FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: T-75WG-OR2-C

Product name(s): TOSCANA TOP 75 WG

Chemical active substance:

Tribenuron methyl, 750 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2020

MS Finalisation date: 15/10/2021

Version history

When	What
December 2020	First submission for product authorization.
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

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zRMS comments:
This report has been completed by the applicant.
The text highlighted in grey was provided by the evaluator.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Critical GAP for TOSCANA TOP 75 WG on cereals (wheat, triticale, barley, rye): 1 appl., max. BBCH-39, max application rate: 18.75 g a.s/ha, PHI- not applicable

EU GAP on wheat, barley, oats and rye (SANTE/11859/2017 Rev 4, 24 October 2018): 1 appl., max application rate 24 g a.s./ha on winter cereals and 22.5 g a.s./ha on spring cereals in max BBCB-39; PHI- not applicable when harvest at maturity. 28 for harvest as forage/ silage before maturity.

EU GAP covers the uses proposed on cereals for TOSCANA TOP 75 WG.

Critical GAP for TOSCANA TOP 75 WG on Miscanthus sp. (MISSS): 1 appl., max. BBCH-14, max application rate: 18.75 g a.s/ha, PHI- not applicable

Critical GAP for TOSCANA TOP 75 WG on grasses grown for seeds: 1 appl., max. BBCH-39, max application rate: 18.75 g a.s/ha, PHI- not applicable

EU GAP on grass for feed or seed (SANTE/11859/2017 Rev 4, 24 October 2018): 1 appl., max. BBCH-13, max application rate: 7.5 g a.s/ha, PHI- not applicable

Miscanthus sp., and grasses grown for seeds are not used as food or feed therefore residue studies are not required.

Stability

The storage stability study were evaluated at EU level. According to the EFSA Journal 2017;15(7):4912:

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)
High water content	Wheat forage	~ -18°C	24 months
High oil content			
	Cotton seed	~ -20°C	14 months
	Sunflower seed	~ -20°C	12 months
High protein content	Dried been	~ -20°C	18 months
High starch content	Wheat grain	~ -20°C	37 months
High acid content	Orange ~ -20°C		18 months
Others			
	Cotton gin trash	~ -20°C	18 months
	Wheat hay	~ -20°C	18 months
	Wheat straw	~ -20°C	37 months

The residue definition including metabolites is still provisional and therefore unprotected stability studies are adequate to support the intended uses proposed in the GAP table for TOSCANA TOP 75 WG. The new residues studies submitted by the Applicant includes tribenuron methyl residue and were performed in less than 30 days. Additional studies are not required.

Plant metabolism

Based on the available data EFSA concluded that *the residue definition for monitoring is proposed by default as tribenuron-methyl. For risk assessment, besides tribenuron-methyl, it is proposed to include*

IN-D5803, IN-G7462, IN-B5685 (sulfonamide-related compounds) and IN-L5296, IN-37739 (free and conjugated), IN-R9805, IN-A4098 (triazine amine related compounds) in the residue definition. This proposal will be reconsidered pending upon the toxicity of these compounds and their magnitude in all relevant crops.

The Applicant submitted additional study on metabolism in wheat however according to this study the metabolism was less extensive, with tribenuron-methyl as the major compound at PHI 16 d (around 60% of TRR). Additionally, only three major metabolites were identified (IN-L5296, IN-D5803 and IN-R9805) and a different metabolic pathway than evaluated at EU level was proposed. Nevertheless, this study was proposed as equivalent to protected metabolism studies and was accepted in data matching (RMS Sweden, October 2019).

Confined rotational crop study

*No tribenuron-methyl was detected, and residues of its degradation products were negligible in any of the crop parts relevant for human consumption. It should be noted however that the relevant metabolite IN-A4908 found in beet foliage (up to 0.019 mg/kg, 30 PBI). The genotoxic potential of IN-A4908 cannot be ruled out. Identified metabolites show a similar metabolic pathway compared with primary metabolism and rotational studies and no specific residue definition has to be derived (*EFSA Journal 2017;15(7):4912).

The genotoxic potential of the metabolite IN-A4098 was evaluated in the Scientific Opinion from the PPR Panel (EFSA Journal 2020;18(3):6053) tends to exclude the potential of triazine-amine to induce gene mutations and clastogenicity but not aneugenicity: *Based on the overall weight of evidence, the cross-cutting WG genotoxicity concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity. The crosscutting WG genotoxicity noted that the potential to induce numerical chromosomal aberrations (aneugenicity) was not adequately investigated. For a conclusion, an in vitro micronucleus assay performed with triazine amine would be needed. The PPR Panel agreed with the assessment of the cross-cutting WG genotoxicity.*

Residues in plants

The Applicant submitted additional studies (n=7, field trials in Poland (n=2), Hungary (n=2), Germany (n=2) and UK) of magnitude the tribenuron methyl residues in wheat. The doses used in the studies were in line with that proposed in GAP (difference does not exceed 25%). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39). Both trials carried out in Poland and both in Hungary came from the same place in each country (distance less than 20 km) and therefore cannot be considered independent. This means that 5 trials can be considered independent. Nevertheless, taking into account that all studies indicate the absence of tribenuron methyl residues in wheat grain and straw above the detection limit (0.003 mg/kg), it should be considered that the number of field trials for tribenuron methyl is sufficient. Information on the analytical parts of the studies is described in Part B5 and has been fully accepted.

According to SANTE/2019/12752, it is possible to extrapolate the results of the residue studies in wheat to barley and rye if the treatment takes place before forming of the edible part. This condition is met, the max BBCH proposed in the GAP for TOSCANA TOP 75 WG is 39.

The Applicant did not provide residue studies of tribenuron methyl metabolites included in the provisional residue definition. Given that no data on their toxicity are available and that the genotoxicity of some metabolites cannot be ruled out, the lack of residue studies showing their absence in the plant after harvest indicates that a complete consumer risk assessment cannot be carried out. However, it should be noted that the genotoxic potential of the metabolite IN-A4098 was evaluated in the Scientific Opinion from the PPR Panel (EFSA Journal 2020;18(3):6053) tends to exclude the potential of triazine-amine to induce gene mutations and clastogenicity but not aneugenicity.

Given that definition which contains metabolites is temporary, and renewal of approval includes, among others, lack of data in this field, the results of field trials presented by the Applicant, relation only to tribenuron-methyl (definition 1) was provisionally considered sufficient. **The Applicant shall provide results of field trials for metabolites included in the provisional residue definition for risk assessment no later than two years after authorization TOSCANA TOP 75 WG for use. In addition,**

due to the data gaps identified during the peer review this assessment is considered tentative and should be reassessed when evaluation of missing data becomes available at Community level.

Residues in succeeding crops

According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl 50SG (L5300 305) was applied to bare soil at a rate of 30 g tribenuron-methyl/ha at 2 test sites. Since for one study only limited investigation was conducted, (tribenuron-methyl, IN-L5296, IN-R9805, IN-D5803 or INB5528), while IN-A4908 found in the metabolism study up to (0.019 mg/kg, 30 PBI) was not analysed for, the field rotational crop studies are considered insufficient (data gap).*

Residues in livestock

No new data submitted in the framework of this application. According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl metabolism in livestock was investigated in laying hens and lactating goats with both triazine- and phenyl-labelled tribenuron methyl. In goat, the major compound was IN-A4098, accounting from 35% up to 81% TRRs in all animal matrices. IN-QKK48 (hydroxyl tribenuron-methyl) was recovered in whole milk (0.6–10% TRR), kidney (14.5–18% TRR) and fat (12% TRR) for both labellings as well as saccharin that occurred in significant levels in all matrices (13–71% TRR). For poultry, IN-A4098 was also recovered at significant levels from 40% up to 62% of TRR in all commodities, in addition IN-L5296 accounted up to 17% of TRRs. Based on these studies, the agreed animal residue definition for monitoring is tribenuron-methyl for all matrices while for risk assessment separate residue definitions are proposed as following:*

1) Ruminant matrices: tribenuron methyl and IN-A4098

2) Poultries matrices: tribenuron-methyl, IN-L5296, IN-A4098, and IN-D5803.

The way the risk assessment residue definitions will be expressed is pending upon the requested toxicological profile of these compounds (see data gap in Section 2).

The potential inclusion of IN-QKK48 and saccharin in the risk assessment residue definition for ruminants was also discussed during the expert's meeting and the majority opinion was not to include these compounds in the residue definition considering the highly overdosed metabolism studies and the lower toxicity of saccharin compared to the parent compound (ADI: 3.8 mg/kg bw per day; Section 2). The finalisation of the livestock exposure assessment is however pending the assessment of the relevant residue in food and feed commodities. Therefore, pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered (data gap). Whether the compounds provisionally included in the risk assessment residue definition for plant, significantly contribute to the livestock dietary burden, their potential transfer in animal matrices may need to be further investigated.

NOTE: Livestock dietary burden cannot be finalised for the time being. Pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered.

Taking into account the above, dietary burden calculations presented by the Applicant for tribenuron methyl should be considered sufficient for the purposes of this assessment. However, as new data assessed at Community level become available, this dossier should be completed and reassessed.

Risk assessment

The risk assessment was conducted for residues of tribenuron-methyl only. The consumer risk assessment (chronic and acute) was calculated using EFSA PRIMo rev. 3.1 for all MRLs in force (Reg. (EU) 2015/1040). Results indicated the highest estimate of chronic dietary intake is 12% of the ADI (NL toddler). The results of the acute dietary assessment (IESTI) do not identify any exceedances of the ARfD (max 0,8% ARfD).

The chronic and the short term intakes of tribenuron methyl residues are unlikely to present a public health concern.

Taking into account the provisional residue definition for risk assessment, and further clarification with regard to the genotoxic potential of metabolites IN-A4098, IN-L5296 and IN-B5685 the consumer risk assessment is not finalised for the representative uses – data gap identified at Community level.

Conclusion

Authorization can be granted. No specific mitigation measures should apply.

The Applicant shall provide results of field trials for metabolites included in the provisional residue definition for risk assessment no later than two years after authorization TOSCANA TOP 75 WG for use. In addition, due to the data gaps identified during the peer review this assessment is considered tentative and should be reassessed when evaluation of missing data becomes available at Community level.

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 TOSCANA TOP 75 WG are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for cereals, Miscanthus sp., Grasses grown for seeds. A list of all intended uses within the central zone is given in Part B, Section 0.

Justification for the selection of the critical GAP

Selection of critical GAP was based on the least favourable conditions. In the selection maximum number of application, the last application prior to harvest that is crucial to residue behaviour in the harvested crop and maximum application rate per treatment were included.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for tribenuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.
Residue trials were not performed for Miscanthus sp., and Grasses grown for seeds because these crops are not used as food or feed therefore residue trials are not needed.
The chronic and the short-term intakes of tribenuron-methyl residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

In some cases the Applicant refers to data owned by Tribenuron TF company, for which poses Letter of Access.

Data gaps

Data gaps identified at EU level (EFSA Journal 2017;15(7):4912) for tribenuron methyl relevant for residue section:

• Further toxicological assessment of the metabolites IN-A4098, IN-L5296 and IN-B5685, for which a genotoxic potential could not be excluded, has to be provided (relevant for all representative uses).

