FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: MT-565SG-OR2-C

Product name(s): HAKSAR TOP 565 SG

Chemical active substance(s):

MCPA, 550 g/kg

Tribenuron methyl, 15 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 01/2021

MS Finalisation date: 06/12/2021

Version history

When	What
January 2021	First submission of product authorization.
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
December 2021	Final 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

Tribenuron methyl

Critical GAP for HAKSAR TOP 565 SG on cereals (wheat, triticale, barley, rye): 1 appl., max. BBCH-39, max application rate: 15 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 HAKSAR TOP 565 SG.

Critical GAP for HAKSAR TOP 565 SG on Miscanthus sp. (MISSS): 1 appl., max. BBCH-14, max application rate: 15 g a.s/ha, PHI- not applicable

Critical GAP for HAKSAR TOP 565 SG on grasses grown for seeds: 1 appl., max. BBCH-39, max application rate: 15 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.

<u>Stability</u>

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 HAKSAR TOP 565 SG. 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.

<u>Plant metabolism</u>

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=4, field trials in Poland, Hungary, Germany 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). 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, oat 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 HAKSAR TOP 565 SG 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 HAKSAR TOP 565 SG 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.**

<u>Residues in succeeding crops</u>

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).*

<u>Residues in livestock</u>

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.

<u>Risk assessment</u>

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.

MCPA

EU GAP for cereals (Review report for the active substance MCPA, SANCO/4062/2001-final 11 July 2008): Winter and spring cereals: 1 appl., Spring, before first node detectable, appl. rate 1.8 kg a.s./ha

GAP proposed for HAKSAR TOP 565 SG:

Cereals (wheat, barley, rye, oats): 1 appl., appl. rate 550 g a.s. /ha, max BBCH 39

The EU critical GAP for MCPA covers GAP proposed for HAKSAR TOP 565 SG.

Stability of residues

After 18 months of storage at a temperature below –18°C, residues of MCPA in supplemented samples of cereal plants, grain and straw were all found above 70% of the initial level. Residues can thus be considered as stable in the described storage conditions over the storage period. (DAR, Wasser C., 2002)

Storage stability studies were evaluated at EU level during the Annex inclusion process and were considered to be acceptable. The studies demonstrated that residues of MCPA are stable when stored under freezer condition for at least 18 months in cereals and for at least 3 months in muscle, milk, fat, kidney and liver. The stability of residues in sample extracts has been confirmed by the recovery of the analytical methods.

Metabolism in plants (MCPA end points, August 2004)

Plant groups covered   Wheat, maize, beans
Rotational crops covered   Do not submitted at GAP 1.8 kg/ha
Plant residue definition for monitoring MCPA
Plant residue definition for risk assessment   MCPA
Conversion factor from enforcement to RA   Not applicable

Metabolism studies in plants and animals were evaluated in DAR for MCPA (March 2001). Results from the metabolism studies in wheat showed a rapid degradation of MCPA via compound of no toxicological importance and no residues were found at harvest in edible parts of plant origin food.

Nature of residue in rotational crops

MCPA addendum to the DAR (2003):

Soil ^{14}C-residue levels declined from 0.276 (Day 0) to 0.045 mg/kg (Day 582) over the duration of the study. A half-life value was calculated and found to be 63 days under the experimental conditions.

All lettuce samples from the 365-day planting were below the limit of detection (limit of detection 0.013 mg/kg) and had a total residue level below 0.05 mg/kg.

There were no residues detected in turnip samples at or above the limit of detection (< 0.013 mg/kg).

Detectable residues were found in the barley forage and straw samples from the 30-day planting and the straw samples from the 120-day planting but all were less than 0.05 mg/kg. In all other samples no residues were detectable (< 0.013 mg/kg).

The levels of total ^{14}C-residues in the rotational crop samples were all less than 0.05 mg/kg.

Due to the very low residue levels in the crop samples, metabolite identification work was not feasible. No detectable ^{14}C-residues were found in the rotational crop and soil samples from the untreated plot.

In the literature (Fryer and Kirkland; 1970) some experiments had already confirmed that MCPA, when used at the recommended rate, is unlikely to have any injurious effect on the capacity of soil to product healthy crops. In this reference possible long-term effects of repeated applications of MCPA were examined on one soil type.

Nature of residues in processed commodities

MCPA addendum vol.3 B6 (October 2003): *Based on results from residue trials conducted to date, no MCPA residues are expected at or above the limit of detection. It is therefore unlikely that MCPA residues will be detected in processed fractions such as flour or bread. Therefore, no study has been* *conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of MCPA residues.*

Metabolism in livestock

Animals covered hens, lactating goats
Animal residue definition for monitoring MCPA
Animal residue definition for risk assessment MCPA
Conversion factor Not applicable
Metabolism in rat and ruminant similar Yes
Fat soluble residue Yes

Results from the metabolism studies in animals showed that MCPA is rapidly excreted (above 99%), within 24 hours.

The residue definition according to the current regulation (Reg. (EU) 491/2014) for plants is MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) and for animal products is MCPA, MCPB and MCPA thioethyl expressed as MCPA.

Magnitude of residues

Residue trials were presented in DAR for MCPA (March 2001) and are adequate. Residues of MCPA in cereals are below current MRL set as 0.2 mg/kg in accordance with current Commission Regulation (EU) No 491/2014 of May 2014.

In addition, the Applicant submitted additional studies (n=4, field trials in Poland, Hungary, Germany and UK) of magnitude the MCPA 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). Results from tree studies indicate the absence of MCPA residues in wheat grain above the detection limit (0.005 mg/kg), in one study residues were at the level 0.0137 mg/kg (below LOQ). 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 HAKSAR TOP 565 SG is 39.

Risk assessment

No concern for the consumer was identified, the highest TMDI was 16 % of the ADI (highest contributor to MS diet was milk– 6%, max 2% ADI for wheat), and the highest IESTI 16 % of the ARfD (bovine liver).

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

Conclusion

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

The Applicant shall provide results of field trials for metabolites of tribenyron methyl included in the provisional residue definition for risk assessment no later than two years after authorization HAKSAR TOP 565 SG 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.

Taking into account the approaching date of the re-evaluation of both active substances, it should be emphasized that after the re-evaluation it will be necessary to re-evaluate this documentation.

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 HAKSAR TOP 565 SG 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.

Comparison of proposed GAPs with GAPs considered acceptable in the DAR for MCPA and Tribenuron-methyl

	Critical GAP proposed in Northern residue Zone (CZ,DE, PL, UK, RO, HU)	**Acceptable DAR uses NEU for MCPA**	**Acceptable DAR uses NEU for Tribenuron-methyl**
Crop	Winter Cereals - Wheat, Barley, Rye, Triticale; Spring Wheat, Spring Barley, Oat	Winter wheat, Winter Barley	Spring barley, Winter barley, Spring wheat, Winter wheat
Maximum individual dose (range)	550 g as/ha of MCPA and 15 g as/ha of Tribenuron-methyl	1.8 kg as/ha	7.5 – 30 g as/ha
Maximum total dose/ number of treatments	550 g as/ha of MCPA and 15 g as/ha of Tribenuron-methyl	1.8 kg as/ha	750 g/kg
Time of application	Spring BBCH 13-39 Autumn BBCH 13-23	Spring before first node detect-able (BBCH 30)	BBCH 9-39 Spring and/or fall application
Application method	Broadcast- foliar	Spraying with tractor mounted boom	Foliar
Water volume	200 / 400	100-1000 L/ha	100-600
Formulation type	SG	Not specified in DAR	WG

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for MCPA of 0.2 mg/kg in barley, oat, rye and wheat and for Tribenuron-methyl of 0.01 mg/kg in barley, oat, rye and wheat 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 MCPA and 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	12
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)**	**Remarks:**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**g as/hL min max**	**water L/ha min max**	**kg as/ha min max**			
2.	Winter soft wheat (TRZAW), Spring soft wheat (TRZAS), Winter rye (SECCW), Winter triticale (TTLWI) Winter barley (HORVW) Spring barley (HORVS) Oats (AVESA)	Northern residue zone	MT-565SG-OR2-C	F	Annual dicotyledonous weeds	SG	565	Broadcast-foliar	Spring BBCH 13 – 39	1	n.a	MCPA 137,5 – 275 g as/ha tribenuron-methyl 3,75 – 7,5 g as/ha	200 / 400	MCPA 550 g as/ha; tribenuron-methyl 15 g as/ha	n.a		R
9	Miscanthus sp. (MISSS)	Northern residue zone	MT-565SG-OR2-C	F	Annual dicotyledonous weeds	SG	565	Broadcast-foliar	BBCH 12 -14	1	n.a.	MCPA 137,5 – 275 g as/ha tribenuron-methyl 3,75 – 7,5 g as/ha	200 / 400	MCPA 550 g as/ha; tribenuron-methyl 15 g as/ha	n.a		A
10	Grasses grown for seeds	Northern residue zone	MT-565SG-OR2-C	F	Annual dicotyledonous weeds	SG	565	Broadcast-foliar	Spring BBCH 13 – 39	1	n.a	MCPA 137,5 – 275 g as/ha tribenuron-methyl 3,75 – 7,5 g as/ha	200 / 400	MCPA 550 g as/ha; tribenuron-methyl 15 g as/ha	n.a		A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation HAKSAR TOP 565 SG is composed of MCPA and Tribenuron methyl

Table 7.1-2: Toxicological reference values for the dietary risk assessment of MCPA and Tribenuron methyl

Reference value	Source	Year	Value	Study relied upon	Safety factor
MCPA					
ADI	SANCO/4062/2001-final	2008	0.05 mg/kg bw/d	2 years, rat	100
ARfD	SANCO/4062/2001-final	2008	0.15 mg/kg bw/d	NOEL: 15 mg/kg bw/d for maternal toxicity in rabbit	100
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	100

7.1.2.1 Summary for MCPA

Table 7.1-3: Summary for MCPA

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?
1,2,7,8	Cereals	Yes	Yes	Yes	Yes	Yes	No	No
9	Miscanthus sp.	NR						
10	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

As residues of MCPA 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.

