FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/TERIZ 650 WG

Product name(s): Undito 650 WG, Jotamun 650 WG, Metodus 650 WG

Chemical active substance(s):

Terbuthylazine, 400 g/kg

Mesotrione, 150 g/kg

Isoxaflutole, 100 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT- renewal of authorisation (authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: October 2019

Update: November 2021

MS Finalisation date: 11/2021; 12/2021; 12/2021; 06/2023

Version history

When	What
October 2019	New data for isoxaflutole based on the renewal of active substance. New data marked in yellow
November 2021	evaluation of new data (isoxaflutole)
December 2021	The application rate has been changed in the GAP table, based on new calculation in Part B8.
December 2021	Assessment update against new application rate
June 2023	Final Registration Report

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7 Metabolism and residue data (KCP section 6)

7.1 Summary and zRMS Conclusion

The Section B7 was updated. Available not protected data is sufficient to support the renewal of authorization of CHR/H/TERIZ 650 WG.

November 2021: evaluation of new data for isoxaflutole based on the renewal of active substance.

Critical GAP for the intended uses of CHR/H/TERIZ 650 WG is within the EU GAP (EFSA Journal 2016;14(2):4416).
Stability of Residues
All samples in the new supervised residues trials were analysed within 30 days after sampling thus no stability of residues is required.
Residue definitions:
Commission Regulation (EU) No 2015/845 of 27 May 2015: Isoxaflutole (sum of isoxaflutole and its diketonitrile-metabolite, expressed as isoxaflutole.
Plant residue definition for risk assessment (EFSA Journal 2016;14(3):4416):
Conventional crops: RPA 203328
Genetically modified crops: RPA 203328 and RPA 202248
Animal residue definition for monitoring and risk assessment: not required for the representative use
Magnitude of residues in plants
New supervised residues trials were performed due to the renewal of active substance isoxaflutole. –
4 new trials in 2017 in northern Europe (Eurofins 2017, Dr. Sönke Lakaschus, Sabrina Fritzsch) were performed. Trials are accepted.
Trials GAP: 1 x 0.1 kg as/ha, BBCH0 0-13, PHI N/A, outdoor
Results:
5 x <0.01 mg/kg
Sufficient trials are available to support the proposed uses in maize.
The residues arising from the proposed uses will not exceed the MRLs established for maize grain (0.02* mg/kg; Reg.(EU) No 2015/845).
Residue data are valid with regard to storage stability.
Livestock Feeding Studies:
According to the dietary burden calculation for isoxaflutole and low resides in maize, no livestock feeding studies are necessary
Industrial Processing and/or Household Preparation:
EFSA Journal 2016;14(2):4416*: Processing studies are not triggered since residue levels of RPA 203328 in maize grain are <0.1 mg/kg. This assessment should be reconsidered pending the outcome of the requested hydrolysis study addressing the nature of RPA 203328 residues in processed commodities.*
No additionally data is required.
Residues in Representative Succeeding Crops:
No additional studies on rotational crops are considered necessary.
No restrictions are necessary.
The consumer risk assessment was performed with the EFSA PRIMo rev.3.1. No chronic and acute intake concerns were identified
PHI: not required
The intended use evaluated in this dossier can be authorized.

December 2021: Assessment update against new application rate
Application rate modification (reduction) does not alter the above conclusions.
The field studies are overdosed but acceptable because the results are below 0.01 mg/kg.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/TERIZ 650 WG are presented in Table 7.1-1. They have been selected from the individual GAPs in the EU for maize. A list of all intended uses within the zone is given in Part B, Section 0.
The critical GAP was selected from the worst case use on maize of plant protection product CHR/H/TERIZ 650 WG with the earliest application BBCH 00 and highest maximum rate of 1kg product/ha/

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of **0.1 mg/kg for terbuthylazine**, **0.02 mg/kg for isoxaflutole, 0.01 mg/kg for mesotrione** as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of terbuthylazine, isoxaflutole and mesotrione residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Maize (ZEAMX)	Central	CHR/H/TERIZ 650 WG	F	Mono and di-cotsweeds	WG	400 g/kg Terbuthylazine 100g/kg isoxaflutole 150 g/kg mesotrione	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	1	N/A	0.1625-0.325	200-400	0.65 kg a.s./ha (T 0.4 + I 0.1 + M 0.15)	Not required	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

December 2021
Updated GAP

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Maize (ZEAMX)	Central	CHR/H/TERIZ 650 WG	F	Mono and di-cotsweeds	WG	400 g/kg Terbuthylazine 100g/kg isoxaflutole 150 g/kg mesotrione	Spray, medium sprayer	Spring BBCH 00, max. 3 days after sowing	1	N/A	0.13-0.26	200-250	0.52 kg a.s./ha (T 0.32 + I 0.08 + M 0.12)	Not required	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CHR/H/TERIZ 650 WG is composed of terbuthylazine, isoxaflutole and mesotrione.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of terbuthylazine, isoxaflutole and mesotrione.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Terbuthylazine					
ADI	EFSA Journal 2011; 9(1):1969	2011	0.004 mg/kg bw/day	dog, 1-year & rat, 2-year	100
ARfD	EFSA Journal 2011; 9(1):1969	2011	0.008 mg/kg bw/day	Rabbit developmental study	100
Isoxaflutole					
ADI	EFSA Journal 2016;14(3):4416	2016	0.02 mg/kg bw/day	Rat, 2-year supported by 2-generation	100
ARfD	EFSA Journal 2016;14(3):4416	2016	0.05 mg/kg bw/day	Rabbit, developmental	100
Mesotrione					
ADI	SANCO/1416/2001 -Final 14 April 2003	2003	0.01 mg/kg bw/day	Mouse multi-generation	200
ARfD	SANCO/1416/2001 -Final 14 April 2003	2003	0.02 mg/kg bw/day	Mouse multi-generation	100

7.1.2.1 Summary for Terbuthylazine

Table 7.1-3: Summary for Terbuthylazine

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	YES	Yes (8 trials)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For maize, no additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: 1 application of 400 g a.s/ha at growth stage BBCH 00. Since studies presented in EU review during Annex I inclusion, were performed on two times higher rate of 844 g a.s/ha at BBCH 12-16, which is the worst case scenario.

Supervised residue trials were provided by both applicants (Sungenta and Oxon) and evaluated during EU review and presented in ***EFSA Journal 2011; 9(1):1969 Peer Review of the pesticide risk assessment of the active substance terbuthylazine*** . Samples were analysed for terbuthylazine but also for the

metabolites MT1 and MT14 in a significant number of experiments. No residues were observed above the LOQ, except for the metabolite MT14 detected at the level of 0.03 mg/kg in maize forage in two locations. In addition, cold rotational crop trials were submitted where cereals, oilseed and tuber/root crops were rotated with maize treated as a primary crop at a dose rate of 844 to 937 g/ha. Parent residues were always below or at the LOQ of 0.02 mg/kg, MT1 was observed at the level of 0.02 to 0.06 mg/kg in cereal straw, sugar beet tops and sunflower seeds and metabolite MT14 was only detected in a single location in rapeseed grain (0.05 mg/kg). These trials confirm that parent residues are not expected to be present in rotational crops above the LOQ of 0.02 mg/kg. The residue data are supported by the storage stability studies, showing the residues of the parent, MT1 and MT14 to be stable up to 2 years when stored frozen at -18°C. Processing studies were not submitted and are not required because of the low residue levels.
As a worst case, the consumer risk assessment was conducted considering the total residue levels (MT0 +MT1+MT14) observed in maize and sorghum grains (primary crop) and in oilseed and root crops (rotational crops). No concern was identified, the IEDI being 10% of the ADI (WHO cluster B) and the IESTI 63% of the ARfD (carrots).

As residues of terbuthylazine do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No risk was identified for Acute and chronic risk assessment.

Summary of residues from supervised reside trials according to the **EFSA Journal 2011; 9(1):1969Peer Review of the pesticide risk assessment of the active substance terbuthylazine**:

Crop	Northern or Southern Region, field or glasshouse	**Trial results relevant to the representative uses** (a)	**Recommendation/comments**	**MRL** estimated from trials according to representative uses	**HR** (mg/kg) (c)	**STMR** (mg/kg) (b)
Maize	North 1x 0.75 kg a.s./ha	**Grain** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 8x <0.02 **Total residues**: 8x <0.06 **Forage** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 7x <0.02, 0.03 **Total residues:** 7x <0.06, 0.07	**MT0:** terbuthylazine (GS 13529) **MT1:** desethyl-terbuthylazine (GS 26379) **MT14:** desethyl-2- hydroxy-terbuthylazine (GS 28620) **Total residues**: Sum MT0+MT1+MT14 4 additional trials on grain and forage available in Northern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14 3 additional trials on grain and forage available in Southern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14 Numerous additional trials available in Northern and Southern EU where samples were analysed for terbuthylazine only. All values below the LOQ (0.02 to 0.08 mg/kg) in grain and forage.	0.02*	**Grain** <0.02 (MT0) <0.06 (Total) **Forage** <0.02 (MT0) 0.07 (Total)	**Grain** <0.02 (MT0) <0.06 (Total) **Forage** <0.02 (MT0) <0.06 (Total)
	South 1x 0.844 kg a.s./ha	**Grain** **MT0:** 4x <0.02 **MT1:** 4x <0.02 **MT14:** 4x <0.02 **Total residues:** 4x <0.06 **Forage** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 7x <0.02, 0.03 **Total residues:** 7x <0.06, 0.07				

7.1.2.2 Summary for Isoxaflutole

Table 7.1-5: Summary for Isoxaflutole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	YES	Yes (5 trials)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The GAP for use of isoxaflutole in maize seem to be identical for both the Northern as the Southern countries of Europe. The critical GAP is considered to be a single pre-emergence field application at a rate of 0.1 kg a.i./ha.

A summary of all trials is given in table 7.1-5. All trials were reported in sufficient detail and acceptable analytical information was supplied.

The analytical method used in these studies converted the residues of isoxaflutole and metabolite RPA 202248 to metabolite RPA 203328.

As residues of isoxaflutole do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

The metabolism studies on rotational crops show that residues of isoxaflutole and RPA 202248 are expected to be < 0.01 mg/kg in rotational crops. Therefore studies on the magnitude of residues in rotational crops are not needed.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Based on the whole data package for the northern region, it is considered that there are sufficient trials to set an MRL for maize. No new trials at use dose rate showed a residue level slightly above the detection limit, it is proposed to set the MRL for grains on the LOQ – 0.01 mg.kg).

No risk was identified for Acute and chronic risk assessment.

7.1.2.3 Summary for Mesotrione

Table 7.1-7: Summary for Mesotrione

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	YES	Yes (17 trials)	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For maize, no additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 150 g a.s/ha at growth stage BBCH 00. Since studies presented in EU review during Annex I inclusion , were performed on the same rate of use and BBCH 12-18, which is the worst case scenario. No new studies are necessary.

The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information on residues in Maize were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated. It may be assumed that the residues in cereals are below MRL of 0.01 mg/kg.

According to DAR_08_Volume3_residue-public:

Data are available from a total of 17 trials on maize, where MESOTRIONE was applied post emergence as a 100 g a.s./l suspension concentrate, at rates and timings which support the critical GAP. The trials were conducted over two years 1995 and 1996, in the areas of Northern and Southern Europe, 9 and 8 trials respectively.

A total of 13 of the above trials included residue decline data; nine trials were conducted in Northern Europe and 4 in Southern Europe. In these 13 trials, the residues of MESOTRIONE and MNBA shortly after treatment (0 day PHI) ranged from 2.6 - 23 mg/kg and 0.03 - 0.21 mg/kg, respectively.

With one exception, residues of MESOTRIONE and MNBA were <0.01 mg/kg (the limit of quantification) in immature maize sampled at 12-15 days PHI. The exception was one trial where immature maize (14 days PHI) contained 0.05 and 0.06 mg/kg of MESOTRIONE and MNBA, respectively following an application at a slightly higher rate, 0.20 kg a.s./ha, than the 0.15 kg a.s./ha GAP rate.

In all the 17 supervised trials, residues of MESOTRIONE and MNBA were <0.01 mg/kg in samples of maize at harvest (forage, silage, grain, grain + cob and grain + cob + husk).

As residues of mesotrione do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No risk was identified for Acute and chronic risk assessment.

Table 7.1-8 Summary of Residue from supervised trials according to DAR-Mesotrione Volume 3 Annex B Peer review of the pesticide risk assessment of the active substance mesotrione:

Country/year	Maize variety	Application rate per treatment			No. of treat-ments	Growth stage at last treatment	Portion analysed	PHI days	Residues mg/kg MESOTRIONE		Comments	References	
		kg a.s./ha	Water l/ha	kg a.s./hl									
Ile de France North France 1995	Bangy	0.15	300	0.05	1	6-8 leaves (16-18 BBCH)	immature	0	4.58	0.15	Limited weather and crop main-tenance data Different 100g/l SC used to that specified in the Submission	Barnes, J.P et al., 1997a DP 59806	
							immature	14	<0.01	<0.01			
							forage	63	<0.01	<0.01			
							silage	80	<0.01	<0.01			
							grain	120	<0.01	<0.01			
							grain + cob	120	<0.01	<0.01			
							grain + cob + husk	120	<0.01	<0.01			
Midi- Pyre-nees South France 1995	Cecilia	0.15	300	0.05	1	6-8 leaves (18 BBCH)	immature	0	2.57	0.03	Limited weather and crop main-tenance data	Barnes, J.P et al., 1997a DP 59806	
							immature	15	<0.01	<0.01			
							forage	60	<0.01	<0.01			
							silage	91	<0.01	<0.01			
							grain	109	<0.01	<0.01			
							grain + cob	109	<0.01	<0.01			
							grain + cob + husk	109	<0.01	<0.01			

Rhone Valley South France 1995	Cecilia	0.15	300	0.05	1	6-8 leaves (17-18 BBCH)	immature	0	7.57	0.06	Limited weather and crop maintenance data Different 100g/l SC used to that specified in the Submission	Barnes, J.P et al., 1997a DP 59806
							immature	14	<0.01	<0.01		
							forage	60	<0.01	<0.01		
							silage	77	<0.01	<0.01		
							grain	128	<0.01	<0.01		
							grain + cob	128	<0.01	<0.01		
							grain + cob + husk	128	<0.01	<0.01		
Cantois, South West France 1996	Volga	0.20	300	0.07	1	7 leaves (17 BBCH)	immature	0	19.0	0.21	Limited weather and crop maintenance data	Barnes, J.P et al., 1997b DP 59808
							immature	12	<0.01	<0.01		
							forage	61	<0.01*	<0.01*		
							silage	91	<0.01*	<0.01*		
							grain	126	<0.01*	<0.01*		
							grain + cob	126	<0.01*	<0.01*		
							grain + cob + husk	126	<0.01*	<0.01*		
Pierrelatte, South East France 1996	Cecilia	0.20	300	0.07	1	6 leaves (16 BBCH)	immature	0	14.4	0.12	Limited weather and crop maintenance data	Barnes, J.P et al., 1997b DP 59808
							immature	14	<0.01	<0.01		
							forage	61	<0.01*	<0.01*		
							silage	92	<0.01*	<0.01*		
							grain	146	<0.01*	<0.01*		
							grain + cob	146	<0.01*	<0.01*		

							grain + cob + husk	146	<0.01*	<0.01*		
Normandy North France 1996	LG2243	0.20	300	0.07	1	6-8 leaves (16-18 BBCH)	immature	0	20.0	0.10	Limited weather and crop main-tenance data	Barnes, J.P et al., 1997b DP 59808
							immature	14	<0.01	<0.01		
							forage	56	<0.01*	<0.01*		
							silage	90	<0.01*	<0.01*		
							grain	119	<0.01*	<0.01*		
							grain + cob	119	<0.01*	<0.01*		
							grain + cob + husk	119	<0.01*	<0.01*		
Sleswig-Holstein Germany 1995	Diamant	0.15	300	0.05	1	7 leaves (17 BBCH)	immature	0	9.23	0.08		Barnes, J.P et al., 1997c DP 59810
							immature	13	<0.01	<0.01		
							forage	32	<0.01	<0.01		
							silage	68	<0.01	<0.01		
							grain	78	<0.01	<0.01		
							grain + cob	78	<0.01	<0.01		
							grain + cob + husk	78	<0.01	<0.01		
Bavaria Germany 1995	General	0.15	300	0.05	1	7 leaves (17 BBCH)	immature	0	10.31	0.08		Barnes, J.P et al., 1997c DP 59810
							immature	14	<0.01	<0.01		
							forage	32	<0.01	<0.01		
							silage	73	<0.01	<0.01		
							grain	114	<0.01	<0.01		

							grain + cob	114	<0.01	<0.01		
							grain + cob + husk	114	<0.01	<0.01		
Bavaria Germany 1995	Graf	0.15	300	0.05	1	6-7 leaves (16-17 BBCH)	immature	0	11.56	0.08		Barnes, J.P et al., 1997c DP 59810
							immature	14	<0.01	<0.01		
							forage	32	<0.01	<0.01		
							silage	78	<0.01	<0.01		
							grain	114	<0.01	<0.01		
							grain + cob	114	<0.01	<0.01		
							grain + cob + husk	114	<0.01	<0.01		
Saxe-Anhalt Germany 1995	Anjou 207	0.15	300	0.05	1	6-7 leaves (16-17 BBCH)	immature	0	5.98	0.20		Barnes, J.P et al., 1997c DP 59810
							immature	15	<0.01	<0.01		
							forage	30	<0.01	<0.01		
							silage	70	<0.01	<0.01		
							grain	112	<0.01	<0.01		
							grain + cob	112	<0.01	<0.01		
							grain + cob + husk	112	<0.01	<0.01		
Sleswig-Holstein Germany 1996	Janna	0.20	200	0.10	1	6 leaves (16 BBCH)	immature	0	23.2	0.10	Samples were received thawed after 9 days in transit	Barnes, J.P et al., 1997d DP 59812
							immature	14	0.05	0.06		
							forage	44	<0.01*	<0.01*		
							silage	86	<0.01*	<0.01*		

							grain	109	<0.01*	<0.01*		
							grain + cob	109	<0.01*	<0.01*		
							grain + cob + husk	109	<0.01*	<0.01*		
Bavaria Germany 1996	Ilias	0.20	250	0.08	1	7 leaves (17 BBCH)	immature	0	10.9	0.10		Barnes, J.P et al., 1997d DP 59812
							immature	14	<0.01	<0.01		
							forage	35	<0.01*	<0.01*		
							silage	110	<0.01*	<0.01*		
							grain	135	<0.01*	<0.01*		
							grain + cob	135	<0.01*	<0.01*		
							grain + cob + husk	135	<0.01*	<0.01*		
Saxe-Anhalt Germany 1996	Helix	0.20	200	0.10	1	8 leaves (18 BBCH)	immature	0	9.21	0.08		Barnes, J.P et al., 1997d DP 59812
							immature	14	<0.01	<0.01		
							forage	36	<0.01*	<0.01*		
							silage	88	<0.01*	<0.01*		
							grain	126	<0.01*	<0.01*		
							grain + cob	126	<0.01*	<0.01*		
							grain + cob + husk	126	<0.01*	<0.01*		
Milano Italy 1995	Samantha	0.15	300	0.05	1	7-8 leaves (17-18 BBCH)	silage	76	<0.01	<0.01		Barnes, J.P et al., 1997e DP 59813
							grain	121	<0.01	<0.01		
							grain + cob	121	<0.01	<0.01		

							grain + cob + husk	121	<0.01	<0.01		
Ravenna Italy 1995	Summer 2	0.15	400	0.04	1	7-8 leaves (17-18 BBCH)	silage	65	<0.01	<0.01		Barnes, J.P et al., 1997e DP 59813
							grain + cob + husk	98	<0.01	<0.01		
Ferrara Italy 1996	Cecilia (Pioneer)	0.20	400	0.05	1	7-8 leaves (17-18 BBCH)	silage	84	<0.01*	<0.01*		Barnes, J.P et al., 1997f DP 59815
							grain	121	<0.01*	<0.01*		
							grain + cob	121	<0.01*	<0.01*		
							grain + cob + husk	121	<0.01*	<0.01*		
Pavia Italy 1996	Caterina	0.20	400	0.05	1	6-8 leaves (16-18 BBCH)	silage	91	<0.01*	<0.01*		Barnes, J.P et al., 1997f DP 59815
							grain	129	<0.01*	<0.01*		
							grain + cob	129	<0.01*	<0.01*		
							grain + cob + husk	129	<0.01*	<0.01*		

* Residue based on the determination of total MESOTRIONE +MNBA = <0.01 mg/kg as MESOTRIONE equivalents

7.1.2.4 Summary for CHR/H/TERIZ 650 WG

Table 7.1-7: Information on CHR/H/TERIZ 650 WG (KCP 6.8)

Crop	PHI for CHR/H/TERIZ proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHR/H/TERIZ proposed by zRMS	zRMS Comments (if different PHI proposed)
		Terbuthylazine	isoxafluotle	mesotrione		
Maize	NR	NR	NR	NR	Not required	NR

NR: not relevant

Due to the early application at BBCH 00 there is no need to set up PHI for application of CHR/H/TERIZ 650 WG to maize.

Table 7.1-8: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for CHR/H/TERIZ 650 WG
Crop group	Led by Terbuthylazine	Led by isoxaflutole	Led by mesotrione	
Leafy vegetables	118 days	34 days	29 days	CHR/H/TERIZ 650 WG degrades in the soil during the growing season without endangering rotational crops. For CHR/H/TERIZ no waiting period is necessary as long as succeeding crops are sown after harvest of the treated crops. However, it is recommended to plough the soil before sowing the succeeding crop when sowing is indented in the autumn directly of treated crop.
Root vegetables	138 days	34 days	29 days	
Oilseeds	90 days	Not relevant	29 days	
Cereals	105 days	34 days	29 days	

NR: not relevant

Assessment

Terbuthylazine Assessment:
Summary for Terbuthylazine is based on studies presented during Annex I inclusion. All studies are presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010) and evaluated in EFSA Journal 2011; 9(1):1969. Short description of studies for Residues in Rotational crops is presented below:

Five trials were conducted in four locations (Italy, Germany, Spain and Switzerland), over three growing seasons (2000-2002); results are shown in Table B.7.9-1 DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010), above. Each trial involved 2-3 crop types in order to investigate the potential for residues in a variety of following crops across a range of crop categories (root vegetables, cereal and oilseed/pulse rotational crops). The crops involved were: sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet.