• Further toxicological assessment of the metabolites IN-37739, IN-D5803 and IN-G7462 should be provided (relevant for all representative uses).

• Sufficient residue trials analysing for the magnitude of residues for all compounds included in the plant risk assessment residue definition (relevant for all representative uses)

• Sufficient rotational field trials conducted on cereals, leafy vegetables and root vegetables at a dose rate representative of the maximum plateau concentration in the soil for the relevant metabolites IN-L5296 and IN-A4098 are required (relevant for the representative uses on spring & winter cereals (with and without underlay), and sunflower).

• The livestock dietary burden calculation to be reconsidered pending upon the final decision on the risk assessment residue definition in plants and their potential transfer to livestock, (relevant for the representative uses on spring and winter cereals (with and without underlay), sunflower, and pasture).

• Potential residue levels in pollen and bee products (relevant for all representative uses evaluated).

Issues that could not be finalised:

1) The overall consumer risk assessment is regarded as not finalised in view of the outstanding residues data needed in order to finalise the risk assessment residue definitions in plants and animals.

2) The groundwater exposure assessment for metabolite M2 and the anaerobic soil metabolite IN-GK521 for the representative use on winter cereals with autumn application.

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 [g/kg]**	**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**		
2	Winter soft wheat (TRZAW), Winter rye (SECCW), Winter triticale (TTLWI), Winter barley (HORVW)	N-EU	T-75WG-OR2-C	F	Annual dicotyledonous weeds	WG	750	Broadcast - foliar	Spring BBCH 13 – 39	1	n.a.	0.00469 - 0.00938	200-400	0.01875	n.a.	**R**
14	Miscanthus sp. (MISSS)	N-EU	T-75WG-OR2-C	F	Annual dicotyledonous weeds	WG	750	Broadcast - foliar	BBCH 12 - 14	1	n.a.	0.00469 - 0.00938	200-400	0.01875	n.a.	**Accepted**
15	Grasses grown for seeds	N-EU	T-75WG-OR2-C	F	Annual dicotyledonous weeds	WG	750	Broadcast - foliar	Spring BBCH 13 – 39	1	n.a.	0.00469 - 0.00938	200-400	0.01875	n.a.	**Accepted**

* 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 TOSCANA TOP 75 WG is composed of tribenuron methyl.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of tribenuron methyl

Reference value	Source	Year	Value	Study relied upon	Safety factor
Tribenuron methyl					
ADI	EFSA Journal 2017;15(7):4912	2017	0.01 mg/kg bw/d	2 years, rat	100
ARfD	EFSA Journal 2017;15(7):4912	2017	0.2 mg/kg bw/d	rabbit, developmental study	100

7.1.2.1 Summary for Tribenuron methyl

Table 7.1-3: Summary for tribenuron methyl

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?
1,2,3, 11,12,13	Wheat (winter and spring soft wheat, durum, spelt, einkorn, emmer, winter and spring triticale)	Yes	Yes (5)	NR PHI covered by the time between the last applica-tion and harvest	Yes	Yes	No	No
1,2,13	Rye (spring and winter)	Yes	Yes (5) extrapolated from wheat	NR PHI covered by the time between the last applica-tion and harvest	Yes	Yes	No	No
1,2,3	Barley (spring and winter)	Yes	Yes (5) extrapolated from wheat	NR PHI covered by the time between the last applica-tion and harvest	Yes	Yes	No	No
14	Miscanthus sp.	NR						
15	Grasses grown for seeds							

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

The residue definition for Tribenuron methyl coming from the EFSA conclusions is still provisional, hence the applicant refers to existing unprotected studies were the current residue definition was used:

Number of trials available for cereals fulfils the requirements for northern Europe.
Residue trials were not performed for Miscanthus sp. and Grasses grown for seeds because these crops are not used as food or feed therefore residue trials are not needed.

The proposed uses of tribenuron methyl in the formulation TOSCANA TOP 75 WG do not represent unacceptable acute and chronic risks for the consumer.

As residues of tribenuron methyl 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.

7.1.2.2 Summary for TOSCANA TOP 75 WG

Table 7.1-4: Information on TOSCANA TOP 75 WG (KCA 6.8)

Crop	PHI for TOSCANA TOP 75 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for TOSCANA TOP 75 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Tribenuron-methyl		
Winter soft wheat, Winter rye, Winter triticale, Winter barley	F	NR		
Spring soft wheat Spring barley				
Durum wheat, Spelt wheat, Spring rye, Spring triticale, einkorn wheat, emmer wheat				
Miscanthus sp.				
Grasses grown for seeds				

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

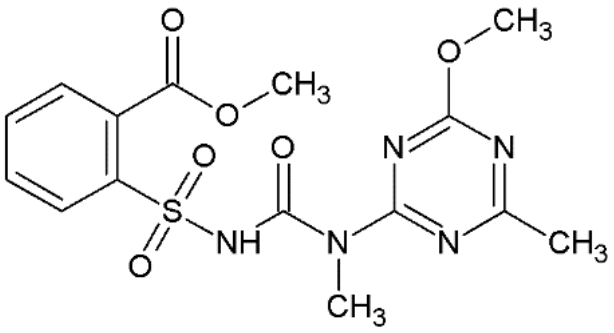
Assessment

7.2 Tribenuron methyl

General data on tribenuron methyl are summarized in the table below

Table 7.2-1: General information on Tribenuron methyl

Active substance (ISO Common Name)	Tribenuron-methyl
IUPAC	methyl 2-[4-methoxy-6-methyl-1,3,5-triazin-2-yl(methyl)carbamoylsulfamoyl]benzoate

Chemical structure	
Molecular formula	$C_{15}H_{17}N_5O_6S$
Molar mass	395.4 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Selective, post-emergence herbicide, acting primarily through foliar uptake with little or no soil activity. Symptoms of chlorosis appear in affected weeds in days, with necrosis and death occurring after 10-25 days under optimal conditions.
Systemic	Yes
Company (ies)	DUP*
Rapporteur Member State (RMS)	SE
Approval status	~~Authorised in:~~ ~~AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK~~ Date of approval -01/02/2019 Expiration of approval 30/01/2034
Restriction	None Specific provisions – Commission Implementing Regulation (EU) 2018/1913 of 6 December 2018
Review Report	~~SANCO/2012/11251 rev. 4~~ SANTE/11859/2017 Rev 4, 24 October 2018
Current MRL regulation	Reg. (EC) No 396/2005 Reg. (EU) 2015/1040
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes *(EFSA Journal 2013;11(11):3457)*
EFSA Journal: Conclusion on the peer review	Yes *(EFSA Journal 2017;15(7):4912)*
EFSA Journal: conclusion on article 12	Yes *(EFSA Journal 2017;15(7):4912)*
Current MRL applications on intended uses	Yes *(EFSA Journal 2013;11(11):3457)*

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2013 - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

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			
Wheat grain	High starch content	37 months	L'Empereur, K.M., 2000
Wheat straw	other	37 months	L'Empereur, K.M., 2000

Conclusion on stability of residues during storage

Storage stability data demonstrates tribenuron-methyl residues to be stable up to 37 months in high starch-content matrices.
In new residues studies presented by the applicant the full provisional residue definition is been analysed in less than 30 days.

zRMS comments:
The storage stability study were evaluated at EU level. According to the EFSA Journal 2017;15(7):4912:

Plant products (Category)	***Commodity***	***T (°C)***	***Stability (Month/Year)***
High water content	*Wheat forage*	*~ -18°C*	*24 months*
High oil content	*Cotton seed*	*~ -20°C*	*14 months*
	Sunflower seed	*~ -20°C*	*12 months*
High protein content	*Dried been*	*~ -20°C*	*18 months*
High starch content	*Wheat grain*	*~ -20°C*	*37 months*
High acid content	*Orange*	*~ -20°C*	*18 months*
Others	*Cotton gin trash*	*~ -20°C*	*18 months*
	Wheat hay	*~ -20°C*	*18 months*
	Wheat straw	*~ -20°C*	*37 months*

The residue definition including metabolites is still provisional and therefore unprotected stability studies are adequate to support the intended uses proposed in the GAP table for TOSCANA TOP 75 WG. In addition new residues studies submitted by the Applicant includes a complete provisional residue definition and were performed in less than 30 days. Additional studies are not required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

There was no significant decrease in the levels of tribenuron-methyl in wheat grain or in wheat straw showing sufficient method performance and analyte stability for analysis of samples stored in a freezer for at least 37 months prior to analysis.

zRMS comments:
Not required. In the studies provided by the Applicant, the extracts were not stored. Time between extraction and analysis was less than 24 hours.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

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/grass crops	Winter Wheat	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Foliar	1 x 72-75 g a.s./ha	1	0, 4, 8, 14, 28, 63	-	Xxxxxx, D.L., Xxxxxx, J.J., 1989
	Spring Wheat	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Greenhouse	55-60 mg as/L	1	48 hrs	-	Xxxxxx, D.L., 1985
New data								
Cereals	Wheat	[C-14 U-ring]Tribenuron-methyl	F	30 actual application rate corresponded to 35 g a.s./ha	1	16	-	Xxxxxx S. 2019, S18-07560
		[Triazine-U-14C]Tribenuron-methyl		30 actual application rate corresponded to 38 g a.s./ha				

Summary of new plant metabolism studies

Wheat plants grown on a sandy-loam soil in a planting container with an area of 1.0 m2 were treated with a single over the top post emergent foliar application with [C-14 U-ring]Tribenuron-methyl (35 g a.s./ha) and with [Triazine-U-^{14}C]Tribenuron-methyl (38 g a.s./ha) at BBCH 29, individually.

- The purity of the respective test item accounted for >95% during the application procedures.
- Harvest of RAC Wheat Forage at BBCH 49 on 14 Feb 2019

- TRR values of individual RACs accounted for 0.190 mg eq/kg and 0.196 mg eq/kg in wheat forage individually applied with [C-14 U-ring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl, respectively.
- The extraction rates after conventional extraction were 96.2% and 97.8% of TRR in wheat forage individually applied with [C-14 U-ring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl, respectively.
- Tribenuron-methyl was the major compound in conventional extracts of wheat forage [C-14 Uring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl accounting for 61.9% of TRR (0.118 mg eq/kg) and 58.8% of TRR (0.115 mg eq/kg), respectively.
- IN-D5803 (Label-specific metabolite) was a major compound in wheat forage [C-14 Uring] Tribenuron-methyl accounting for 12.9% of TRR (0.025 mg eq/kg).
- IN-R9805 (Label-specific metabolite) was a minor compound in wheat forage [Triazine-U- ^{14}C] Tribenuron-methyl for 9.3% of TRR (0.018 mg eq/kg).
- IN-L5296 was a minor compound in wheat forage [Triazine-U-^{14}C] Tribenuron-methyl for 11.1% of TRR (0.022 mg eq/kg).
- In total eight and three unknown minor metabolites (<10% of TRR, <0.05 mg eq/kg) were detected in conventional extracts of wheat forage [C-14 U-ring] Tribenuron-methyl and wheat forage [Triazine-U-^{14}C] Tribenuron-methyl, respectively and characterised by their chromatographic behaviour.