Number of trials available for winter cereals fulfils the requirements for central 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 MCPA in the formulation HAKSAR TOP 565 SG do not represent unacceptable acute and chronic risks for the consumer.

7.1.2.2 Summary for Tribenuron methyl

Table 7.1-4: 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?
1,2,7,8	Cereals	Yes	Yes	Yes	Yes	Yes	No	No
9	Miscanthus sp.	NR						
10	Grasses grown for seeds							

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 winter and spring 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 HAKSAR TOP 565 SG 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.

7.1.2.3 Summary for HAKSAR TOP 565 SG

Table 7.1-5: Information on HAKSAR TOP 565 SG (KCA 6.8)

Crop	PHI for HAKSAR TOP 565 SG proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for HAKSAR TOP 565 SG proposed by zRMS	zRMS Comments (if different PHI proposed)
		MCPA	Tribenuron-methyl		
Cereals	F	NR	NR		
Miscanthus sp.	F	NR	NR		
Grasses grown for seeds	F	NR	NR		

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).

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for HAKSAR TOP 565 SG
Crop group	**Led by MCPA**	**Led by Tribenuron-methyl**	
NR	NR	NR	

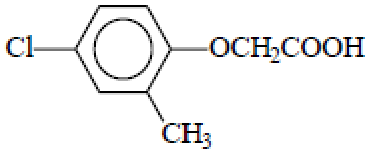
NR: not relevant

Assessment

7.2 MCPA

General data on MCPA are summarized in the table below:

Table 7.2-1: General information on MCPA

Active substance (ISO Common Name)	MCPA
IUPAC	4-chloro-*o*-tolyloxyacetic acid
Chemical structure	
Molecular formula	$C_9H_9ClO_3$
Molar mass	200.6
Chemical group	Aryloxyalkanoic acid
Mode of action (if available)	Selective, systemic with translocation. Synthetic auxin.
Systemic	Yes
Company (ies)	Industry Task Force on MCPA Research Data*
Rapporteur Member State (RMS)	IT
Approval status	Approved Date of (01/05/2006) and reference to decision Commission Implementing Regulation (EU) No 2005/57/UE of 21 September 2005 No 762/2013 of 7 August 2013 Expiration of approval 31/10/2021, Reg. (EU) 2020/1511
Restriction	-
Review Report	SANCO/4062/2001 – rev. final 11/07/2008
Current MRL regulation	Regulation (EC) No 491/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	No*
EFSA Journal: conclusion on article 12	No**
Current MRL applications on intended uses	Regulation (EC) No 491/2014

* Notifier in the EU process to whom the a.s. belong(s)

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			
Cereals	High protein content Dry commodities (high protein/high starch content)	18 months	RMS, 2001 Wasser C., 2002

Conclusion on stability of residues during storage

The stability of residues for the active substances of this product was reviewed during the Annex I inclusion process. After 18 months of storage at a temperature below –18°C, residues of MCPA in supplemented samples of cereal plants, grain and straw were all found above 70% of the initial level. Residues can thus be considered as stable in the described storage conditions over the storage period. Taking above into consideration there is no need to conduct a new stability studies of residues during storage.
Taking above into consideration additional studies on storage stability are not regarded as necessary.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

All extract samples were analyzed directly after extraction and therefore the stability of residues in sample extracts is not necessary.

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

No new data submitted in the framework of this application.

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								
Pulses and oilseeds	Beans	^{14}C-MCPA acid	heated greenhouse	MCPA Na salt of 500; 1,000; 5,000 and 10,000 mg/kg	-	2 5 7	-	RMS, 2001 Achhireddy N, Kirkwood R ,C, Fletcher W W, *J. of Pesticide Science*
Cereals	Winter wheat	MCPA acid (4-Chloro-2-methyl[ring-U^{14}C] phenoxy) acetic acid	foliar treatment, F	6.8 l/ha	1	1 25 49 102 days	-	RMS, 2001 Keller W, Otto S, 1979
	Maize	^{14}C-MCPA acid	heated greenhouse	MCPA Na salt of 500; 1,000; 5,000 and 10,000 mg/kg	-	2 5 7	-	RMS, 2001 Achhireddy N, Kirkwood R ,C, Fletcher W W, *J. of Pesticide Science*

Summary of plant metabolism studies reported in the EU

As the metabolism study in wheat showed a rapid degradation of MCPA via compounds of no toxicological importance and no residues were found at harvest in edible parts of plant origin food, the residue should be defined as MCPA only. No metabolites need to be included in any analytical methods for checking the MRLs values. The expression of the residues in crops may need to change after review of further data.
Examination of the distribution of ^{14}C-MCPA within the test species revealed differentials in translocation. In the broad bean the ^{14}C accumulates rather in the shoot and the root apices. Absorption was greater in maize than in the broad bean. The release of $^{14}C-CO_2$ from MCPA was greater in broad bean than in maize indicating faster rates of breakdown of MCPA in the broad bean. Most of the radioactivity found in the ether extracts was not identified. In maize 24% of the applied radioactivity was identified as MCPA and in broad bean 32%. These figures confirm the results previously mentioned in the metabolism study conducted with winter wheat.

Conclusion on metabolism in primary crops

All metabolism data are active substance data and were evaluated in the EU review of MCPA
MCPA product is applied early in the season to winter wheat. The levels of MCPA residues in winter wheat grain at the time of harvest were below the limit of determination in all residues trials conducted. Moreover MCPA is also not deemed to accumulate in crops.
MCPA is also not deemed to accumulate in crops. Taking above into consideration additional studies on metabolism in primary crops are not regarded as necessary.

zRMS comments:
The residue definition according to the current regulation (Reg. (EU) 491/2014) for plants is MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) and for animal products is MCPA, MCPB and MCPA thioethyl expressed as MCPA.

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

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								
Leafy vegetables	Lettuce	^{14}C-radiolabelled MCPA acid	F	0,84 kg MCPA/ha	30	114 140 185	-	RMS, 2002-2003 Ewing D D, 1988
					120	172 199 218 247		
					365	409 428 455		
Root and tuber vegetables	Turnip	^{14}C-radiolabelled MCPA acid	F	0.84 kg MCPA/ha	30	172	-	RMS, 2002-2003 Ewing D D, 1988
					120	233		
					365	455		
Cereals	Barley	^{14}C-radiolabelled MCPA acid	F	0.84 kg MCPA/ha	30	199 233	-	RMS, 2002-2003 Ewing D D, 1988
					120	218 268		
					365	409 582		

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

Summary of plant metabolism studies reported in the EU

The levels of total ^{14}C-residues in the rotational crop samples were all less than 0.05 mg/kg.
Due to the very low residue levels in the crop samples, metabolite identification work was not feasible. No detectable ^{14}C-residues were found in the rotational crop and soil samples from the untreated plot. In the literature (Fryer and Kirkland; 1970) some experiments had already confirmed that MCPA, when used at the recommended rate, is unlikely to have any injurious effect on the capacity of soil to product healthy crops. In this reference possible long-term effects of repeated applications of MCPA were examined on one soil type.

Conclusion on metabolism in rotational crops

All metabolism data are active substance data and were evaluated in the EU review of MCPA.
MCPA product is applied early in the season to winter wheat. The levels of MCPA residues in winter wheat grain at the time of harvest were below the limit of determination in all residues trials conducted. Moreover MCPA is also not deemed to accumulate in crops.

MCPA is also not deemed to accumulate in crops. Taking above into consideration additional studies on metabolism in rotational crops are not regarded as necessary.

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.

Summary of nature of residues in processed commodities reported in the EU

Based on results from residue trials conducted to date, no MCPA residues are expected at or above the limit of detection. It is therefore unlikely that MCPA residues will be detected in processed fractions such as flour or bread. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of MCPA residues.

Conclusion on nature of residues in processed commodities

MCPA product is applied early in the season to cereaks. The levels of MCPA residues in winter wheat grain at the time of harvest were below the limit of quantification in all residues trials conducted. Moreover MCPA is also not deemed to accumulate in crops.
Taking above into consideration additional studies of residues in processed commodities are not regarded as necessary.