The crops were tested in parallel and the terbuthylazine was applied as an SC using the formulation (A-9476) for which Annex I inclusion is being sought.

Samples were analysed for residues of terbuthylazine, GS 26379/MT1 and GS 28620/MT14, i.e. the major components found in the confined crop rotation study.

Succeeding crops of sunflowers, cereal, oil seed rape, sugar beet and potatoes were planted into soil treated with terbuthylazine at rates of 0.844 – 0.938kg/ha. These rates are close to the various GAPs proposed by the notifiers and in certain cases are below the rate specified in the GAP (rates are between 1N and 1.3N for Syngenta and OXON).

Winter oilseed rape was planted between 90 and 121 days after treatment (DAT) in three separate studies and the residues (for all analytes) in seed and remaining plant material were ≤0.02 mg/kg, except in one trial (Luetolf, 2003) where residues of GS 28620/MT14 were 0.05 mg/kg and 0.04 mg/kg in seed.

In sunflowers planted 407 DAT, residues in the seed were <0.02 mg/kg for each analyte, while in a second trial, where the seeds were sown 266 DAT seeds were taken at both BBCH 89 and 92. At BBCH 89 (fully ripe) residues of terbuthylazine and GS 26379/MT1 were 0.02 and 0.05 mg/kg in whole plant and 0.06 mg/kg in seeds mg/kg; at BBCH 92 (over ripe) residues were all <0.02 mg/kg.

Cereals were grown in 4 trials with planting intervals of between 119 and 160 DAT.

Residues in all samples of grain were <0.02 mg/kg and ≤0.02 mg/kg in straw.
Sugar beet was grown in 4 of the trials with planting intervals of 138 – 350 DAT, in all cases residues in roots were <0.02 mg/kg.

When planted 336 DAT sugar beet residues of GS 26379/MT1 in samples taken at BBCH 39-49 were 0.04 mg/kg in the head and in samples taken at BBCH12-14 were 0.05 mg/kg in the whole plant.
Potatoes were also planted in one trial at an interval of 401 DAT, residues were <0.02 mg/kg for all analytes.

Isoxaflutole Assessment:

In a rotational crop study in six tanks treatments were performed(Hampton, R.E. and Pettaway, J., 1995b) : two tanks were the non-treated control tanks, two tanks were treated with the spray to the soil surface to simulate a preemergence application and two tanks were treated with the spray which was incorporated with a hand cultivator to simulate a preplant incorporated application. The spray consisted of ^{14}C-phenyl labelled isoxaflutole (purity 98.5%) and was applied on sandy loam soil at a rate of 200 g a.i./ha. The treated soil was aged under aerobic conditions for period of 34, 123 and 365 days to simulate normal rota-

tion intervals. At each of the rotation interval radish, lettuce and mustard and wheat grain and sorghum were planted as representatives of root crops, leaf vegetables and small grains, respectively.

All Raw Agricultural Commodities (RAC's) were sampled randomly without replacement at immature and mature stages in each rotation interval. Samples were counted by LSA after combusting for the determination of the total radioactive residue. Residues were quantified by LSC and metabolites/degradates identified by HPLC.

Parent compound was found only in trace amounts in certain 34-day RACs. RPA 202248 and RPA 203328 were identified. The latter was the major metabolite in the 34-day rotation crop (0.007-0.241 mg/kg isoxaflutole equiv.) and also present in 123- and 365-day RACs (0.005-0.031 mg/kg isoxaflutole equiv. and 0.002-0.019 mg/kg isoxaflutole equiv., respectively). The highest concentration of RPA 202248 was found in the 34-day RAC in raddish leaf (0.005 mg/kg isoxaflutole equiv.). In the mature lettuce in the 34-day RAC RPA 205834 was found in trace amounts. An unknown metabolite was found after 34 (lettuce, sorghum), 123 (wheat) and 365 (radish, sorghum) days. Levels ranged between 0.003 and 0.022 mg/kg isoxaflutole equiv.
The relatively short half-life of isoxaflutole does not require rotation interval restrictions in the year. In case of cropfailure, it is not possible to sow soybean, sunflower, mustard and spinach, because they are too susceptible

Mesotrione Assessment:

Two trials were undertaken in Illinois and North Carolina, USA in 1995-6, in which mesotrione was applied either a) to soil and incorporated prior to the planting of the maize crop, or b) to both the soil as above and post emergence to the maize crop at 24-36 inches tall. After the maize crop was removed, succession crops were grown and sampled at normal harvest to enable residue analysis (HPLC method, DAR 1997 Section B.4.2.1).

The first application was used to simulate early season crop failure and the second to simulate normal application post emergence. The varieties of maize employed, and the varieties of the succeeding crops are listed in the report, Barnes and Wiebe, 1997.

The formulation used for these was applied in admixture with a spray additive of crop oil concentrate, 1% volume:volume. Adequate data were provided concerning the field and analysis phases, with the exception that daily weather records and the harvesting dates for the maize crops were not supplied. The report states that rainfall was normal for the period of each trial, and that no unusual environmental conditions were recorded.

In two trials in the USA, residues of mesotrione and MNBA were determined in a range of rotational crops planted after ageing periods of 29 to 100 days, following applications of MESOTRIONE to both soil and soil + crop. The soil and crop application rates were approximately 2x and 1.5x the GAP post emergence application rate, respectively, and no residues of MESOTRIONE or MNBA were present in the succession/rotational crops at harvest, with a limit of quantification of 0.01 mg/kg.

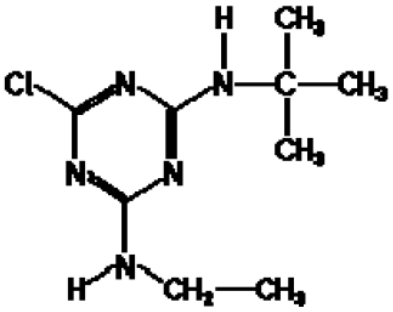
In the Event of crop failure, maize can be re-drilled immediately.
For autumn sown crops, there is no restriction for winter wheat, winter barley, durum wheat and ryegrass. For winter oilseed rape rape, deep ploghing is recommended to be sown in the autumn following application of mesotrione. For spring sown crops, the following restrictions apply:

Maize, ryegrass, spring wheat and spring barley, may be sown in the spring following application of mesotrione, but no other crops should be sown at this time.

7.2 Terbuthylazine

General data on Terbuthylazine are summarized in the table below (last updated 2016/10/29):

Table 7.2-1: General information on Terbuthylazine

Active substance (ISO Common Name)	**Terbuthylazine**
IUPAC	N^2-tert-butyl-6-chloro-N^4-ethyl-1,3,5-triazine- 2,4-diamine
Chemical structure	
Molecular formula	$C_9H_{16}ClN_5$
Molar mass	229.7 g/mol
Chemical group	chlorotriazine
Mode of action (if available)	Inhibitor of photosystem II(PSII) – HRAC mode of action group C1, WSSA group 5
Systemic	YES
Company (ies)	Syngenta/Oxon
Rapporteur Member State (RMS)	UK
Approval status	Approved 01/01/2012 Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011.
Restriction	See Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011
Review Report	SANCO/11337/2011 rev 2 17 June 2011
Current MRL regulation	Regulation (EC) No 149/2008 of 29 January 2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	EFSA Journal 2011; 9(1):1969
EFSA Journal: conclusion on article 12	NO
Current MRL applications on intended uses	EFSA-Q-2009-00077 (EMS) Review of all existing MRLs Status: Evaluation ongoing

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCP 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Residues of terbuthylazine, MT1 and MT14 stable for up to 24 months in cereal commodities when stored frozen at -18°C. The stability data are sufficient to support the residues trials (RMS, 2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues)

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereals (wheat grain, straw)	High starch content	24 months	RMS, 2010 (DAR Terbuthylazine - Volume 3, Annex B.7: Residues)
Animal Products - not required			

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/TERIZ 650 WG according to the label, therefore no new studies are necessary.

7.2.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues 2010 , analysis time were less than 24 hours between extraction and analysis.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

The nature of residues in primary crops were evaluated during Annex I inclusion, and presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues 2010.

No new data submitted in the framework of this application
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Table 7.2-3: Summary of plant metabolism studies

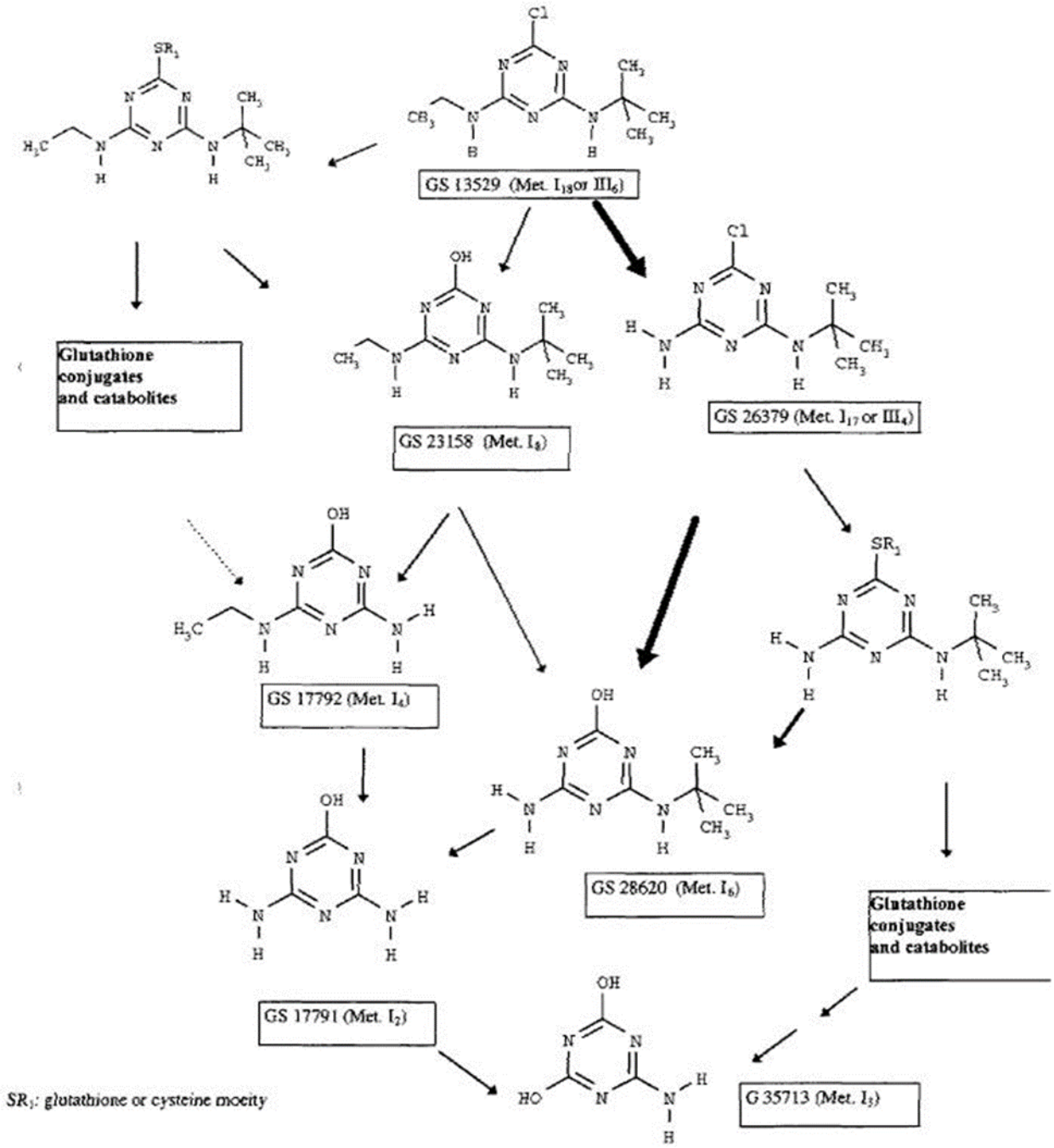
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	[triazine-U-14C]-terbuthylazine	F	1.45 kg a.s./ha	1	134	Oxon study	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
Cereals	Maize	[triazine-U-^{14}C]-terbuthylazine	F	1.5 kg a.s./ha	1	153	Syngenta study	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues

Summary of plant metabolism studies reported in the EU

Terbuthylazine is rapidly and extensively metabolised in maize, representing less than 5% of the TRR in all plant parts, and being not detected in mature grains at harvest. The metabolism in primary crop proceeds by desalkylation to the desethyl metabolite (MT1) and by dechlorination resulting in the 2- hydroxy-terbuthylazine (MT13), which are further metabolised to the desethyl-hydroxy-terbuthylazine (MT14).
The nature of the residue as a result of primary crop treatment was investigated in maize only. The Oxon notifier performed an investigation in maize (cereals) as a post-emergence study. The Syngenta notifier performed a similar investigation in maize as a pre-emergence (one day after seeding) study. Syngenta also performed a stem injection experiment. The studies were conducted at application rates relevant to the requested application rate. The findings of both notifiers' studies are in agreement with each other, these are summarized below:

- Once absorbed terbuthylazine is distributed over the whole plant with the highest levels seen in leaves and stem and only trace levels seen in the grain at the full ripe stage;
- Residues of terbuthylazine (MT0) are generally low – especially in grain indicating that terbuthylazine is metabolized rapidly;
- It appears that terbuthylazine is mainly metabolized into polar conjugates: in foliage the residue comprised a complex mixture of components (up to 16 discrete components were found in the Syngenta study) and in grain no single component of the residue exceeded 0.1 mg/kg;
- The major component of the residue is MT14/GS 28620;
- In grain MT14, while representing a large propor ion of the TRR, accounted for a small mass of residue (<0.01 mg/kg);
- In no part of the maize plant did MT1 repres nt more than 5% TRR (0.003 mg/kg) at harvest.
- Extractabilities were generally sufficiently high and characterization of components in the extracted fractions was adequate.

Proposed metabolic pathway for terbuthylazine in corn plants:



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/TERIZ 650 WG. No new studies were necessary.

7.2.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

The nature of residues in rotational crops were evaluated during Annex I inclusion, and presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues 2010.

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data Syngenta studies on Annex I								
Leafy vegetables	Lettuce	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118,364	64, 69	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
Root and tuber vegetables	Radish	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118,364	64, 69	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
Cereals	Wheat	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118, 182, 364	64,130, 104,132,	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
EU data OXON studies on Annex I								
Leafy vegetables	Spinach	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
Root and tuber vegetables	Radish	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
Cereals	Wheat	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7:

								Residues

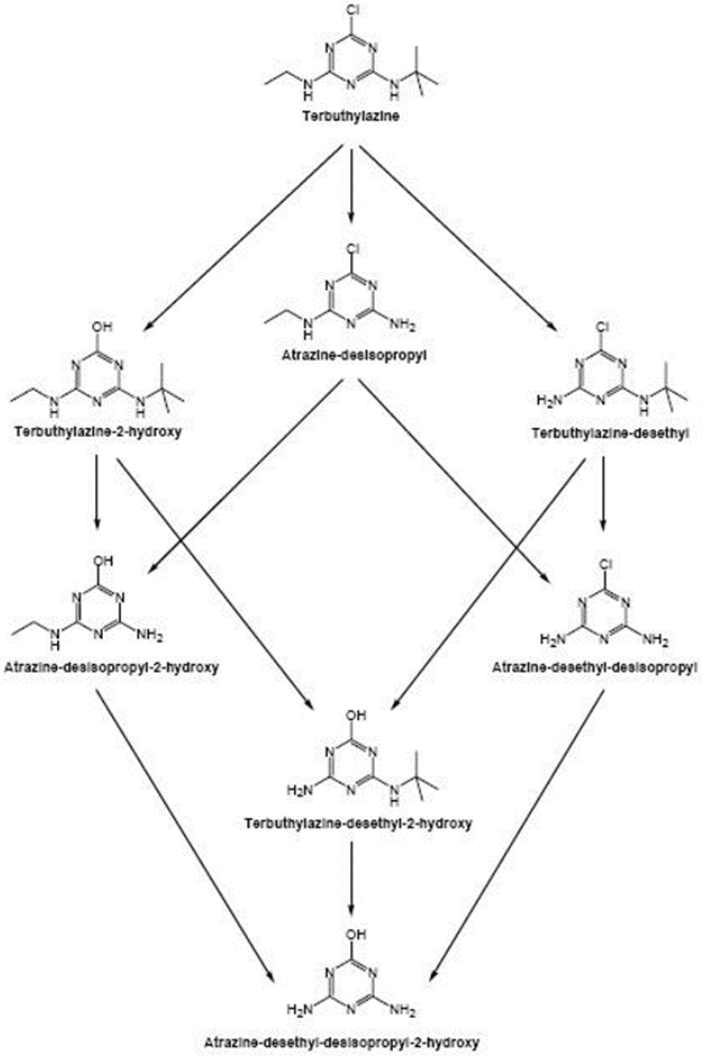
Summary of plant metabolism studies reported in the EU

The Oxon notifier did not submit reports of field tests to investigate residues in succeeding and rotational crops. They did however provide the findings of 'preliminary tests' (up to Step 3, according to guideline 7524/VI/95 Rev 2) which were used to justify non-submission of field tests.
The Syngenta study (Krauss, J, 2000) indicated that the nature of the residues in rotational crops is the same as those identified in the primary crop, maize. The total radioactive residues in food items from typically rotated crops grown in soil treated at 1.5 kg a.s./ha were low, i.e. ≤0.05 mg/kg. No individual compo ent of the residues (found in food items) represented >0.015 mg/kg.

Overall residues were higher in radish foliage and wheat forage; for example immature wheat foliage from the 118 day plant back interval conta ned approximately 0.1 mg/kg of GS 26379/MT1 and wheat straw from the 118 day plant back interval contained 0.3 mg/kg of the same metabolite.

The additional study (Mamouni, A, 2006) which i cludes a 30 -day plant back interval appears to support the findings of Krauss, J., 2000. However, in order to draw a fully robust conclusion, the notifiers should be asked to address the outstanding issues associated with this study. These issues have been satisfactorily addressed in the resubmission DAR and it has been possible to draw a robust conclusion (see Section B.7.1.2.B- DAR RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues).

Proposed metabolic pathway for terbuthylazine in rotational crops:



Conclusion on metabolism in rotational crops

A similar profile as in primeary crops is observed in the rotational crops where the TRRs are mainly composed of these three metabolites: MT1 (up to 41% TRR in spinach leaves), MT13 (up to 37% TRR in cereal grain) and MT14 (up to 70% TRR in radish roots). The metabolism in rotational crops covers use of CHR/H/TERIZ 650 WG according to the label

7.2.2.3 Nature of residues in processed commodities (KCP 6.5.1)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No new studies are necessary for CHR/H/TERIZ 650 WG, since all residues are expected to be below 0.1 mg/kg.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCP 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize) - foliar treatment (OXON: 3-4 leaf stage) and - soil treatment (SYN: pre-emergence)
Rotational crops covered	Lettuce, radish, wheat (SYN only) and spinach, radish, summer/winter wheat (SYN & OXON)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (terbuthylazine and metabolites MT1, MT13 and MT14 main components in rotational crops)
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Terbuthylazine (MT0) Commission Regulation (EC) No 149/2008 of 29 January 2008
Plant residue definition for risk assessment	Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14) *EFSA Journal 2011; 9(1):1969*
Conversion factor from enforcement to RA	Not necessary for maize grains (all residue data <LOQ)

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.2.5 Nature of residues in livestock (KCP 6.2.2-6.2.5)

Available data

The metabolism in livestock was evaluated during Annex I inclusion, and presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues 2010 and EFSA Journal 2011; 9(1):1969

No new data submitted in the framework of this application.

Table 7.2-5: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[triazine-U-14C]-terbuthylazine	1 control, 1 dosed animal	39 mg per day	10 days	Milk	daily	RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues
						Urine and faeces	daily	
						Tissues	daily	

Summary of plant metabolism studies reported in the EU

The results of this study appear to demonstrate that metabolism of terbuthylazine is rapid and its metab lites are eliminated from the animal quickly. The study was carried out using an exaggerated dose rate (10N/13N) and the results must be interpreted accordingly.

Approximately 80% of the applied radioactivity was excreted in the urine with small amounts remaining in tissue and milk (0.4 and 0.1% TRR respectively).

Residues in tissues were significant (at the exaggerated dose rate of the study, 10N/13N). Residues as terbuthylazine equivalents in liver and kidney were 0.9 mg/kg and 0.6 mg/kg respectively and in other tissues between 0.02 – 0.5mg/kg.

Residues in milk were lower than in tissues but were significant (at the exaggerated dose rate of the study, 10N/13N) and reached plateau after the first day. The average value for the Total Radioactive Residue (TRR) in milk was 0.082 mg/kg as terbuthylazine equivalents. Residues of metabolites in milk were also low;

0.039mg/kg (GS 26379) and 0.005mg/kg (GS 28273) and 0.036mg/kg (other polar metabolites) expressed as terbuthylazine equivalents.

It should also be noted that the study is approximately 30 years old and was not conducted according to GLP since these principles had not been established at the time. Despite this the notifiers have statread that the study complies with the current EC guidelines.

A number of inadequacies in the study have been identified and discussed in the evaluation above; they are also gathered together here for convenience:

- radiochemical purity was not reported;

- radioactivity (39% of TRR in milk, 0.029 mg/kg) in milk not characterised;
- insufficient details of the methods of analysis used to demonstrate the quality of the data and to indicate the confidence which can be attached to characterisations and identifications;
- insufficient work done to characterise or identify the metabolites present in the sampled tissues;
- no information on storage of samples and extracts was reported.

Not withstanding these inadequacies the study provides evidence that terbuthylazine is metabolised quickly and its metabolites are eliminated (in the urine and faeces) from the animal quickly.