On the basis of the nature and amount found in the extracts in the present study, the following metabolic pathway of Tribenuron-methyl in wheat forage is proposed.

- Hydrolysis of the sulfonylurea bridge to form IN-D5803.
- Hydrolysis of the sulfonylurea bridge resulting in formation of IN-L5296 followed oxidative dealkylation of the methyl ether to form IN-R9805.

Summary of plant metabolism studies reported in the EU

The metabolism of tribenuron-methyl was studied in winter and spring wheat using two radiolabelled forms. Tribenuron-methyl was extensively metabolised in growing wheat plants via multiple pathways resulting in many metabolites. A major metabolic reaction in wheat plants was N-demethylation of tribenuron-methyl to form IN-T6376 (metsulfuron-methyl), which is an herbicide by itself. The major residue in grain was IN-B5685 (sulphonamide urea), a metabolite only containing the phenyl ring, present at harvest at 44.6 % of TRR (equal to 0.02 mg/kg). IN-B5685 is also a metabolite of metsulfuron-methyl and was evaluated to be of low toxicological concern. Not found in that extent in the mature plant parts (grain, straw) up to 12 unidentified compounds were present in cereal forage samples. Nevertheless the metabolic pathway of tribenuron-methyl in cereals is adequately understood. The residue of concern is defined as tribenuron-methyl for risk assessment and monitoring purposes. Due to the fact, that the investigation of the metabolic behaviour of tribenuron-methyl is limited to cereals only, a residue definition for plants in general can not be proposed.

Conclusion on metabolism in primary crops

All metabolism data are sufficient to support registration of Toscana Top 75 WG. No additional studies required

zRMS comments:
According to the EFSA Journal 2017;15(7):4912: *Metabolism of tribenuron-methyl in primary crops was investigated upon foliar application in cereals/grass (wheat), pulses/oilseed (canola, genetically modified (GM) soyabean, cotton) and miscellaneous fruits (olives) using ^{14}C tribenuron-methyl labelled, respectively, on the phenyl and triazine rings (0.8–3.5 N rate). Most of the radioactivity was recovered in leafy crop parts while the total residues in wheat grain and canola seeds ranged between 0.01 and 0.05 mg eq/kg and accounted for up to 0.13 mg eq/kg in GM soyabean seeds. Tribenuron-methyl was mainly identified in the immature green parts of all crops at an early stage (i.e. 25% total radioactive residue (TRR) canola) and was hardly detected in the edible parts at maturity (0.3% TRR in grain only). Degradation of tribenuron-methyl takes place mainly through the cleavage of the sulfonylurea linkage of*

the parent molecule with the formation of triazine amine and sulfonamide moiety-related metabolites. Prior to cleavage, N-demethylation of tribenuron-methyl was also observed, hereby forming metsulfuronmethyl which is an active substance itself. Triazine amine metabolites (IN-R9805, IN-37739, IN-L5296 and IN-A4098) were recovered at significant proportions in all wheat matrices with up to 26% TRR in straw, 36% TRR in forage, 46% TRR in hay, 8% TRR in grain and also in canola seeds (17% TRR). The sulfonamide-related compounds (IN-D5803, IN-G7462, IN-B5685 and IN-D5119) were also detected in significant proportions in all wheat plant parts with up to 31% TRR in forage, 15% TRR in straw, 11%TRR in hay, 44.6% TRR in grain and 26% TRR in canola pods. In the treated GM soyabean and besides the presence of the triazine amine and sulfonamide-related compounds in pods and seeds the metabolic pattern of the parent compound showed also the presence of IN-QKQ78 (25% of TRR), L9622 glucoside (12% TRR), IN-QHM63 (10% TRR), IN-QLQ76 (12% TRRs) in the seeds. It is, however, highlighted that this metabolism study was conducted on a GM crop with an application at a later growth stage (BBCH 60-63) and cannot therefore be considered as representative of the use on sunflower. It should be highlighted, however that in case of any import tolerance request on GM pulses and oilseeds crops, the investigation of the toxicological profile of these compounds might be required. In olives, following foliar application within the tree rows, the total residues were very low (0.01 mg/kg). Hence, for the specific representative use in olives, residues are not expected and no further metabolites' identification is requested. There was also no identification in cotton because of the very low total residues in seeds (0.01–0.03 mg/kg).
Based on these metabolism studies in primary and rotational crops and in the absence of specific valid marker of the residues in cereal grain, canola/cotton seed and olive fruit, ***the residue definition for monitoring is proposed by default as tribenuron-methyl****.* ***For risk assessment, besides tribenuron-methyl, it is proposed to include IN-D5803, IN-G7462, IN-B5685 (sulfonamide-related compounds) and IN-L5296, IN-37739 (free and conjugated), IN-R9805, IN-A4098 (triazine amine related compounds) in the residue definition. This proposal will be reconsidered pending upon the toxicity of these compounds (see data gap in Section 2) and their magnitude in all relevant crops.***
The Applicant submitted additional study on metabolism in wheat however according to this study the metabolism was less extensive, with tribenuron-methyl as the major compound at PHI 16 d (around 60% of TRR). Additionally, only three major metabolites were identified (IN-L5296, IN-D5803 and IN-R9805) and a different metabolic pathway than evaluated at EU level was proposed. Nevertheless, this study was proposed as equivalent to protected metabolism studies and was accepted in data matching (RMS Sweden, October 2019).

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Summary of plant metabolism studies reported in the EU

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 and tuber vegetables	Red beet	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Application on bare soil. G	35 g a.s/ha	30, 120, 366	At maturity	-	Xxxxxx, D.L., 1985
				32 g a.s./ha	30, 120			Xxxxxx, J.J., 1987

Leafy crops	Cabbage	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Application on bare soil. G	35 g a.s/ha	30, 120, 366	At maturity	-	Xxxxxx, D.L., 1985
				32 g a.s./ha	30, 120			Xxxxxx, J.J., 1987
Cereals	Wheat	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Application on bare soil. G	35 g a.s/ha	30, 120, 366	At maturity	-	Xxxxxx, D.L., 1985
	Sorghum			35 g a.s/ha	30, 120			Xxxxxx, D.L., 1985
				32 g a.s./ha	30, 120			Xxxxxx, J.J., 1987
Pulses and oilseeds	Soybean	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	Application on bare soil. G	35 g a.s/ha	30 120	At maturity	-	Xxxxxx, D.L., 1985

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The majority of residues deriving from crops planted in soils treated with 32 to 35 g a.s./ha [phenyl (U)-^{14}C]tribenuron-methyl or [triazine-2- ^{14}C]tribenuron-methyl 30 days prior to planting, were water-soluble compounds of a very polar nature indicating that further metabolism of the soil residues had occurred in the succeeding crops. Therefore, there is no concern about exposure to tribenuron-methyl through incorporation of soil residues into succeeding crops.

Conclusion on metabolism in rotational crops

All metabolism data are active substance data and were evaluated in the EU review of tribenuron methyl. The detailed studies about metabolism in rotational crops are presented in Draft Assessment Report (DAR, 2003). There were no significant residues in human food items (cabbage, beet root, wheat grain, sorghum grain and soybean seed). Therefore, it was not deemed necessary to conduct further field studies or set MRLs on rotated crops.
The metabolic pattern of tribenuron methyl in rotational crops is deemed similar to the one depicted in primary crops, thus the same residue definitions are applicable. Additional studies are not regarded as necessary.

zRMS comments:
According to the EFSA Journal 2017;15(7):4912:

Rotational crops (metabolic pattern) OECD Guideline 502	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops	Radish	30, 120, 366	Max application rate of 35g a.s./ha on bare soil (1.2N, cf GAP on cereals, sunflower). Studies were conducted with both applied radiolabelled [^{14}C tribenuron-methyl]phenyl and triazine respectively.
		Red beets	30, 120	
	Leafy crops	Lettuce	30, 120, 366	
		Cabbage	30, 120	
	Cereal (small grain)	Barley	30, 120, 366	
		Wheat	30, 120	
		Sorghum	30, 120	
	Pulses/oilseeds	Soybean	30, 120	
Rotational crop and primary crop metabolism similar?	Tribenuron-methyl was not detected. The same metabolic pathway as for primary crops was identified; the main metabolite was IN-A4098 (0.019 mg/kg).			

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Processing studies are not needed for tribenuron-methyl based on lack of quantifiable cereal grain residues. Therefore, high temperature hydrolysis studies to establish the nature of residue for processing are not required.

zRMS comments:
As quantifiable residues of tribenuron-methyl are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

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

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

Endpoints	
Plant groups covered	Cereals/grass crops (Winter/Spring wheat)
Rotational crops covered	Root and tuber vegetables (Red beet, radish) Leafy crops (Cabbage, Lettuce) Cereals (Wheat, Sorghum, Barley) Pulses and oilseeds (Soybean)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No data available and none are necessary.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	Tribenuron-methyl
Plant residue definition for risk assessment	1) Tribenuron-methyl 2) (provisional) : tribenuron methyl , sulphonamide's (IN-D5803, IN-G7462, IN-B5685) and triazineamine's (IN-L5296, IN-37739, IN-R9805, IN-A4098) (the way the residue definition will be expressed is pending the outcome of their toxicological evaluation)
Conversion factor from enforcement to RA	Open

* 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 2017).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: 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	[phenyl (U)-^{14}C]tribenuron methyl [triazine-2-^{14}C]tribenuron methyl	2	6.7 mg/k feed	5	Milk	daily	XXXX,1989
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

No quantifiable tribenuron-methyl residues were found in cereal grains and straw at the time of harvest and tribenuron-methyl and/or its metabolites are not deemed to accumulate in animal tissue. Therefore metabolism studies in livestock are not necessary as long as cereal green forage is not used in animal diet. Nevertheless a study on the metabolism of tribenuron-methyl in the lactating goat was submitted and evaluated in the DAR. Since this study is not necessary for the assessment of the representative uses no residue definition or MRLs for food of animal origin is proposed.

Conclusion on metabolism in livestock

All metabolism data are active substance data and were evaluated in the EU review of tribenuron methyl. The detailed studies about metabolism in livestock are presented in Draft Assessment Report (DAR, 2003).
Additional studies are not regarded as necessary.

According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl metabolism in livestock was investigated in laying hens and lactating goats with both triazine- and phenyl-labelled tribenuron methyl. In goat, the major compound was IN-A4098, accounting from 35% up to 81% TRRs in all animal matrices. IN-QKK48 (hydroxyl tribenuron-methyl) was recovered in whole milk (0.6–10% TRR), kidney (14.5–18% TRR) and fat (12% TRR) for both labellings as well as saccharin that occurred in significant levels in all matrices (13–71% TRR). For poultry, IN-A4098 was also recovered at significant levels from 40% up to 62% of TRR in all commodities, in addition IN-L5296 accounted up to 17% of TRRs. Based on these studies, the agreed animal residue definition for monitoring is tribenuron-methyl for all matrices while for risk assessment separate residue definitions are proposed as following:*
1) Ruminant matrices: tribenuron methyl and IN-A4098
2) Poultries matrices: tribenuron-methyl, IN-L5296, IN-A4098, and IN-D5803.
The way the risk assessment residue definitions will be expressed is pending upon the requested toxicological profile of these compounds (see data gap in Section 2).
The potential inclusion of IN-QKK48 and saccharin in the risk assessment residue definition for ruminants was also discussed during the expert's meeting and the majority opinion was not to include these compounds in the residue definition considering the highly overdosed metabolism studies and the lower toxicity of saccharin compared to the parent compound (ADI: 3.8 mg/kg bw per day; Section 2). The finalisation of the livestock exposure assessment is however pending the assessment of the relevant residue in food and feed commodities. Therefore, pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered (data gap). Whether the compounds provisionally included in the risk assessment residue definition for plant, significantly contribute to the livestock dietary burden, their potential transfer in animal matrices may need to be further investigated.