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 (Wheat)
Rotational crops covered	Cereals (Wheat) Leafy vegetables (Lettuce) Root and tuber vegetables (Turnip) Cereals (Barley)
Metabolism in rotational crops similar to metabolism in primary crops?	~~Yes~~ Unknown Due to the very low residue levels in the rotational crop samples, metabolite identification work was not feasible, DAR (March 2001).
Processed commodities	a.s. is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	~~Yes~~ NR
Plant residue definition for monitoring	MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (Regulation n°491/2014)

Plant residue definition for risk assessment	MCPA (according to the submitted PROFile)*
Conversion factor from enforcement to RA	-

* EFSA Journal 2013;11(7):3312

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 samp-ling	
EU data								
Lactating ruminants	Goat	^{14}C-MCPA (2-Methyl-4-chlorophenoxyacetic acid; ring (U)- ^{14}C-labeled)	2	target dose equivalent to 750 ppm dietary feed	3	Milk	daily	RMS, 2001 xxxxxxxxxxxxxxxxxxx 1995
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	^{14}C-MCPA (2-Methyl-4-chlorophenoxyacetic acid; ring (U)- ^{14}C-labeled)	15	dose equivalent to 100 ppm dietary feed	7	Eggs	daily	RMS, 2001 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx 1995
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

From the two animal studies submitted one in hen and one in goat, the MCPA administered to animals was completely excreted within 24 hours as parent compound.

Conclusion on metabolism in livestock

All metabolism data are active substance data and were evaluated in the EU review of MCPA and additional studies are not regarded as necessary.
MCPA product is applied early in the season to winter wheat. The levels of MCPA residues in winter wheat grain at the time of harvest were below the limit of determination used in all residues trials conducted and therefore under normal agricultural circumstances it is unlikely that MCPA residues will be found in animal tissues. MCPA is also not deemed to accumulate in crops. Taking above into consideration additional studies on metabolism in livestock are not regarded as necessary.

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	-
	~~MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (Regulation n°491/2014)~~
Animal residue definition for monitoring	~~MCPA (according to the submitted PROFile)**~~ MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (Regulation n°491/2014)
Animal residue definition for risk assessment	MCPA
Conversion factor	~~Yes~~ None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	~~Lactating goats~~ Yes

* If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
** EFSA Journal 2013;11(7):3312

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 HAKSAR TOP 565 SG 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/Rounded OECD calculator MRL (mg/kg)**	**Current EU MRL (mg/kg) ***	**MRL compliance**
Wheat Grain →extrapolated to triticale, rye and oat	Addendum to DAR, 2003 Old J., Venuti J., 2001 Old J., Duncan P., 2001	N-EU	GAP on which MRL/EU a.s. assessment is based: 1.8 kg as/ha one treatment per crop/season, BBCH 30, outdoor 4x<~~0.01~~ 0.05	N/A				
	New trials	N-EU	Trials GAP: (Germany): 1x 595.8 g a.s/ha, BBCH 39, PHI 77, outdoor (UK): 1x 568.3 g a.s/ha, BBCH 39, PHI 82, outdoor (Hungary): 1x 566.5 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1x 550 g a.s/ha, BBCH 39, PHI 90, outdoor 3x<0.005; 0.0137					
	Overall supporting data for	N-EU	4x<~~0.01~~ 0.05; 3x<0.005; 0.0137	~~0.01~~ 0.032	0.05	0.121/0.15	0.2	Yes

	cGAP							
Wheat Straw →extrapolated to triticale, rye and oat	Addendum to DAR, 2003 Old J., Venuti J., 2001 Old J., Duncan P., 2001	N-EU	GAP on which MRL/EU a.s. assessment is based: 1.8 kg as/ha one treatment per crop/season, BBCH 30, outdoor 2x<0.01; 0.05; 0.09	N/A				
	New trials	N-EU	Trials GAP: Germany): 1x 595.8 g a.s/ha, BBCH 39, PHI 77, outdoor (UK): 1x 568.3 g a.s/ha, BBCH 39, PHI 82, outdoor (Hungary): 1x 566.5 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1x 550 g a.s/ha, BBCH 39, PHI 90, outdoor 0.0655; 0.0322; 0.1578; 0.0316					
	Overall supporting data for cGAP	N-EU	Trials GAP: 2x<0.01; 0.05; 0.09; 0.0655; 0.0322; 0.1578; 0.0316	0.04	0.16	-	-	n.a
Barley Grain→ekstrapolated from wheat grain	Addendum to DAR, 2003 Old J., Venuti J., 2001 Old J., Duncan P., 2001		GAP on which MRL/EU a.s. assessment is based: 1.8 kg as/ha one treatment per crop/season, BBCH 30, outdoor 0.01; 2x<0.05; 0.16; 4x<0.01	N/A				
	New trials	N-EU	3x<0.005; 0.0137					
	Overall supporting data for	N-EU	5 x <0.01; 2x<0.05; 0.16; 3x<0.005; 0.0137	0.01	0.16	0.2	0.2	Yes

	cGAP							
Barley Straw→ekstrapolated from wheat straw	Addendum to DAR, 2003 Old J., Venuti J., 2001 Old J., Duncan P., 2001		GAP on which MRL/EU a.s. assessment is based: 1.8 kg as/ha one treatment per crop/season, BBCH 30, outdoor 2x<0.01; 0.05; 0.07; 2x<0.01; 0.05; 0.09	N/A				
	New trials		0.0655; 0.0322; 0.1578; 0.0316					
	Overall supporting data for cGAP		4x<0.01; 2x 0.05; 0.07; 0.09; 0.0655; 0.0322; 0.1578; 0.0316	0.04	0.16	-	-	n.a
Miscanthus sp., and Grasses grown for seeds	n.r.							

* Source of EU MRL: COMMISSION REGULATION (EU) No 491/2014 of 5 May 2014

Wheat (soft, durum, spelt, einkorn, emmer) and Barley
Twelve studies on cereals in according with GAPs proposed of 1.8 kg/ha, have been submitted in July 2002. Eight studies were conducted in the North of Europe. The results are summarized in the table below.

Cereal Variety	PHI day	MCPA in grain mg/kg	MCPA in straw mg/kg
Winter barley Sanja (North)	106	< 0.01	< 0.01
Winter wheat Isengrain (North)	118	< 0.01	0.09
Winter barley Regina (North)	116	< 0.05	0.07
Winter wheat Consort (North)	109	< 0.01	0.05
Winter wheat Horeward (North)	127	< 0.01	< 0.01
Winter barley Regina (North)	121	< 0.05	< 0.01
Winter wheat Soissons (North)	109	< 0.01	< 0.01
Winter barley Majestic (North)	99	0.16	< 0.05

Triticale, Rye, Oat
For HAKSAR TOP 565 SG no new trials were conducted because of possibility of extrapolation the results from wheat trials. Available wheat trials are presented in Appendix 2 and in DAR. Therefore number of trials carried out of wheat fulfils the requirements for northern Europe.

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. HAKSAR TOP 565 SG will be used for protection of Miscanthus sp., and Grasses grown for seeds therefore no additional studies are necessary to support this use of HAKSAR TOP 565 SG.

zRMS comments:
Summary of critical residues data evaluated in the DAR for MCPA (August 2004) for 1 appl., appl. rate per treatment 1.8 kg a.s./ha.:

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Wheat	Northern Southern	4 x <0.05 mg/Kg 5 x <0.05 mg/Kg		0.1 mg/kg	
Mais	Northern Southern	2 x <0.05 mg/Kg 2 x <0.05 mg/Kg		0.1 mg/kg	
Oats	Northern	Intended use		0.1 mg/kg	
Barley	Northern Southern	4 x <0.05 mg/Kg 7 x <0.05 mg/Kg; 1 x 0.12 mg/Kg		0.1 mg/kg	
Rye	Northern	Intended use		0.1 mg/kg	

Grassland	Northern Southern	< 0.008; 0.08; 0.20; 0.38; 0.62; 1.4 0.33; 0.55; 0.66; 3.0.	PHI 60 days	2.5 mg/kg 8.0 mg/Kg	

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

According to appendix D of EU guidelines, extrapolation to wheat (winter and spring soft wheat, durum, spelt, einkorn, emmer), triticale, oat 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 data submitted show that after use of HAKSAR TOP 565 SG according to the proposed GAP no exceedance of the MRL will occur.

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 7.2-9: 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
Risk assessment residue definition: MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA)				
Wheat, Oat, Rye, Triticale grain	0,01	STMR	0,01	STMR
Wheat, Oat, Rye, Triticale straw	0,04	STMR	0,16	HR
Barley grain	0,01	STMR	0,01	STMR
Barley straw	0,04	STMR	0,16	HR

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Brewer's grain dried	0,01	STMR PF=1	-	-
Distiller's grain dried	0,01	STMR PF=1	-	-
Wheat gluten meal	0,01	STMR PF=1	-	-
Wheat milled by-pdts	0,01	STMR PF=1	-	-

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA)					
Dairy cattle*	0,001	0,002	Rye straw	0,05	N
Ram/ewe	0,001	0,003	Rye straw	0,08	N
Lamb	0,003	0,004	Rye straw	0,08	N
Finishing swine*	0,0	0,0	Barley grain	0,01	N
Layer poultry*	0,001	0,002	Wheat straw	0,03	N

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 MCPA 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.

