

Art. 51
Extension of authorisation for minor uses

REGISTRATION REPORT

Part A

Risk Management

Product code: Alto 240 EC

Active Substance:

Cyproconazole 240 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: 24/11/2015

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Alto 240 EC containing Cyproconazole 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 Alto 240 EC have been made using endpoints agreed in the EU reviews of Cyproconazole.

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	Alto 240 EC
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	005207-00/03
Applicant	Syngenta Agro GmbH, Am Technologiepark 1 -5, 63477 Maintal, Deutschland
Authorisation holder	Syngenta Agro GmbH, Am Technologiepark 1 -5, 63477 Maintal, Deutschland
Function	Fungicide
Type of formulation	Emulsifiable concentrate
Expiration of authorisation	2018-12-31

1.2 Annex I inclusion

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

Active substance (BVL Number)

Cyproconazole

Content in PPP	240 g/L
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011, 2011/56/EU
Expiration of approval	31/05/2021

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	winter barley	powdery mildew (<i>Erysiphe graminis</i>), brown rust of barley (<i>Puccinia hordei</i>), leaf blotch of cereals (<i>Rhynchosporium secalis</i>), net blotch (<i>Pyrenophora teres</i>)	Authorise
002	winter barley	stem break of cereals (<i>Pseudocercospora herpotrichoides</i>), culm rot of cereals (<i>Fusarium culmorum</i>), snow mould (<i>Monographella nivalis</i>), typhula rot (<i>Typhula incarnata</i>), snow rot of cereals	Authorise

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

In Germany, the cultivated area of winter barley (seed production) is about 8000 ha, of which approx. 3200 ha need to be controlled. Calculation shows that authorisation holder will not profit from an authorisation of the requested uses.

Upon this calculation and the examination of available alternative measures for the applied uses, it can be stated that the applied uses is minor in nature and the authorisation is in the public interest.

1.4 Data protection claims

Not relevant. No new studies submitted.

1.5 Letters of Access

Not relevant. Authorisation holder is the applicant of the current application to extend the authorisation.

2 Details of the authorisation

2.1 Product identity

Product name	Alto 240 EC
Authorisation number	005207-00
Composition	Cyproconazole 240 g/L
Type of formulation	Emulsifiable concentrate
Function	Fungicide
Authorisation holder	Syngenta Agro GmbH, Am Technologiepark 1 -5, 63477 Maintal, Deutschland

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
T	Toxic
R36/38	Irritating to eyes and skin
R37	Irritating to respiratory system
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R61	May cause harm to the unborn child
S1/2	Keep locked away and out of the reach of children
S13	Keep away from food, drink and animal feeding stuffs
S23	Do not inhale gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)
S26	In case of contact with the eyes, rinse thoroughly and seek medical advice
S35	This material and its container must be disposed of in a safe way
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
S45	In case of an accident, or if you feel unwell, seek medical advice immediately (where possible, show this label)
S53	Avoid exposure - obtain special instructions before use
S57	Use appropriate container to avoid environmental contamination

S62	If swallowed, do not induce vomiting. Seek medical advice immediately and show this container or label
GHS09	Environment
S1	Warning
SP001	To avoid risks to man and the environment, comply with the instructions for use

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

None

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

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

Operator protection

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

Ecosystem protection

- NW262 The product is toxic for algae.
- NW264 The product is toxic for fish and aquatic invertebrates
- NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Mode of action (FRAC-Group): G1

Active substance

None

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)

- NN161 The product is classified as harmless for populations of the species *Coccinella septempunctata* (seven-spotted ladybird).
- NN165 The product is classified as harmless for populations of the species *Poecilus cupreus* (ground beetle).
- NN170 The product is classified as harmless for populations of the species *Chrysoperla carnea* (lacewing).
- NN1842 The product is classified as harmless for populations of the species *Aphidius rhopalosiphii* (braconid wasp).
- NN191 The product is classified as harmless for populations of the species *Episyrphus balteatus* (hover fly).

2.2.3.2 Specific restrictions linked to the intended uses

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

Ecosystem protection

- NW642-1 The product is not authorised for use in or in the immediate vicinity of surface waters or coastal waters (§ 6 (2) 'PflSchG' [Plant Protection Act]). Irrespective of this fact, the binding minimum buffer zone to be kept from surface waters, provided for by state law, must be observed. Violations may be punished by fines of up to Euro 50.000.