In summary the study suggests that residue levels in products of animal origin are significant at the exaggerated dose rate of the study (approximately 10N in dairy cattle/13N in beef cattle). Considering the highest residues seen in tissue and milk at N rate the residues in liver and kidney could be 0.09 mg/kg (0.9 mg/kg ÷ 10) and 0.06 mg/kg (0.6 mg/kg ÷ 10) respectively (assuming 10N for dairy cattle i.e. worst case when compared with 13N for beef cattle) and in milk 0.0082 mg/kg (10N for dairy cattle: 0.082 mg/kg ÷ 10). These are the maximum possible residue levels and assume that the TRR consists entirely of GS 13529/MT0 and/or GS 26379/MT1; it is clear from the results for milk that this is not the case although the RMS accepts that due to the various inadequacies of the study it is not possible to be absolutely certain what proportion of the TRR will consist of any single compound.

The RMS believes it is very unlikely that at 1N residues of GS 13529/MT0, GS 26379/MT1 or any individual metabolite will be found at significant levels (>0.01 mg/kg) in any edible animal tissue or milk.

Conclusion on metabolism in livestock

A cow metabolism study was provided where animals were dosed with 14C-terbuthylazine over 10 days at a dose rate calculated to represent a 18N and 15N dose rate for dairy and beef cattle respectively. This study has however to be considered as not appropriate to propose a residue definition as no characterisation was performed in animal tissues, except in milk where MT1 and MT20 were identified as major metabolites (c.a. 50% and 12% TRR). Considering that TRRs are expected to be <0.01 mg/k in milk, muscle and fat and <0.05 mg/kg in liver and kidney when expressed on a 1N dose basis, it was concluded that no significant residues of any metabolite are expected to be present in animal matrices. The setting of a residue definition and proposals for MRLs for animal products were therefore considered not necessary with regard to the representative uses.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCP 6.7.1)

Table 7.2-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating cow
Time needed to reach a plateau concentration	Within 24 hours
	Within 24 hours
Animal residue definition for monitoring	No data, not necessary for the representative uses *EFSA Journal 2011; 9(1):1969*
Animal residue definition for risk assessment	No data, not necessary for the representative uses *EFSA Journal 2011; 9(1):1969*
Conversion factor	Not available *EFSA Journal 2011; 9(1):1969*
Metabolism in rat and ruminant similar	Not available EFSA Journal 2011; 9(1):1969
Fat soluble residue	Not available EFSA Journal 2011; 9(1):1969

7.2.3 Magnitude of residues in plants (KCP 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Both Applicants provide supervised residues studies for Annex I inclusion , which covers critical GAP for Annex I inclusion and cGAP for CHR/H/TERIZ containing terbuthylazine. Please refer to the RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues. Summary of available studies is presented in Table 7.2.-9.

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

Table 7.2-7: Summary of EU reported and new data supporting the intended uses of CHR/H/TERIZ 650 WG and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize	EFSA Journal 2011; 9(1):1969	N-EU	GAP on which MRL/EU a.s. assessment is based:1 x 0.75 kg as/ha, BBCH 12-16 PHI is not relevant, outdoor **Grain:** E: 8 X <0.02 mg/kg RA: MT0: 8x <0.02 MT1: 8x <0.02 MT14: 8x <0.02 Total residues: 8x <0.06 **Forage:** MT0: 8x <0.02 MT1: 8x <0.02 MT14: 7x <0.02, 0.03 Total residues: 7x <0.06, 0.07	N/A				
	New trials	N-EU	Now new trials submitted					

	Overall supporting data for cGAP	N-EU	E: 8 X <0.02 mg/kg RA: MT0: 8x <0.02 MT1: 8x <0.02 MT14: 8x <0.02 Total residues: 8x <0.06	E: 0.02 RA: 0.06	E: 0.02 RA: 0.06	-	0.1 mg/kg	Yes

* Source of EU MRL: Reg. (EC) No 149/2008

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize are considered acceptable, for both outdoor use.
Supervised residue trials were provided by both applicants. Samples were analysed for terbuthylazine but also for the metabolites MT1 and MT14 in a significant number of experiments. No residues were observed above the LOQ, except for the metabolite MT14 detected at the level of 0.03 mg/kg in maize forage in two locations.
All available data presented in EU conclusion is sufficient to support use of CHR/H/TERIZ 650 WG containing terbuthylazine, therefore no new studies are necessary.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary Burden calculations were perfomed during Annex I inclusion. New calculations were presented below witth MRL-Calculator.

Table 7.2-8: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : Terbuthylazine				
Maize (grain)	0.02	Median residue (EFSA Journal 2011; 9(1):1969)	0.02	Highest residue (EFSA Journal 2011; 9(1):1969)
Maize (as silage)	0.02	Median residue (EFSA Journal 2011; 9(1):1969)	0.02	Highest residue (EFSA Journal 2011; 9(1):1969)

Table 7.2-9: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition 1: Terbuthylazine					
Beef cattle*	0.0011	-	forage/silage	0.04	N
Dairy cattle*	0.0014	-	forage/silage	0.04	N
Ram/ewe	0.0002	-	grain	0.01	N
Lamb	0.0003	-	grain	0.01	N

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Breeding swine	0.001	-	forage/silage	0.03	N
Finishing swine*	0.000	-	grain	0.02	N
Broiler poultry	0.001	-	grain	0.02	N
Layer poultry*	0.001		grain	0.02	N
Turkey	0.001	-	grain	0.01	N

According to the DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010)

Considering maize only (as maize and maize silage) the expected exposure in the diet of beef and dairy cattle is 0.2 mg/kg diet (DM) – an animal metabolism study is therefore required and has been evaluated (xxx, 1970). Even if intakes of terbuthylazine only are considered the expected exposure in the diet of beef and dairy cattle is 0.1 mg/kg diet (DM) and an animal metabolism study would therefore still be required.
Considering maize (as maize and maize silage) and potential rotational crops the expected exposure in the diet of beef and dairy cattle is 0.408 mg/kg diet and 0.288 mg/kg diet (DM) respectively.
Intakes by domestic animals from the consumption of potential rotational crops were not taken into account for the purposes of calculating the N rate of the animal metabolism study as this was considered an overly conservative approach given the residues in potential rotated crops were predominantly LOQ and the relevant crops (see Table B.7.6-1 and Section B.7.9.1) are unlikely to form the majority of the diet of domestic animals over an extended length of time.

In consideration of the animal metabolism study (xxx, 1970) the RMS believes that residues of GS 13529/MT0, GS 26379/MT1 or any individual metabolite will not be found at significant levels (>0.01 mg/kg) in any edible animal tissue or milk (see Section B.7.2, Part vii – Conclusions) for full discussion. With regard to the consumer risk assessment no further consideration has therefore been given to residues in products of animal origin.

7.2.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010):
In view of the animal metabolism study submitted for the resubmission the RMS believes that residues of GS 13529/MT0, GS 26379/MT1 or any individual metabolite will not be found at significant levels (>0.01 mg/kg) in any edible animal tissue or milk.

It was stated in the original DAR that studies are not required due to the very low level of residues of terbuthylazine in maize

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

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCP 6.5.2-6.5.3)

No significant residues, i.e. >0.1 mg/kg, were found in grain (both notifiers) and therefore processing studies are not required. No further studies have been performed

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

Due to the residues from supervised trials for representative use in maize, all residues are below LOQ, therefore no processing studies are necessary.

7.2.6 Magnitude of residues in representative succeeding crops

The Oxon and Syngenta studies indicated that the nature of the residues in rotational crops is the same as those identified in the primary crop, maize. The total radioactive residues in food items from typically rotated crops grown in soil treated at 1.5 kg a.s./ha were low, i.e. ≤0.05 mg/kg. No individual component of the residues (found in food items) represented >0.015 mg/kg.

Overall residues were higher in radish foliage and wheat forage; for example immature wheat foliage from the 118 day plant back interval contained approximately 0.1 mg/kg of GS 26379/MT1 and wheat straw from the 118 day plant back interval contained 0.3 mg/kg of the same metabolite.

The SYN notifier has submitted rotational crop residues trials and these data allow a full assessment of the potential for uptake of terbuthylazine from the soil into following crops.

The Oxon notifier did not submit reports of field tests to investigate residues in succeeding and rotational crops. It was also noted that the SYN notifier submitted results of rotational crop field trials which provide evidence of significant residues in rotational crops.

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCP 6.6.2)

Available data According to the DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010)

Field trials on sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet as succeeding crops have also been conducted. In one study, terbuthylazine was applied to the soil prior to sowing maize and in the remaining 4 trials the application was made to maize as a post emergence application, i.e. BBCH 11-14. At appropriate intervals (typical for rotational/succeeding crops) crops were sown into the soil after destruction of the maize. Crops were sampled at appropriate intervals, and samples were analysed using Analytical Method 148.06.

No new data submitted in the framework of this application.

Table 7.2-10: Summary of available studies in field rotational crops

Country, year Soil Type	Application					PHI
	Form	kg a.s./ha	kg a.s./hL (actual)	water, L/ha	no. (inc. growth stage BBCH) Application Date	Crop Commodity, (DAT Planting) Growth Stage at harvest
Italy 2000 Silt loam	A-9476 SC 500	0.938	0.234	400	1 (00 – prior to sowing) 23/03/00	**Sunflowers (407)** Whole Plant (BBCH 14-18) Seeds BBCH 85 Seeds BBCH 89 **Potatoes (401)** Tubers BBCH 43 Tubers BBCH 47 Tubers BBCH 48
Germany 2001 Silty Sand	A-9476B SC 500	0.844		400	1 (13-14) 17/05/00	**Winter oilseed rape (105)** BBCH 12-14 Whole plant BBCH 87 Pods BBCH 87 Rest of plant BBCH 89-92 Grain BBCH 89-92 Straw **Winter barley (132)** BBCH 13 Whole plant BBCH 87 Ears BBCH 87 Rest of plant BBCH 89-92 Grain BBCH 89-92 Straw **Sugar beet (336)** BBCH 12-14 Whole plant BBCH 39-49 Head BBCH 39-49 Roots BBCH 49 Head BBCH 49 Roots
Germany 2002 Loamy Sand	A-9476B SC 500	0.844		300	1 (14) 31/5/01	**Winter oilseed Rape (90)** BBCH 14 Whole plant BBCH 85-87 Pods BBCH 87 Rest of plant BBCH 89 Grain BBCH 89 Straw **Winter barley (119)** BBCH 11-21 Whole plant BBCH 85-87 Ears BBCH 85 87 Rest of plant BBCH 89 Grain BBCH 89 Straw **Sugar beet (314)** BBCH 12-14 Whole plant BBCH 49 Head + leaves BBCH 49 Roots BBCH 49 Head BBCH 49 Roots
Spain 2002 Sandy Loam	A-9476B SC 500	0.937		300	1 (13-14) 31/5/00	**Sunflowers (266)** BBCH 15-18 Whole plant BBCH 89 Seeds

						BBCH 92 Seeds **Winter wheat (160)** BBCH 21-22 Whole plant BBCH 75-83 Ears BBCH 75-83 Stalks BBCH 99 Grain BBCH 99 Straw **Sugar beet (138)** BBCH 15-18 Whole plant BBCH 39 Head + leaves BBCH 39 Roots BBCH 49 Head + leaves BBCH 49 Roots
Switzerland 2002 Sandy Loam	A-9476B SC 500	0.844		500	1 (11) 16/5/00	**Winter oilseed rape (121)** BBCH 14 Whole plant BBCH 80 Pods BBCH 89 Seeds **Winter wheat (135)** BBCH 21 Whole plant BBCH 83 Ears BBCH 83 Stalks BBCH 89 Grain BBCH 89 Straw **Sugar beet (350)** BBCH 15 Whole plant BBCH 47 Head BBCH 47 Roots BBCH 48 Head BBCH 48 Roots

Conclusion on rotational crops studies

Five trials were conducted in four locations (Italy, Germany, Spain and Switzerland), over three growing seasons (2000-2002); results are shown in Table B.7.9-1, above. Each trial involved 2-3 crop types in order to investigate the potential for residues in a variety of following crops across a range of crop categories (root vegetables, cereal and oilseed/pulse rotational crops). The crops involved were: sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet.

The crops were tested in parallel and the terbuthylazine was applied as an SC using the formulation (A-9476) for which Annex I inclusion is being sought. Samples were analysed for residues of terbuthylazine, GS 26379/MT1 and GS 28620/MT14, i.e. the major components found in the confined crop rotation study.

Succeeding crops of sunflowers, cereal, oil seed rape, sugar beet and potatoes were planted into soil treated with terbuthylazine at rates of 0.844 – 0.938kg/ha. These rates are close to the various GAPs proposed by the notifiers and in certain cases are below the rate specified in the GAP (rates are between 1N and 1.3N for Syngenta and OXON).

Winter oilseed rape was planted between 90 and 121 days after treatment (DAT) in three separate studies and the residues (for all analytes) in seed and remaining plant material were ≤0.02 mg/kg, except in one trial (Luetolf, 2003) where residues of GS 28620/MT14 were 0.05 mg/kg and 0.04 mg/kg in seed.

In sunflowers planted 407 DAT, residues in the seed were <0.02 mg/kg for each analyte, while in a second trial, where the seeds were sown 266 DAT seeds were taken at both BBCH 89 and 92. At BBCH 89 (fully ripe) residues of terbuthylazine and GS 26379/MT1 were 0.02 and 0.05 mg/kg in whole plant and 0.06 mg/kg in seeds mg/kg; at BBCH 92 (over ripe) residues were all <0.02 mg/kg.

Cereals were grown in 4 trials with planting intervals of between 119 and 160 DAT.

Residues in all samples of grain were <0.02 mg/kg and ≤0.02 mg/kg in straw.

Sugar beet was grown in 4 of the trials with planting intervals of 138 – 350 DAT, in all cases residues in roots were <0.02 mg/kg. When planted 336 DAT sugar beet residues of GS 26379/MT1 in samples taken at BBCH 39-49 were 0.04 mg/kg in the head and in samples taken at BBCH12-14 were 0.05 mg/kg in the whole plant. Potatoes were also planted in one trial at an interval of 401 DAT, residues were <0.02 mg/kg for all analytes.

7.2.7 Other / special studies (KCP6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/TERIZ 650 WG containing Terbutylazine. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCP 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment.

The Consumer risk assessment was performed using PRIMO EFSA MODEL-TMDI Calculator using input parameters presented in Table 7.2-15.

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize	0.1	MR (worst case) according Reg. (EC) No 149/2008	0.1	MR (worst case) according Reg. (EC) No 149/2008

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in 0. Summary of results is presented below in table 7.2.-16.

Table 7.2-12: Consumer risk assessment

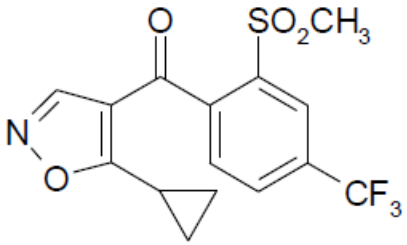
TMDI (% ADI) according to EFSA PRIMo	6.2 % (based on WHO Cluster diet B)
IEDI (% ADI) according to EFSA PRIMo	6.2 % (based on WHO Cluster diet B)
IESTI (% ARfD) according to EFSA PRIMo*	8.4 % (based on UK Infant)

The proposed uses of terbuthylazine in the formulation CHR/H/TERIZ do not represent unacceptable acute and chronic risks for the consumer.

7.3 Isoxaflutole

General data on Isoxaflutole are summarized in the table below (last updated 2016/10/30)

Table 7.3-1: General information on

Active substance (ISO Common Name)	Isoxaflutole
IUPAC	(5-cyclopropyl-1,2-oxazol-4-yl)(α,α,α-trifluoro-2-mesyl-p-tolyl)methanone
Chemical structure	
Molecular formula	$C_{15}H_{12}F_3NO_4S$
Molar mass	359.32 g/mol
Chemical group	oxazole
Mode of action (if available)	4-HPPD inhibition
Systemic	Yes
Company (ies)	Bayer CropScience
Rapporteur Member State (RMS)	Italy
Approval status	Approved Date of (01/10/2003) and reference to decision (Commission Directive 2003/68/EC of 11 July 2003 - Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011)
Restriction	see Commission Directive 2003/68/EC of 11 July 2003
Review Report	SANTE/11653/2017 Rev 2- 22 March 2019
Current MRL regulation	Regulation (EC) No 2015/845 of 27 May 2015
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA Journal 2016;14(3):4416)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2013;11(2):3123)
Current MRL applications on intended uses	EFSA-Q-2008-571 (EMS) Reasoned opinion available (EFSA Journal 2013;11(2):3123)

7.3.1 Stability of Residues (KCP 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

The storage stability was previously evaluated in the DAR (KCP 6.1/01 and /02), for maize raw agricultural commodities (grain, silage and fodder) and maize processed commodities (flour, meal, grits, starch andrefined oil) at -10°C. The results of these studies indicate that the residues of isoxaflutole (sum of isoxaflutole, DKN metabolite and IFT acid), are stable in corn matrices when stored under freezer conditions for 3 months (processed commodities) and for 15 months (raw agricultural commodities).

Additionally, in residue studies all samples were analysed within 30 days after sampling thus no stability of residues is required.

7.3.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion , analysis time were less than 24 hours between extraction and analysis.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

The nature of residues in primary crops were evaluated during renewal Annex I inclusion, and presented in RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7.

No new data submitted in the framework of this application.

Table 7.3-2: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Corn (old study)	[phenyl-UL-14C]-isoxaflutole	F	0.209, 0.657, 0.227, 1.075	1	41, 138	none	RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7

Summary of plant metabolism studies reported in the EU

Plant metabolism was studied in maize with isoxaflutole labelled in the [phenyl-UL-14C] ring only. Radioactive residues were low with only small amounts of the active ingredient isoxaflutole found, indicating a rapid decline of IFT. No isoxaflutole active ingredient was observed in the raw agricultural commodities for human consumption. Extraction efficiencies were high for all matices observed consequently amounts of bound residues were generally below 10% of the TRR.
The same metabolic profile was observed in all metabolism studies. A hydrolytic attack on isoxaflutole promoted isoxazole-ring opening to form IFT diketonitrile (DKN, RPA 202248). Further hydrolytical

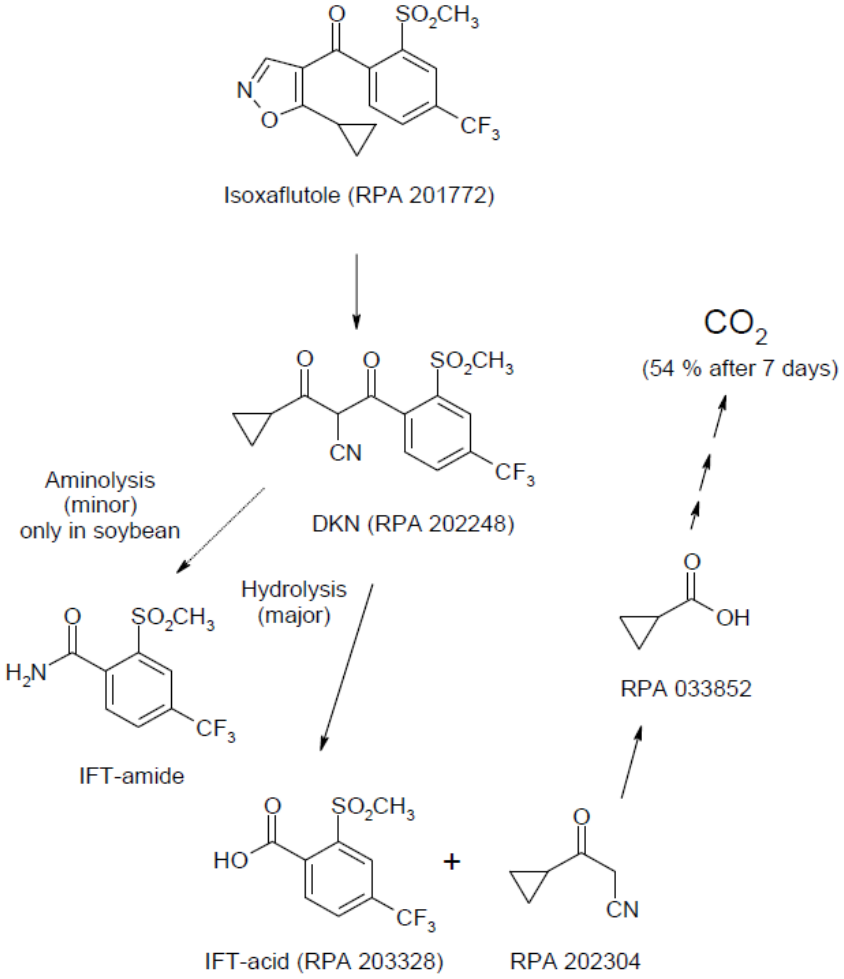
cleavage of the carbonyl bridge and loss of the complete isoxazole moiety lead to the corresponding benzoic acid derivative (IFT- benzoic acid, RPA 203328). The two major metabolites IFT-diketonitrile and IFT-benzoic acid occur as a result of crop metabolism, soil metabolism, soil photolysis, aqueous photolysis, and rat metabolism.

Based on similar metabolic pathways depicted in primary and rotational crops, the metabolite RPA 203328 was considered quantitatively relevant and a valid residue marker for monitoring for plant commodities.

Considering that the residues in plants are almost constituted of RPA 203328, EFSA proposes to set the residue definition for enforcement as RPA 203328 for all crops. The residue definition for risk assessment should include RPA 203328 only for conventional crops.

No studies with 14C label in the isoxazole ring position were submitted. It is in the opinion of RMS that due to the rapid degradation by the opening of the isoxazole ring, a 14C label in the isoxazole would not contribute to further information other than the loss of the isoxazole moiety to form the benzoic acid metabolite (RPA 205834). Since the two major metabolites IFT-diketonitrile and IFT- acid were also observed in soil metabolism, soil photolysis, aqueous photolysis, and rat metabolism, no specific studies with 14C label in the isoxazole ring position were performed.

Proposed Metabolic/degradative Pathway of Isoxaflutole in Plants:



Conclusion on metabolism in primary crops

Regarding the representative uses on maize of isoxaflutole, sufficient GAP-compliant metabolism studies in plants are sufficient to cover use of CHR/H/TERIZ 650 WG containing isoxafluole on maize at BBCH 00.

No New studies are necessary.

Maize is only crop included in INNVIGO`s GAP table, therefore no additional plant metabolism study is required.

7.3.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

The nature of residues in rotational crops were evaluated during renewal Annex I inclusion and renewal process, and presented in RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7.

No new data submitted in the framework of this application.