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

Based on results from residue trials conducted to date, no MCPA residues are expected at or above the limit of detection. It is therefore unlikely that MCPA residues will be detected in processed fractions such as flour or bread. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of MCPA residues.
No further studies have been performed.

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.

7.2.7 Other / special studies (KCA 6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of HAKSAR TOP 565 SG 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 7.2-11: Input values for the consumer risk assessment

<table>
<tr><th rowspan="2">Commodity</th><th colspan="2">Chronic risk assessment</th><th colspan="2">Acute risk assessment</th></tr>
<tr><th>Input value (mg/kg)</th><th>Comment</th><th>Input value (mg/kg)</th><th>Comment</th></tr>
<tr><td colspan="5">Risk assessment residue definition 1 (if applicable) MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA)</td></tr>
<tr><td>Wheat/ Triticale</td><td>0,2</td><td rowspan="4">EU MRL (In force MRL according to Reg. (EU) No 293/2013)</td><td>0,2</td><td rowspan="4">EU MRL (In force MRL according to Reg. (EU) No 293/2013)</td></tr>
<tr><td>Rye</td><td>0,2</td><td>0,2</td></tr>
<tr><td>Oat</td><td>0,2</td><td>0,2</td></tr>
<tr><td>Barley</td><td>0,2</td><td>0,2</td></tr>
<tr><td>All commodities</td><td>various</td><td>MRL</td><td colspan="2">Not applicable</td></tr>
</table>

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	4,0 % (based on DK child)
IEDI (% ADI) according to EFSA PRIMo	Not necessary as TDMI values were acceptable
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities:

	Wheat: 2 % Processed commodities: Wheat/milling (flour): 2 % Wheat: 2% (based on results for children)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

* include raw and processed commodities if both values are required for PRIMo
** if national model is available
For the IESTI calculations, only the crops under assessment were considered using the 'Refined mode' of Primo Model revision 3

The proposed uses of MCPA in the formulation HAKSAR TOP 565 SG do not represent unacceptable acute and chronic risks for the consumer.

RMS comments:
Additionally, calculations were made taking into account all applicable MRL values using the PRIMo rev. 3.1. Results are presented below:

EFSA PRIMo revision 3.1; 2019/03/19

MCPA

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0,05**	ARfD (mg/kg bw):	**0,15**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

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)
16%	NL toddler	8,11	6%	Milk: Cattle	2%	Wheat	1%	Apples		
9%	NL child	4,62	2%	Milk: Cattle	2%	Wheat	0,8%	Sugar beet roots		
9%	UK infant	4,41	4%	Milk: Cattle	1%	Wheat	1,0%	Bovine: Edible offals (other than liver		
8%	DK child	4,17	2%	Rye	2%	Wheat	1%	Milk: Cattle		
8%	DE child	3,95	2%	Milk: Cattle	2%	Wheat	1%	Apples		
8%	FR child 3 15 yr	3,86	2%	Milk: Cattle	2%	Wheat	0,4%	Sugar beet roots		
7%	GEMS/Food G07	3,73	2%	Wheat	0,8%	Bovine: Liver	0,6%	Milk: Cattle		
7%	FR toddler 2 3 yr	3,57	3%	Milk: Cattle	1%	Wheat	0,3%	Apples		
7%	GEMS/Food G15	3,54	2%	Wheat	0,7%	Milk: Cattle	0,6%	Swine: Liver		
7%	GEMS/Food G06	3,41	3%	Wheat	0,4%	Tomatoes	0,3%	Bovine: Liver		
7%	GEMS/Food G08	3,32	2%	Wheat	0,6%	Milk: Cattle	0,4%	Soyabeans		
7%	GEMS/Food G11	3,27	1%	Wheat	0,8%	Milk: Cattle	0,7%	Soyabeans		
7%	GEMS/Food G10	3,25	2%	Wheat	0,7%	Soyabeans	0,5%	Milk: Cattle		
6%	UK toddler	3,19	2%	Milk: Cattle	2%	Wheat	0,3%	Potatoes		
6%	IE adult	3,17	1%	Sheep: Liver	0,9%	Wheat	0,6%	Sheep: Edible offals (other than liver		
6%	ES child	3,00	2%	Wheat	1%	Milk: Cattle	0,4%	Swine: Liver		
6%	RO general	2,81	2%	Wheat	1%	Milk: Cattle	0,4%	Potatoes		
5%	SE general	2,62	1%	Wheat	1%	Milk: Cattle	0,9%	Bovine: Muscle/meat		
5%	DE general	2,35	1%	Milk: Cattle	0,8%	Wheat	0,4%	Sugar beet roots		
5%	DE women 14-50 yr	2,34	1%	Milk: Cattle	0,9%	Wheat	0,5%	Sugar beet roots		
4%	NL general	2,11	0,8%	Milk: Cattle	0,8%	Wheat	0,3%	Sugar beet roots		
4%	IT toddler	1,83	3%	Wheat	0,2%	Other cereals	0,1%	Tomatoes		
3%	PT general	1,72	2%	Wheat	0,5%	Potatoes	0,2%	Wine grapes		
3%	ES adult	1,70	0,9%	Wheat	0,5%	Milk: Cattle	0,2%	Barley		
3%	FR infant	1,68	2%	Milk: Cattle	0,3%	Wheat	0,2%	Potatoes		
3%	FR adult	1,67	0,9%	Wheat	0,4%	Milk: Cattle	0,2%	Wine grapes		
3%	LT adult	1,36	0,4%	Rye	0,4%	Wheat	0,4%	Milk: Cattle		
3%	DK adult	1,36	0,5%	Milk: Cattle	0,4%	Wheat	0,2%	Swine: Liver		
2%	FI 3 yr	1,24	0,5%	Wheat	0,5%	Potatoes	0,3%	Rye		
2%	IT adult	1,24	2%	Wheat	0,1%	Tomatoes	0,1%	Apples		
2%	FI adult	1,10	1%	Coffee beans	0,3%	Rye	0,1%	Wheat		
2%	UK vegetarian	1,09	0,8%	Wheat	0,3%	Milk: Cattle	0,1%	Potatoes		
2%	UK adult	1,06	0,7%	Wheat	0,3%	Milk: Cattle	0,1%	Potatoes		
2%	FI 6 yr	0,98	0,4%	Wheat	0,4%	Potatoes	0,2%	Rye		
1%	IE child	0,62	0,5%	Wheat	0,4%	Milk: Cattle	0,1%	Potatoes		
1,0%	PL general	0,49	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes		

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

Acute risk assessment /children — Acute risk assessment / adults / general population

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

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI – children

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Bovine: Liver	3 / 3	24
15%	Bovine: Edible offals (other	3 / 3	22
8%	Bovine: Kidney	3 / 3	11
6%	Swine: Edible offals (other	3 / 3	9,0
5%	Potatoes	0,05 / 0,05	7,7
5%	Melons	0,05 / 0,05	7,6
5%	Pears	0,05 / 0,05	6,9
4%	Oranges	0,05 / 0,05	6,6
4%	Milk: Cattle	0,05 / 0,05	6,2
4%	Watermelons	0,05 / 0,05	6,1
4%	Apples	0,05 / 0,05	5,4
3%	Pineapples	0,05 / 0,05	5,1
3%	Bananas	0,05 / 0,05	4,9
3%	Peaches	0,05 / 0,05	4,8
3%	Mangoes	0,05 / 0,05	3,9

IESTI – adults

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Bovine: Liver	3 / 3	12
7%	Bovine: Edible offals (other	3 / 3	10,0
6%	Sheep: Liver	3 / 3	8,4
5%	Swine: Edible offals (other	3 / 3	7,8
4%	Swine: Kidney	3 / 3	6,6
4%	Bovine: Kidney	3 / 3	6,3
3%	Swine: Liver	3 / 3	4,2
1%	Head cabbages	0,05 / 0,05	2,1
1%	Sheep: Edible offals (other	3 / 3	2,1
1%	Watermelons	0,05 / 0,05	2,0
1%	Melons	0,05 / 0,05	2,0
1%	Milk: Cattle	0,05 / 0,05	1,9
1%	Swedes/rutabagas	0,05 / 0,05	1,7
1%	Table grapes	0,05 / 0,05	1,7
1%	Wheat	0,2 / 0,2	1,7

IESTI new – children

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Bovine: Liver	3 / 3	24
15%	Bovine: Edible offals (other	3 / 3	22
8%	Bovine: Kidney	3 / 3	11
6%	Swine: Edible offals (other	3 / 3	9,0
4%	Milk: Cattle	0,05 / 0,05	6,2
3%	Melons	0,05 / 0,05	4,6
3%	Swine: Kidney	3 / 3	3,8
2%	Swine: Liver	3 / 3	3,7
2%	Watermelons	0,05 / 0,05	3,7
2%	Oranges	0,05 / 0,05	3,3
2%	Potatoes	0,05 / 0,05	3,3
2%	Apples	0,05 / 0,05	3,1
2%	Bananas	0,05 / 0,05	3,1
2%	Pineapples	0,05 / 0,05	3,0
2%	Pears	0,05 / 0,05	3,0