All uses

2.3 Product uses

PPP (product name/code) **Alto 240 EC (005207-00)**
active substance 1 **Cyproconazole**

Formulation type: **EC**
Conc. of as 1: **240 g/L**

safener -
synergist -

Conc. of safener: -
Conc. of synergist: -

Applicant: **Syngenta Agro GmbH**
Zone(s): **central EU**

professional use
non professional use

Verified by MS: j

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	winter barley (hybrid seed production)	F	powdery mildew (<i>Erysiphe graminis</i>) (ERYSGR), brown rust of barley (<i>Puccinia hordei</i>) (PUCCHD), leaf blotch of cereals (<i>Rhynchosporium secalis</i>) (RHYNSE), net blotch (<i>Pyrenophora teres</i>) (PYRNTE)	spraying	BBCH 27 – 29; in autumn at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0,4 L/ha b) 0,4 L/ha	a) 0.096 kg as/ha b) 0,096 kg as/ha	200 – 400	F*	Restrictions (see 2.2.3.2) NW642-1 * The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.
002	DE	winter barley	F	stem break of cereals	spraying	BBCH 27 – 29;	a) 1	a) 0,4 L/ha	a) 0.096 kg	200 – 400	F	NW642-1

		(hybrid seed production)	<p><i>(Pseudocercospora herpotrichoides)</i> (PSDCHE), culm rot of cereals (<i>Fusarium culmorum</i>) (FUSACU), snow mould (<i>Monographella nivalis</i>) (MONGNI), typhula rot (<i>Typhula incarnata</i>), snow rot of cereals (TYPHIN)</p>	in autumn at beginning of infestation and/or when first symptoms become visible	b) 1	b) 0,4 L/ha	as/ha b) 0,096 kg as/ha			
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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

Sufficiently validated analytical methods based on HPLC-MS/MS are available for enforcing cyproconazole in barley. It is referred to the data reported in the DAR and the Conclusion on the peer review issued by EFSA in 2010.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.

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

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

The intended use is not relevant in terms of consumer health protection, since the crop is intended for hybrid seed production (non-food). Hence the use does not need to be supported by supervised residue trials. However, an exceedance of the current MRL of 0.1 mg/kg for cyproconazole in barley as laid down in Reg. (EU) 396/2005 is not expected.

3.1.4.2 Consumer exposure

An assessment of residue uptake by consumers (TMDI calculation, EFSA PRIMo) results in the following maximum ADI consumption:

Cyproconazole (0.02 mg/kg bw/d) – 23 % (UK toddlers)

Long-term dietary intake of residues of cyproconazole is unlikely to present a public health concern for European consumers. No acute risk is expected 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 005207-00/00 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 005207-00/00 according the uniform principles of directive 91/414/EEC.

The PPP Alto 240 EC and the active substance cyproconazol are toxic to the aquatic environment (Oncorhynchus mykiss: NOEC (ELS) = 160 µg/L, Daphnia magna: NOEC: 23 µg/L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW262, NW264, NW468 and NW 642-1 are assigned, see also 2.2.

Risk Assessment for Honeybees

The honeybee risk assessment for the main application covers the uses 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 applied for under the terms of Article 51 of regulation (EC) No 1107/2009.
- The categories and labelling for mode of action for the main application cover the use applied for under the terms of Article 51 of regulation (EC) No 1107/2009.

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

3.2 Conclusions

PPP Alto 240 EC 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.

The intended uses in barley will not result in residues above the MRL set in or proposed for cyproconazole) Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues of cyproconazole 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.

An authorisation can be recommended.

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

None

Appendix 1 – Copy of the product authorisation

See below.

Appendix 2 – Copy of the product label

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

Appendix 3 – Letter of Access

No letter of access necessary. No new studies submitted. Authorisation holder is the applicant of the current application to extend the authorisation.