Table 7.3-3: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Root/tuber crops	Radish leaf	14C-phenyl-labelled isoxaflutole;	F	0.2	34, 123, 365	-	-	RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7
Leafy vegetables	Lettuce	14C-phenyl-labelled isoxaflutole	F	0.2	34, 123, 365	-	-	RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7
Cereal (small grain)	Sorghum	14C-phenyl-labelled isoxaflutole	F	0.2	34, 123, 365	-	-	RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7

Summary of plant metabolism studies reported in the EU

RPA 203328 was found to be the most abundant metabolite observed in all crops at all plant-back intervals, with up to 82% TRR in radish leaf, 63% TRR in lettuce and 67% TRR in sorghum grain. Parent isoxaflutole was never detected whilst RPA 202248 was identified in radish leaf only (26% TRR; 0.005 mg/kg).

Conclusion on metabolism in rotational crops

Based on similar metabolic pathways depicted in primary and rotational crops, the metabolite RPA 203328 was considered quantitatively relevant and a valid residue marker for monitoring for plant commodities.
No new studies are necessary, since all studies covers use of CHR/H/TERIZ 650 WG containing isoxaflutole.

7.3.2.3 Nature of residues in processed commodities (KCP 6.5.1)

Since residues of isoxaflutole are below <0.01 mg/kg no studies investigating nature of residues in processed commodities are required.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCP 6.7.1)

Table 7.3-4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals/grass crops (corn~~, wheat~~) ~~Pulses/Oilseeds (soybean, poppy)~~ ~~Miscellaneous (Sugarcane)~~
Rotational crops covered	Root/tuber crops (Radish leaf) Leafy crops (Lettuce) Cereal (Sorghum)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	not stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Isoxaflutole (sum of isoxaflutole and its diketonitrile-metabolite, expressed as isoxaflutole) (Regulation n° 2015/845 of 27 May 2015)
Plant residue definition for risk assessment	Conventional crops: RPA 203328 Genetically modified crops: RPA 203328 and RPA 202248 EFSA Journal 2016;14(3):4416
Conversion factor from enforcement to RA	Not relevant

7.3.2.5 Nature of residues in livestock (KCP 6.2.2-6.2.5)

Available data

The nature of residues in livestock were evaluated during renewal Annex I inclusion, and presented in RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7.

No new data submitted in the framework of this application.

Table 7.3-5: Summary of animal metabolism studies

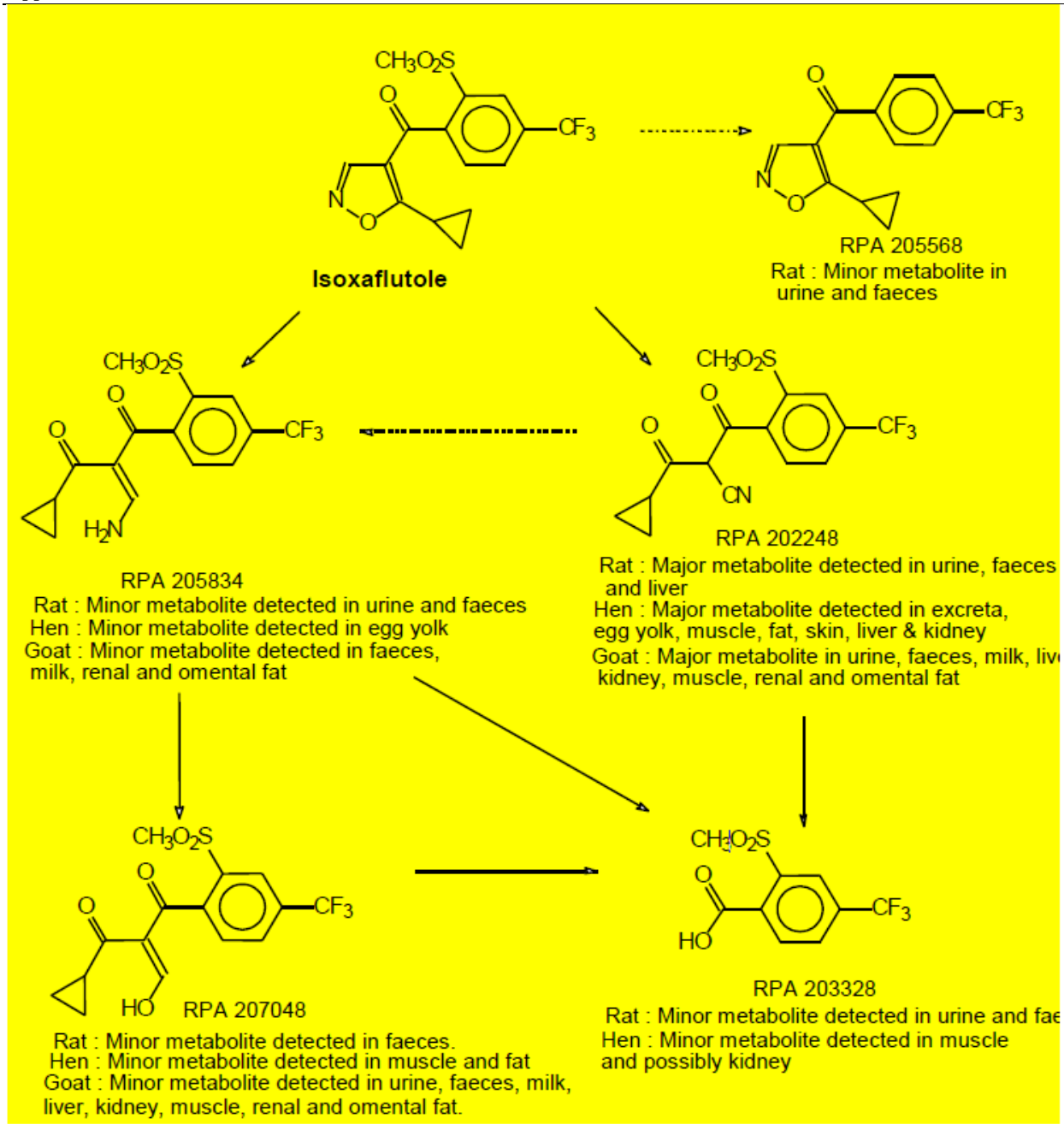
Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating	Goat	14C-	4	0.03;0.3;1.5	7	Milk	Twice a	RAR

ruminants		phenyl-labelled isoxaflutole					day	(2016) isoxaflutole Volume 3 – Annex CA - B.7
						Urine and faeces	daily	
						Tissues	daily	
Laying poultry	Hen	14C-phenyl-labelled isoxaflutole	10	0.152;1.52	14	Eggs	daily	RAR (2016) isoxaflutole Volume 3 – Annex CA - B.7
						Excreta	daily	
						Tissues	daily	

Summary of plant metabolism studies reported in the EU

Information on metabolism in animals were reviewed during Annex 1 inclusion process and no further data have been generated. The studies reported adequately described the metabolism of isoxaflutole in lactating ruminants and poultry. The same metabolic profile was observed in goat, hen and rat and consequently a metabolism study in pig is not necessary.
Following oral administration, 14C-isoxaflutole has been shown to be rapidly absorbed and metabolized in rat, goat and hen. The main product eliminated in both urine and faeces in the rat and goat and in the excreta of chicken was the diketonitrile derivative (DKN RPA 202248). Elimination was observed to be relatively rapid in all three species with very low to moderate levels of radioactive residues being found in the tissues, with the higher levels in liver and kidney.
The major metabolite formed following repeated administration of isoxaflutole to the lactating goat was RPA 202248. The metabolites RPA 207048 and RPA 205834 were also identified as being present.
Residue levels in the milk at the low dose were below the LOD (Limit Of Detection, < 0.002 µg equiv/g) and in the 10 mg/kg food level below 0.095 µg equiv/g. A steady state was appearent by 48 hours after the first dose. At the high dose a steady state was appearent by 120 hours at a mean concentration of 0.338 µg equiv/g. The concentration of 14C-residues in egg white and egg yolk sampled from hens from the higher dose group were low. A steady state in the egg yolk was reached by 7 days after the first dose.

Proposed General Metabolic Pathway for Isoxaflutole in Animals:



Conclusion on metabolism in livestock

livestock metabolism studies were conducted with isoxaflutole. The parent compound was never detected whilst the predominant compound of the total residues was RPA 202248 in liver (86–93% TRR), kidney (74–82% TRR), muscle (6–41% TRR), fat (24–29% TRR), eggs (26% TRR) and milk (42% TRR). Since RPA 203328 was recovered at a very low level in poultry muscle only (6% TRR; 0.002 mg/kg), it is not possible to conclude on whether this compound may undergo further degradation as a result of the metabolism of RPA 203328 in animals

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCP 6.7.1)

Table 7.3-6: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2 days (LD); 5 days (HD)
	7 days
Animal residue definition for monitoring	Not required for the representative uses.
Animal residue definition for risk assessment	Not required for the representative uses.
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Not relevant as no residue definition is set.

7.3.3 Magnitude of residues in plants (KCP 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

New supervised residues trials were performed due to the renewal of active substance isoxaflutole. 4 new trials in 2017 in northern Europe (Eurofins 2017, Dr. Sönke Lakaschus, Sabrina Fritzsch) were performed summary of this study is presented below and in Appendix 2 .

Table 7.3-7: Summary of EU reported and data supporting the intended uses of CHR/H/TERIZ 650 WG containing isoxaflutole and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	Eurofins 2017 Dr. Sönke Lakaschus Sabrina Fritzsch	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha, BBCH0 0-13, PHI N/A, outdoor E: ~~<0.003, <0.003, <0.003, <0.003, <0.003,~~ 5 x < 0.01 mg/kg (LOQ) RA: <0.003, <0.003, <0.003, < 0.003, <0.003, 5 x < 0.01 mg/kg (LOQ)	N/A				
	Overall supporting data for cGAP	N-EU	E:<0.003, <0.003, <0.003, <0.003, <0.003, RA: <0.003, <0.003, <0.003, < 0.003, <0.003	E:0.003 RA: 0.003	E: 0.003 RA: 0.003	0.01	0.01	Yes
Maize whole plant	Eurofins 2017 Dr. Sönke Lakaschus Sabrina Fritzsch	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.1 kg as/ha, BBCH0 0-13, PHI N/A, outdoor E:<0.003, <0.01, <0.003, 0.016, <0.003, RA: <0.003, <0.001, <0.003, 0.016, <0.003,	N/A				
	Overall supporting data for cGAP	N-EU	E:<0.003, <0.01, <0.003, 0.016, <0.003, RA: <0.003, <0.001, <0.003, 0.016, <0.003,	E: <0.003	E: 0.016	-	-	Yes

*

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize are considered acceptable, for both outdoor uses.
The data submitted show that no exceedance of the MRL will occur for CHR/H/TERIZ 650 WG containing isoxaflutole and applies at highest rate (100 g isoxaflutole/ha) with an accord to the label.

The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration) according to the EFSA Journal 2016;14(3):4416

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Corn forage/silage	0.01	STMR	0.04	HR
Corn stover	0.01	STMR	0.04	HR
Pop corn stover	0.01	STMR	0.04	HR
Corn grain	0.01	STMR	0.01	STMR
Pop corn grain	0.01	STMR	0.01	STMR

Table 7.3-8: Results of the dietary burden calculation according to the EFSA Journal 2016;14(3):4416

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.002	Ram/Ewe	0.0001	Breeding	0.001	Broiler	0.001	Carp	-
	Dairy cattle	0.002	Lamb	0.0001	Finishing	0.0002	Layer	0.001	Trout	-
							Turkey	0.0004	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	Not required		Not required		Not required		Not required		Not required	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals	Estimated HR[a] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[b]										
Liver										
Kidney										
Milk[a]										
Eggs										
Method of calculation[c]										

(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).
(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0005	Ram/Ewe	0.0001	Breeding	0.0003	Broiler	0.001	Carp	
	Dairy cattle	0.0007	Lamb	0.0001	Finishing	0.0002	Layer	0.001	Trout	
							Turkey	0.0004		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N	Mean level in feeding level	Estimated **STMR**[b] at 1N
Muscle										
Fat										
Meat[a]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[c]										

(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.
(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf),by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

7.3.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According to the dietary burden calculation for isoxaflutole and low resides in maize, no livestock feeding studies are necessary.

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

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCP 6.5.2-6.5.3)

Processing studies are not triggered since residue levels in maize grain are <0.1 mg/kg.

7.3.5.1 Available data for all crops under consideration

Processing studies are not triggered since residue levels in maize grain are <0.01 mg/kg.

7.3.5.2 Conclusion on processing studies

Processing studies are not triggered since residue levels in maize grain are <0.01 mg/kg.

7.3.6 Magnitude of residues in representative succeeding crops

According to the EFSA Journal 2016;14(3):4416 the Confined rotational crop study ((Quantitative aspect) OECD Guideline 502). RPA 203328 was found to be the most abundant metabolite observed in all crops at all plant-back intervals, with up to 82% TRR in radish leaf, 63% TRR in lettuce and 67% TRR in sorghum grain. Parent isoxaflutole was never detected whilst RPA 202248 was identified in radish leaf only (26% TRR; 0.005 mg/kg).

7.3.6.1 Field rotational crop studies (KCP 6.6.2)

Field rotational crop study is not required.

Conclusion on rotational crops studies

The IFT acid was the major metabolite in the 34-day rotation and also present in 123- and 365-day RACs at maximum concentrations of 0.005 mg/kg isoxaflutole equiv. (34-day RAC in raddish leaf). In mature lettuce the IFT acid was found at trace amounts (34-day RAC). An unknown metabolite was found after 34 (lettuce, sorghum), 123 (wheat) and 365 (radish, sorghum) days, although at maximum levels of 0.022 mg/kg isoxaflutole equiv.. Although the IFT acid was also the main metabolite at har-vest in maize, RMS is in the opinion that it should not be considered as a relevant metabolite for plant products, being of lower concern when compared to the active substance, and hence of no concern when potentially present in succeeding crops at levels down to the LOQ..

7.3.7 Other / special studies (KCP6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/TERIZ 650 WG. Therefore, other special studies are not needed.

7.3.8 Estimation of exposure through diet and other means (KCP 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-9: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment for Isoxaflutole				
Maize	0.02	MRL	0.02	MRL

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in 0.

Table 3-10: Consumer risk assessment

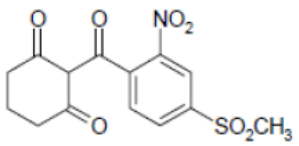
TMDI (% ADI) according to EFSA PRIMo ver3.1	0.7 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo ver 3.1	0.7 % (based on NL toddler))
IESTI (% ARfD) according to EFSA PRIMo ver 3.1	0.3 % (based on NL toddler)

The proposed uses of isoxaflutole in the formulation CHR/H/TERIZ 650 WG (containing 100 g/kg of isoxaflutole do not represent unacceptable acute and chronic risks for the consumer.

7.4 Mesotrione

General data on Mesotrione are summarized in the table below (last updated 2016/10/31)

Table 7.4-1: General information on Mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol
Chemical group	triketones
Mode of action (if available)	(HPPD) inhibitor
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	UK
Approval status	Approved

	Date of (01/10/2003) Commission Directive 2003/68/EC of 11 July 2003- Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011
Restriction	See Approval Directive / Regulation
Review Report	SANCO/1416/2001 -Final 14 April 2003
Current MRL regulation	Commission Regulation (EU) 2016/53 of 19 January 2016
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2016;14(3):4419
EFSA Journal: conclusion on article 12	Yes EFSA Journal 2015;13(1):3976
Current MRL applications on intended uses	EFSA-Q-2008-585 Status: Reasoned opinion available (EFSA Journal 2015;13(1):3976

7.4.1 Stability of Residues (KCP 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

In an interim report untreated samples of the three matrices were fortified separately with either MESO-TRIONE or metabolite MNBA at 0.1 mg/kg and stored frozen at -18°C ±5°C. Sampleswere analysed in duplicate at intervals using the HPLC method described in Section B.5.1.2.1.2. DAR_08_Volume3_residue B7-public 1999.

No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration		Reference
Data relied on in EU				
Plant products		**A.S**	**MNBA**	
Maize forage	High water content	17 months	17 months	Wiebe, L.A. 1997 DAR_08_Volume3_residue B7-public 1999
Maize grain	High starch content	17months	17 months	Wiebe, L.A. 1997 DAR_08_Volume3_residue B7-public 1999
Animal Products not required				

Conclusion on stability of residues during storage

All the samples were stored frozen for less than 15 months prior to analysis, and the storage stability study indicated that both MESOTRIONE and MNBA residues are stable for at least 17 months when stored at -18°C ±5°C.

7.4.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion process and presented in DAR_08_Volume3_residue B7-public 1999., analysis time were less than 24 hours between extraction and analysis**.**

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

The nature of residues in primary crops were evaluated during Annex I inclusion, and presented in DAR_08_Volume3_residue B7-public 1999.

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals/grass crops	Maize	cyclohexane-2-14C	F	280-307g a.s./ha (pre-emergence)	1	Forage: 27 Fodder: 154 Grain: 154	none	Wei, Y et al, 1997 DAR_08_Volume3_residue B7-public 1999
	Maize	phenyl-U-14C.	F	164 g a.s./ha (post-emergence)	1	Forage: 28 Fodder: 125 Grain: 125	none	Tarr, J.B et al, 1997 DAR_08_Volume3_residue B7-public 1999

Summary of plant metabolism studies reported in the EU

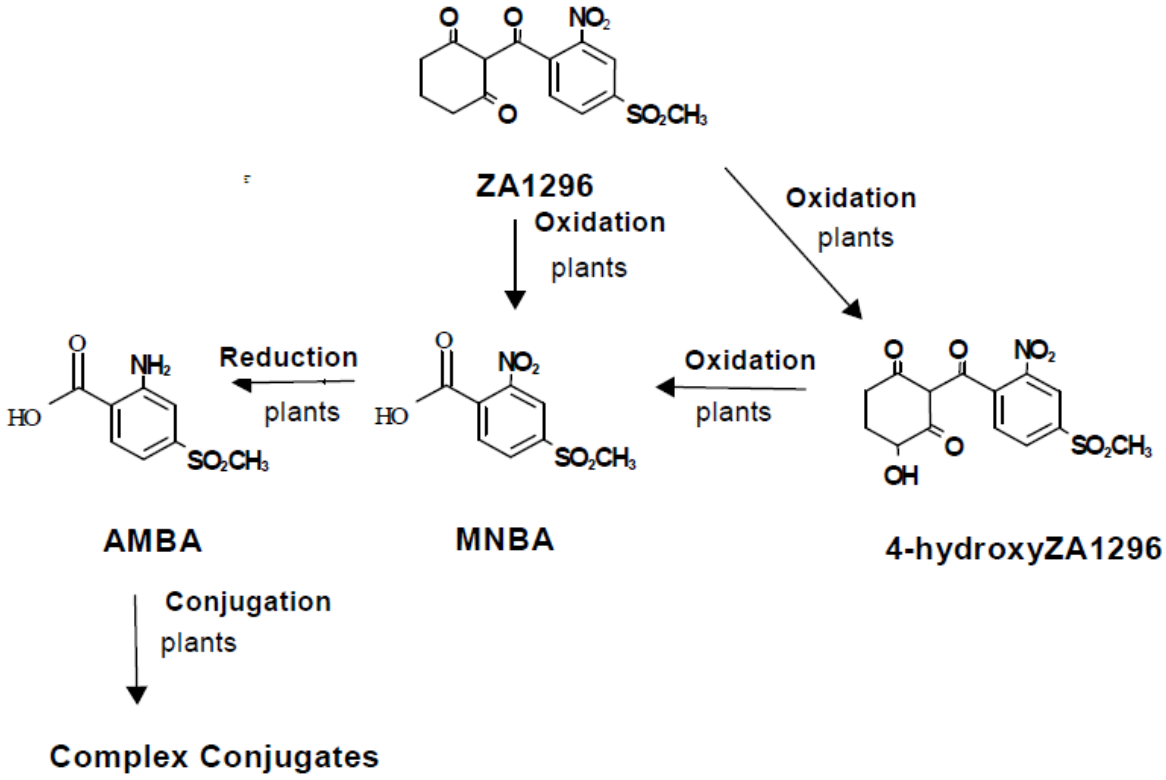
Plant metabolism studies have been conducted with [14C] MESOTRIONE labelled either in the phenyl ring or position 2 on the cyclohexane ring. In the maize metabolism study where [14C] MESOTRIONE was applied at N rate, 28 days after planting TRR in the forage, fodder and grain

were 0.098, 0.33 and 0.011 mg/kg respectively for the cyclohexane label and 0.244, 1.07 and 0.014 for the phenyl label respectively.
MESOTRIONE was rapidly and extensively metabolised. In the forage samples, harvested 28 days after treatment MESOTRIONE accounted for less than 1% TRR and 4-hydroxy MESOTRIONE accounted for *ca* 3 and 6% TRR (phenyl and cyclohexane labels respectively). In the study using phenyl labelled MESOTRIONE, MNBA accounted for a further 3.5% TRR, free AMBA accounted for ca 2% TRR and AMBA conjugates for *ca* a further 12% TRR. For the cyclohexane label there was evidence of incorporation of the radioactivity into carbohydrate.
MESOTRIONE was not detectable in the fodder samples (either label). In the [14C] phenyl labelled studies traces of 4-hydroxy MESOTRIONE (0.007 mg/kg, 0.7% TRR), MNBA (0.019 mg/kg 1.9% TRR) and free AMBA (0.006 mg/kg, 0.6% TRR) were detected.

Various conjugates of AMBA accounted for *ca* 28% TRR (0.30 mg/kg). For the cyclohexane label there was evidence for incorporation of radioactive residues into carbohydrate and lignin.
Limited analysis was conducted on the grain samples due to the low levels of radioactivity; no single extract or component accounted for >0.01 mg/kg. MESOTRIONE was not detected in grain.

Conclusion on metabolism in primary crops

Presented studies on Annex I inclusion of active substance, support use of mesotrione in CHR/H/TERIZ 650 WGm therefore no new studies are necessary and pathway of metabolism in plants can be proposed:



7.4.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

The nature of residues in rotational crops were evaluated during Annex I inclusion, and presented in DAR_08_Volume3_residue B7-public 1999

No New metabolism studies have been submitted by the applicant in the framework of this application.