IESTI new – adults

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Bovine: Liver	3 / 3	12
7%	Bovine: Edible offals (other than	3 / 3	10,0
6%	Sheep: Liver	3 / 3	8,4
5%	Swine: Edible offals (other than liver	3 / 3	7,8
4%	Swine: Kidney	3 / 3	6,6
4%	Bovine: Kidney	3 / 3	6,3
3%	Swine: Liver	3 / 3	4,2
2%	Oranges	0,05 / 0,05	2,3
1%	Sheep: Edible offals (other than liver	3 / 3	2,1
1%	Plums	0,05 / 0,05	2,0
1%	Milk: Cattle	0,05 / 0,05	1,9
1%	Pears	0,05 / 0,05	1,8
1%	Wheat	0,2 / 0,2	1,7
1%	Mandarins	0,05 / 0,05	1,6
1%	Potatoes	0,05 / 0,05	1,6

Expand/collapse list

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

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

Processed commodities

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

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

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

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

IESTI – children

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root) / sugar	0,05 / 0,6	5,5
3%	Potatoes / fried	0,05 / 0,05	4,7
3%	Pumpkins / boiled	0,05 / 0,05	4,4
3%	Witloofs / boiled	0,05 / 0,05	4,4
3%	Broccoli / boiled	0,05 / 0,05	3,9
2%	Cauliflowers / boiled	0,05 / 0,05	3,5
2%	Escaroles/broad-leaved endi	0,05 / 0,05	3,3
2%	Potatoes / dried (flakes)	0,05 / 0,23	3,0
2%	Leeks / boiled	0,05 / 0,05	2,9
2%	Apples / juice	0,05 / 0,05	2,7
2%	Oranges / juice	0,05 / 0,05	2,6
2%	Turnips / boiled	0,05 / 0,05	2,5
2%	Parsnips / boiled	0,05 / 0,05	2,5
2%	Sweet potatoes / boiled	0,05 / 0,05	2,5
2%	Wheat / milling (flour)	0,2 / 0,2	2,4

IESTI – adults

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Pumpkins / boiled	0,05 / 0,05	2,8
1%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
1%	Cauliflowers / boiled	0,05 / 0,05	2,1
1%	Beetroots / boiled	0,05 / 0,05	1,9
1%	Celeries / boiled	0,05 / 0,05	1,7
1%	Apples / juice	0,05 / 0,05	1,7
1,0%	Barley / beer	0,2 / 0,04	1,4
0,8%	Broccoli / boiled	0,05 / 0,05	1,2
0,8%	Courgettes / boiled	0,05 / 0,05	1,1
0,7%	Parsnips / boiled	0,05 / 0,05	1,1
0,7%	Kohlrabies / boiled	0,05 / 0,05	1,1
0,7%	Wine grapes / juice	0,05 / 0,05	1,0
0,7%	Escaroles/broad-leaved	0,05 / 0,05	1,0
0,6%	Florence fennels / boiled	0,05 / 0,05	0,97
0,6%	Turnips / boiled	0,05 / 0,05	0,95

IESTI new – children

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root) / sugar	0,05 / 0,6	5,5
2%	Potatoes / dried (flakes)	0,05 / 0,23	3,0
2%	Apples / juice	0,05 / 0,05	2,7
2%	Pumpkins / boiled	0,05 / 0,05	2,7
2%	Oranges / juice	0,05 / 0,05	2,6
2%	Wheat / milling (flour)	0,2 / 0,2	2,4
2%	Broccoli / boiled	0,05 / 0,05	2,4
2%	Witloofs / boiled	0,05 / 0,05	2,4
1%	Potatoes / fried	0,05 / 0,05	2,2
1%	Wine grapes / juice	0,05 / 0,05	2,2
1%	Cauliflowers / boiled	0,05 / 0,05	2,1
1%	Escaroles/broad-leaved	0,05 / 0,05	2,0
1%	Carrots / juice	0,05 / 0,05	1,8
1%	Leeks / boiled	0,05 / 0,05	1,6
1%	Pears / juice	0,05 / 0,05	1,6

IESTI new – adults

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Sugar beets (root) / sugar	0,05 / 0,6	2,2
1%	Pumpkins / boiled	0,05 / 0,05	2,0
1%	Apples / juice	0,05 / 0,05	1,7
1,0%	Barley / beer	0,2 / 0,04	1,4
0,8%	Cauliflowers / boiled	0,05 / 0,05	1,2
0,7%	Witloofs / boiled	0,05 / 0,05	1,1
0,7%	Wine grapes / juice	0,05 / 0,05	1,0
0,7%	Celeries / boiled	0,05 / 0,05	1,0
0,7%	Broccoli / boiled	0,05 / 0,05	1,0
0,6%	Rhubarbs / sauce/puree	0,05 / 0,05	0,97
0,6%	Wheat / bread/pizza	0,2 / 0,2	0,88
0,6%	Beetroots / boiled	0,05 / 0,05	0,83
0,5%	Courgettes / boiled	0,05 / 0,05	0,80
0,5%	Escaroles/broad-leaved endives /	0,05 / 0,05	0,78
0,5%	Wheat / pasta	0,2 / 0,2	0,76

Expand/collapse list

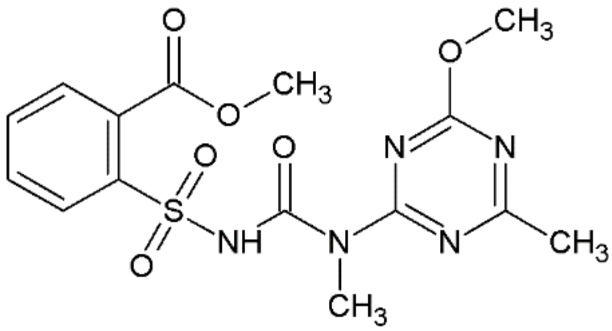
Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of MCPA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

No concern for the consumer was identified, the highest TMDI was 16 % of the ADI (highest contributor to MS diet was milk– 6%, max 2% ADI for wheat), and the highest IESTI 16 % of the ARfD (bovine liver).

7.3 Tribenuron methyl

General data on Tribenuron methyl are summarized in the table below:

Table 7.3-1: 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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: 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 HAKSAR TOP 565 SG. In addition new residues studies submitted by the Applicant includes a tribenuron methyl residue and were performed in less than 30 days. Additional studies are not required.

7.3.1.2 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.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Table 7.3-3: 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	-	Ryan, D.L., Dulka, 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	-	Ryan, 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	-	Tobias 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~~ HAKSAR TOP 565 SG. 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).

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: 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	-	Ryan, D.L., 1985
				32 g a.s./ha	30, 120			Dulka, 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	-	Ryan, D.L., 1985
				32 g a.s./ha	30, 120			Dulka, 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	-	Ryan, D.L., 1985
	Sorghum			35 g a.s/ha	30, 120			Ryan, D.L., 1985
				32 g a.s./ha	30, 120			Dulka, 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	-	Ryan, 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).			

7.3.2.3 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.

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

Table 7.3-5: 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.

7.3.2.5 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 7.3-6: 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 samp-ling	
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	[redacted],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.

zRMS comments:
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.

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

Table 7.3-7: 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.
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

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 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 7.3-8: Summary of EU reported and new data supporting the intended uses of HAKSAR TOP 565 SG 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 → extrapolated from barley	DAR	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.030 kg as/ha, outdoor 8 x <0.01	N/A				
	New trials	N-EU	Trials GAP: (Germany): 1 x 16.2 g a.s/ha, BBCH 39, PHI 77, outdoor (UK): 1x 15.5 g a.s/ha, BBCH 39, PHI 82, outdoor (Hungary): 1x 15.5 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1x 15 g a.s/ha, BBCH 39, PHI 90, outdoor 4x<0.003					
	Overall supporting data for cGAP	N-EU	4 x <0.003; 8 x <0.01	0,01	0,01	0,01	0,01	Yes

Wheat straw → extrapolated from barley	DAR	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				
	New trials	N-EU	(Germany): 1 x 16.2 g a.s/ha, BBCH 39, PHI 77, outdoor (UK): 1x 15.5 g a.s/ha, BBCH 39, PHI 82, outdoor (Hungary): 1x 15.5 g a.s/ha, BBCH 39, PHI 49, outdoor (Poland): 1x 15 g a.s/ha, BBCH 39, PHI 90, outdoor 4x<0.003					
	Overall supporting data for cGAP	N-EU	4 x <0.003; 8x <0.05	0,05	0,05	-	-	n.a
Barley grain	DAR	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				
	New trials	N-EU	-					
	Overall supporting data for cGAP	N-EU	8x<0.01	0,01	0,01	0,01	0,01	yes
Barley straw	DAR	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				
	New trials	N-EU	-					
	Overall supporting data for cGAP	N-EU	8x <0.05	0,05	0,05	-	-	n.a

* 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

Residue trials based on the current residue definition *(EFSA Scientific Report (2004)):*

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 Norther Europe.
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:
The studies of Reichert and Jin (2001a) and Zietz and and Jin (2000a) are unprotected, and were accepted for the evaluation by RMS and EFSA.
A total of 16 residue trials were conducted according to proposed GAP, in wheat and barley. The trials were performed in both Northern and Southern European regions (8 in each) over two growing seasons 1999-2000. Grain residues were determined to be below the limit of quantification (LOQ) of the analytical method 0.01 mg/kg in all trials. Straw residues were determined to be below the limit of quantification (LOQ) of the analytical method 0.05 mg/kg in all trials.
Therefore number of trials carried out of wheat fulfils the requirements for northern Europe.
For more details about trials evaluated in the DAR please refer to the table below.

