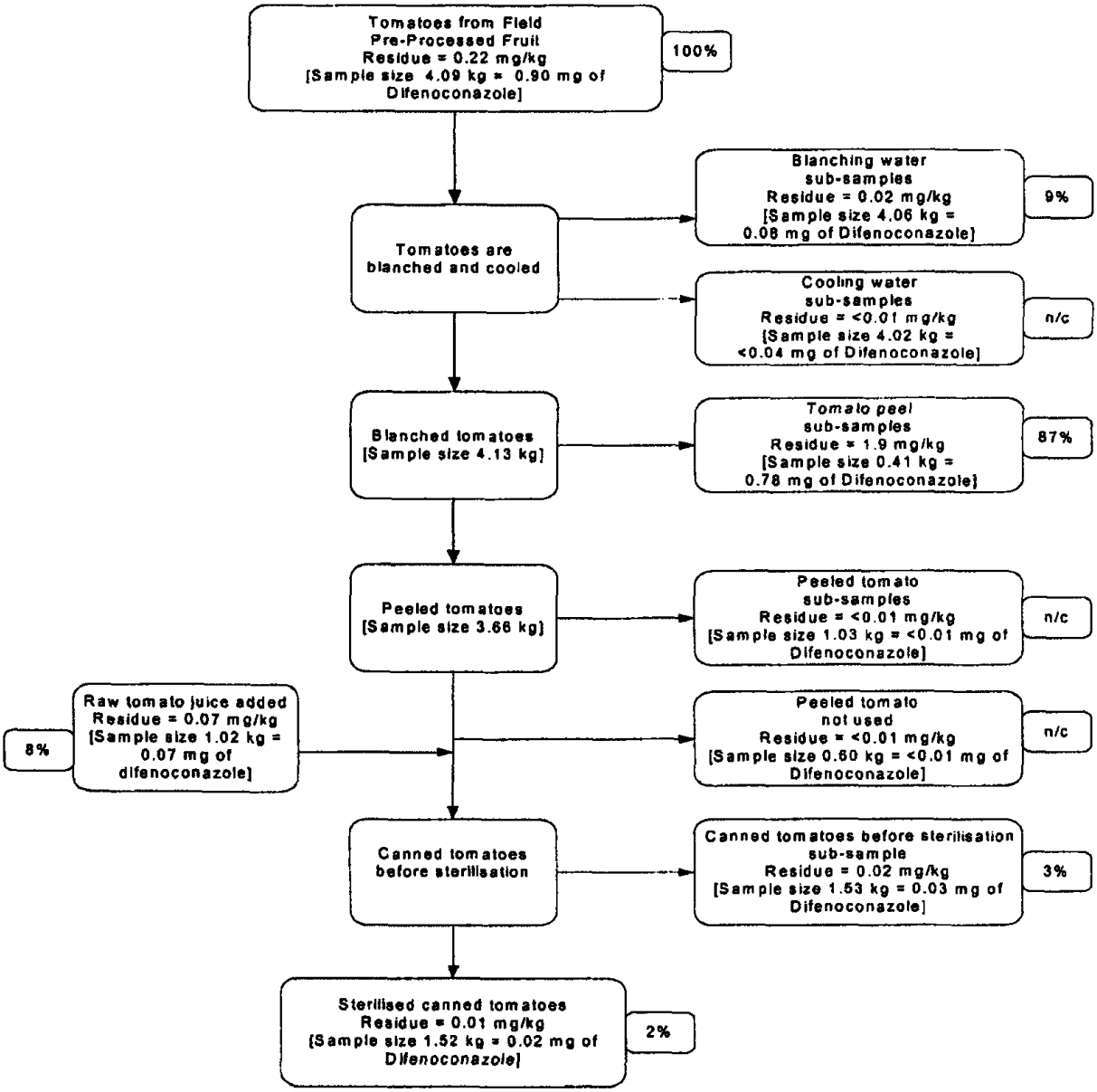


Figure A 4: Processing flowchart for canned tomato



Conclusion

Based on the presented study, PFs for difenoconazole in processed tomatoes can be derived (see summary).

Comments of zRMS:	Acceptable

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

Seite

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 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 - 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
92,0	WHO Cluster diet B	22,2	Tomatoes	10,8	Lettuce	9,0	Olives for oil production
76,5	UK Toddler	45,7	Sugar beet (root)	4,2	Tomatoes	3,9	Wheat
73,1	FR toddler	14,2	Spinach	11,0	Beans (with pods)	7,3	Carrots
69,5	NL child	7,6	Apples	7,4	Spinach	5,9	Potatoes
68,6	DE child	14,5	Apples	7,0	Tomatoes	6,3	Table grapes
61,7	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
50,2	WHO cluster diet E	8,0	Wine grapes	3,9	Wheat	3,8	Potatoes
49,9	FR infant	8,9	Spinach	8,4	Beans (with pods)	7,9	Carrots
48,2	WHO regional European diet	11,3	Lettuce	7,9	Tomatoes	4,0	Potatoes
45,1	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
40,9	ES adult	16,1	Lettuce	5,6	Tomatoes	2,3	Wheat
40,2	FR all population	20,0	Wine grapes	3,3	Wheat	3,1	Tomatoes
39,9	WHO cluster diet D	7,3	Tomatoes	6,5	Wheat	4,1	Potatoes
38,6	WHO Cluster diet F	9,0	Lettuce	4,9	Tomatoes	3,6	Wheat
38,6	IT kids/toddler	10,3	Tomatoes	8,7	Lettuce	6,6	Wheat
38,4	SE general population 90th percentile	5,5	Tomatoes	4,2	Potatoes	4,0	Chinese cabbage
37,5	IT adult	11,3	Lettuce	8,4	Tomatoes	4,1	Wheat
37,2	DK child	5,5	Wheat	4,4	Rye	4,2	Lettuce
35,3	NL general	3,6	Lettuce	3,1	Wine grapes	3,1	Tomatoes
32,8	UK vegetarian	7,6	Sugar beet (root)	4,5	Tomatoes	4,2	Lettuce
30,1	UK Adult	8,0	Sugar beet (root)	5,4	Wine grapes	3,5	Lettuce
22,0	DK adult	7,0	Wine grapes	3,0	Tomatoes	2,0	Wheat
21,2	PL general population	6,4	Tomatoes	3,4	Potatoes	2,5	Apples
18,0	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

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