Table 7.4-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Root/tuber crops	Radish	cyclohexane-2-14C phenyl-U-14C	F	0.164	120,300	56	none	Gorder, G.W et al, 1997; Spillner, C.J et al ,1997 DAR_08_Volume3_residue B7-public 1999
Leafy vegetables	Broad leaves Endive	cyclohexane-2-14C phenyl-U-14C	F	0.164	120,300	78	none	Gorder, G.W et al, 1997; Spillner, C.J et al ,1997 DAR_08_Volume3_residue B7-public 1999
Cereals	Wheat	cyclohexane-2-14C phenyl-U-14C	F	0.164	120,300	Wheat forage-22 Wheat hay 57 Wheat straw 134 Wheat grain 134	none	Gorder, G.W et al, 1997; Spillner, C.J et al ,1997 DAR_08_Volume3_residue B7-public 1999

Summary of plant metabolism studies reported in the EU

The metabolism and distribution of MESOTRIONE was investigated in the rotational crops wheat, endive and radish planted 120 and 300 days following soil application of [14C] MESOTRIONE to soil in pots at *ca* 1.2N. A replanting interval of 30 days was not investigated but is not of concern since replanting after this interval would not be anticipated for this crop.

TRR in the plants grown in the soil treated with [14C]-cyclohexane labelled MESOTRIONE were <0.001-0.002 mg/kg. TRR in the crops grown in soil treated with [14C]-phenyl labelled MESOTRIONE were 0.004 mg/kg in both radish roots and tops, 0.012 mg/kg in endive and 0.033, 0.018, 0.031 and 0.006 mg/kg in wheat forage, hay, straw and grain respectively. The 300 DAT crops were not harvested due to the low levels of radioactivity in the 120 DAT crops.

MNBA, AMBA sulphate and AMBA conjugate were present in all extracts of wheat forage, hay and straw, the only significant component was MNBA at 0.011 mg/kg in wheat forage (33% TRR). MESOTRIONE was not detected.

All of the plant metabolites have also been determined in mammalian metabolism studies.

Conclusion on metabolism in rotational crops

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops. Studies evaluated during EU review, are sufficient and no new studies are necessary for CHR/H/TERIZ 650 WG.

7.4.2.3 Nature of residues in processed commodities (KCP 6.5.1)

Available data

No data were submitted. However, all samples at harvest contained no residues of mesotrione or MNBA, with a limit of quantification of 0.01 mg/kg. In addition, consumer intakes accounted for less than 1% of the ADI. Therefore it is considered that processing studies are not required.
Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg).

No new data submitted in the framework of this application.

7.4.2.4 Conclusion on the nature of residues in commodities of plant origin (KCP 6.7.1)

Table 7.4-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Maize)
Rotational crops covered	Root/tuber crops (Radish) Leafy crops (Broad leaves Endive) Cereal (small grain) (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No studies provided
Residue pattern in processed commodities similar to pattern in raw commodities?	No studies provided
Plant residue definition for monitoring	Mesotrione Commission Regulation (EU) 2016/53 of 19 January 2016
Plant residue definition for risk assessment	Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and Amba
Conversion factor from enforcement to RA	Not applicable SANCO/1416/2001 -Final

7.4.2.5 Nature of residues in livestock (KCP 6.2.2-6.2.5)

Available data

The nature of residues in livestock were evaluated during Annex I inclusion, and presented in DAR_08_Volume3_residue B7-public 1999
No new data submitted in the framework of this application.

Table 7.4-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat/Cow	phenyl-U-14C AMBA		0.4	7	Milk	daily	Hand, L.H, 1997 DAR_08_Volume3_residue B7-public 1999
						Tissues	once	
						Urine	once	
						Faeces	once	

Summary of plant metabolism studies reported in the EU

MESOTRIONE is rapidly and extensively metabolised. In the maize metabolism study the metabolite 4-hydroxy MESOTRIONE was detected at low levels (<0.01 mg/kg) in forage and fodder, the metabolite MNBA was detected at *ca* 0.01 and 0.02 mg/kg in forage and fodder respectively. The major single component of the radioactivity was AMBA but largely in the conjugated form; residues of free AMBA were low, up to 0.006 mg/kg.
The AMBA conjugates were not successfully released by acid or base hydrolysis carried out on fodder samples. In addition none of a series of enzyme preparations (porcine carboxylic acid esterase, papain and pancreatin) proved effective. The applicant has stated that a residue method for total AMBA based on the hydrolysis of its diverse conjugates would be difficult to develop.
In the residue trials analysis was carried out for MESOTRIONE and MNBA. In all cases residues in the maize grain and fodder at harvest were below the limit of determination of 0.01 mg/kg.
The proposed residue definition is MESOTRIONE and MNBA expressed as MESOTRIONE. The applicant has stated that MNBA is a specific metabolite of MESOTRIONE.
Animal intakes are not significant and therefore a residue definition for animal products does not need to be considered.

Conclusion on metabolism in livestock

Livestock metabolism studies are not triggered considering the estimated dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data.

No new studies for CHR/H/TERIZ 650 WG are necessary for representative use.

7.4.2.6 Conclusion on the nature of residues in commodities of animal origin (KCP 6.7.1)

Table 7.4-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats/cow
Time needed to reach a plateau concentration	5 days in milk
Animal residue definition for monitoring	Not required for the representative use (provisional) SANCO/1416/2001 -Final
Animal residue definition for risk assessment	Not required for the representative use (provisional) SANCO/1416/2001 -Final
Conversion factor	Not required for the representative use (provisional) SANCO/1416/2001 -Final
Metabolism in rat and ruminant similar	Yes SANCO/1416/2001 -Final
Fat soluble residue	AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

7.4.3 Magnitude of residues in plants (KCP 6.3)

7.4.3.1 Summary of European data and new data supporting the intended uses

Supervised residues studies for Annex I inclusion , which covers critical GAP for Annex I inclusion and cGAP for CHR/H/TERIZ containing Mesotrione. Please refer to the DAR_08_Volume3_residue B7-public 1999. Summary of available studies is presented in Table 7.4.-9.

A summary of trials conforming to critical GAP (± 25%, based on the rate as kg a.s/ha, and the number and timing of the applications) for Northern Member States, all of which were conducted in 1995, are given in Table B. 7.4.-9. Data for all the trials conducted in these regions during 1996 are also included as they are considered to support the critical GAP. Although the 1996 trials employed a slightly higher application rate of 0.20 kg a.s./ha *vs* GAP 0.15 kg a.s./ha, this would be expected to increase any residues, and the residues in crops at harvest (i.e. maize forage, silage, grain, grain + cob and grain + cob + husk) were all <0.01 mg/kg for both mesotrione and MNBA. No other trials were submitted for review. In view of the above, all trials in Table Table 7.4.-9.are considered to support the critical GAP.

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

Table 7.4-8: Summary of EU reported and new data supporting the intended uses of CHR/H/TERIZ 650 WG and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize	DAR_08_Volume3_residue B7-public 1999	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 150 g as/ha, BBCH 12-18, PHI N/A, outdoor E: Forage:9x<0.01 Silage: 9x<0.01 Grain:	N/A				

			9x<0.01 RA: Forage:9x<0.01 Silage: 9x<0.01 Grain: 9x<0.01					
	Overall supporting data for cGAP	N-EU	E: Forage:9x<0.01 Silage: 9x<0.01 Grain: 9x<0.01 RA: Forage:9x<0.01 Silage: 9x<0.01 Grain: 9x<0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.01	Yes

* Source of EU MRL: Commission Regulation (EU) 2016/53 of 19 January 2016

7.4.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize are considered acceptable, for both outdoor uses.
Sufficient GAP-compliant residue trials supported by acceptable storage stability data are available to derive a MRL for mesotrione on maize grain.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

The livestock dietary burden was tentatively estimated using the highest magnitude of AMBA conjugates residues in maize forage, fodder from the metabolism study and the total residues in maize grain. In this case, livestock metabolism studies are not triggered. A ruminant metabolism study was however conducted with phenyl-U-14C AMBA. The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively. At the estimated dietary burden, the transfer of AMBA residues in all matrices was shown to be negligible and residue definitions for animal commodities are provisionally not required for the representative use. Furthermore, the setting of residue definitions for products of animal origin will also have to be assessed with regard to the authorized European uses for mesotrione (maize forage, grass) .

Since all residues are below LOQ 0.01 mg/kg, no dietary calculations are necessary.

7.4.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

No data have been provided but are not required since the intake of mesotrione or MNBA by animals is not significant. Ruminant metabolism data have been provided for AMBA dosed at ca 150N total free and conjugated AMBA or ca 3000N based on free AMBA only. The conjugates of AMBA were not readily released by acid, base or enzyme hydrolysis. Based on the proposed GAP, residues in animal products are not expected to be significant (>0.01 mg/kg). Therefore livestock feeding studies for AMBA are not required.
No new data were submitted in the framework of this application.

7.4.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCP 6.5.2-6.5.3)

Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg).

Not required, mesotrione residues do not exceed 0.01 mg/kg

7.4.5.1 Available data for all crops under consideration

Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain <0.01 mg/kg).

Not required, mesotrione residues do not exceed 0.01 mg/kg

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

7.4.5.2 Conclusion on processing studies

No studies required.

7.4.6 Magnitude of residues in representative succeeding crops

Confined rotational crop study were evaluated during EU review, according to DAR_08_Volume3_residue B7-public 1999. Bare soil application of mesotrione labelled respectively on cyclohexane-2-14C and phenyl-U-14C at a dose rate of 164 g a.s./ha (1N). At 120 day plant back interval (PBI), TRRs are very low in all crop parts: <0.01 mg/kg in wheat grain and radish root, 0.012 mg/kg in broad-leaves endive and up to 0.033 mg/kg in wheat forage and straw.

Metabolites' identification at 300 d PBI not further investigated.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

Field rotational crop study Not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.

7.4.6.1 Field rotational crop studies (KCP 6.6.2)

Available data

Field rotational studies were performed in US and presented during EU review as a additional information.
Two trials (Barnes, J.P *et al*, 1997) were undertaken in Illinois and North Carolina, USA in 1995-6, in which mesotrione was applied either a) to soil and incorporated prior to the planting of the maize crop, or b) to both the soil as above and post emergence to the maize crop at 24-36 inches tall. After the maize crop was removed, succession crops were grown and sampled at normal harvest to enable residue analysis.

The first application was used to simulate early season crop failure and the second to simulate normal application post emergence.
In two trials in the USA, residues of MESOTRIONE and MNBA were determined in a range of rotational crops planted after ageing periods of 29 to 100 days, following applications of MESOTRIONE to both soil and soil + crop. The soil and crop application rates were approximately 2x and 1.5x the GAP post emergence application rate, respectively, and no residues of MESOTRIONE or MNBA were present in the succession/rotational crops at harvest, with a limit of quantification of 0.01 mg/kg.

Table 7.4-9 Summary of residues of mesotrione and metabolite MNBA in succeeding crops following treatment of maize with mesotrione in US studies

Country/ year (maize variety)	Succession crop	Application rate* kg a.s./ha	No. of treat-ments	Plant back interval (days)	Pre-harvest interval (days)	Residues (mg/kg) ZA 1296	Residues (mg/kg) MNBA	Comment	Reference
Illinois, USA 1995-6	**Leaves**							No daily weather data supplied.	Barnes and Wiebe, 1997 (DP 59819)
	Soybean forage	0.34	1	30	71	<0.01	<0.01		
	Soybean hay	0.34	1	30	121	<0.01	<0.01		
(Pioneer 3394)	Soybean seed	0.34	1	30	152	<0.01	<0.01		
	Endive leaves	0.34 +0.22	2	74	123	<0.01	<0.01		
	Roots								
	Radish tops	0.34	1	30	56	<0.01	<0.01		
	Radish tops	0.34 + 0.22	2	85	122	<0.01	<0.01		
	Radish roots	0.34	1	30	56	<0.01	<0.01		
	Radish roots	0.34 + 0.22	2	85	122	<0.01	<0.01		
	Small grain								
	Millet forage	0.34	1	30	56	<0.01	<0.01		
	Sorghum forage	0.34	1	30	118	<0.01	<0.01		
	Wheat forage	0.34 + 0.22	2	100	337	<0.01	<0.01		
	Millet hay	0.34	1	30	67	<0.01	<0.01		
	Wheat hay	0.34 + 0.22	2	100	361	<0.01	<0.01		
	Millet straw	0.34	1	30	92	<0.01	<0.01		
	Wheat straw	0.34 + 0.22	2	100	386	<0.01	<0.01		
	Millet grain	0.34	1	30	92	<0.01	<0.01		
	Wheat grain	0.34 + 0.22	2	100	386	<0.01	<0.01		

Country/year (maize variety)	Succession crop	Application rate* kg as/ha	No. of treat-ments	Plant back interval (days)	Pre-harvest interval (days)	Residues (mg/kg) ZA 1296	Residues (mg/kg) MNBA	Comment	Reference
North Carolina, USA, 1995-6	**Leaves**							No daily weather data supplied.	Barnes and Wiebe, 1997 (DP 59819)
	Soybean forage	0.34	1	29	68	<0.01	<0.01		
	Soybean hay	0.34	1	29	99	<0.01	<0.01		
(Pioneer 3165)	Soybean seed	0.34	1	29	189	<0.01	<0.01		
	Endive leaves	0.34 +0.22	2	98	179	<0.01	<0.01		
	Roots								
	Radish tops	0.34	1	29	63	<0.01	<0.01		
	Radish tops	0.34 + 0.22	2	98	166	<0.01	<0.01		
	Radish roots	0.34	1	29	63	<0.01	<0.01		
	Radish roots	0.34 + 0.22	2	98	166	<0.01	<0.01		
	Small grain								
	Millet forage	0.34	1	29	68	<0.01	<0.01		
	Sorghum forage	0.34	1	29	119	<0.01	<0.01		
	Wheat forage	0.34 + 0.22	2	98	172	<0.01	<0.01		
	Millet hay	0.34	1	29	81	<0.01	<0.01		
	Wheat hay	0.34 + 0.22	2	98	322	<0.01	<0.01		
	Millet straw	0.34	1	29	98	<0.01	<0.01		
	Wheat straw	0.34 + 0.22	2	98	362	<0.01	<0.01		
	Millet grain	0.34	1	29	98	<0.01	<0.01		
	Wheat grain	0.34 + 0.22	2	98	362	<0.01	<0.01		

*0.34 kg as/ha incorporated into soil before the maize crop was planted, and the 0.22 kg a.s./ha applied post emergent to the maize. The maize crop was removed prior to the planting of the succession crops.
Plantback interval is the number of days between last application of mesotrione and planting of succession crop.
Pre-harvest interval is the number of days between last application of mesotrione and harvest of succession crop.

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

US rotational crop field trials were conducted on pulses/oilseeds (soya bean), leafy vegetables (endive), root vegetables (radish) and cereals (small grains (wheat)) after bare soil application at 0.34 kg a.s./ha or

after bare soil application (0.34 kg a.s./ha) followed by a post-emergence application (0.22 kg a.s./ha). Residues of mesotrione and of MNBA were < 0.01 mg/kg in all crop parts.

7.4.7 Other / special studies (KCP6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/TERIZ. Therefore, other special studies are not needed.

7.4.8 Estimation of exposure through diet and other means (KCP 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

Table 7.4-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessmen				
		0.01 MRL (2016)		0.01 MRL (2016)

7.4.8.1 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in 0.

Table 7.4-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.2% (based on WHO Cluster diet B)
IEDI (% ADI) according to EFSA PRIMo	0.2% (based on WHO Cluster diet B)
IESTI (% ARfD) according to EFSA PRIMo*	0.3 % (based on UK vegetarian)

The proposed uses of mesotrione in the formulation CHR/H/TERIZ 650 WG do not represent unacceptable acute and chronic risks for the consumer.

7.5 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The following paragraphs are to be considered as proposals, based on “standard” criteria.

The product is a mixture of three active substances Terbuthylazine, isoxaflutole and mesotrione. For three

two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.5.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.2) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.5-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Maize	Terbuthylazine	e.g. 0.084
	Isoxaflutole	e.g. 0.003
	Mesotrione	**e.g. 0.003**
	Cumulative risk Maize (HI)	**0.009**

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in CHR/H/TERIZ 650 WG (containing Terbuthylazine 400 g/kg; isoxaflutole 100 g/kg and mesotrione 150 g/kg) is not expected to present a consumer risk. No further refinement of the assessment is required.

7.5.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

7.6 References

EFSA conclusion on the active substance terbuthylazine according to Article 20 of Commission Regulation (EC) No. 33/2008. EFSA Journal 2011;9(1):1969

DAR_08_Volume3_residue B7-public 1999- Mesotrione

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3/01	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04983 (field phase) GLP unpublished	N	Chemirol
KCP 6.3/02	Dr. Sönke Lakaschus Sabrina Fritzsch	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04983 (Analytical phase) GLP unpublished	N	Chemirol
KCP 6.3/03	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04903 (field phase) GLP unpublished	N	Chemirol
KCP 6.3/04	Dr. Sönke Lakaschus Sabrina Fritzsch	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04903 (Analytical phase) GLP unpublished	N	Chemirol
KCP 6.3/05	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04904 (field phase) GLP unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3/06	Dr. Sönke Lakaschus Sabrina Fritzsch	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04904 (Analytical phase) GLP unpublished	N	Chemirol
KCP 6.3/07	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04905 (field phase) GLP unpublished	N	Chemirol
KCP 6.3/08	Dr. Sönke Lakaschus Sabrina Fritzsch	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04905 (Analytical phase) GLP unpublished	N	Chemirol
KCP 6.3/09	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04906 (field phase) GLP unpublished	N	Chemirol
KCP 6.3/10	Dr. Sönke Lakaschus Sabrina Fritzsch	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04906 (Analytical phase) GLP unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.1/01	Giannone, C.	1998	Stability of residues of terbuthylazine (GS13529) and GS 26379 (metabolite of terbuthylazine) in plant materials (analytical specimens of wheat grain and wheat straw) stored under deep freeze conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 136/96 GLP Not Published	N	Syngenta
KCP 6.1/02	Giannone, C.	2003	Stability of Residues of GS 28260 (Metabolite of Terbuthylazine) in Deep Freeze Stored Analytical Specimens of Wheat Grain, Beans and Sunflower Seeds Syngenta Crop Protection AG, Basel, Switzerland, Report No 302/01 GLP Not Published	N	Syngenta
KCP 6.1/03	Nandihalli, U. B.	1996	Freezer storage stability of RPA201772 in field corn samples Corning Hazleton, Inc., Madison, WI, USA Bayer CropScience, Report No.: R016771, Edition Number: M-192327-01-1 Date: 1996-11-07 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.1/04	Wiebe, L.A.	1997	MESOTRIONE: Stability of MESOTRIONE and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT GLP, not published	N	Syngenta
KCP 6.1/05	Wiebe LA, Peyton CS	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-042B FIN GLP, not published	N	Syngenta
KCP 6.2.1/ 01	Willems H.	1998	METABOLISM, DISTRIBUTION, AND EXPRESSION OF TERBUTHYLAZINE RESIDUES IN CORN Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197764 GLP: yes published: no	N	Oxon
KCP 6.2.1/ 02	Hampton, R. E.; Pettaway, J.	1995	14C-RPA201772: Metabolic fate and distribution in corn (Zea mays L.) - (171-4 Nature of residue - Plants) A&L Great Lakes Laboratories, Fort Wayne, IN, USA BCS, Report No.: R002551,	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Edition Number: M-162883-01-1 Date: 1995-02-13 GLP/GEP: yes, unpublished		
KCP 6.2.1/ 03	Wei, Y. et al	1997	[Cyclohexane-2-14C]MESOTRIONE: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B GLP no notpublished	N	Syngenta
KCP 6.2.1/ 04	Tarr, J.B. et al	1997	[Phenyl-U-14C]MESOTRIONE: nature of the residues in corn Syngenta GLP no notpublished	N	Syngenta
KCP 6.2.1/ 05	Nicollier, G.	1997	Behaviour and Metabolism of GS 13529 in Field Grown Corn after Soil Application of [Triazine-(U)-14C] Labelled Material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No CMR 07/97 GLP Not Published	N	Syngenta
KCP 6.2.1/ 06	Wei, Y. et al	1997	[Cyclohexane-2-14C]MESOTRIONE: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B GLP no notpublished	N	Syngenta
KCP 6.2.2/ 01	xxx	1970	METABOLISM STUDY OF C14 GS-13529 IN A COW – A PLATEAU STUDY D.R.C 606 xx 70030 6-29-70 GLP: no Published: no	Y	Syngenta/Oxon
KCP 6.2.2/ 02	xxx	1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen Report No.: M-170844-01-2, Report includes Trial Nos.: 198/77-1011 Edition Number: M-170844-01-2 Date: 1995-11-30 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCP 6.2.2/ 03	xxx	1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat Report No.: R004900, Report includes Trial Nos.: 198/78-1011 Edition Number: M-166744-01-1 Date: 1995-12-27 GLP/GEP: yes, unpublished	Y	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.2.2/ 04	-	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow In DAR (1999)	Y	Syngenta
KCP 6.3/01	Salvi, M.	2002a	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3002/00 GLP Not Published	N	Syngenta
KCP 6.3/02	Salvi, M.	2002 b	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3003/00 GLP Not Published	N	Syngenta
KCP 6.3/03	Stolze, K	1997a	Residues of CGA 77102 and Terbuthylazine (GS 13529) in Maize Novartis Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, Report No GR 15596 GLP Not Published	N	Syngenta
KCP 6.3/04	Stolze, K.	1997 b	Residues of CGA 77102 and Terbuthylazine (GS 13529) in Maize Novartis Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, Report No GR 14196 GLP Not Published	N	Syngenta
KCP 6.3/05	Mostert, I.	1997a	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3054/95 GLP Not Published	N	Syngenta
KCP 6.3/06	Mostert, I.	1997 b	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3055/95 GLP	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Not Published		
KCP 6.3/07	Luetolf, W.	1999a	Residue Study with Terbuthylazine (GS 13529) in or on Maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP Not Published	N	Syngenta
KCP 6.3/08	Luetolf, W.	1999 b	Residue Study with Terbuthylazine (GS 13529) in or on Maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3005/96 GLP Not Published	N	Syngenta
KCP 6.3/09	Stolze, K.	2004a	Determination of Residues of CGA 77102 and GS 13529 in Maize after Application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06400 GLP Not Published	N	Syngenta
KCP 6.3/10	Stolze, K	2004 b	Determination of Residues of CGA 77102 and GS 13529 in Maize after Application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06100 GLP Not Published	N	Syngenta
KCP 6.3/11	Stolze, K.	2004c	Determination of Residues of CGA 77102 and GS 13529 in Maize after Application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06200 GLP Not Published	N	Syngenta
KCP 6.3/12	Stolze, K	2004 d	Determination of Residues of CGA 77102 and GS 13529 in Maize after Application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06300 GLP Not Published	N	Syngenta
KCP 6.3/13	Kuehne-Thu,H.	2003a	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3037/01 GLP	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Not Published		
KCP 6.3/14	Kuehne-Thu,H.	2003 b	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3038/01 GLP Not Published	N	Syngenta
KCP 6.3/15	Mostert, I	1997c	Magnitude of residues in maize and s il after application of CGA77102 ans GS13529 as formultaion SC 500, A-9476 B, Italy Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3084/95 GLP Not Published	N	Syngenta
KCP 6.3/16	Mostert, I.	1997 d	Magnitude of R sidues in Maize after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Nov rtis Crop Protection AG, Basel, Switzerland, Report No 3052/96 GLP Not Published	N	Syngenta
KCP 6.3/17	Mostert, I.	1997e	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3085/95 GLP Not Published	N	Syngenta
KCP 6.3/18	Mostert, I.	1997f	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3053/96 GLP Not Published	N	Syngenta
KCP 6.3/19	Mostert, I.	1997 g	Magnitude of Residues in Maize after Application of CGA 77102 and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3051/96 GLP Not Published	N	Syngenta
KCP	Mostert, I.	1997	Magnitude of Residues in Maize after Application of CGA 77102	N	Syngent