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

Table 7.2-7: 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	Milk: 5 days Eggs: 12 days
Animal residue definition for monitoring	Tribenuron-methyl
Animal residue definition for risk assessment	1) Ruminants: tribenuron-methyl and IN A4098 2) Poultry: tribenuron-methyl, IN-L5296, IN-A4098 and IN-D5803. The way the residue definitions will be expressed is pending the outcome of their toxicological evaluation
Conversion factor	Open
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA 2017)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of TOSCANA TOP 75 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
Wheat grain	New trials	N-EU	Trials GAP: (Germany): 1 x 18.75 g a.s/ha, BBCH 39, PHI 77, outdoor (Hungary): 1 x 18.75 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1 x 18.75 g a.s/ha, BBCH 39, PHI 90, outdoor (Poland): 1 x 15 g a.s./ha, BBCH 39, PHI 90, outdoor (Germany): 1 x 15 g a.s./ha, BBCH 39, PHI 77, outdoor (United Kingdom): 1 x 15 g a.s./ha, BBCH 39, PHI 74, outdoor (Hungary): 1 x 15 g a.s./ha, BBCH 39, PHI 48, outdoor 7 x <0.003	N/A				
	Overall supporting data for cGAP	N-EU	7 x <0.003	0,003	0,003	0,01	0,01	Yes
Wheat straw	New trials	N-EU	Trials GAP: (Germany): 1 x 18.75 g a.s/ha, BBCH 39, PHI 77, outdoor (Hungary): 1 x 18.75 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1 x 18.75 g a.s/ha, BBCH 39, PHI 90, outdoor (Poland): 1 x 15 g a.s./ha, BBCH 39, PHI 90, outdoor (Germany): 1 x 15 g a.s./ha, BBCH 39, PHI 77, outdoor (United Kingdom): 1 x 15 g a.s./ha, BBCH 39, PHI 74, outdoor (Hungary): 1 x 15 g a.s./ha, BBCH 39, PHI 48, outdoor	N/A				

			7 x <0.003					
	Overall supporting data for cGAP	N-EU	7x <0.003	0,003	0,003	-	-	n.a
Barley grain → extrapolated to wheat, triticale, rye	DAR Xxxxxx, E.; Xxxxxx, L., 2001 Xxxxxx, N., Xxxxxx, L.	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.030 kg as/ha, one treatment per crop/season, outdoor 8 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	8x<0.01	0,01	0,01	0,01	0,01	Yes
Barley straw extrapolated to wheat, triticale, rye	DAR, Xxxxxx, E.; Xxxxxx, L., 2001 Xxxxxx, N., Xxxxxx, L.	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.030 kg as/ha, outdoor 8x <0.05	N/A				
	Overall supporting data for cGAP	N-EU	8x <0.05	0,05	0,05	-	-	n.a
Miscanthus sp., and Grasses grown for seeds	n.r.							

* Source of EU MRL: Commission Regulation (EU) 2015/1040 of 30 June 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as

regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products.

The residue definition for Tribenuron methyl coming from the EFSA conclusions is still provisional, hence the applicant refers to existing unprotected studies were the current residue definition was used:

Wheat (winter and spring soft wheat, durum, spelt, einkorn, emmer)

The details of new studies are presented in Appendix 2,
For more details about trials evaluated in the DAR please refer to the table below.

Wheat is a major crop in Northern Europe (EU guideline Document SANCO 7525/VI/95 – rev. 10.2, 23 September 2016). A minimum eight trials are necessary to cover Northern Europe. For TOSCANA TOP 75 WG seven new trials were conducted. One application were made at the target rate 15-18.75 g a.s./ha in these studies. As all residue trials show that the residue levels are lower than the LOQ therefore the numbers of studies to be performed may be reduced to four. To sum up number of trials carried out of wheat fulfils the requirements for wheat in N-EU.

Barley (spring and winter)
For more details about trials evaluated in the DAR please refer to the table below.

Barley is a major crop in Northern Europe (EU guideline Document SANCO 7525/VI/95 – rev. 10.2, 23 September 2016). A minimum eight trials are necessary to cover Northern Europe.

Table 7.2-9 Supervised trials conforming to GAP. Summary of average magnitude tribenuron methyl residues (mg/kg) in cereal growing seasons 1999-2000

Crop, Country, Region, Year	Application				Days[b]	Residues (mg/kg)		References
	Test Material	No.	kg as/ha	kg[a] as/hL		Straw	Grain	
Spring Barley								
Belgium, North Ophain-Bois-Seigneur-Isaac, 1999	Tribenuron methyl-205[c]	1	0.031	0.0097	56	<0.05	<0.01	2261
France, North Saisseval, 1999	tribenuron methyl-205[c]	1	0.031	0.0150	65	<0.05	<0.01	2261
Germany, North Hohenstein-Hennethal, 1999	tribenuron methyl-205[c]	1	0.030	0.0100	60	<0.05	<0.01	2261
Germany, North Strasburg, 1999	tribenuron methyl-205[c]	1	0.032	0.0100	63	<0.05	<0.01	2261

Spring Barley								
France, North Saulty, 2000	tribenuron methyl-208[d]	1	0.031	0.0102	64	<0.05	<0.01	4029
Belgium, North Ophain-bois-Seigneur-Isaac, 2000	tribenuron methyl-208[d]	1	0.031	0.0102	67	<0.05	<0.01	4029
Germany, North Huenstetten-Kettern-schwalbach, 2000	tribenuron methyl-208[d]	1	0.031	0.0102	73	<0.05	<0.01	4029
Winter Barley								
Germany, North Neugatter sleben, 2000	tribenuron methyl-208[d]	1	0.033	0.0102	70	<0.05	<0.01	4029

[a] Values not given in the original reports. Values were calculated from application rates and volumes given in the report.
[b] Days after last application.
[c] Tribenuron methyl WG formulation, 75.3% measured concentration.
[d] Tribenuron methyl WG formulation, 76.8% measured concentration.

The application rates for the trials presented in DAR are higher than the maximum recommended rate of TOSCANA TOP 75 WG. Moreover residues trials show that residues are below the limit of quantification. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration for TOSCANA TOP 75 WG.

Triticale and Rye (spring and winter)
Triticale and rye are a major crop in Northern Europe (EU guideline Document SANCO 7525/VI/95 – rev. 10.2, 23 September 2016). A minimum eight trials are necessary to cover Norther Europe. For TOSCANA TOP 75 WG no new trials were conducted in triticale and rye because of possibility of extrapolation the results from wheat and barley trials. Available wheat and barley trials are presented in Appendix 2 and in DAR. Thus number of trials carried out of cereals fulfils the requirements for triticale and rye in N-EU.

Miscanthus sp., and Grasses grown for seeds
Residue studies shall always be performed where plant protection product is to be applied to plants or plant products that are used as food or feed. Toscana Top 75 WG will be used for protection of Miscanthus sp., and Grasses grown for seeds therefore no additional studies are necessary to support this use of Toscana Top 75 WG.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter and spring cereals, Miscanthus sp., and Grasses grown for seeds are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to wheat (winter and spring soft wheat, durum, spelt, einkorn, emmer), triticale and rye is possible with 8 trials on barley, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable

zRMS comments:
The Applicant submitted additional studies (n=7, field trials in Poland (n=2), Hungary (n=2), Germany (n=2) and UK) of magnitude the tribenuron methyl residues in wheat. The doses used in the studies were in line with that proposed in GAP (difference does not exceed 25%). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39). Both trials carried out in Poland and both in Hungary came from the same place in each country (distance less than 20 km) and therefore cannot be considered independent. This means that 5 trials can be considered independent. Nevertheless, taking into account that all studies indicate the absence of tribenuron methyl residues in wheat grain and straw above the detection limit (0.003 mg/kg), it should be considered that the number of field trials for tribenuron methyl is sufficient. Information on the analytical parts of the studies is described in Part B5 and has been fully accepted.
According to SANTE/2019/12752, it is possible to extrapolate the results of the residue studies in wheat to barley and rye if the treatment takes place before forming of the edible part. This condition is met, the max BBCH proposed in the GAP for TOSCANA TOP 75 WG is 39.
However, the Applicant did not provide residue studies of tribenuron methyl metabolites included in the provisional residue definition – data gap.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The median and maximum dietary burdens were calculated for different groups of livestock using the new EFSA Animal model 2017.
Input values are summarised in Table 7.2-10, results are presented in Table 7.2-11.
Dietary burden is below the trigger value (0.004 mg/kg bw/day). No further studies are required.

Table 7.2-10: Input values for the dietary burden calculation (considering the intended uses)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tribenuron-methyl				
Wheat, Triticale grain	0,003	STMR	0,003	STMR
Wheat, Triticale straw	0,003	STMR	0,003	STMR
Barley grain	0,01	STMR	0,01	STMR
Barley straw	0,05	STMR	0,05	STMR

Table 7.2-11: 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)
Tribenuron-methyl					
Beef cattle*	0,001	0,001	Barley straw	0,029	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)
Dairy cattle*	0,001	0,001	Barley straw	0,029	N
Ram/ewe	0,002	0,002	Barley straw	0,046	N
Lamb	0,002	0,002	Barley straw	0,043	N
Breeding swine	0,000	0,000	Barley straw	0,018	N
Finishing swine*	0,001	0,001	Wheat milled bypdt	0,018	N
Broiler poultry	0,001	0,001	Barley straw	0,013	N
Layer poultry*	0,001	0,001	Barley straw	0,016	N

* These categories correspond to those (formerly) assessed at EU level.

zRMS comments:
According to the EFSA Journal 2017;15(7):4912: *Inputs for animal burden calculations (OPEN)*

NOTE: Livestock dietary burden cannot be finalised for the time being. Pending upon the outcome of the outstanding data on the magnitude of the pertinent compounds identified in primary and rotational crops and their toxicity, the livestock dietary burden calculation should be reconsidered.

Taking into account the above, calculations presented by the Applicant for tribenuron methyl should be consideted sufficient for the purposes of this assessment. Hovewer, as new data assessed at Community level become available, this dossier should be completed and reassessed.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

According to requirements of Reg (EU) No 283/2013 the submission of feeding studies (to determine residues in products of animal origin which result from residues in feed) is not required if the intake is below 0.004 mg a.s./kg bw/day and the residue does not tend to accumulate. Animal intake calculations (see point 7.2.4.1) clearly show that residues of tribenuron-methyl in animal feed are not significant i.e. do not exceed 0.004 mg/kg bw/day of the total diet, therefore significant residues (>0.004 mg/kg bw/day) will not occur in edible animal tissue.