Table 7.3.9-1 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 Hohenstei n-Hennethal , 1999	tribenuron methyl-205[c]	1	0.030	0.0100	60	<0.05	<0.01	2261
Germany,	tribenuron	1	0.032	0.0100	63	<0.05	<0.01	

North Strasburg, 1999	methyl-205[c]							2261
Spring Wheat								
France, South Astaffort, 1999	tribenuron methyl-205[c]	1	0.030	0.0120	69	<0.05	<0.01	2261
France, South Poudis, 1999	tribenuron methyl-205[c]	1	0.030	0.0120	64	<0.05	<0.01	2261
Winter Wheat								
Italy, South Mediglia, 1999	tribenuron methyl-205[c]	1	0.030	0.0075	65	<0.05	<0.01	2261
Italy, South Tortoreto, 1999	tribenuron methyl-205[c]	1	0.030	0.0075	82	<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-Kettemschwalbach, 2000	tribenuron methyl-208[d]	1	0.031	0.0102	73	<0.05	<0.01	4029
Winter Barley								
Germany, North Neugattersleben, 2000	tribenuron methyl-208[d]	1	0.033	0.0102	70	<0.05	<0.01	4029
Spring Wheat								
France, South Blan, 2000	tribenuron methyl-208[d]	1	0.030	0.0122	70	<0.05	<0.01	4029
France, South Borcq sur Airvault, 2000	tribenuron methyl-208[d]	1	0.032	0.0154	71	<0.05	<0.01	4029
Winter Wheat								

Italy, South Corropoli, 2000	tribenuron methyl-208[d]	1	0.031	0.0052	65	<0.05	<0.01	4029
Italy, South Mediglia, 2000	tribenuron methyl-208[d]	1	0.030	0.0077	67	<0.05	<0.01	4029
Number of tests						**16**	**16**	

[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.

Wheat (soft, durum, spelt, einkorn, emmer), Triticale, Rye, Oat
For HAKSAR TOP 565 SG four new trials in Northern Zone were conducted in 2017.
Moreover exist possibility of extrapolation the results from barley trials.
Available wheat trials are presented in Appendix 2.
Number of trials carried out of fulfils the requirements for northern Europe.

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. HAKSAR TOP 565 SG will be used for protection of Miscanthus sp., and Grasses grown for seeds therefore no additional studies are necessary to support this use of HAKSAR TOP 565 SG.

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter and spring cereals 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, oat 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=4, field trials in Poland, Hungary, Germany 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). 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 HAKSAR TOP 565 SG is 39.
However, the Applicant did not provide residue studies of tribenuron methyl metabolites included in the provisional residue definition – data gap.

7.3.4 Magnitude of residues in livestock

7.3.4.1 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 7.3-10, results are presented in Table 7.3-11.
Dietary burden is below the trigger value (0.004 mg/kg bw/day). No further studies are required

Table 7.3-9: 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
Risk assessment residue definition: Tribenuron-methyl				
Wheat, Oat, Rye, Triticale grain	0,01	STMR	0,01	STMR
Wheat, Oat, Rye, Triticale straw	0,05	STMR	0,05	STMR
Barley grain	0,01	STMR	0,01	STMR
Barley straw	0,05	STMR	0,05	STMR

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Brewer's grain dried	0,01	STMR PF=1	-	-
Distiller's grain dried	0,01	STMR PF=1	-	-
Wheat gluten meal	0,01	STMR PF=1	-	-
Wheat milled by-pdts	0,01	STMR PF=1	-	-

Table 7.3-10: 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					
Dairy cattle*	0,001	0,002	Rye straw	0,05	N
Ram/ewe	0,001	0,003	Rye straw	0,08	N
Lamb	0,001	0,004	Rye straw	0,08	N
Finishing swine*	0,0	0,0	Barley grain	0,01	N
Layer poultry*	0,001	0,001	Wheat straw	0,02	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.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

According to requirements of Reg (EU) No 283/2013 the submission of feeding studies (to deter-mine 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 in-take 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.

7.3.5 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).

7.3.6 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).*

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of HAKSAR TOP 565 SG. Therefore, other special studies are not needed.

7.3.8 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).

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-11: Input values for the consumer risk assessment

<table>
<tr><th rowspan="2">Commodity</th><th colspan="2">Chronic risk assessment</th><th colspan="2">Acute risk assessment</th></tr>
<tr><th>Input value (mg/kg)</th><th>Comment</th><th>Input value (mg/kg)</th><th>Comment</th></tr>
<tr><td colspan="5">Risk assessment residue definition: Tribenuron-methyl</td></tr>
<tr><td>Wheat/ Triticale</td><td>0,01</td><td rowspan="4">EU MRL (In force MRL according to Reg. (EU) No 293/2013)</td><td>0,01</td><td rowspan="4">EU MRL (In force MRL according to Reg. (EU) No 293/2013)</td></tr>
<tr><td>Rye</td><td>0,01</td><td>0,01</td></tr>
<tr><td>Oat</td><td>0,01</td><td>0,01</td></tr>
<tr><td>Barley</td><td>0,01</td><td>0,01</td></tr>
<tr><td>All commodities</td><td>various</td><td>MRL</td><td colspan="2">Not applicable</td></tr>
</table>

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-12: 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
For the IESTI calculations, only the crops under assessment were considered using the 'Refined mode' of Primo Model revision 3.1

The proposed uses of Tribenuron-methyl in the formulation HAKSAR TOP 565 SG 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:
Year of evaluation:

Source of ARfD:
Year of evaluation:

Input values
Details - chronic risk assessment
Supplementary results - chronic risk assessment
Details - acute risk assessment/children
Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
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 | **Acute risk assessment / adults / general population** | **Acute risk assessment /children** | **Acute risk assessment / adults / general population**

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

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI (children)

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

IESTI (adults)

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

IESTI new (children)

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 (adults)

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

Expand/collapse list

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

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

Processed commodities

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

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

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

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

IESTI (children)

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

IESTI (adults)

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 (children)

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 (adults)

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

Expand/collapse list

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.

7.4 Combined exposure and risk assessment

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

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

The product is a mixture of two active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.3.1) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

Crop	**Active Ingredient**	**HQ (based on IESTI according to EFSA PRIMo)**	**HQ (based on NESTI according to national model)***
Wheat	MCPA	0,019	-
	Tribenuron-methyl	0,0007	-
	Cumulative risk wheat (HI)	**0,0197**	**-**
Barley	MCPA	0,0073	-
	Tribenuron-methyl	0,0003	-
	Cumulative risk barley (HI)	**0,0076**	**-**
Rye	MCPA	0,0086	-
	Tribenuron-methyl	0,0003	-
	Cumulative risk rye (HI)	**0,0089**	**-**
Oat	MCPA	0,0015	-
	Tribenuron-methyl	0,00005	-
	Cumulative risk oat (HI)	**0,00155**	**-**

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in HAKSAR TOP 565 SG is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

7.5 References

SANCO/4062/2001-final, 11 July 2008 Review report for the active substance MCPA Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 April 2005 in view of the inclusion of MCPA in Annex I of Directive 91/414/EEC

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

COMMISSION REGULATION (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fludioxonil, fluopyram, flutriafol, fluxapyroxad, glufosinate- ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products

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

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	Tobias S.	2019	Metabolism of [14C]-Tribenuron-methyl in Wheat Eurofins S18-07560 GLP, Unpublished.	N	TF PROPLAN-SARABIA
KCA 6.3/01	B. Raufer	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, 2018, Eurofins Agroscience Services GmbH Study Code: S17-04789 GLP: Yes Unpublished	N	CIECH Sarzyna S.A.
KCA 6.3/02	G. Dąbrowski	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, 2019, SynTech Research Poland Study Code: 428SRPL17R02 GLP: Yes Unpublished	N	CIECH Sarzyna S.A.