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
6.3/20		h	and Terbuthylazine (GS 13529) as Formulation SC 500 (A-9476) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3083/95 GLP Not Published		a
KCP 6.3/21	Salvi, M.	2002c	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3006/00 GLP Not Published	N	Syngenta
KCP 6.3/22	Salvi, M.	2002d	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3007/00 GLP Not Published	N	Syngenta
KCP 6.3/23	Salvi, M.	2002e	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3008/00 GLP Not Published	N	Syngenta
KCP 6.3/24	Salvi, M.	2002f	Residue Study with Terbuthylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3009/00 GLP Not Published	N	Syngenta
KCP 6.3/25	Kuehne-Thu,H.	2003c	Residue Study with S-Metolachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3054/01 GLP Not Published	N	Syngenta
KCP 6.3/26	Kuehne-Thu,H.	2003d	Residue Study with S-Metolachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3053/01 GLP Not Published	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.3/27	Kuehne-Thu,H.	2003e	Residue Study with S-Metolachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3052/01 GLP Not Published	N	Syngenta
KCP 6.3/28	Kuehne-Thu,H.	2003f	Residue Study with S-Metolachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3051/01 GLP Not Published	N	Syngenta
KCP 6.3/29	Pollmann B.	2001	DETERMINATION OF RESIDUES OF TERBUTHYLAZINE AFTER APPLICATION OF TERBUTHYLAZINE 500 G/L SC AND TERBUTHYLAZINE 75% WG IN MAIZE – 1 SITE IN FRANCE AND 3 SITES IN GERMANY, 2000 ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20001117/E1-FPMA GLP: yes published: no	N	Oxon
KCP 6.3/30	Freschi G.	2001a	GENERATION OF MAIZE SAMPLES, SUITABLE FOR RESIDUES ANALYSIS FOLLOWING APPLICATION IN POST- EMERGENCE OT TERBUTHYLAZINE 75% WG AND 500 G7L SC Sipcam Experimental Service, Salerano Sul Lambro Lo, Italy Oxon Italia S.P.A, Pero, Italy Report-no. TZ1 GLP: yes published: no	N	Oxon
KCP 6.3/31	Freschi G.	2000a	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (PLANT) Sipcam Residue Analysis Unit, Salerano sul Lambro (Lo),Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1245 GLP: yes published: no	N	Oxon
KCP 6.3/32	Freschi G.	2000c	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (GRAIN) Sipcam Residue Analysis Unit, Salerano sul Lambro (Lo),Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1247 GLP: yes published: no	N	Oxon
KCP 6.3/32	Domenichini P.	2002	GENERATION OF MAIZE GRAIN OR GREEN SILAGE MAIZE SAMPLES, SUITABLE FOR RESIDUE ANALYSIS FOLLOWING APPLICATION ON POST- EMERGENCE OF	N	Oxon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			TERBUTHYLAZINE 75% WG AND TERBUTHYLAZINE 500 G/L SC (FIELD TRIALS CARRIED OUT IN ITALY IN THE YEAR 2001) Sipcam Experimental Service, Salerano Sul Lambro Lo, Italy Oxon Italia S.P.A, Pero, Italy Report-no. TZ/2 GLP: yes published: no		
KCP 6.3/33	Freschi G.	2002a	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (GRAIN) Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1308 GLP: yes published: no	N	Oxon
KCP 6.3/34	Freschi G.	2002 b	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (WHOLE PLANT) Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1309 GLP: yes published: no	N	Oxon
KCP 6.3/35	Schulz J	1996	FINAL REPORT ABOUT TESTING THE RESIDUAL BEHAVIOUR OF OXN 924 SC 500 IN MAIZE UNDER FIELD CONDITIONS (FIELD REPORT) Agroplan, Berliner Straße 75, D-47574 Goch-Nierswalde Oxon Italia S.P.A, Pero, Italy Report-no. AGR/RP-H 95/OXN 924 SC 500 GLP: yes published: no	N	Oxon
KCP 6.3/36	Domenichini P.	2004	DETERMINATION OF THE MAGNITUDE OF THE RESIDUES OF TERBUTHYLAZINE 500G/L SC IN SILAGE MAIZE TREATED IN POST-EMERGENCE Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1336 GLP: yes published: no	N	Oxon
KCP 6.3/37	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-562 Date of report: November 7, 1995	N	Bayer CropScience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6.3/38	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Silage) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-563 Date of report: November 7, 1995	N	Bayer CropScience
KCP 6.3/39	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Sweet Maize (Cob) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-564 Date of report: October 26, 1995	N	Bayer CropScience
KCP 6.3/40	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize, Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-565 Date of report: October 24, 1995	N	Bayer CropScience
KCP 6.3/41	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Germany 1994, Residues in Maize, Decline Study, Residues in Maize Processing Products Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-605 Date of report: January 5, 1996	N	Bayer CropScience
KCP 6.3/42	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1994, Residues in Maize (Grain, Straw) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-658 Date of report: October 18, 1995	N	Bayer CropScience
KCP 6.3/43	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Italy 1994, Residues in Maize (Silage, Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-669 Date of report: October 18, 1995	N	Bayer CropScience
KCP 6.3/44	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Greece 1994,	N	Bayer CropSci

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Residues in Maize (Silage, Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-680 Date of report: October 18, 1995, unpublished		ence
KCP 6.3/45	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1995, Residues in Maize , Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-531 Date of report: January 5, 1996	N	Bayer CropSci ence
KCP 6.3/46	Muller, M. A.	1996	RPA201772 or Isoxaflutole and its metabolites (RPA202248 and RPA203328) formulation EXP31130A (wg) trials italy 1994 residues in maize (silage, grain) Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C027228, Report includes Trial Nos.: 94-669 Edition Number: M-212937-01-1 Date: 1995-10-18 GLP/GEP: yes, unpublished	N	Bayer CropSci ence
KCP 6.3/47	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1995, Residues in Sweet Maize (Cob) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-711 Date of report: January 5, 1996	N	Bayer CropSci ence
KCP 6.3/48	Muller, M.A.,	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Italy 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-756 Date of report: January 5, 1996	N	Bayer CropSci ence
KCP 6.3/49	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1995, Residues in Maize , Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-757 Date of report: January 4, 1996	N	Bayer CropSci ence
KCP	Muller, M.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
6.3/50	A.		RPA 203328), Formulation EXP 31130A (WG), Trial Germany 1995, Residues in Maize , Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-757 Date of report: January 4, 1996		CropScience
KCP 6.3/51	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA 202248 and RPA 203328), Aclonifen, Formulation EXP 31325A (SC), Trial Italy 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-769 Date of report: January 5, 1996	N	Bayer CropScience
KCP 6.3/52	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Aclonifen, Formulation EXP 31325A (SC), Trial France 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-532 Date of report: January 8, 1996	N	Bayer CropScience
KCP 6.3/53	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Atrazine, Formulation EXP 31330A (SC), Trial France 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-533 Date of report: January 12, 1996	N	Bayer CropScience
KCP 6.3/54	Muller, M. A.	1996	RPA201772 or Isoxaflutole and its metabolites (RPA202248 and RPA203328) formulation EXP31130A (WG) trials Germany 1995 residues in maize decline study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C027242, Report includes Trial Nos.: 95-684 Edition Number: M-212965-01-1 Date: 1996-01-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCP 6.3/55	Cappy, J.J.,	1995	EXP 30953B - Field Corn / Magnitude of Residues in Processing Fractions Generated by: Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US 93703R Date of report: February 24, 1995	N	Bayer CropScience
KCP 6.3/56	Muller, M. A.	1996	RPA201772 or isoxaflutole and its metabolites (RPA202248 and RPA203328) - ACLONIFEN - Formulation EXP31325A (SC) -	N	Bayer CropSci

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Trials Italy 1995 - Residues in maize (silage and grain) Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R007334, Report includes Trial Nos.: 95-769 Edition Number: M-174697-01-1 GLP/GEP: no, unpublished		ence
KCP 6.3/57	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1995 (WRC-96- 099) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-071B GLP, not published	N	Syngenta
KCP 6.3/58	Barnes J.	1997a	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP, not published	N	Syngenta
KCP 6.3/59	Barnes J., Atger J., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-045B GLP, not published	N	Syngenta
KCP 6.3/60	Miller M.,	1998	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Preemergence) (WRC-97-138) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-062B GLP, not published	N	Syngenta
KCP 6.3/61	Miller M.,	1998	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Pre emergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-063B GLP, not published Syngenta File No ZA1296/0418	N	Syngenta
KCP 6.3/67	Barnes J.,	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-048B GLP, not published	N	Syngenta
KCP 6.3/72	Barnes J.	1997 b	ZA1296: Residue Levels in Maize from Trials Carried out in Italy During 1995 (WRC-96-113) Zeneca Agrochemicals, Jealott's Hill, United Kingdom	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			, RR 96-077B GLP, not published		
KCP 6.3/73	Barnes J.,	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Italy During 1996 (Postemergence) (WRC-97-104) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-049B GLP, not published	N	Syngenta
KCP 6.4/01	Tew, E.L.,	1995	Isoxaflutole: Magnitude of Residues in Milk and Tissues of Lactating Dairy Cows Generated by: Southwest Bio-Labs, Las Cruces, NM, USA. & Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US95704R Date of report: December 27, 1995	N	Bayer CropScience
KCP 6.4/02	Tew, E.L.,	1995	Isoxaflutole: Magnitude of Residues in Tissues and Eggs of Laying Hens Generated by: Southwest Bio-Labs, Las Cruces, NM, USA. & Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US95705R Date of report: December 28, 1995	N	Bayer CropScience
KCP 6.5/01	Cappy, J. J.	1995	EXP 30953B/ Field corn / Magnitude of residue in processing fractions (US93703R) Heartland Technologies, Inc., Indianapolis, Indiana, USA Bayer CropScience, Report No.: C026230, Edition Number: M-211010-01-1 Date: 1995-02-23 GLP/GEP: yes, unpublished	N	Bayer Crop-Science
KCP 6.6.1/ 01	Krauss, J.	2000	Outdoor Confined Accumulation Study on Rotational Crops after Bareground Application of [Triazine-(U)-14C]GS 13529 Novartis Crop Protection AG, Basel, Switzerland, Report No 96GN32 GLP Not Published	N	Syngenta
KCP 6.6.1/ 02	Salvi, M.	2002 g	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Follow-up Crop after Treatment of Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 310/00 GLP Not Published	N	Syngenta
KCP	Stolze, K.	2004e	Determination of Residues of CGA 77102 and GS 13529 in Maize	N	Syngent

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
6.6.1/ 03			and Rotational Crops Winter Barley, Winter Oilseed Rape and Sugar Beet after Application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 10200 GLP Not Published		a
KCP 6.6.1/ 04	Stolze, K.	2004f	Determination of Residues of CGA 77102 and GS 13529 in Maize and Rotational Crops Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2001 and 2002 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gmz91001 GLP Not Published	N	Syngent a
KCP 6.6.1/ 05	Sole, C.	2003	Crop Rotation Study with S-Metolachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on Follow-up Crop After Treatment of Maize in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 311/00 GLP Not Published	N	Syngent a
KCP 6.6.1/ 06	Luetolf, W.	2003	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on follow-up Crop after Treatment of Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 307/00 GLP Not Published	N	Syngent a
KCP 6.6.1/ 07	Mamouni A.	2006	Terbuthylazine: Confined accumulation of 14c-terbuthylazine in rotational crops. RCC AG., Itingen, Switzerland Oxon Italia S.p.A, Pero, Italy Report-no. A05940 GLP: Yes Published: No	N	Syngent a
KCP 6.6.1/ 08	Hampton, R. E.; Pettaway, J.	1995	14C-RPA 201772 - Accumulation Study on Confined Rotational Crops Generated by: Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-93-242 Date of report: December 28, 1995	N	Bayer CropSci ence
KCP 6.6.1/ 09	Hampton, R. E.	1996	Supplemental report: 14C-RPA201772: Accumulation study on confined rotational crops - (MRID no. 43904839) Rhone-Poulenc Ag Company, RTP, NC, USA	N	Bayer CropSci ence

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Bayer CropScience, Report No.: R016770, Edition Number: M-192325-01-1 EPA MRID No.: 43904839 Date: 1996-11-27 GLP/GEP: yes, unpublished		
KCP 6.6.1/ 10	Spillner, C. et al	1997	[Cyclohexane-2-14C]MESOTRIONE: confined accumulation studies on rotational crops – low Rate In DAR(1999)	N	Syngenta
KCP 6.6.1/ 11	Gorder, G.W. et al	1997	[Phenyl-U-14C]MESOTRIONE: confined accumulation studies on rotational crops – low rate In DAR (1999)	N	Syngenta
KCP 6.6.1/ 12	Barnes, J.P., Wiebe, L.A.	1997	MESOTRIONE: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B In DAR (1999) GLP unpublished	N	Syngenta

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

List of data relied on and not submitted by the applicant but necessary for evaluation

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

Appendix 2 Detailed evaluation of the additional studies relied upon

zRMS comment: Study is accepted

Reference:	KCP 6.3/01-10
Report	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017. Jörg Semrau, Dr. Sönke Lakaschus, Sabrina Fritzsch, 2018, Study code: S17-04983, S17-04903, S17-04904, S17-04905, S17-04906
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 and repealing Council Directives 79/117/EEC and 91/414/EEC OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD Test Guideline 509: Crop field trials OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM(98)17 SANCO/3029/99 rev.4.
Deviations:	NO
GLP:	Yes

S17-04983 / TERIZ2017_UK

Summary
The objective of the study was to determine residue levels of terbuthylazine (MT0) and its metabolites (desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)), of mesotrione, as well as of isoxaflutole (RPA 201772) and its metabolites (RPA 202248 and RPA 203328) in the raw agricultural commodity maize.
One trial was conducted on maize during 2017 in the United Kingdom (S17-04983-01). The trial comprised two plots, one untreated plot and one plot treated with TERIZ 650 WG (WG formulation containing 400 g/kg terbuthylazine, 200 g/kg mesotrione, 90 g/kg isoxaflutole, nominal content). One application of TERIZ 650
WG was performed 5 day after drilling at a nominal rate of 1.0 kg / ha. The test item was diluted with water immediately prior to application to a spray volume of 200-400 L/ha (nominal).

Specimens for whole plant samples from the untreated and treated plots were taken at BBCH 85 (forage) and sampled with scissors and reduced. Grain samples from the untreated and treated plots were taken by hand at BBCH 85 and dried in a glasshouse to BBCH 89 (normal commercial harvest).
Crop specimens of maize (whole plant and grain) were analysed for residues of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328.
Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS.
Quantification was performed by use of LC-MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).
No residues of the analytes were detected at or above the limit of detection in any of the untreated specimens.

The following residues were detected in the untreated and treated specimens:

Terbuthylazine (MT0), Desethyl-terbuthylazine (MT1) and Desethyl-hydroxy-terbuthylazine (MT14)

EAS Chem Sample No.	Eurofins Sample Code	Sample Timing	Commodity	Plot No.	Residue [mg/kg]	Residue [mg/kg]	Residue [mg/kg]
		DAA			Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)
S17-04983-01							
1	S17-04983-01-001R1	139	whole plant	U1	<0.003 n.d.	<0.003 n.d.	< 0.003 n.d.
2	S17-04983-01-002R1	139	whole plant	2	<0.003 n.d.	<0.003 n.d.	< 0.003 n.d.
3	S17-04983-01-003A	146	grain	U1	<0.003 n.d.	<0.003 n.d.	< 0.003 n.d.
4	S17-04983-01-004A	146	grain	2	<0.003 n.d.	<0.003 n.d.	< 0.003 n.d.

DAA = days after application;
U1 = untreated plot; 2 = plot treated with TERIZ 650 WG
All samples were analysed within 30 days after sampling, as prescribed by the analytical phase plan

Mesotrione

EAS Chem Sample No.	Eurofins Sample Code	Sample Timing	Commodity	Plot No.	Residue [mg/kg]
		DAA			Mesotrione
S17-04983-01					
1	S17-04983-01-001R1	139	whole plant	U1	<0.003 n.d.
2	S17-04983-01-002R1	139	whole plant	2	<0.003 n.d.
3	S17-04983-01-003A	146	grain	U1	<0.003 n.d.
4	S17-04983-01-004A	146	grain	2	<0.003 n.d.

DAA = days after application;
U1 = untreated plot; 2 = plot treated with TERIZ 650 WG
All samples were analysed within 30 days after sampling, as prescribed by the analytical phase plan

Isoxaflutole (RPA 201772), RPA 202248 and RPA 203328

EAS Chem Sample No.	Eurofins Sample Code	Sample Timing	Commodity	Plot No.	Residue [mg/kg]	Residue [mg/kg]	Residue [mg/kg]
		DAA			Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
S17-04983-01							
1	S17-04983-01-001R1	139	whole plant	U1	<0.003 n.d.	<0.003 n.d.	<0.003 n.d.
2	S17-04983-01-002R1	139	whole plant	2	<0.003 n.d.	<0.003 n.d.	<0.003 n.d.
3	S17-04983-01-003A	146	grain	U1	<0.003 n.d.	<0.003 n.d.	<0.003 n.d.
4	S17-04983-01-004A	146	grain	2	<0.003 n.d.	<0.003 n.d.	<0.003 n.d.

DAA = days after application;
U1 = untreated plot; 2 = plot treated with TERIZ 650 WG
All samples were analysed within 30 days after sampling, as prescribed by the analytical phase plan

Analytical Method
Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS.
Quantification was performed by use of LC-MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

Method Validation
The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine
(MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg.

For the four studies S17-04903, S17-04904, S17-04905 and S17-04906 and the current study S17-04983 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation.
The accuracy and precision of the method during specimen analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes in accordance with SANCO/3029/99 rev.4

Procedural Recoveries
For each analytical set of specimen analysis, the method's applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method(s).
Fortifications were performed at the level of 0.01 mg/kg and 0.1 mg/kg and were thus in the range of the level or higher than the level of the highest residues found in a specimen.
No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations.
The accuracy and precision of the method during specimen analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes in accordance with SANCO/3029/99 rev.4.

Method Performance

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens.
Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study.
At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.
The blank values at the expected retention times of the analytes of the control sample materials that were used for determinations of the (procedural) recoveries did not exceed 30 % of the LOQ.
Since blank peaks were not observed, blank correction was not necessary.
Furthermore, at least one (1) reagent blank sample, which is a sample work up without matrix present, was conducted with each analytical set. Reagent blank values did not exceed 30 % of the LOQ.

Matrix Effects

The effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of 90 % matrix amount with solvent standards at identical nominal concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	= [(100 x $A_{Matrix-Std}$) / ($A_{Solv-Std}$)] - 100
$A_{Solv-Std}$	Peak area of solvent standard
$A_{Matrix-Std}$	Peak area of matrix-matched standard

The matrix effects are summarised in the table below:

Matrix / Commodity	Standard Concentration	Mesotrione	Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
	(ng/mL)	338/291	202/146	230/174	184/128	360/251	358/64	267/159
whole plant	1.0	-4.1	-32	-48	-55	-39	20	5.8
	2.5	0.0	-24	-29	-51	-38	14	6.3
	5.0	-0.9	-37	-47	-52	-54	15	5.9
	7.0	12	-42	-43	-42	-33	8.9	7.4
	10	-2.3	-30	-33	-42	-48	13	6.1
	15	-3.5	-39	-34	-52	-58	7.0	2.6
	20	-1.2	-46	-26	-	-47	3.4	3.6
Mean (%)		**0.0**	**-36**	**-37**	**-49**	**-45**	**12**	**5.4**
grain	1.0	-8.1	-38	-27	-67	-41	26	0.0
	2.5	0.0	-33	-29	-65	-40	23	2.6
	5.0	-2.0	-34	-24	-61	-53	35	19
	7.0	-1.0	-34	-35	-64	-34	19	6.1
	10	-9.5	-31	-19	-61	-49	28	11
	15	-2.6	-40	-29	-60	-49	22	9.6
	20	-8.1	-31	-22	-58	-44	22	5.9
Mean (%)		**-4.5**	**-34**	**-27**	**-62**	**-44**	**25**	**7.7**

(+) matrix enhancement; (-) matrix suppression

Matrix suppression or enhancement was < 20 % for mesotrione (maize whole plant and grain), RPA 202248 (only for maize (whole plant) and RPA 203328 in maize (whole plant and grain) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification throughout the analytical phase. Matrix effects were ≥ ± 20 % and deemed to be significant for RPA 202248 (only for maize

(grain)), terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14) and isoxaflutole in both maize matrices. Therefore, matrix-matched standards were used for quantification throughout the analytical phase. Detailed result tables about the determination of matrix effects are given in Appendix B.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched calibration standards at a minimum of eight (8) concentration levels ranging from 0.21 ng/mL to 20 ng/mL. This range corresponds to a fortification level of 0.0021 mg/kg to 0.20 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any specimen extract. The calibration curves obtained for all analytes and all matrices were linear with coefficients of determination (R^2) ≥ 0.980.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The linear regression equation was used for calculation of the analyte concentrations.