Based on dietary burden calculation the trigger of intake is not exceed therefore additional studies are not regarded as necessary.

zRMS comments:
See point 7.2.4.1.

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

Not applicable. Studies on the magnitude of residues in processed commodities are not required as residues in cereal grain were below the limit of quantification (<LOQ).

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

zRMS comments:
According to the EFSA Journal 2017;15(7):4912: *Tribenuron-methyl 50SG (L5300 305) was applied to bare soil at a rate of 30 g tribenuron-methyl/ha at 2 test sites. Since for one study only limited investigation was conducted, (tribenuron-methyl, IN-L5296, IN-R9805, IN-D5803 or INB5528), while IN-A4908 found in the metabolism study up to (0.019 mg/kg, 30 PBI) was not analysed for, the field rotational crop studies are considered insufficient (data gap).*

7.2.7 Other / special studies (KCA 6.10, KCA 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of TOSCANA TOP 75WG. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 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

Table 7.2-12: 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 residue definition: Tribenuron-methyl				
Wheat/ Triticale	0,01	EU MRL (In force MRL according to Reg. (EU) No 293/2013)	0,01	EU MRL (In force MRL according to Reg. (EU) No 293/2013)
Rye	0,01		0,01	
Barley	0,01		0,01	
All commodities	various		Not applicable	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	1.0 % (based on DK child)
IEDI (% ADI) according to EFSA PRIMo	TMDI values do not exceed ADI therefore IEDI calculations are not required.
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities:

	Wheat: 0.07 % Processed commodities: Wheat/milling (flour): 0.1 %
NTMDI (% ADI) **	Not Relevant
NEDI (% ADI)**	Not Relevant
NESTI (% ARfD) **	Not Relevant

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Tribenuron-methyl in the formulation TOSCANA TOP 75 WG do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
In addition consumer risk assessment (chronic and acute) was calculated using EFSA PRIMo rev. 3.1 for all MRLs in force (Reg. (EU) 2015/1040) (overestimated).

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Tribenuron methyl

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): **0,01** ARfD (mg/kg bw): **0,2**

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	Exposure (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)
12%	NL toddler	1,24	6%	Milk: Cattle	1%	Apples	0,7%	Maize/corn		
7%	NL child	0,66	2%	Milk: Cattle	0,8%	Sugar beet roots	0,6%	Apples		
6%	DE child	0,64	2%	Milk: Cattle	1%	Apples	0,4%	Wheat		
6%	UK infant	0,61	4%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat		
6%	FR toddler 2 3 yr	0,56	3%	Milk: Cattle	0,3%	Apples	0,3%	Wheat		
6%	FR child 3 15 yr	0,55	2%	Milk: Cattle	0,5%	Wheat	0,4%	Sugar beet roots		
4%	UK toddler	0,45	2%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes		
4%	GEMS/Food G11	0,42	0,8%	Milk: Cattle	0,4%	Potatoes	0,4%	Soyabeans		
4%	DK child	0,41	1%	Milk: Cattle	0,6%	Rye	0,4%	Wheat		
4%	GEMS/Food G07	0,38	0,6%	Milk: Cattle	0,4%	Wheat	0,4%	Potatoes		
4%	GEMS/Food G06	0,38	0,7%	Wheat	0,4%	Tomatoes	0,2%	Milk: Cattle		
4%	GEMS/Food G15	0,38	0,7%	Milk: Cattle	0,5%	Wheat	0,4%	Potatoes		
4%	GEMS/Food G08	0,38	0,6%	Milk: Cattle	0,4%	Wheat	0,4%	Potatoes		
4%	RO general	0,38	1%	Milk: Cattle	0,5%	Wheat	0,4%	Potatoes		
4%	ES child	0,38	1%	Milk: Cattle	0,4%	Wheat	0,3%	Cocoa beans		
4%	SE general	0,37	1%	Milk: Cattle	0,4%	Bovine: Muscle/meat	0,4%	Potatoes		
4%	DE women 14-50 yr	0,37	1%	Milk: Cattle	0,5%	Sugar beet roots	0,3%	Apples		
4%	GEMS/Food G10	0,37	0,5%	Milk: Cattle	0,4%	Wheat	0,3%	Soyabeans		
4%	DE general	0,36	1%	Milk: Cattle	0,4%	Sugar beet roots	0,2%	Apples		
4%	FI adult	0,35	3%	Coffee beans	0,1%	Potatoes	0,1%	Rye		
3%	IE adult	0,33	0,4%	Milk: Cattle	0,4%	Sweet potatoes	0,2%	Wheat		
3%	NL general	0,30	0,8%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Potatoes		
3%	FR infant	0,29	2%	Milk: Cattle	0,2%	Potatoes	0,2%	Apples		
2%	FR adult	0,22	0,4%	Milk: Cattle	0,2%	Wine grapes	0,2%	Wheat		
2%	PT general	0,21	0,5%	Potatoes	0,4%	Wheat	0,2%	Wine grapes		
2%	ES adult	0,21	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Oranges		
2%	FI 3 yr	0,18	0,5%	Potatoes	0,1%	Bananas	0,1%	Wheat		
2%	IT toddler	0,16	0,7%	Wheat	0,2%	Other cereals	0,1%	Tomatoes		
2%	DK adult	0,16	0,5%	Milk: Cattle	0,1%	Potatoes	0,1%	Wheat		
2%	LT adult	0,16	0,4%	Milk: Cattle	0,3%	Potatoes	0,2%	Apples		
1%	UK vegetarian	0,15	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes		
1%	FI 6 yr	0,14	0,4%	Potatoes	0,1%	Cocoa beans	0,1%	Wheat		
1%	UK adult	0,14	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes		
1%	IT adult	0,12	0,4%	Wheat	0,1%	Tomatoes	0,1%	Apples		
1,0%	PL general	0,10	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes		
0,8%	IE child	0,08	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes		

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

Acute risk assessment /children — Details - acute risk assessment /children

Acute risk assessment / adults / general population — Details - acute risk assessment/adults

Acute risk assessment /children — Hide IESTI new calculations

Acute risk assessment / adults / general population — 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

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Potatoes	0,01 / 0,01	1,5
0,8%	Melons	0,01 / 0,01	1,5
0,7%	Pears	0,01 / 0,01	1,4
0,7%	Oranges	0,01 / 0,01	1,3
0,6%	Milk: Cattle	0,01 / 0,01	1,2
0,6%	Watermelons	0,01 / 0,01	1,2
0,5%	Apples	0,01 / 0,01	1,1
0,5%	Pineapples	0,01 / 0,01	1,0
0,5%	Bananas	0,01 / 0,01	0,97
0,5%	Peaches	0,01 / 0,01	0,95
0,4%	Mangoes	0,01 / 0,01	0,79
0,4%	Grapefruits	0,01 / 0,01	0,79
0,4%	Table grapes	0,01 / 0,01	0,73
0,3%	Cucumbers	0,01 / 0,01	0,66
0,3%	Carrots	0,01 / 0,01	0,63

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,2%	Head cabbages	0,01 / 0,01	0,42
0,2%	Watermelons	0,01 / 0,01	0,41
0,2%	Melons	0,01 / 0,01	0,39
0,2%	Milk: Cattle	0,01 / 0,01	0,39
0,2%	Swedes/rutabagas	0,01 / 0,01	0,34
0,2%	Table grapes	0,01 / 0,01	0,34
0,2%	Oranges	0,01 / 0,01	0,31
0,2%	Pears	0,01 / 0,01	0,31
0,1%	Potatoes	0,01 / 0,01	0,30
0,1%	Pineapples	0,01 / 0,01	0,30
0,1%	Yams	0,01 / 0,01	0,28
0,1%	Apples	0,01 / 0,01	0,28
0,1%	Cucumbers	0,01 / 0,01	0,28
0,1%	Aubergines/egg plants	0,01 / 0,01	0,27
0,1%	Mangoes	0,01 / 0,01	0,26

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,6%	Milk: Cattle	0,01 / 0,01	1,2
0,5%	Melons	0,01 / 0,01	0,91
0,4%	Watermelons	0,01 / 0,01	0,73
0,3%	Oranges	0,01 / 0,01	0,67
0,3%	Potatoes	0,01 / 0,01	0,66
0,3%	Apples	0,01 / 0,01	0,62
0,3%	Bananas	0,01 / 0,01	0,61
0,3%	Pineapples	0,01 / 0,01	0,61
0,3%	Pears	0,01 / 0,01	0,59
0,3%	Peaches	0,01 / 0,01	0,54
0,2%	Apricots	0,01 / 0,01	0,49
0,2%	Mangoes	0,01 / 0,01	0,47
0,2%	Grapefruits	0,01 / 0,01	0,47
0,2%	Table grapes	0,01 / 0,01	0,44
0,2%	Kiwi fruits (green, red,	0,01 / 0,01	0,40

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,2%	Oranges	0,01 / 0,01	0,47
0,2%	Plums	0,01 / 0,01	0,39
0,2%	Milk: Cattle	0,01 / 0,01	0,39
0,2%	Pears	0,01 / 0,01	0,36
0,2%	Mandarins	0,01 / 0,01	0,33
0,2%	Potatoes	0,01 / 0,01	0,31
0,2%	Apples	0,01 / 0,01	0,30
0,1%	Bananas	0,01 / 0,01	0,28
0,1%	Yams	0,01 / 0,01	0,27
0,1%	Kaki/Japanese persimmons	0,01 / 0,01	0,27
0,1%	Head cabbages	0,01 / 0,01	0,25
0,1%	Watermelons	0,01 / 0,01	0,24
0,1%	Wine grapes	0,01 / 0,01	0,24
0,1%	Melons	0,01 / 0,01	0,24
0,1%	Mangoes	0,01 / 0,01	0,23

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): ---

IESTI new Results for children — No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new Results for adults — No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,6%	Sugar beets (root) / sugar	0,01 / 0,12	1,1
0,5%	Potatoes / fried	0,01 / 0,01	0,93
0,4%	Pumpkins / boiled	0,01 / 0,01	0,89
0,4%	Witloofs / boiled	0,01 / 0,01	0,89
0,4%	Broccoli / boiled	0,01 / 0,01	0,79
0,3%	Cauliflowers / boiled	0,01 / 0,01	0,70
0,3%	Escaroles/broad-leaved endi	0,01 / 0,01	0,66
0,3%	Potatoes / dried (flakes)	0,01 / 0,05	0,59
0,3%	Leeks / boiled	0,01 / 0,01	0,57
0,3%	Apples / juice	0,01 / 0,01	0,54
0,3%	Oranges / juice	0,01 / 0,01	0,53
0,3%	Turnips / boiled	0,01 / 0,01	0,51
0,3%	Parsnips / boiled	0,01 / 0,01	0,51
0,3%	Sweet potatoes / boiled	0,01 / 0,01	0,50
0,2%	Florence fennels / boiled	0,01 / 0,01	0,45