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Verbraucherschutz und
Lebensmittelsicherheit

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.005207-00/03.87611
(bitte bei Antwort angeben)

DATUM 24. November 2015

GV1 005207-00/03

Alto 240 EC

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

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 240 g/l Cyproconazol

Zulassungsnummer: 005207-00

Versuchsbezeichnungen: SYD-14280-F-0-EC

Antrag vom: 20. August 2013

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
005207-00/03-001	Echter Mehltau (<i>Erysiphe graminis</i>), Zwergrost (<i>Puccinia hordei</i>), Blattfleckenkrankheit (<i>Rhynchosporium secalis</i>), Netzfleckenkrankheit (<i>Pyrenophora teres</i>)	Wintergerste	Hybridsaatguterzeugung
005207-00/03-002	Halmbruchkrankheit (<i>Pseudocercospora herpotrichoides</i>), Fusarium culmorum, Schneesimmel (<i>Monographella nivalis</i>), Typhula-Fäule (<i>Typhula incarnata</i>)	Wintergerste	Hybridsaatguterzeugung

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 375 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:
Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

- keine -

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 005207-00/03-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Erysiphe graminis*), Zwergrost (*Puccinia hordei*), Blattfleckenkrankheit (*Rhynchosporium secalis*), Netzfleckenkrankheit (*Pyrenophora teres*)

Pflanzen/-erzeugnisse/Objekte: Wintergerste

Verwendungszweck: Hybridsaatguterzeugung

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Stadium der Kultur: 27 bis 29

Anwendungszeitpunkt: Im Herbst bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 0,4 l/ha in 200 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)

Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

(F) Freiland: Wintergerste
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 005207-00/03-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Halmbbruchkrankheit (*Pseudocercospora herpotrichoides*), *Fusarium culmorum*, Schneeschimmel (*Monographella nivalis*), Typhula-Fäule (*Typhula incarnata*)

Pflanzen/-erzeugnisse/Objekte: Wintergerste

Verwendungszweck: Hybridsaatguterzeugung

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Stadium der Kultur: 27 bis 29

Anwendungszeitpunkt: Im Herbst bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 0,4 l/ha in 200 bis 400 l Wasser/ha

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(NW642-1)

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2.3 Wartezeiten

(F) Freiland: Wintergerste

Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues
Detailed summary of the risk assessment

Product code: Alto 240 EC

Active Substance: 240 g/L Cyproconazole

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: 24/11/2015

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4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

An evaluation of the active substance was not conducted in the framework of applications according to Article 51 of Regulation (EC) No 1107/2009. It is referred to the data reported in the DAR ([ASB2010-10438](#)) and the Conclusion on the peer review issued by EFSA in 2010 ([ASB2012-3334](#)).

4.2 Evaluation of the intended use(s)

4.2.1 Selection of critical use and justification

The critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

Table 4.2-1: Critical Uses (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop) (a)	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Application			Application rate			PHI (days) (i)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)
					Method / Kind (d-f)	Timing / Growth stage of crop & season (g)	Max. number (min. interval between applications) a) per use b) per crop/ season (h)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001, 002	DE	winter barley	F	powdery mildew (<i>Erysiphe graminis</i>), brown rust of barley (<i>Puccinia hordei</i>), leaf blotch of cereals (<i>Rhynchosporium secalis</i>), net blotch (<i>Pyrenophora teres</i>), stem break of cereals (<i>Pseudocercospora herpotrichoides</i>), culm rot of cereals (<i>Fusarium culmorum</i>), snow mould (<i>Monographella nivalis</i>), typhula rot (<i>Typhula incarnata</i>), snow rot of cereals	spraying	BBCH 27-29, in autumn at beginning of infestation and/or when first symptoms become visible	a) 1 b) 1	a) 0.4 L/ha	a) 0.096 kg as/ha	200-400	F	hybrid seed production

- 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

4.2.2 Winter Barley

4.2.2.1 Residues in primary crops

The intended use is not relevant in terms of consumer health protection, since the crop is intended for hybrid seed production (non-food). Hence the use does not need to be supported by supervised residue trials.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.2.3 Residues in processed commodities

Not relevant. Due to low residues at harvest, no processing studies are required.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

The pre-harvest interval (PHI) is covered by the time elapsing between application and commercial harvest. Setting of a specific PHI in days is not required.

4.3 Consumer intake and risk assessment

The envisaged uses are not relevant in terms of consumer health protection. Moreover, no significant transfer of cyproconazole to food-relevant parts of rotational crops is envisaged.

Risk assessment is made for long-term exposure only. The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-1. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMo is displayed in Appendix 3.