If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range.

Formula and exemplary calculation are part of the analytical method description Appendix A.

Method Validation

The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg

For the four studies S17-04903, S17-04904, S17-04905, S17-04906 and the current study S17-04983 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation.

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 % in accordance with SANCO/3029/99 rev.4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

The analytes were fortified jointly and quantified separately.

Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set.

At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.

The following procedural recoveries were obtained:

Commodity	Fortification Level	Recovery	Replicates	Overall Mean Recovery
	(mg/kg)	(%)		(%)
Mesotrione, Mass Transition 338→291 *m/z* (Quantification)				
whole plant	0.010	104	1	101
	0.10	97	1	
grain	0.010	91	1	91
	0.10	91	1	

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Terbuthylazine (MT0), Mass Transition 202→146 m/z (Quantification)				
whole plant	0.010	95	1	98
	0.10	100	1	
grain	0.010	91	1	91
	0.10	91	1	
Desethyl-terbuthylazine (MT1), Mass Transition 230→174 m/z (Quantification)				
whole plant	0.010	95	1	94
	0.10	93	1	
grain	0.010	75	1	83
	0.10	91	1	
Desethyl-hydroxy-terbuthylazine (MT14), Mass Transition 184→128 *m/z* (Quantification)				
whole plant	0.010	71	1	83
	0.10	94	1	
grain	0.010	70	1	71
	0.10	72	1	
Isoxaflutole (RPA 201772), Mass Transition 360→251 *m/z* (Quantification)				
whole plant	0.010	104	1	97
	0.10	89	1	
grain	0.010	91	1	83
	0.10	75	1	
RPA 202248, Mass Transition 358→64 m/z (Quantification)				
whole plant	0.010	98	1	97
	0.10	96	1	
grain	0.010	93	1	90
	0.10	86	1	
RPA 203328, Mass Transition 267→159 *m/z* (Quantification)				
whole plant	0.010	89	1	90
	0.10	90	1	
grain	0.010	93	1	92
	0.10	90	1	

No observable peak was detected in any control sample extract
Recoveries are without any blank correction

S17-04903 / TERIZ2017_Austria

The objective of the study was to determine residue levels of terbuthylazine (MT0) and its metabolites (desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)), of mesotrione, as well as of isoxaflutole (RPA 201772) and its metabolites (RPA 202248 and RPA 203328) in the raw agricultural commodity maize.
One trial was conducted on maize during 2017 in Austria (S17-04903). The trial comprised two plots, one untreated plot and one plot treated with TERIZ 650 WG (WG formulation containing 400 g/kg terbuthylazine, 200 g/kg mesotrione, 100 g/kg isoxaflutole nominal content). One application of TERIZ 650

WG was performed 0 day after drilling at a nominal rate of 1.0 kg / ha. The test item was diluted with water immediately prior to application to a spray volume of 200-400 L/ha (nominal).
Specimens for whole plant samples from the untreated and untreated plots were taken at BBCH 85 (for-age) and sampled with knife and scissors, cut above ground level and reduced. Grain samples from the untreated and untreated plots were taken by hand at BBCH 89 (normal commercial harvest).
Crop specimens of maize (whole plant and grain) were analysed for residues of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328.
Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS
Quantification was performed by use of LC-MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).
No residues of analytes were detected at or above the limit of detection in any of the untreated specimens.

A 4 TIER 1 Summary

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Terbuthylazine (MT0)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Austria	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	400 g/kg	Other active substance in the formulation (common name and content):	Mesotrione, isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14)

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Terbuthylazine (MT0) (mg/kg)	Desethyl-terbuthylazine (MT1) (mg/kg)	Desethyl-hydroxy-terbuthylazine (MT14) (mg/kg)		
S17-04903-01, 8200, Gleisdorf, Styria, Austria	Maize / LG30222	1) 17 May 2017 2) Jun - Jul 2017 3) 05 Oct 2017 (whole plant) 24 Oct 2017 (grain)	bare soil with boom sprayer with DG Tee Jet, 02 110 VS flat fan nozzle	0.200	214	0.428	17 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	141 DALA 160 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Mesotrione	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Austria	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	200 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg mesotrione

1 Report No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Mesotrione (mg/kg)		
S17-04903-01, 8200, Gleisdorf, Styria, Austria	Maize / LG30222	1) 17 May 2017 2) Jun - Jul 2017 3) 05 Oct 2017 (whole plant) 24 Oct 2017 (grain)	bare soil with boom sprayer with DG Tee Jet, 02 110 VS flat fan nozzle	0.100	214	0.214	17 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	141 DALA 160 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Isoxaflutole (RPA 201772)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Austria	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	90 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), mesotrione
Formulation:	WG	Residues calculated as:	mg/kg isoxaflutole (RPA 201772), RPA 202248, RPA 203328

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Isoxaflutole (RPA 201772) (mg/kg)	RPA 202248 (mg/kg)	RPA 203328 (mg/kg)		
S17-04903-01, 8200, Gleisdorf, Styria, Austria	Maize / LG30222	1) 17 May 2017 2) Jun - Jul 2017 3) 05 Oct 2017 (whole plant) 24 Oct 2017 (grain)	bare soil with boom sprayer with DG Tee Jet, 02 110 VS flat fan nozzle	0.045	214	0.096	17 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	141 DALA 160 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

Method Performance

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens. Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study.
At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.
The blank values at the expected retention times of the analytes of the control sample materials that were used for determinations of the recoveries did not exceed 30 % of the LOQ. Since blank peaks were not observed, blank correction was not necessary.

Furthermore, at least one (1) reagent blank sample, which is a sample work up without matrix present, was conducted with each analytical set. Reagent blank values did not exceed 30 % of the LOQ. Example chromatograms for each matrix and analytes representing at least control specimens, specimens fortified at the LOQ and treated residue samples are included in Appendix D.

Matrix Effects

The effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of 90 % matrix amount with solvent standards at identical nominal concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	= [(100 x $A_{Matrix-Std}$) / ($A_{Solv-Std}$)] - 100
$A_{Solv-Std}$	Peak area of solvent standard
$A_{Matrix-Std}$	Peak area of matrix-matched standard

The matrix effects are summarised in the table below:

Matrix / Commodity	Standard Concentration	Mesotrione	Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
		Q	Q	Q	Q	Q	Q	Q
	(ng/mL)	338/291	202/146	230/174	184/128	360/251	358/64	267/159
whole plant	1.0	-18	-24	-17	-64	-37	44	41
	2.5	-14	-18	-35	-	-56	32	19
	5.0	-23	-23	-13	-62	-37	49	28
	7.0	-17	-37	-18	-	-53	31	21
	10	-8.2	-5.5	-23	-68	-31	34	18
	15	-11	-6.7	-27	-	-35	19	13
	20	-24	-13	-18	-67	-21	24	20
Mean (%)		**-16**	**-18**	**-22**	**-65**	**-39**	**33**	**23**
grain	1.0	-8.4	-14	-21	-82	-32	27	-8.9
	2.5	-20	-25	-18	-83	-36	27	-7.0
	5.0	-18	-22	-6.5	-82	-36	26	-2.9
	7.0	-12	-11	-15	-82	-38	23	-3.8
	10	-16	-18	-13	-79	-33	20	-4.1
	15	-11	-26	-7.9	-81	-26	-	-1.1
	20	-12	-15	-	-	-10	-	-
Mean (%)		**-14**	**-19**	**-14**	**-81**	**-30**	**25**	**-4.6**

(+) matrix enhancement; (-) matrix suppression

Matrix effects were ≥ ± 20 % and deemed to be significant for desethyl-terbuthylazine, desethyl hydroxy-terbuthylazine, isoxaflutole, RPA 202248 and RPA 203328 in maize (whole plant). Furthermore matrix effects were ≥ ± 20 % and deemed to be significant for desethyl-hydroxy-terbuthylazine, isoxaflutole and RPA 202248 in maize (grain) Therefore, matrix-matched standards were used for quantification throughout the analytical phase.

Matrix suppression or enhancement was < 20 % for mesotrione and terbuthylazine in maize (whole plant and grain), and for desethyl-terbuthylazine and RPA 203328 in maize (grain) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification throughout the analytical phase.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched calibration standards at a minimum of eight (8) concentration levels ranging from 0.21 ng/mL to 20 ng/mL. This range corresponds to a fortification level of 0.0021 mg/kg to 0.20 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any specimen extract.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The linear regression equation was used for calculation of the analyte concentrations.

If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range.

Formula and exemplary calculation are part of the analytical method description in Appendix A.

Method Validation

The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg.

For the four studies S17-04983, S17-04904, S17-04905, S17-04906 and the current study S17-04903 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix

C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation. Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of

70 - 110 % in accordance with SANCO/3029/99 rev.4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

The analytes were fortified jointly and quantified separately.

Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set.

At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.

The following procedural recoveries were obtained:

Commodity	Fortification Level	Recovery	Replicates	Overall Mean Recovery
	(mg/kg)	(%)		(%)
Mesotrione, Mass Transition 338→291 *m/z* (Quantification)				
whole plant	0.010	74	1	74
	0.10	74	1	
grain	0.010	78	1	79
	0.10	80	1	

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Terbuthylazine (MT0), Mass Transition 202→146 *m/z* (Quantification)				
whole plant	0.010	93	1	90
	0.10	86	1	
grain	0.010	93	1	95
	0.10	96	1	
Desethyl-terbuthylazine (MT1), Mass Transition 230→174 *m/z* (Quantification)				
whole plant	0.010	95	1	91
	0.10	87	1	
grain	0.010	106	1	102
	0.10	98	1	
Desethyl-hydroxy-terbuthylazine (MT14), Mass Transition 184→128 *m/z* (Quantification)				
whole plant	0.010	71	1	71
	0.10	71	1	
grain	0.010	74	1	76
	0.10	78	1	
Isoxaflutole (RPA 201772), Mass Transition 360→251 *m/z* (Quantification)				
whole plant	0.010	97	1	86
	0.10	75	1	
grain	0.010	94	1	94
	0.100	84	1	
RPA 202248, Mass Transition 358→64 *m/z* (Quantification)				
whole plant	0.010	95	1	94
	0.10	93	1	
grain	0.010	98	1	91
	0.10	84	1	
RPA 203328, Mass Transition 267→159 *m/z* (Quantification)				
whole plant	0.010	92	1	92
	0.10	91	1	
grain	0.010	93	1	93
	0.10	93	1	

No observable peak was detected in any control sample extract
Recoveries are without any blank correction

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 %.

Conclusion
With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the specimens of the study.

S17-04904 / TERIZ2017_Germany

The objective of the study was to determine residue levels of terbuthylazine (MT0) and its metabolites (desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)), of mesotrione, as well as of

isoxaflutole (RPA 201772) and its metabolites (RPA 202248 and RPA 203328) in the raw agricultural commodity maize.
One trial was conducted on maize during 2017 in Germany (S17-04904-01). The trial comprised two plots, one untreated plot and one plot treated with TERIZ 650 WG (WG formulation containing 400 g/kg terbuthylazine, 200 g/kg mesotrione, 90 g/kg, isoxaflutole nominal content). One application of TERIZ 650 WG was performed 2 day after drilling at a nominal rate of 1.0 kg / ha. The test item was diluted with water immediately prior to application to a spray volume of 200-400 L/ha (nominal).
Specimens for whole plant samples from the untreated and treated plots were taken at BBCH 85 (forage) and sampled with a knife and subsequently reduced. Grain samples from the untreated and treated plots were taken by hand and threshed by hand at BBCH 89 (normal commercial harvest).
Crop specimens of maize (whole plant and grain) were analysed for residues of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328.
Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS.
Quantification was performed by use of LC-MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).
No residues of analytes were detected at or above the limit of detection in any of the untreated specimens.

A 4 TIER 1 Summary

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Terbuthylazine (MT0)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	400 g/kg	Other active substance in the formulation (common name and content):	Mesotrione, isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14)

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Terbuthylazine (MT0) (mg/kg)	Desethyl-terbuthylazine (MT1) (mg/kg)	Desethyl-hydroxy-terbuthylazine (MT14) (mg/kg)		
S17-04904-01, 27432, Ebersdorf, Lower Saxony, Germany	maize / Stabil	1) 24 May 2017 2) 20 Jul - 01 Aug 2017 3) 19 Sep 2017 (whole plant) 16 Oct 2017 (grain)	Bare soil with boom sprayer with Lechler, IDK 12002 flat fan nozzle	0.133	300	0.400	26 May 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	116 DALA 143 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Mesotrione	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	200 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg mesotrione

1 Report No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Mesotrione (mg/kg)		
S17-04904-01, 27432, Ebersdorf, Lower Saxony, Germany	maize / Stabil	1) 24 May 2017 2) 20 Jul - 01 Aug 2017 3) 19 Sep 2017 (whole plant) 16 Oct 2017 (grain)	Bare soil with boom sprayer with Lechler, IDK 12002 flat fan nozzle	0.067	300	0.200	26 May 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	116 DALA 143 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Isoxaflutole (RPA 201772)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	90 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), mesotrione
Formulation:	WG	Residues calculated as:	mg/kg isoxaflutole (RPA 201772), RPA 202248, RPA 203328

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Isoxaflutole (RPA 201772) (mg/kg)	RPA 202248 (mg/kg)	RPA 203328 (mg/kg)		
S17-04904-01, 27432, Ebersdorf, Lower Saxony, Germany	maize / Stabil	1) 24 May 2017 2) 20 Jul - 01 Aug 2017 3) 19 Sep 2017 (whole plant) 16 Oct 2017 (grain)	Bare soil with boom sprayer with Lechler, IDK 12002 flat fan nozzle	0.030	300	0.090	26 May 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	<0.01 (0.006) < 0.003 n.d.	116 DALA 143 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

Method Performance

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens.
Untreated samples for accompanying control sample work up, for determination of (procedural) recovries and, if needed, for preparation of matrix-matched standards originated from the current study.
At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.
The blank values at the expected retention times of the analytes of the control sample materials that were used for determinations of the recoveries did not exceed 30 % of the LOQ.
Since blank peaks were not observed, blank correction was not necessary.

Furthermore, at least one (1) reagent blank sample, which is a sample work up without matrix present, was conducted with each analytical set. Reagent blank values did not exceed 30 % of the LOQ.

Matrix Effects

The effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of 90 % matrix amount with solvent standards at identical nominal concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	= [(100 x $A_{Matrix-Std}$) / ($A_{Solv-Std}$)] - 100
$A_{Solv-Std}$	Peak area of solvent standard
$A_{Matrix-Std}$	Peak area of matrix-matched standard

The matrix effects are summarised in the table below:

Matrix / Commodity	Standard Concentration	Mesotrione	Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
		Q	Q	Q	Q	Q	Q	Q
	(ng/mL)	338/291	202/146	230/174	184/128	360/251	358/64	267/159
whole plant	1.0	8.6	-4.5	-5.8	-55	-47	-6.0	-14
	2.5	2.8	-36	-33	-47	-41	-2.4	-14
	5.0	14	-10	-17	-56	-51	4.7	-6.0
	7.0	7.4	-23	-21	-58	-38	7.2	-8.2
	10	18	-7.8	-35	-58	-58	10	0.5
	15	-14	4.4	-23	-50	-31	11	2.5
	20	-4.0	-9.6	-5.8	-54	-39	15	-8.9
Mean (%)		**4.7**	**-12**	**-20**	**-54**	**-44**	**5.7**	**-6.9**
grain	1.0	16	-17	18	-72	-32	2.4	5.1
	2.5	0.3	-15	1.7	-73	-27	5.4	-0.4
	5.0	5.8	-4.5	-17	-76	-37	4.3	-3.9
	7.0	-5.5	-39	-6.1	-75	-29	1.6	2.4
	10	8.1	-23	17	-74	-32	1.1	5.0
	15	2.4	7.1	7.2	-71	-22	2.2	2.1
	20	4.8	-20	-4.9	-71	-	-	-
Mean (%)		**4.5**	**-16**	**2.3**	**-73**	**-30**	**2.9**	**1.7**

(+) matrix enhancement; (-) matrix suppression

Matrix effects were ≥ ± 20 % and deemed to be significant desethyl-terbuthylazine (MT1) in maize (whole plant) and for desethyl-hydroxy-terbuthylazine (MT14) and isoxaflutole in maize (whole plant and grain). Therefore, matrix-matched standards were used for quantification throughout the analytical phase.
Matrix suppression or enhancement was < 20 % for mesotrione, terbuthylazine, RPA 202248 and RPA203328 in maize (whole plant and grain) and for desethyl-terbuthylazine (MT1) in maize (grain) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification throughout the analytical phase.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched calibration standards at a minimum of eight (8) concentration levels ranging from 0.21 ng/mL to 20 ng/mL. This range corresponds to a fortification level of 0.0021 mg/kg to 0.20 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any (diluted) specimen extract.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The linear regression equation was used for calculation of the analyte concentrations.
If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent (to be within the calibration range. Formula and exemplary calculation are part of the analytical method description Appendix A.

Method Validation

The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg.
For the four studies S17-04903, S17-04905, S17-04906 and S17-04983 and the current study S17-04904 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation.
Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 % in accordance with SANCO/3029/99 rev.4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The analytes were fortified jointly and quantified separately.
Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set. At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.
The following procedural recoveries were obtained:

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Mesotrione, Mass Transition 338→291 *m/z* (Quantification)				
whole plant	0.010	76	1	76
	0.10	75	1	
grain	0.010	74	1	77
	0.10	79	1	

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Terbuthylazine (MT0), Mass Transition 202→146 *m/z* (Quantification)				
whole plant	0.010	87	1	97
	0.10	106	1	
grain	0.010	109	1	99
	0.10	88	1	
Desethyl-terbuthylazine (MT1), Mass Transition 230→174 *m/z* (Quantification)				
whole plant	0.010	94	1	102
	0.10	109	1	
grain	0.010	86	1	84
	0.10	82	1	
Desethyl-hydroxy-terbuthylazine (MT14), Mass Transition 184→128 *m/z* (Quantification)				
whole plant	0.010	73	1	72
	0.10	70	1	
grain	0.010	71	1	76
	0.10	81	1	
Isoxaflutole (RPA 201772), Mass Transition 360→251 *m/z* (Quantification)				
whole plant	0.010	97	1	100
	0.10	103	1	
grain	0.010	109	1	96
	0.10	83	1	
RPA 202248, Mass Transition 358→64 *m/z* (Quantification)				
whole plant	0.010	89	1	86
	0.10	83	1	
grain	0.010	93	1	92
	0.10	91	1	
RPA 203328, Mass Transition 267→159 m/z (Quantification)				
whole plant	0.010	95	1	95
	0.10	95	1	
grain	0.010	91	1	94
	0.10	97	1	

No observable peak was detected in any control sample extract
Recoveries are without any blank correction

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 %.

Conclusion
With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the specimens of the study.

S17-04905 / TERIZ2017_Germany nr 2

The objective of the study was to determine residue levels of terbuthylazine (MT0) and its metabolites (desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)), of mesotrione, as well as

of isoxaflutole (RPA 201772) and its metabolites (RPA 202248 and RPA 203328) in the raw agricultural commodity maize.

One trial was conducted on maize during 2017 in Germany (S17-04905-01). The trial comprised two plots, one untreated plot and one plot treated with TERIZ 650 WG (WG formulation containing 400 g/kg terbuthylazine, 200 g/kg mesotrione, 90 g/kg isoxaflutole, nominal content). One application of TERIZ 650 WG was performed 1 day after drilling at a nominal rate of 1.0 kg / ha. The test item was diluted with water immediately prior to application to a spray volume of 200-400 L/ha (nominal).

Specimens for whole plant samples from the untreated and treated plots were taken at BBCH 85 (forage) and sampled with a knife and subsequently reduced. Grain samples from the untreated and treated plots were taken by hand at BBCH 89 (normal commercial harvest).

Crop specimens of maize (whole plant and grain) were analysed for residues of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328.

Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS.

Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations.

A 4 TIER 1 Summary

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Terbuthylazine (MT0)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	400 g/kg	Other active substance in the formulation (common name and content):	Mesotrione, isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14)

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Terbuthylazine (MT0) (mg/kg)	Desethyl-terbuthylazine (MT1) (mg/kg)	Desethyl-hydroxy-terbuthylazine (MT14) (mg/kg)		
S17-04905-01, 21739, Dollern. Lower Saxony, Germany	Maize / KWS Stabil S 210	1) 31 May 2017 2) 25 Jul - 08 Aug 2017 3) 19 Sep 2017 (whole plant) 30 Oct 2017 (grain)	Bare soil with boom sprayer with Teejet DG, 110-02VS flat fan nozzle	0.133	300	0.400	01 Jun 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	110 DALA 151 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Mesotrione	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	200 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg mesotrione

1 Report No. Location (region)	2 Commodity / Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date	8 Portion analysed	9 Residues (mg/kg) (*)	10 DALA (days)	11 Remarks:
	(a)	(b)	(c)	kg as/hL	Water (L/ha)	kg as/ha	(d)	(e) BBCH	(a)	Mesotrione (mg/kg)	(f)	(g)
S17-04905-01, 21739, Dollern. Lower Saxony, Germany	Maize / KWS Stabil S 210	1) 31 May 2017 2) 25 Jul - 08 Aug 2017 3) 19 Sep 2017 (whole plant) 30 Oct 2017 (grain)	Bare soil with boom sprayer with Teejet DG, 110-02VS flat fan nozzle	0.067	300	0.200	01 Jun 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	110 DALA 151 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg. n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Isoxaflutole (RPA 201772)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	90 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), mesotrione
Formulation:	WG	Residues calculated as:	mg/kg isoxaflutole (RPA 201772), RPA 202248, RPA 203328

1 Report No. Location (region)	2 Commodity, Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date	8 Portion analysed	9 Residues (mg/kg) (*)			10 DALA (days)	11 Remarks:
	(a)	(b)	(c)	kg as/hL	Water (L/ha)	kg as/ha	(d)	(e) BBCH	(a)	Isoxaflutole (RPA 201772) (mg/kg)	RPA 202248 (mg/kg)	RPA 203328 (mg/kg)	(f)	(g)
S17-04905-01, 21739, Dollern. Lower Saxony, Germany	Maize / KWS Stabil S 210	1) 31 May 2017 2) 25 Jul - 08 Aug 2017 3) 19 Sep 2017 (whole plant) 30 Oct 2017 (grain)	Bare soil with boom sprayer with Teejet DG, 110-02VS flat fan nozzle	0.030	300	0.090	01 Jun 2017	00	Whole plant Grain	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	< 0.003 n.d. < 0.003 n.d.	110 DALA 151 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg. n.d. = not detectable

Method Performance

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens.
Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study.
At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention times of the analytes.
The blank values at the expected retention times of the analytes of the control sample materials that were used for determinations of the (procedural) recoveries did not exceed 30 % of the LOQ.
Since blank peaks were not observed, blank correction was not necessary.
Furthermore, at least one (1) reagent blank sample, which is a sample work up without matrix present, was conducted with each analytical set. Reagent blank values did not exceed 30 % of the LOQ.