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 6.1/01	Wasser C.	2002	Storage Stability of MCPA, MCPB, and HMCPA residues in cereals GLP Unpublished	N	MCPA TASK FORCE
KCA 6.1/02	L´Empereur 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	Keller W, Otto S	1979	Investigations into the Metabolsim of MCPA in Winter Wheat. BASF AG/TPH Report No: 1161a	N	MCPA TASK FORCE
KCA 6.2.1/02	Achhireddy N, Kirkwood R ,C, Fletcher W W	1984	J. of Pesticide Science 9; pp 617-622	N	-
KCA 6.2.1/03	Ryan, D.L., Dulka, 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 6.2.1/04	Ryan, 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	Ewing D D	1988	MCPA Confined Accumulation Study on Rotational Crops. Industry Task Force I on MCPA Research Data Report No: PAL-EF-86-31	N	MCPA TASK FORCE

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	Ryan, 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
KCA 6.6.1/03	Dulka, 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 6.2.2-6.2.5/01	Xxxxxxxxxxxxxx xxxxxxxxxx	1995	Nature of the Residue Study of 14C-MCPA using Lactating Goats xxxxxxxxxxxxxx Report No: SC930051 GLP Unpublished	Y	MCPA TASK FORCE
KCA 6.2.2-6.2.5/02	Xxxxxxxxxxx xxxxxx	1995	Nature of the Residue Study of 14C-MCPA using Egg-Laying White Leghorn Hens xxxxxxxxxxxxxxxxxxx MCPA Task Force III Report No: SC920100 GLP Unpublished	Y	MCPA TASK FORCE
KCA 6.2.2-6.2.5/03	Anonymous	1989	Metabolism of [triazine-2-^{14}C]-DPX-L5300 and [phenyl(U)-^{14C}]-DPX-L5300 in lactating goats xxxxxxxxxx GLP: No Published: No	Y	DuPont
KCA 6.3/01	Old J., Venuti J.	2001	MCPA Dimethylamine Salt Residue Decline in Cereals in Northern Europe Field Phase Inveresk Report Number 18192 Report No: AHM R 99 103 GLP Unpublished	N	MCPA TASK FORCE
KCA	Old J., Duncan P.,	2001	Agroxone 75 (Product Code T021A (R))	N	MCPA

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
6.3/02			Harvest Residues of MCPA Dimethylamine Salt in Cereals in Northern Europe: Field Phase Inveresk Report Number 19522 A H Marks Report No: AHM R 00 103 GLP Unpublished		TASK FORCE
KCA 6.3/03	Zietz, E.; Jin, 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 6.3/04	Reichert, N., Jin, 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 MCPA

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

No new or additional studies have been submitted

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A 1: 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 (DAR, RMS, year)	1	1.8 kg as/ha	-	Spring before first node detectable	-
Intended cGAP (1,7)	1	550 g as/ha	n.a	Autumn BBCH 13-23	n.a
Intended cGAP (2,8)	1	550 g as/ha	n.a	Spring BBCH 13-39	n.a

A 2.1.3.1.1

A 2.1.3.1.2 Study 1

Comments of zRMS:	The field part of the studies (n=3) of magnitude the MCPA residues in wheat (UK, Hungary and Germany) is accepted. The dose of MCPA used in the studies was 595.8 to 568.3 g a.s./ha (max 550 g a.s./ha proposed in GAP for HAKSAR TOP 565 SG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) in all trials.

Reference: KCA 6.3/01

Report: 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, B. Raufer, 2018, S17-04789

Guideline(s): Yes (OECD (2009), OECD Test Guideline 509, OECD (2011))

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 and 550 g/ha of MCPA).
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 2.
The residues of MCPA 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 0.2 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A2 Summary of the study 1

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)				MCPA and MCPB expressed as MCPA (mg/kg)	
S17-04789-01, Diefenbach, Baden-Württemberg, Germany	Winter wheat	1. 16.10.2016 2. 05.06..2017-15.06.2017 3. 07.08.2017	595.8	217	22.05.2017	BBCH 39	Grain Straw	< LOD 0.0655	77
S17-04789-02, Bishop Burton, East Yorkshire, UK	Winter wheat	1. 20.08.2016 2. 06.2017 3. 16.08.2017	568.3	207	26.05.2017	BBCH 39	Grain Straw	< LOD 0.0322	82
S17-04789-03, Pàzmànd, Fejèr, Hungary	Winter wheat	1. 04.11.2016 2. 07.06.2017-15.06.2017 3. 03.07.2017	566.5	206	15.05.2017	BBCH 39	Grain Straw	< LOQ 0.1578	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 = 0.005 mg/kg (for MCPA)
LOQ = 0.0188 mg/kg (for MCPA)

A 2.1.3.1.3 Study 2

Comments of zRMS:	The field part of the study (n=1) of magnitude the MCPA residues in wheat (Poland) is accepted. The dose of MCPA used in the study was 550 g a.s./ha (max 550 g a.s./ha proposed in GAP for HAKSAR TOP 565 SG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) with addition of adjuvant SAR-BIO 90 EC at a rate 1 kg/ha.

Reference:	KCA 6.3/02
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, Study Number 428SRPL17R02, E. Potocka, SynTech
Guideline(s):	Yes (OECD (2009), OECD Test Guideline 509, OECD (2011))
Deviations:	No
GLP:	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 and 550 g/ha of MCPA).
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 3.
The residues of MCPA 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 0.2 mg/kg in wheat.

Detailed method validation is presented in section B5

Table A3 Summary of the study 2

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)				MCPA and MCPB expressed as MCPA (mg/kg)	
SPRL17-057-428HR, Jabłowo Pałuckie / Kujawsko - Pomorskie, Poland	Winter wheat, Arkadia	1. 18.10.2016 2. 06.07..2017- 13.07.2017 3. 21.08.2017- 31.08.2017	550	250	23.05.2017	BBCH 39	Grain Straw	< LOD 0.0316	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 = 0.005 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

A 2.2 Tribenuron - methyl

A 2.2.1 Stability of residues

No new or additional studies have been submitted

A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 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	1	7.5- 30 g a.s/ha	-	BBCH 9-39 Spring and/or fall application	-
cGAP EU (Art. 12, EFSA, 2013)	1	29 g as/ha	-	BBCH 13-30	n.a
Intended cGAP (1,7)	1	15 g a.s./ha	n.a	Autumn BBCH 13-23	n.a
Intended cGAP (2,8)	1	15 g a.s./ha	n.a	Spring BBCH 13-39	n.a

A 2.2.3.1.1 Study 1

Comments of zRMS:	The field part of the studies (n=3) of magnitude the tribenuron methyl residues in wheat (UK, Hungary and Germany) is accepted. The dose of tribenuron methyl used in the studies was 15.5 and 16.2 g a.s./ha (max 15 g a.s./ha proposed in GAP for HAKSAR TOP 565 SG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) in all trials.

Reference: KCA 6.3/01

Report	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, B. Raufer, 2018, S17-04789
Guideline(s):	Yes (OECD (2009), OECD Test Guideline 509, OECD (2011))
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 5.
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 A5 Summary of the study 1

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment		Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)
			g a.s./ ha	Water (l/ha)				Tribenuron-Methyl	
S17-04789-01, Diefenbach, Baden-Württemberg, Germany	Winter wheat	1. 16.10.2016 2. 05.06..2017-15.06.2017 3. 07.08.2017	16.2	217	22.05.2017	BBCH 39	Grain Straw	<LOD <LOD	77
S17-04789-02, Bishop Burton, East Yorkshire, UK	Winter wheat	1. 20.08.2016 2. 06.2017 3. 16.08.2017	15.5	207	26.05.2017	BBCH 39	Grain Straw	<LOD <LOD	82
S17-04789-03, Pàzmànd, Fejèr, Hungary	Winter wheat	1. 04.11.2016 2. 07.06.2017-15.06.2017 3. 03.07.2017	15.5	206	15.05.2017	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 (for tribenuron-methyl)

A 2.2.3.1.2 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 study was 15 g a.s./ha (max 15 g a.s./ha proposed in GAP for HAKSAR TOP 565 SG). Application was performed in 39 BBCH (max BBCH proposed in the GAP is 39) with addition of adjuvant SAR-BIO 90 EC at a rate 1 kg/ha.