Table 4.3-1: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	23% (based on UK toddlers, 14.5 kg bw)
NTMDI (% ADI) according to German NVS II	22 % (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	not required
NEDI (% ADI) according to German NVS II	not required
Factors included in IEDI and NEDI	not applicable

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.5 Conclusion

The available data are sufficient for dietary risk assessment.

An exceedance of the current MRL of 0.1 mg/kg for cyproconazole in barley as laid down in Reg. (EU) 396/2005 is not expected.

The long-term and the short-term intake of cyproconazole residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended uses.

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 Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
All	EFSA	2010	Conclusion on the peer review of the pesticide risk assessment of the active substance cyproconazole EFSA Journal 2010;8(11):1897, 1-73 ASB2012-3334			
All	Ireland	2006	Cyproconazole: (Draft Assessment Report) Vol. 1-4 GLP: Open Published: Yes ASB2010-10438	Open		

* Y: Yes, relied on
 N: No, not relied on
 Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

No further studies submitted/needed.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.2)

Cyproconazole (F)			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,02	ARID (mg/kg bw):	0,02
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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

Chronic risk assessment								
		TMDI (range) in % of ADI minimum - maximum						
		3 - 23						
No of diets exceeding ADI:								
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
23,4	UK Toddler	11,4	Sugar beet (root)	5,2	Milk and cream,	2,3	CEREALS	
21,4	UK Infant	9,7	Milk and cream,	5,0	Sugar beet (root)	2,3	CEREALS	
20,8	NL child	7,3	Milk and cream,	3,4	Pome fruit	2,8	CEREALS	
19,3	DE child	6,4	Pome fruit	3,6	Milk and cream,	2,8	CEREALS	
18,9	FR toddler	9,9	Milk and cream,	2,0	Root and tuber vegetables	1,5	CEREALS	
17,9	WHO Cluster diet B	5,9	CEREALS	2,1	Table and wine grapes	1,4	Fruiting vegetables	
13,1	DK child	5,2	CEREALS	3,2	Milk and cream,	1,5	Pome fruit	
12,4	IE adult	3,3	CEREALS	1,2	Table and wine grapes	1,0	Root and tuber vegetables	
12,3	FR infant	6,4	Milk and cream,	1,8	Root and tuber vegetables	1,4	Pome fruit	
12,3	WHO cluster diet E	3,0	CEREALS	1,8	Table and wine grapes	1,3	Root and tuber vegetables	
10,9	ES child	3,1	Milk and cream,	2,6	CEREALS	0,8	Pome fruit	
10,5	WHO cluster diet D	4,2	CEREALS	1,3	Milk and cream,	1,1	Root and tuber vegetables	
10,3	SE general population 90th percentile	3,1	Milk and cream,	2,5	CEREALS	1,4	Root and tuber vegetables	
9,5	WHO Cluster diet F	2,7	CEREALS	1,1	Root and tuber vegetables	1,0	Milk and cream,	
9,1	WHO regional European diet	1,8	CEREALS	1,2	Milk and cream,	1,1	Root and tuber vegetables	
9,1	FR all population	4,1	Table and wine grapes	1,7	CEREALS	0,7	Milk and cream,	
8,5	PT General population	2,8	Table and wine grapes	2,7	CEREALS	0,7	Pome fruit	
7,8	NL general	1,6	Milk and cream,	1,4	CEREALS	0,9	Table and wine grapes	
6,9	UK vegetarian	1,9	Sugar beet (root)	1,3	CEREALS	0,9	Table and wine grapes	
6,8	IT kids/toddler	4,2	CEREALS	0,6	Pome fruit	0,5	Fruiting vegetables	
6,6	UK Adult	2,0	Sugar beet (root)	1,1	Table and wine grapes	1,0	CEREALS	
6,6	ES adult	1,6	CEREALS	1,2	Milk and cream,	0,6	Pome fruit	
6,3	DK adult	1,5	Table and wine grapes	1,4	CEREALS	1,3	Milk and cream,	
5,3	LT adult	1,4	CEREALS	1,0	Pome fruit	1,0	Milk and cream,	
4,9	IT adult	2,5	CEREALS	0,5	Pome fruit	0,5	Fruiting vegetables	
4,3	FI adult	1,4	Milk and cream,	1,0	CEREALS	0,4	Root and tuber vegetables	
3,3	PL general population	1,2	Pome fruit	1,0	Root and tuber vegetables	0,3	Table and wine grapes	

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