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Pumpkins / boiled	0,01 / 0,01	0,55
0,2%	Sugar beets (root) / sugar	0,01 / 0,12	0,44
0,2%	Cauliflowers / boiled	0,01 / 0,01	0,42
0,2%	Beetroots / boiled	0,01 / 0,01	0,39
0,2%	Celeries / boiled	0,01 / 0,01	0,34
0,2%	Apples / juice	0,01 / 0,01	0,33
0,1%	Broccoli / boiled	0,01 / 0,01	0,24
0,1%	Coffee beans / extraction	0,05 / 0,01	0,24
0,1%	Courgettes / boiled	0,01 / 0,01	0,23
0,1%	Parsnips / boiled	0,01 / 0,01	0,21
0,1%	Kohlrabies / boiled	0,01 / 0,01	0,21
0,1%	Wine grapes / juice	0,01 / 0,01	0,21
0,1%	Escaroles/broad-leaved	0,01 / 0,01	0,20
0,10%	Florence fennels / boiled	0,01 / 0,01	0,19
0,10%	Turnips / boiled	0,01 / 0,01	0,19

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,6%	Sugar beets (root) / sugar	0,01 / 0,12	1,1
0,3%	Potatoes / dried (flakes)	0,01 / 0,05	0,59
0,3%	Apples / juice	0,01 / 0,01	0,54
0,3%	Pumpkins / boiled	0,01 / 0,01	0,53
0,3%	Oranges / juice	0,01 / 0,01	0,53
0,2%	Broccoli / boiled	0,01 / 0,01	0,47
0,2%	Witloofs / boiled	0,01 / 0,01	0,47
0,2%	Potatoes / fried	0,01 / 0,01	0,44
0,2%	Wine grapes / juice	0,01 / 0,01	0,44
0,2%	Cauliflowers / boiled	0,01 / 0,01	0,42
0,2%	Escaroles/broad-leaved	0,01 / 0,01	0,40
0,2%	Carrots / juice	0,01 / 0,01	0,36
0,2%	Leeks / boiled	0,01 / 0,01	0,33
0,2%	Pears / juice	0,01 / 0,01	0,33
0,1%	Currants (red, black and	0,01 / 0,01	0,29

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,2%	Sugar beets (root) / sugar	0,01 / 0,12	0,44
0,2%	Pumpkins / boiled	0,01 / 0,01	0,40
0,2%	Apples / juice	0,01 / 0,01	0,33
0,1%	Cauliflowers / boiled	0,01 / 0,01	0,25
0,1%	Coffee beans / extraction	0,05 / 0,01	0,24
0,1%	Witloofs / boiled	0,01 / 0,01	0,22
0,1%	Wine grapes / juice	0,01 / 0,01	0,21
0,1%	Celeries / boiled	0,01 / 0,01	0,20
0,1%	Broccoli / boiled	0,01 / 0,01	0,20
0,10%	Rhubarbs / sauce/puree	0,01 / 0,01	0,19
0,08%	Beetroots / boiled	0,01 / 0,01	0,17
0,08%	Courgettes / boiled	0,01 / 0,01	0,16
0,08%	Escaroles/broad-leaved endives /	0,01 / 0,01	0,16
0,08%	Oranges / juice	0,01 / 0,01	0,15
0,07%	Leeks / boiled	0,01 / 0,01	0,14

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

Results indicated the highest estimate of chronic dietary intake is 12% of the ADI (NL toddler). The results of the acute dietary assessment (IESTI) do not identify any exceedances of the ARfD (max 0,8% ARfD).

The risk assessment was conducted for residues of tribenuron-methyl only.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

References

EFSA Scientific Report (2004) 15, 1-52, Conclusion on the peer review of tribenuron.

Peer review of the pesticide risk assessment of the active substance tribenuron-methyl. EFSA Journal 2017;15(7):4912.

Draft Assessment Report (DAR), Tribenuron metyl. December 2004.

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for tribenuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(11):3457.

Commission Regulation (EU) 2015/1040 of 30 June 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products

SANCO 7525/VI/95 – rev. 10.2, 23 September 2016. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs

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
KCA 6.2.1	Xxxxxx S.	2019	Metabolism of [14C]-Tribenuron-methyl in Wheat Eurofins S18-07560 GLP, Unpublished.	N	TF PROPLAN-SARABIA
KCA 6.3/01	Xxxxxx B.	2018	Generation of crop samples for the determination of residues of tribenuron-methyl after 1 application of T-75WG-OR2-C in winter wheat at 2 sites in Northern Europe in 2017, Eurofins Agroscience Services GmbH, Germany Study code: S17-04788 GLP: Yes Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/02	Xxxxxx E.	2018	Determination of residues of tribenuron-methyl in/on winter wheat at harvest under open field conditions following one application of T-75WG-OR2-C with adjuwant SAR-BIO 90 EC in Poland in 2017, SynTech Research Poland, Study code: 428SRPL17R01 GLP: Yes Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/03	Xxxxxx G.	2018	Determination of residues of MCPA and tribenuron-methyl in/on winter wheat at harvest under open field conditions following one application of MT-565SG-OR2-C with adjuvant SAR-BIO 90 EC in Poland in 2017 Study number: 428SRPL17R02 GLP: Yes Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/04	Xxxxxx B.	2018	Generation of crop samples for the determination of residues of MCPA + tribenuron-methyl after 1 application of MT-565SG-OR2-C in winter wheat at 3 sites in Northern Europe in 2017,	N	CIECH Sarzyna S.A.

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**
			Eurofins Agroscience Services GmbH, Germany Study code: S17-04789 GLP: Yes Unpublished		

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**	**Vertebrate study Y/N**	**Owner**
KCA 6.1	L´xxxxx K.M.	2000	Position Paper Title Final presentation of the freezer storage stability data for tribenuron-methyl fortified wheat grain and straw DuPont-4708 GLP: No Published: No	N	DuPont
KCA 6.2.1/01	Xxxxxx, D.L., Xxxxxx, J.J.	1989	Metabolism of [phenyl(U)-14C] and [triazine-2-14C]tribenuron-methyl in field-grown wheat. AMR 787-87, Revision No. 1. GLP: No Published: No	N	DuPont
KCA 6.2.1/02	Xxxxxx, D.L.	1985	Metabolism of [phenyl(U)-^{14}C] and [triazine-2-^{14}C]tribenuron-methyl in excised wheat plants. AMR 361-85, Interim Report GLP: No Published: No	N	DuPont
KCA 6.6.1/01	Xxxxxx, D.L.	1985	Crop rotation studies with [phenyl-^{14}C(U)] DPX-L5300 in the greenhouse AMR 427-85 GLP: No Published: No	N	DuPont

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**
KCA 6.6.1/02	Xxxxxx, J.J.	1987	Crop rotation studies with [triazine-2-^{14}C]DPX-L5300 in the greenhouse AMR 509-86, Revision No. 1 GLP: No Published: No	N	DuPont
KCA 6.2.2-6.2.5	[redacted]	1989	Metabolism of [triazine-2-^{14}C]-DPX-L5300 and [phenyl(U)-^{14C}]-DPX-L5300 in lactating goats AMR 610-86 GLP: No Published: No	Y	DuPont
KCA 6.3/01	Xxxxxx, E.; Xxxxxx, L.	2001	Combined decline and magnitude of residue of tribenuron-methyl in cereal (spring barley, spring wheat, winter wheat) following application of Tribenuron-methyl 75WG - Europe, season 1999 Institut Fresenius Chemische und Biologische/GmbH DuPont-2261, Revision No. 1 GLP: Yes Published: No	N	DuPont
KCA 6.3/02	Xxxxxx, N., Xxxxxx, L.	2000	Combined decline and magnitude of residues of tribenuron-methyl cereals (spring barley, spring wheat, winter wheat) following application of Tribenuron-methyl (DPX-L5300) 75WG (paste extruded granule) - Europe, season 2000 Institut Fresenius Chemische und Biologische/GmbH DuPont-4029, Revision No. 1 GLP: Yes Published: No	N	DuPont

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Tribenuron methyl

A 2.1.1 Stability of residues

No new or additional studies have been submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in primary crops

Comments of zRMS:	The study is accepted

Reference:	KCP 6.2.1
Report	Metabolism of [14C]- Tribenuron-methyl in Wheat, Xxxxxx S., 2019, S18-07560
Guideline(s):	Yes (OECD Test Guideline No. 501)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The metabolism of the herbicide Tribenuron-methyl was investigated in wheat plants as a result of an over the top post emergent foliar application at BBCH 29. Radiolabelled [C-14 U-ring]Tribenuron-methyl and radiolabelled [Triazine-U-^{14}C]Tribenuron-methyl were dissolved individually with a water dispersible granule (WDG) and applied individually at a nominal application rate of 30 g a.s./ha, which represents the maximum agricultural use rate (the proposed GAP application rate).
For [C-14 U-ring]Tribenuron-methyl the actual application rate corresponded to 35 g a.s./ha which was slightly above the intended maximum agricultural use rate.
For [Triazine-U-^{14}C]Tribenuron-methyl the actual application rate corresponded to 38 g a.s./ha which was slightly above the intended maximum agricultural use rate.
Wheat Forage was harvested at BBCH 49, 16 days after the application. The total radioactive residues (TRR) in all raw agricultural commodities (RACs) were determined by summing up the extractable and un-extractable radioactivity.
Homogenized forage plant material from both labels was conventionally extracted with acetonitrile/ammonium carbonate-solution mixtures.

Residues in the conventional extract were analysed and quantified by HPLC. The test item Tribenuronmethyl and its metabolites were identified by the methodology listed below:

- Comparison of the HPLC retention times of reference item with the one of the respective components in the sample extracts
- Comparison of metabolic profiles of all RACs, as analysed by HPLC among themselves
- Confirmation of identity of isolated parent/metabolite compound by LC-MS/MS comparison with reference item

Overall, identification rates amounted to 74.9% of TRR for [C-14 U-ring]Tribenuron-methyl wheat

forage and 79.2% of TRR for [Triazine-U-14C]Tribenuron-methyl wheat forage.

All conventional extraction experiments of the raw agricultural commodities and the first HPLC analyses were performed within 109 days after harvest of the respective samples. Samples were stored at temperature ≤-18°C.
As analyses of the conventional extract were conducted within 4 months after harvest, no storage stability investigations were required.

Results and discussion

[C-14 U-ring]Tribenuron-methyl
The efficiencies of conventional solvent extraction procedures were 96.2% of TRR (0.183 mg eq/kg). The post extraction solids after extraction accounted for 3.8% of TRR (0.007 mg eq/kg).
In extracts of [C-14 U-ring]Tribenuron-methyl Wheat forage 21.4% of TRR (0.041 mg eq/kg) were characterised in total. Eight unknown compounds were detected besides the parent compound Tribenuron methyl and one identified major component. The test item Tribenuron-methyl represented 61.9% of TRR (0.118 mg eq/kg) and was a major component of the residue. IN-D5803 was a major compound representing 12.95% of TRR (0.025 mg eq/kg). In total 74.9% of TRR (0.142 mg eq/kg) were identified in wheat forage.
[Triazine-U-^{14}C]Tribenuron-methyl
The efficiencies of conventional solvent extraction procedures were 97.8% of TRR (0.192 mg eq/kg). The post extraction solids after extraction accounted for 2.2% of TRR (0.004 mg eq/kg).
In extracts of [Triazine-U-^{14}C] Tribenuron-methyl Wheat forage 14.6% of TRR (0.029 mg eq/kg) were characterised in total. Four unknown compounds were detected besides the parent compound Tribenuron methyl and two identified components. The test item Tribenuron-methyl and IN-L5296 were major components of the residue representing 58.8% of TRR (0.115 mg eq/kg) and 11.1% of TRR (0.022 mg eq/kg), respectively. IN-R9805 was a minor compound representing 9.3% of TRR (0.018 mg eq/kg). In total 79.2% of TRR (0.155 mg eq/kg) were identified in wheat forage.