Example chromatograms for each matrix and analytes representing at least control specimens, specimens fortified at the LOQ and treated residue samples are included in Appendix D.

Matrix Effects

The effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of 90 % matrix amount with solvent standards at identical nominal concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	= [(100 x $A_{Matrix-Std}$) / ($A_{Solv-Std}$)] - 100
$A_{Solv-Std}$	Peak area of solvent standard
$A_{Matrix-Std}$	Peak area of matrix-matched standard

The matrix effects are summarised in the table below:

Matrix / Commodity	Standard Concentration	Mesotrione	Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
	(ng/mL)	338/291	202/146	230/174	184/128	360/251	358/64	267/159
whole plant	1.0	-23	-34	-42	-33	-46	14	-7.6
	2.5	-24	-36	-52	-41	-63	8.3	-3.8
	5.0	-16	-18	-32	-	-27	-4.7	-14
	7.0	-15	-31	-35	-56	-43	3.4	-13
	10	-15	-25	-27	-	-50	13	-9.6
	15	-4.8	-28	-28	-59	-48	3.3	-14
	20	-4.3	-1.3	-	-54	-61	2.9	-11
Mean (%)		**-15**	**-25**	**-36**	**-48**	**-48**	**5.8**	**-10**
grain	1.0	-21	-20	-33	-83	-38	28	3.4
	2.5	-18	-30	-30	-82	-46	15	0.5
	5.0	-26	-21	-27	-81	-50	20	-0.8
	7.0	-8.7	-24	-11	-78	-37	23	5.0
	10	-10	-12	-7.8	-78	-35	18	1.0
	15	-23	-20	-	-77	-40	-	-
	20	-21	-24	-	-76	-43	-	-
Mean (%)		**-18**	**-22**	**-22**	**-79**	**-41**	**21**	**1.8**

(+) matrix enhancement; (-) matrix suppression

Matrix suppression or enhancement was < 20 % for mesotrione, RPA 202248 and RPA 203328 in maize (whole plant and grain) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification throughout the analytical phase.

Matrix effects were ≥ ± 20 % and deemed to be significant for terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14) and isoxaflutole in both maize matrices. Therefore, matrixmatched standards were used for quantification throughout the analytical phase.

Detailed result tables about the determination of matrix effects are given in Appendix B.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched calibration standards at a minimum of eight (8) concentration levels ranging from 0.21 ng/mL to 20 ng/mL. This range corresponds to a fortification level of 0.0021 mg/kg to 0.20 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any specimen extract.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The linear regression equation was used for calculation of the analyte concentrations.
If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range.
Formula and exemplary calculation are part of the analytical method description Appendix A.

Method Validation

The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg
For the four studies S17-04903, S17-04904, S17-04906, S17-04983 and the current study S17-04905 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation.
Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 % in accordance with SANCO/3029/99 rev.4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.
The analytes were fortified jointly and quantified separately.
Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set.
At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.
The following procedural recoveries were obtained in the current study:

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Mesotrione, Mass Transition 338→291 *m/z* (Quantification)				
whole plant	0.010	93	1	88
	0.10	82	1	
grain	0.010	86	1	85
	0.10	83	1	

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Terbuthylazine (MT0), Mass Transition 202→146 *m/z* (Quantification)				
whole plant	0.010	108	1	108
	0.10	107	1	
grain	0.010	108	1	107
	0.10	106	1	
Desethyl-terbuthylazine (MT1), Mass Transition 230→174 m/z (Quantification)				
whole plant	0.010	115	1	110
	0.10	105	1	
grain	0.010	109	1	96
	0.10	83	1	
Desethyl-hydroxy-terbuthylazine (MT14), Mass Transition 184→128 *m/z* (Quantification)				
whole plant	0.010	66	1	76
	0.10	86	1	
grain	0.010	70	1	73
	0.10	75	1	
Isoxaflutole (RPA 201772), Mass Transition 360→251 *m/z* (Quantification)				
whole plant	0.010	100	1	94
	0.10	87	1	
grain	0.010	110	1	100
	0.10	89	1	
RPA 202248, Mass Transition 358→64 *m/z* (Quantification)				
whole plant	0.010	89	1	92
	0.10	94	1	
grain	0.010	92	1	88
	0.10	84	1	
RPA 203328, Mass Transition 267→159 *m/z* (Quantification)				
whole plant	0.010	91	1	95
	0.10	99	1	
grain	0.010	87	1	87
	0.10	86	1	

No observable peak was detected in any control sample extract
Recoveries are without any blank correction

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 %.

Conclusion

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the specimens of the study.

S17-04906 / TERIZ2017_Denmark

The objective of the study was to determine residue levels of terbuthylazine (MT0) and its metabolites (desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)), of mesotrione, as well as of isoxaflutole (RPA 201772) and its metabolites (RPA 202248 and RPA 203328) in the raw agricultural

commodity maize. One trial was conducted on maize during 2017 in Denmark (S17-04906-01). The trial comprised two plots, one untreated plot and one plot treated with TERIZ 650 WG (WG formulation containing 400 g/kg terbuthylazine, 200 g/kg mesotrione, 100 g/kg isoxaflutole, nominal content). One application of TERIZ 650 WG was performed 4 days after drilling at a nominal rate of 1.0 kg/ha. The test item was diluted with water immediately prior to application to a spray volume of 200-400 L/ha (nominal).
Specimens for whole plant samples from the untreated and untreated plots were taken at BBCH 85 (forage) and sampled with scissors and subsequently reduced. Grain samples from the untreated and untreated plots were taken by hand at BBCH 89 (normal commercial harvest). Crop specimens of maize (whole plant and grain) were analysed for residues of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328.
Specimen extraction and determination of residues were performed according to the multi-residue QuEChERS. Quantification was performed by use of LC-MS/MS detection.
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).
No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations.

A 4 TIER 1 Summary

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Terbuthylazine (MT0)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Denmark	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	400 g/kg	Other active substance in the formulation (common name and content):	Mesotrione, isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg terbuthylazine (MT0), desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14)

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Terbuthylazine (MT0) (mg/kg)	Desethyl-terbuthylazine (MT1) (mg/kg)	Desethyl-hydroxy-terbuthylazine (MT14) (mg/kg)		
S17-04906-01, 5471, Søndersø, South Denmark, Denmark	Maize / Ambition	1) 22 May 2017 2) 24 Jul - 03 Aug 2017 3) 24 Oct 2017 (whole plant) 30 Oct 2017 (grain)	Bare soil with boom sprayer with Teejet, AIXR 11002 VP, flat fan nozzle	0.200	218	0.436	26 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	151 DALA 157 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Mesotrione	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Denmark	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	200 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), isoxaflutole (RPA 201772)
Formulation:	WG	Residues calculated as:	mg/kg mesotrione

1 Report No. Location (region)	2 Commodity / Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)	10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Mesotrione (mg/kg)		
S17-04906-01, 5471, Søndersø, South Denmark, Denmark	Maize / Ambition	1) 22 May 2017 2) 24 Jul - 03 Aug 2017 3) 24 Oct 2017 (whole plant) 30 Oct 2017 (grain)	bare soil with boom sprayer with Teejet, AIXR 11002 VP, flat fan nozzle	0.100	218	0.218	26 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	151 DALA 157 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Isoxaflutole (RPA 201772)	Commercial Product (name):	TERIZ 650 WG
Crop/crop group, EPPO Code:	**Maize, ZEAMX**	Producer of commercial product:	PUH Chemirol sp. z o.o.
Responsible body for reporting (name. address)	PUH Chemirol sp. z o.o. Przemysłowa 3 Street 88-300 Mogilno, Poland		
Country (of trial sites):	Denmark	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	90 g/kg	Other active substance in the formulation (common name and content):	Terbuthylazine (MT0), mesotrione
Formulation:	WG	Residues calculated as:	mg/kg isoxaflutole (RPA 201772), RPA 202248, RPA 203328

1 Report No. Location (region)	2 Commodity, Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)			10 DALA (days) (f)	11 Remarks: (g)
				kg as/hL	Water (L/ha)	kg as/ha				Isoxaflutole (RPA 201772) (mg/kg)	RPA 202248 (mg/kg)	RPA 203328 (mg/kg)		
S17-04906-01, 5471, Søndersø, South Denmark, Denmark	Maize / Ambition	1) 22 May 2017 2) 24 Jul - 03 Aug 2017 3) 24 Oct 2017 (whole plant) 30 Oct 2017 (grain)	bare soil with boom sprayer with Teejet, AIXR 11002 VP, flat fan nozzle	0.045	218	0.098	26 May 2017	00	Whole plant Grain	<0.003 n.d. <0.003 n.d.	<0.003 n.d. <0.003 n.d.	0.016 <0.01 (0.009)	151 DALA 157 DALA	-

(a) According to EPPO codes
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
(*) Limit of quantification = 0.01 mg/kg, limit of detection = 0.003 mg/kg.
n.d. = not detectable

Method Performance

Selectivity

The analytes were determined in the final specimen extracts by use of LC-MS/MS detection.
For each analyte, one (1) mass transition was evaluated. A second mass transition was monitored for confirmation of peak identity but was not used for quantification of specimens.
Untreated samples for accompanying control sample work up, for determination of (procedural) recoveries and, if needed, for preparation of matrix-matched standards originated from the current study. At least one (1) control sample per each matrix type and analytical set was analysed to investigate the residue level of the analytes and to check for any background interferences at the expected retention Times of the analytes.
The blank values at the expected retention times of the analytes of the control sample materials that were used for determinations of the recoveries did not exceed 30 % of the LOQ.
Since blank peaks were not observed, blank correction was not necessary.
Furthermore, at least one (1) reagent blank sample, which is a sample work up without matrix present, was conducted with each analytical set. Reagent blank values did not exceed 30 % of the LOQ.
Example chromatograms for each matrix and analytes representing at least control specimens, specimens

fortified at the LOQ and treated residue samples are included in Appendix D.

Matrix Effects

The effect of matrix on the LC-MS/MS response was assessed by comparing peak areas of matrix-matched standards of 90 % matrix amount with solvent standards at identical nominal concentrations. Matrix effects were calculated as follows:

Matrix effect (%)	= [(100 x $A_{Matrix-Std}$) / ($A_{Solv-Std}$)] - 100
$A_{Solv-Std}$	Peak area of solvent standard
$A_{Matrix-Std}$	Peak area of matrix-matched standard

The matrix effects are summarised in the table below:

Matrix / Commodity	Standard Concentration	Mesotrione	Terbuthylazine (MT0)	Desethyl-terbuthylazine (MT1)	Desethyl-hydroxy-terbuthylazine (MT14)	Isoxaflutole (RPA 201772)	RPA 202248	RPA 203328
		Q	Q	Q	Q	Q	Q	Q
	(ng/mL)	338/291	202/146	230/174	184/128	360/251	358/64	267/159
whole plant	1.0	-18	-33	-32	-69	-64	4.3	-12
	2.5	-23	-28	-45	-73	-53	-1.2	-4.3
	5.0	-28	-23	-33	-68	-62	-1.8	-9.2
	7.0	-17	-41	-20	-71	-55	-4.0	-4.8
	10	-17	-28	-2.2	-65	-57	6.1	-1.2
	15	-19	2.1	-17	-68	-	-3.2	-3.3
	20	-21	-8.2	-3.6	-	-	6.9	4.4
Mean (%)		**-21**	**-23**	**-22**	**-69**	**-58**	**1.0**	**-4.3**
grain	1.0	-2.9	-17	-26	-84	-31	20	1.7
	2.5	-20	-23	-27	-84	-37	17	-1.3
	5.0	-20	-26	-25	-83	-42	17	2.4
	7.0	-17	-16	-14	-83	-39	13	2.5
	10	-18	-17	-17	-83	-38	11	-0.5
	15	-20	-14	-15	-83	-36	9.9	3.4
	20	-24	-23	-	-	-35	-	-
Mean (%)		**-17**	**-19**	**-21**	**-84**	**-37**	**15**	**1.4**

(+) matrix enhancement; (-) matrix suppression

Matrix effects were ≥ ± 20 % and deemed to be significant for mesotrione, terbuthylazine (MT0), desethylterbuthylazine(MT1), desethyl-hydroxy-terbuthylazine (MT14) and isoxaflutole in maize (whole plant).

Furthermore matrix effects were ≥ ± 20 % and deemed to be significant for desethyl-terbuthylazine (MT1), desethyl-hydroxy-terbuthylazine (MT14) and isoxaflutole in maize (grain). Therefore, matrix-matched standards were used for quantification throughout the analytical phase.

Matrix suppression or enhancement was < 20 % for mesotrione and terbuthylazine in maize (grain) and RPA 202248 and RPA 203328 in maize (whole plant and grain) and thus deemed to be insignificant. However, matrix-matched standards were used for quantification throughout the analytical phase.

Detailed result tables about the determination of matrix effects are given in Appendix B.

Linearity

The linearity of the detector response was demonstrated by single determination of matrix-matched calibration standards at a minimum of eight (8) concentration levels ranging from 0.21 ng/mL to 20 ng/mL. This range corresponds to a fortification level of 0.0021 mg/kg to 0.20 mg/kg and thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration detected in any

specimen extract.

Quantification

Quantification was performed using a calibration curve that fulfilled the above given criteria. The injection of standard solutions was spread evenly over the whole analytical sequence. The linear regression equation was used for calculation of the analyte concentrations.

If necessary, specimen extracts and extracts from high level recovery samples were diluted with solvent to be within the calibration range.

Formula and exemplary calculation are part of the analytical method description Appendix A.

Method Validation

The analytical method followed in this analytical phase was previously validated for the determination of terbuthylazine (MT0) including its metabolites desethyl-terbuthylazine (MT1) and desethyl-hydroxyterbuthylazine (MT14), residues of mesotrione, and isoxaflutole (RPA 201772) including the metabolites RPA 202248 and RPA 203328 in maize (whole plant and grain) with an LOQ of 0.10 mg/kg

For the four studies S17-04903, S17-04904, S17-04905, S17-04983 and the current study S17-04906 Ref [3] - [6] which were analysed together, the concurrent recoveries are summarised in this report in Appendix C. In total five recoveries at the LOQ and five recoveries at the tenfold LOQ were performed and are representing a full method validation.

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 % in accordance with SANCO/3029/99 rev.4.

Procedural Recoveries

The method's applicability in terms of accuracy and repeatability was assessed for each analytical set by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

The analytes were fortified jointly and quantified separately.

Procedural recoveries were handled and stored in the same way and for the same time period as the analytical specimen extracts that were prepared within the same analytical set.

At least one (1) procedural recovery was performed at the level of LOQ and one (1) at the level of 10x LOQ per analytical set of each respective matrix.

The following procedural recoveries were obtained:

Commodity	Fortification Level	Recovery	Replicates	Overall Mean Recovery
	(mg/kg)	(%)		(%)
Mesotrione, Mass Transition 338→291 *m/z* (Quantification)				
whole plant	0.010	75	1	77
	0.10	78	1	
grain	0.010	81	1	81
	0.10	80	1	

Commodity	Fortification Level (mg/kg)	Recovery (%)	Replicates	Overall Mean Recovery (%)
Terbuthylazine (MT0), Mass Transition 202→146 *m/z* (Quantification)				
whole plant	0.010	87	1	99
	0.10	110	1	
grain	0.010	107	1	103
	0.10	98	1	
Desethyl-terbuthylazine (MT1), Mass Transition 230→174 *m/z* (Quantification)				
whole plant	0.010	106	1	95
	0.10	84	1	
grain	0.010	103	1	100
	0.10	96	1	
Desethyl-hydroxy-terbuthylazine (MT14), Mass Transition 184→128 *m/z* (Quantification)				
whole plant	0.010	67	1	72
	0.10	77	1	
grain	0.010	71	1	80
	0.10	89	1	
Isoxaflutole (RPA 201772), Mass Transition 360→251 *m/z* (Quantification)				
whole plant	0.010	92	1	81
	0.10	70	1	
grain	0.010	98	1	98
	0.100	89	1	
RPA 202248, Mass Transition 358→64 *m/z* (Quantification)				
whole plant	0.010	91	1	91
	0.10	90	1	
grain	0.010	96	1	94
	0.10	92	1	
RPA 203328, Mass Transition 267→159 *m/z* (Quantification)				
whole plant	0.010	95	1	95
	0.10	95	1	
grain	0.010	97	1	96
	0.10	95	1	

Single recoveries were in the range of 60 - 120 % each, while the mean recoveries were in the range of 70 - 110 %.

Conclusion

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the specimens of the study.

Appendix 3 Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Terbuthylazine

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.004**	ARfD (mg/kg bw):	**0.008**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

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 (prop
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	6
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 (i
6.2	WHO Cluster diet B	6.2	Maize		FRUIT (FRESH OR FROZEN)	
5.7	IE adult	5.7	Maize		FRUIT (FRESH OR FROZEN)	
2.6	UK Infant	2.6	Maize		FRUIT (FRESH OR FROZEN)	
1.4	WHO cluster diet E	1.4	Maize		FRUIT (FRESH OR FROZEN)	
1.3	WHO cluster diet D	1.3	Maize		FRUIT (FRESH OR FROZEN)	
1.2	PT General population	1.2	Maize		FRUIT (FRESH OR FROZEN)	
0.7	ES child	0.7	Maize		FRUIT (FRESH OR FROZEN)	
0.4	DE child	0.4	Maize		FRUIT (FRESH OR FROZEN)	
0.4	WHO regional European diet	0.4	Maize		FRUIT (FRESH OR FROZEN)	
0.4	NL child	0.4	Maize		FRUIT (FRESH OR FROZEN)	
0.3	WHO Cluster diet F	0.3	Maize		FRUIT (FRESH OR FROZEN)	
0.2	ES adult	0.2	Maize		FRUIT (FRESH OR FROZEN)	
0.1	NL general	0.1	Maize		FRUIT (FRESH OR FROZEN)	
0.1	IT kids/toddler	0.1	Maize		FRUIT (FRESH OR FROZEN)	
0.1	FI adult	0.1	Maize		FRUIT (FRESH OR FROZEN)	
0.0	IT adult	0.0	Maize		FRUIT (FRESH OR FROZEN)	
0.0	UK Toddler	0.0	Maize		FRUIT (FRESH OR FROZEN)	
0.0	UK vegetarian	0.0	Maize		FRUIT (FRESH OR FROZEN)	
0.0	LT adult	0.0	Maize		FRUIT (FRESH OR FROZEN)	
0.0	UK Adult	0.0	Maize		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Maize		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

Mesotrione

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.02**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

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 (
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum

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
0.2	WHO Cluster diet B	0.2	Maize		FRUIT (FRESH OR FROZEN)
0.2	IE adult	0.2	Maize		FRUIT (FRESH OR FROZEN)
0.1	UK Infant	0.1	Maize		FRUIT (FRESH OR FROZEN)
0.1	WHO cluster diet E	0.1	Maize		FRUIT (FRESH OR FROZEN)
0.1	WHO cluster diet D	0.1	Maize		FRUIT (FRESH OR FROZEN)
0.0	PT General population	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	ES child	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	DE child	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	WHO regional European diet	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	NL child	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	WHO Cluster diet F	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	ES adult	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	NL general	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	IT kids/toddler	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	FI adult	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	IT adult	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	UK Toddler	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	UK vegetarian	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	LT adult	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	UK Adult	0.0	Maize		FRUIT (FRESH OR FROZEN)
0.0	PL general population	0.0	Maize		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)

Conclusion:

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

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

isoxaflutole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.05
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.7%	NL toddler	0.14	0.7%	Maize/corn						
0.1%	GEMS/Food G06	0.03	0.1%	Maize/corn		FRUIT AND TREE NUTS				
0.1%	UK infant	0.02	0.1%	Maize/corn		FRUIT AND TREE NUTS				
0.1%	RO general	0.02	0.1%	Maize/corn		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G10	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G15	0.01	0.1%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	PT general	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	GEMS/Food G08	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FR child 3 15 yr	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	GEMS/Food G07	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	ES child	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	NL child	0.01	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	IE adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	DE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	GEMS/Food G11	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	NL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FR toddler 2 3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	ES adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	DE women 14-50 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FR adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	DE general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	IT toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FI 6 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FR infant	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	IT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FI 3 yr	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	UK toddler	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	UK vegetarian	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	LT adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	FI adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	UK adult	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	PL general	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	IE child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
0.0%	DK child	0.00	0.0%	Maize/corn		FRUIT AND TREE NUTS				
	DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	DK adult			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of isoxaflutole is unlikely to present a public health concern.

A 3.2 IEDI calculations

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Maize/corn	0.02 / 0.02	0.13	0.09%	Maize/corn	0.02 / 0.02	0.04	0.3%	Maize/corn	0.02 / 0.02	0.13	0.09%	Maize/corn	0.02 / 0.02	0.04
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Maize / oil	0.02 / 0.5	0.47	0.5%	Maize / oil	0.02 / 0.5	0.25	0.9%	Maize / oil	0.02 / 0.5	0.47	0.5%	Maize / oil	0.02 / 0.5	0.25
0.1%	Maize / processed (not speci	0.02 / 0.02	0.04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.09%	Maize / processed (not	0.02 / 0.02	0.04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of isoxaflutole is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.3 IESTI calculations - Raw commodities

Not required

A 3.4 IESTI calculations - Processed commodities

Not required