Table A 1: Total Radioactive Residues (TRRs) in wheat forage.

Matrix	Timing and Applic. No.	PHI (days)	TRR (ppm) (= mg eq/kg)* (100% TRR)	
			[C-14 U-ring]	[Triazine-U-14C]
Wheat Forage	Spray application at BBCH 29; Target rate 30 g a.s. /ha	16	0.190	0.196

* TRR values were determined by summing up the radioactivity measured in the extracts and in the remaining solids.

Table A 2: Summary of characterization and identification of Radioactive Residues in plant matrices following application of radiolabeled tribenuron methyl at 30 g a.s./ha.

Compound	[C-14 U-ring]		[Triazine-U-^{14}C]	
	Wheat forage TRR = 0.190 ppm		Wheat forage TRR = 0.196 ppm	
	% TRR	ppm	% TRR	ppm
Tribenuron methyl	61.9	0.118	58.8	0.115
IN-D5803***	12.9	0.025	-	-
IN-R9805***	-	-	9.3	0.018

Compound	[C-14 U-ring]		[Triazine-U-^{14}C]	
	Wheat forage TRR = 0.190 ppm		Wheat forage TRR = 0.196 ppm	
	% TRR	ppm	% TRR	ppm
IN-L5296***	-	-	11.1	0.022
Total identified	74.9	0.142	79.2	0.155
Total characterized****	21.4	0.041	14.6	0.029
Total extractable	96.2	0.183	97.8	0.192
Unextractable (PES)*	3.8	0.007	2.2	0.004
Accountability**	100.0	0.190	100.0	0.196

* Residues remaining after exhaustive extractions.
** Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.
*** label specific metabolite
**** Non-identified metabolites were characterised by their extraction and chromatographic behaviour.

Table A 3: Identification of compounds from metabolism study

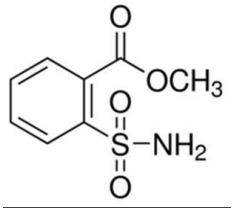
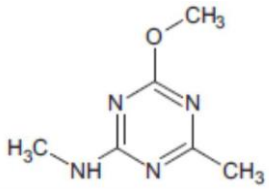
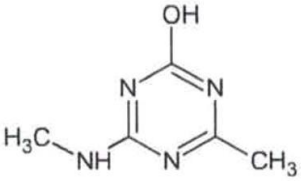
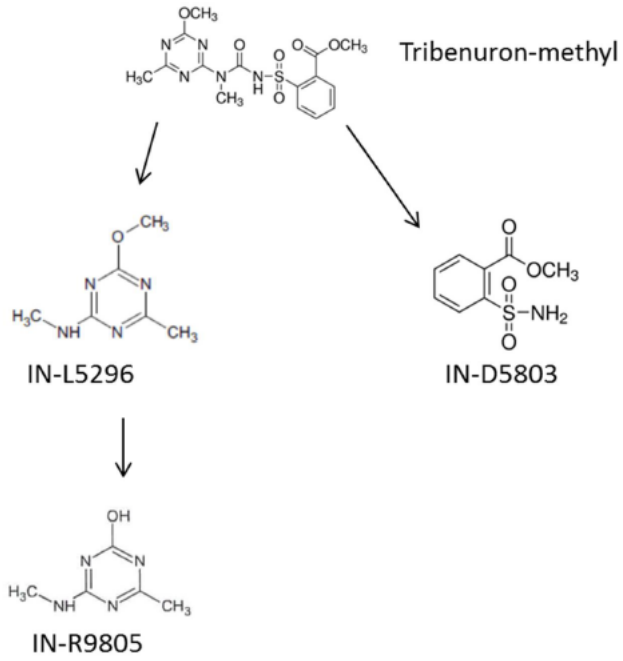
Common name/code	Chemical name	Chemical structure
IN-D5803	Methyl 2-(aminosulfonyl)benzoate	
IN-L5296	2-methoxy-4-methyl-6-(methylamino)1,3,5-triazone	
IN-R9805	4-methyl-6-(methylamino)-1,3,5-triazin-2-ol	

Figure A 1: Proposed Metabolic Profile of tribenuron methyl in wheat



Conclusions

Wheat plants grown on a sandy-loam soil in a planting container with an area of 1.0 m2 were treated with a single over the top post emergent foliar application with [C-14 U-ring]Tribenuron-methyl (35 g a.s./ha) and with [Triazine-U-^{14}C]Tribenuron-methyl (38 g a.s./ha) at BBCH 29, individually.

- The purity of the respective test item accounted for >95% during the application procedures.
- Harvest of RAC Wheat Forage at BBCH 49 on 14 Feb 2019
- TRR values of individual RACs accounted for 0.190 mg eq/kg and 0.196 mg eq/kg in wheat forage individually applied with [C-14 U-ring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl, respectively.
- The extraction rates after conventional extraction were 96.2% and 97.8% of TRR in wheat forage individually applied with [C-14 U-ring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl, respectively.
- Tribenuron-methyl was the major compound in conventional extracts of wheat forage [C-14 Uring] Tribenuron-methyl and [Triazine-U-^{14}C] Tribenuron-methyl accounting for 61.9% of TRR (0.118 mg eq/kg) and 58.8% of TRR (0.115 mg eq/kg), respectively.
- IN-D5803 (Label-specific metabolite) was a major compound in wheat forage [C-14 Uring] Tribenuron-methyl accounting for 12.9% of TRR (0.025 mg eq/kg).
- IN-R9805 (Label-specific metabolite) was a minor compound in wheat forage [Triazine-U- ^{14}C] Tribenuron-methyl for 9.3% of TRR (0.018 mg eq/kg).
- IN-L5296 was a minor compound in wheat forage [Triazine-U-^{14}C] Tribenuron-methyl for 11.1% of TRR (0.022 mg eq/kg).
- In total eight and three unknown minor metabolites (<10% of TRR, <0.05 mg eq/kg) were detected in conventional extracts of wheat forage [C-14 U-ring] Tribenuron-methyl and wheat forage [Triazine-U-^{14}C] Tribenuron-methyl, respectively and characterised by their chromatographic behaviour.

On the basis of the nature and amount found in the extracts in the present study, the following metabolic pathway of Tribenuron-methyl in wheat forage is proposed.

- Hydrolysis of the sulfonylurea bridge to form IN-D5803.
- Hydrolysis of the sulfonylurea bridge resulting in formation of IN-L5296 followed oxidative dealkylation of the methyl ether to form IN-R9805.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, RMS, 2017)	1	24 g a.s/ha	-	BBCH 30-39 Spring application	PHI n/a when harvest at maturity. 28 for harvest as forage/ silage before maturity.
Intended cGAP (2*)	1	18.75 g a.s/ha	-	Spring BBCH 13-39	n.a

A 2.1.3.1.1 Study 1

Comments of zRMS:	The field part of the studies (n=2) of magnitude the tribenuron methyl residues in wheat (Hungary and Germany) is accepted. The dose of tribenuron methyl used in the studies is 20.3 and 17.7 g a.s./ha (max 18.75 g a.s./ha proposed in GAP for TOSCANA TOP 75 WG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) in both trials.
Reference:	KCA 6.3/01
Report	Generation of crop samples for the determination of residues of tribenuron-methyl after 1 application of T-75WG-OR2-C in winter wheat at 2 sites in Northern Europe in 2017, B. Xxxxxx, Study Code: S17-04788, Eurofins Agroscience Services GmbH, Germany
Guideline(s):	Yes (OECD (2009), OECD Test Guideline 509, OECD (2011))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two new residue trials in wheat were conducted in the growing season 2016/2017 in different localizations. The test item was wheat grains and straw samples (different varieties) treated with product TOSCANA TOP 75 WG and control samples. The product was applied once at rate of 0.025 kg/ha (corresponding to 18.75 g/ha of tribenuron methyl).
Specimens were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Wheat samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 6 months. Results on residue trials in wheat are detailed summarised in Table A 5.
The residues of tribenuron methyl in samples treated with TOSCANA TOP 75 WG were below the limit of determination, i.e. 0.003 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A 5: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment		Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)				Tribenuron methyl		
	(a)	(b)			(c)				(d)	(e)
S17-04788-01, Dollern, Lower Saxony, Germany	Winter Wheat	1. 27.10.2016 2. 14.06.2017-30.06.2017 3. 08.08.2017	20.3	217	23 May 2017	BBCH 39	Grain Straw	<LOD <LOD	77	
S17-04788-03, Pàzmànd, Fejèr, Hungary	Winter Wheat	1. 04.11.2016 2. 07.06.2017-15.06.2017 3. 03.07.2017	17.7	188	15 May 2017	BBCH 39	Grain Straw	<LOD <LOD	49	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
LOD = 0.003 mg/kg

A 2.1.3.1.2 Study 2

Comments of zRMS:	The field part of the study (n=1) of magnitude the tribenuron methyl residues in wheat (Poland) is accepted. The dose of tribenuron methyl used in the studies is 18.75 g a.s./ha (max 18.75 g a.s./ha proposed in GAP for TOSCANA TOP 75 WG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39).
Reference:	KCA 6.3/02
Report	Determination of residues of tribenuron-methyl in/on winter wheat at harvest under open field conditions following one application of T-75WG-OR2-C with adjuvant SAR-BIO 90 EC in Poland in 2017, E. Xxxxxx, Study code: 428SRPL17R01, SynTech Research Poland, 2018
Guideline(s):	Yes (SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

One new residue trial in wheat were conducted in the growing season 2016/2017. The test item was wheat grains and straw samples treated with product TOSCANA TOP 75 WG and control samples. The product was applied once at rate of 0.025 kg/ha (corresponding to 18.75 g/ha of tribenuron methyl).
Specimens were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Wheat samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 183 days. Results on residue trials in wheat are detailed summarised in Table A 6.
The residues of tribenuron methyl in samples treated with TOSCANA TOP 75 WG were below the limit of determination, i.e. 0.003 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A 6: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment		Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)
			g a.s./ ha	Water (l/ha) g a.s./hl				Tribenuron methyl	
	(a)	(b)			(c)				(d)
SRPL17-056-428HR, Jabłowo Pałuckie, Poland	Winter Wheat, Arkadia	1. 18.10.2016 2. 06.07.2017-13.07.2017 3. 21.08.2017-31.08.2017	18.75	264.4	23 May 2017	BBCH 39	Grain Straw	<LOD <LOD	90

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

LOD = 0.003 mg/kg

A 2.1.3.1.3 Study 3

Comments of zRMS:	The field part of the study (n=1) of magnitude the tribenuron methyl residues in wheat (Poland) is accepted. The dose of tribenuron methyl used in the studies is lower (15.00 g a.s./ha) than proposed in GAP for TOSCANA TOP 75 WG (max 18.75 g a.s./ha), but the difference does not exceed 25% (SANCO 7525/VI/95 Rev. 10.3). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39).
Reference:	KCA 6.3/03
Report	Determination of residues of MCPA and tribenuron-methyl in/on winter wheat at harvest under open field conditions following one application of MT-565SG-OR2-C with adjuvant SAR-BIO 90 EC in Poland in 2017, Xxxxxx G., Study code: 428SRPL17R02, SynTech Research Poland, 2018
Guideline(s):	Yes (SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

One new residue trial in wheat were conducted in the growing season 2016/2017. The test item was wheat grains and straw samples treated with product MT-565SG-OR2-C and control samples. The product was applied once at rate of 1 kg/ha (corresponding to 15 g/ha of tribenuron methyl).
Specimens were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Wheat samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 12 months. Results on residue trials in wheat are detailed summarised in Table A 7.
The residues of tribenuron methyl in samples treated with MT-565SG-OR2-C were below the limit of determination, i.e. 0.003 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A 7: Summary of the study 3 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment		Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)
			g a.s./ ha	Water (l/ha) g a.s./hl				Tribenuron methyl	
	(a)	(b)			(c)				(d)
SRPL17-057-428HR, Jabłowo Pałuckie, Poland	Winter Wheat, Arkadia	1. 18.10.2016 2. 06.07.2017-13.07.2017 3. 21.08.2017-31.08.2017	15	261.1	23 May 2017	BBCH 39	Grain Straw	<LOD <LOD	90

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

LOD = 0.003 mg/kg

A 2.1.3.1.4 Study 4

Comments of zRMS:	The field part of the studies (n=3) of magnitude the tribenuron methyl residues in wheat (Hungary, UK and Germany) is accepted. The dose of tribenuron methyl used in the studies is lower (15.00 g a.s./ha) than proposed in GAP for TOSCANA TOP 75 WG (max 18.75 g a.s./ha), but the difference does not exceed 25% (SANCO 7525/VI/95 Rev. 10.3). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) in all trials.
Reference:	KCA 6.3/04
Report	Determination of residues of MCPA and tribenuron-methyl in/on winter wheat at harvest under open field conditions following one application of MT-565SG-OR2-C with adjuvant SAR-BIO 90 EC in Poland in 2017, Xxxxxx G., Study code: 428SRPL17R02, SynTech Research Poland, 2017
Guideline(s):	Yes (SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three new residue trials in wheat were conducted in the growing season 2016/2017. The test item was wheat grains and straw samples treated with product MT-565SG-OR2-C and control samples. The product was applied once at rate of 1 kg/ha (corresponding to 15 g/ha of tribenuron methyl).
Specimens were collected at normal commercial harvest.. All samples were frozen immediately after sampling and storage at temperature lower than -18°C before test. Wheat samples were provided to laboratory in good conditions. The maximum interval between specimen collection and extraction for analysis was 12 months. Results on residue trials in wheat are detailed summarised in Table A 8.
The residues of tribenuron methyl in samples treated with MT-565SG-OR2-C were below the limit of determination, i.e. 0.003 mg/kg. Hence, they were below the maximum residue limits, i.e 0.01 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A 8: Summary of the study 4 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment		Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)
			g a.s./ ha	Water (l/ha) g a.s./hl				Tribenuron methyl	
	(a)	(b)			(c)				(d)
S17-04789-01 Diefenbach, Baden-Württemberg, Germany	Winter Wheat, Pamier	1. 16.10.2016 2. 05.06.2017-15.06.2017 3. 07.08.2017	15	217	22 May 2017	BBCH 39	Grain Straw	<LOD <LOD	77
S17-04789-02 Bishop Burton, East Yorkshire, UK	Winter Wheat, Barrel	1. 20.09.2016 2. 06.2017 3. 16.08.2017	15	207	26.05.2017	BBCH 39	Grain Straw	<LOD <LOD	74
S17-04789-03 Pàzmànd, Fejèr, Hungary	Winter Wheat, Toborzò	1. 04.11.2016 2. 07.06.2017-15.06.2017 3. 03.07.2017	15	206	15.05.2017	BBCH 39	Grain Straw	<LOD <LOD	48

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

LOD = 0.003 mg/kg

A 2.1.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.1.7 Other/Special Studies

No new or additional studies have been submitted

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

A 3.1.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Tribenuron-methyl

LOQs (mg/kg) range from: 0,01 to: 0,05

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,2
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:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (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)
1,0%	DK child	0,10	0,6%	Rye	0,4%	Wheat			1,0%	1,0%
0,7%	GEMS/Food G06	0,07	0,7%	Wheat	0,0%	Barley	0,0%	Rye	0,7%	0,7%
0,7%	IT toddler	0,07	0,7%	Wheat	0,0%	Barley			0,7%	0,7%
0,6%	GEMS/Food G08	0,06	0,4%	Wheat	0,1%	Barley	0,1%	Rye	0,6%	0,6%
0,6%	GEMS/Food G15	0,06	0,5%	Wheat	0,1%	Barley	0,0%	Rye	0,6%	0,6%
0,5%	RO general	0,05	0,5%	Wheat		FRUIT AND TREE NUTS			0,5%	0,5%
0,5%	DE child	0,05	0,4%	Wheat	0,1%	Rye	0,0%	Barley	0,5%	0,5%
0,5%	GEMS/Food G07	0,05	0,4%	Wheat	0,1%	Barley	0,0%	Rye	0,5%	0,5%
0,5%	GEMS/Food G10	0,05	0,4%	Wheat	0,1%	Barley	0,0%	Rye	0,5%	0,5%
0,5%	FR child 3 15 yr	0,05	0,5%	Wheat	0,0%	Rye	0,0%	Barley	0,5%	0,5%
0,5%	NL toddler	0,05	0,4%	Wheat	0,0%	Rye	0,0%	Barley	0,5%	0,5%
0,4%	ES child	0,04	0,4%	Wheat	0,0%	Barley			0,4%	0,4%
0,4%	GEMS/Food G11	0,04	0,4%	Wheat	0,1%	Barley	0,0%	Rye	0,4%	0,4%
0,4%	NL child	0,04	0,4%	Wheat	0,0%	Rye	0,0%	Barley	0,4%	0,4%
0,4%	IT adult	0,04	0,4%	Wheat	0,0%	Barley			0,4%	0,4%
0,4%	PT general	0,04	0,4%	Wheat	0,0%	Rye	0,0%	Barley	0,4%	0,4%
0,4%	UK toddler	0,04	0,4%	Wheat	0,0%	Barley	0,0%	Rye	0,4%	0,4%
0,3%	SE general	0,03	0,3%	Wheat	0,0%	Rye			0,3%	0,3%
0,3%	FR toddler 2 3 yr	0,03	0,3%	Wheat	0,0%	Rye	0,0%	Barley	0,3%	0,3%
0,3%	DE general	0,03	0,2%	Wheat	0,1%	Rye	0,1%	Barley	0,3%	0,3%
0,3%	ES adult	0,03	0,2%	Wheat	0,0%	Barley			0,3%	0,3%
0,3%	DE women 14-50 yr	0,03	0,2%	Wheat	0,0%	Rye	0,0%	Barley	0,3%	0,3%
0,3%	UK infant	0,03	0,3%	Wheat		FRUIT AND TREE NUTS			0,3%	0,3%
0,2%	IE adult	0,02	0,2%	Wheat	0,0%	Rye	0,0%	Barley	0,2%	0,2%
0,2%	NL general	0,02	0,2%	Wheat	0,0%	Barley	0,0%	Rye	0,2%	0,2%
0,2%	FR adult	0,02	0,2%	Wheat	0,0%	Rye	0,0%	Barley	0,2%	0,2%
0,2%	LT adult	0,02	0,1%	Rye	0,1%	Wheat	0,0%	Barley	0,2%	0,2%
0,2%	UK vegetarian	0,02	0,2%	Wheat	0,0%	Barley	0,0%	Barley	0,2%	0,2%
0,2%	FI 3 yr	0,02	0,1%	Wheat	0,1%	Rye	0,0%	Barley	0,2%	0,2%
0,2%	UK adult	0,02	0,2%	Wheat	0,0%	Barley	0,0%	Rye	0,2%	0,2%
0,2%	DK adult	0,02	0,1%	Wheat	0,1%	Rye			0,2%	0,2%
0,2%	FI 6 yr	0,02	0,1%	Wheat	0,1%	Rye	0,0%	Barley	0,2%	0,2%
0,1%	IE child	0,01	0,1%	Wheat	0,0%	Barley			0,1%	0,1%
0,1%	FI adult	0,01	0,1%	Rye	0,0%	Wheat	0,0%	Barley	0,1%	0,1%
0,1%	FR infant	0,01	0,1%	Wheat	0,0%	Rye	0,0%	Barley	0,1%	0,1%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

A 3.1.2 IEDI calculations

TMDI values do not exceed ADI therefore IEDI calculations are not required.

A 3.1.3 IESTI calculations - Raw commodities

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)
0,07%	Wheat	0,01 / 0,01	0,14	0,04%	Wheat	0,01 / 0,01	0,08	0,07%	Wheat	0,01 / 0,01	0,14	0,04%	Wheat	0,01 / 0,01	0,08
0,03%	Rye	0,01 / 0,01	0,06	0,02%	Rye	0,01 / 0,01	0,05	0,03%	Rye	0,01 / 0,01	0,06	0,02%	Rye	0,01 / 0,01	0,05
0,03%	Barley	0,01 / 0,01	0,06	0,02%	Barley	0,01 / 0,01	0,05	0,03%	Barley	0,01 / 0,01	0,06	0,02%	Barley	0,01 / 0,01	0,05
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)**							

A 3.1.4 IESTI calculations - Processed commodities

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): ---			
IESTI				**IESTI**			
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)
0,1%	Wheat / milling (flour)	0,01 / 0,01	0,12	0,0%	Barley / beer	0,01 / 0	0,07
0,0%	Wheat / milling (wholemea	0,01 / 0,01	0,06	0,02%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,0%	Rye / boiled	0,01 / 0,01	0,04	0,02%	Wheat / pasta	0,01 / 0,01	0,04
0,0%	Barley / cooked	0,01 / 0,01	0,04	0,02%	Wheat / bread	0,01 / 0,01	0,03
0,0%	Rye / milling (wholemeal)-	0,01 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Barley / milling (flour)	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

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 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)
0,06%	Wheat / milling (flour)	0,01 / 0,01	0,12	0,04%	Barley / beer	0,01 / 0	0,07
0,03%	Wheat / milling	0,01 / 0,01	0,06	0,02%	Wheat / bread/pizza	0,01 / 0,01	0,04
0,02%	Rye / boiled	0,01 / 0,01	0,04	0,02%	Wheat / pasta	0,01 / 0,01	0,04
0,02%	Barley / cooked	0,01 / 0,01	0,04	0,02%	Wheat / bread (wholemeal)	0,01 / 0,01	0,03
0,02%	Rye / milling (wholemeal)-	0,01 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,01%	Barley / milling (flour)	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

A 3.1.5 NTMDI calculations

NTMDI calculations are not required

A 3.1.6 NESTI calculations

NTMDI calculations are not required

Appendix 4 Additional information provided by the applicant

No information has been provided.