Reference:	KCA 6.3/02
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, Study Number 428SRPL17R02, E. Potocka, SynTech, 2019
Guideline(s):	Yes (OECD (2009), OECD Test Guideline 509, OECD (2011))
Deviations:	No
GLP:	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 6.
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 A6 Summary of the study 2

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment		Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)
			g a.s./ ha	Water (l/ha)				Tribenuron-Methyl	
SPRL17-057-428HR, Jabłowo Pałuckie / Kujawsko - Pomorskie, Poland	Winter wheat. Arkadia	1. 18.10.2016 2. 06.07..2017-13.07.2017 3. 21.08.2017-31.08.2017	15	250	23.05.2017	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 (for tribenuron-methyl)

A.2.2.4 Magnitude of residues in livestock

No new or additional studies have been submitted

A.2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted

A.2.2.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

A.2.2.7 Other/Special Studies

No new or additional studies have been submitted

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 MCPA

A 3.1.1 TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (F) (R) (F)			
LOQs (mg/kg) range from:	0,05	to:	0,50
Toxicological reference values			
ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	0,15
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/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
4%	DK child	2,06	2%	Rye	2%	Wheat	0,2%	Oat		4%
3%	GEMS/Food G06	1,47	3%	Wheat	0,0%	Barley	0,0%	Rye		3%
3%	IT toddler	1,33	3%	Wheat	0,0%	Barley	0,0%	Oat		3%
2%	GEMS/Food G08	1,13	2%	Wheat	0,4%	Barley	0,2%	Rye		2%
2%	GEMS/Food G15	1,12	2%	Wheat	0,3%	Barley	0,1%	Rye		2%
2%	DE child	1,04	2%	Wheat	0,3%	Rye	0,1%	Oat		2%
2%	RO general	1,01	2%	Wheat		FRUIT AND TREE NUTS				2%
2%	GEMS/Food G07	1,00	2%	Wheat	0,2%	Barley	0,1%	Oat		2%
2%	NL toddler	0,94	2%	Wheat	0,2%	Rye	0,1%	Oat		2%
2%	GEMS/Food G10	0,94	2%	Wheat	0,2%	Barley	0,0%	Rye		2%
2%	FR child 3 15 yr	0,94	2%	Wheat	0,0%	Oat	0,0%	Rye		2%
2%	GEMS/Food G11	0,89	1%	Wheat	0,3%	Barley	0,0%	Oat		2%
2%	ES child	0,89	2%	Wheat	0,0%	Barley				2%
2%	NL child	0,87	2%	Wheat	0,1%	Rye	0,0%	Oat		2%
2%	IT adult	0,83	2%	Wheat	0,0%	Barley	0,0%	Oat		2%
2%	PT general	0,82	2%	Wheat	0,1%	Rye	0,0%	Barley		2%
2%	UK toddler	0,80	2%	Wheat	0,0%	Oat	0,0%	Barley		2%
1%	SE general	0,70	1%	Wheat	0,1%	Rye				1%
1%	FR toddler 2 3 yr	0,63	1%	Wheat	0,0%	Oat	0,0%	Rye		1%
1%	DE general	0,62	0,8%	Wheat	0,2%	Rye	0,2%	Barley		1%
1%	DE women 14-50 yr	0,58	0,9%	Wheat	0,2%	Rye	0,1%	Barley		1%
1%	UK infant	0,57	1%	Wheat	0,1%	Oat				1%
1%	ES adult	0,57	0,9%	Wheat	0,2%	Barley				1%
1%	IE adult	0,53	0,9%	Wheat	0,1%	Oat	0,1%	Rye		1%
1,0%	FI 3 yr	0,50	0,5%	Wheat	0,3%	Rye	0,2%	Oat		1,0%
0,9%	NL general	0,47	0,8%	Wheat	0,1%	Barley	0,0%	Rye		0,9%
0,9%	LT adult	0,46	0,4%	Rye	0,4%	Wheat	0,0%	Oat		0,9%
0,9%	FR adult	0,45	0,9%	Wheat	0,0%	Oat	0,0%	Rye		0,9%
0,9%	UK vegetarian	0,43	0,8%	Wheat	0,0%	Oat	0,0%	Barley		0,9%
0,8%	FI 6 yr	0,39	0,4%	Wheat	0,2%	Rye	0,1%	Oat		0,8%
0,7%	UK adult	0,35	0,7%	Wheat	0,0%	Barley	0,0%	Oat		0,7%
0,7%	DK adult	0,33	0,4%	Wheat	0,2%	Rye	0,0%	Oat		0,7%
0,5%	IE child	0,24	0,5%	Wheat	0,0%	Oat	0,0%	Barley		0,5%
0,5%	FI adult	0,24	0,3%	Rye	0,1%	Wheat	0,1%	Oat		0,5%
0,3%	FR infant	0,16	0,3%	Wheat	0,0%	Oat	0,0%	Rye		0,3%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (F) (R) (F) is unlikely to present a public health concern.

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				Results for adults				IESTI new Results for children				IESTI new Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI new):			---	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	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0,2 / 0,2	2,9	1%	Wheat	0,2 / 0,2	1,7	2%	Wheat	0,2 / 0,2	2,9	1%	Wheat	0,2 / 0,2	1,7
0,8%	Rye	0,2 / 0,2	1,3	0,6%	Rye	0,2 / 0,2	0,97	0,8%	Rye	0,2 / 0,2	1,3	0,6%	Rye	0,2 / 0,2	0,97
0,7%	Barley	0,2 / 0,2	1,1	0,6%	Barley	0,2 / 0,2	0,97	0,7%	Barley	0,2 / 0,2	1,1	0,6%	Barley	0,2 / 0,2	0,97
0,1%	Oat	0,2 / 0,2	0,22	0,09%	Oat	0,2 / 0,2	0,13	0,1%	Oat	0,2 / 0,2	0,22	0,09%	Oat	0,2 / 0,2	0,13
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 for MCPA

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	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)
2%	Wheat / milling (flour)	0,2 / 0,2	2,4	1,0%	Barley / beer	0,2 / 0,04	1,4
0,7%	Wheat / milling (wholem	0,2 / 0,2	1,1	0,6%	Wheat / bread/pizza	0,2 / 0,2	0,88
0,5%	Rye / boiled	0,2 / 0,2	0,73	0,5%	Wheat / pasta	0,2 / 0,2	0,76
0,5%	Oat / boiled	0,2 / 0,2	0,73	0,5%	Wheat / bread	0,2 / 0,2	0,70
0,5%	Barley / cooked	0,2 / 0,2	0,73	0,2%	Oat / boiled	0,2 / 0,2	0,30
0,5%	Rye / milling (wholemea	0,2 / 0,2	0,70	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,4%	Oat / milling (flakes)	0,2 / 0,2	0,60	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,2%	Barley / milling (flour)	0,2 / 0,2	0,36	#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!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list							

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	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)
2%	Wheat / milling (flour)	0,2 / 0,2	2,4	1,0%	Barley / beer	0,2 / 0,04	1,4
0,7%	Wheat / milling	0,2 / 0,2	1,1	0,6%	Wheat / bread/pizza	0,2 / 0,2	0,88
0,5%	Rye / boiled	0,2 / 0,2	0,73	0,5%	Wheat / pasta	0,2 / 0,2	0,76
0,5%	Oat / boiled	0,2 / 0,2	0,73	0,5%	Wheat / bread (wholemeal)	0,2 / 0,2	0,70
0,5%	Barley / cooked	0,2 / 0,2	0,73	0,2%	Oat / boiled	0,2 / 0,2	0,30
0,5%	Rye / milling	0,2 / 0,2	0,70	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,4%	Oat / milling (flakes)	0,2 / 0,2	0,60	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,2%	Barley / milling (flour)	0,2 / 0,2	0,36	#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 MCPA and MCPB (MCPA, MCPB including their salts, esters and conjugates expressed as MCPA) (F) (R) (E)
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 calculation

NESTI calculations are not required

A 3.2 Tribenuron methyl

A 3.2.1 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/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)
1%	DK child	0,10	0,6%	Rye	0,4%	Wheat	0,0%	Oat	1%	1%
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	0,0%	Oat	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%	DE child	0,05	0,4%	Wheat	0,1%	Rye	0,0%	Oat	0,5%	0,5%
0,5%	RO general	0,05	0,5%	Wheat		FRUIT AND TREE NUTS			0,5%	0,5%
0,5%	GEMS/Food G07	0,05	0,4%	Wheat	0,1%	Barley	0,0%	Oat	0,5%	0,5%
0,5%	NL toddler	0,05	0,4%	Wheat	0,0%	Rye	0,0%	Oat	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%	Oat	0,0%	Rye	0,5%	0,5%
0,4%	GEMS/Food G11	0,04	0,4%	Wheat	0,1%	Barley	0,0%	Oat	0,4%	0,4%
0,4%	ES child	0,04	0,4%	Wheat	0,0%	Barley			0,4%	0,4%
0,4%	NL child	0,04	0,4%	Wheat	0,0%	Rye	0,0%	Oat	0,4%	0,4%
0,4%	IT adult	0,04	0,4%	Wheat	0,0%	Barley	0,0%	Oat	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%	Oat	0,0%	Barley	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%	Oat	0,0%	Rye	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%	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	0,0%	Oat			0,3%	0,3%
0,3%	ES adult	0,03	0,2%	Wheat	0,0%	Barley			0,3%	0,3%
0,3%	IE adult	0,03	0,2%	Wheat	0,0%	Oat	0,0%	Rye	0,3%	0,3%
0,2%	FI 3 yr	0,02	0,1%	Wheat	0,1%	Rye	0,1%	Oat	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%	LT adult	0,02	0,1%	Rye	0,1%	Wheat	0,0%	Oat	0,2%	0,2%
0,2%	FR adult	0,02	0,2%	Wheat	0,0%	Oat	0,0%	Rye	0,2%	0,2%
0,2%	UK vegetarian	0,02	0,2%	Wheat	0,0%	Oat	0,0%	Barley	0,2%	0,2%
0,2%	FI 6 yr	0,02	0,1%	Wheat	0,1%	Rye	0,0%	Oat	0,2%	0,2%
0,2%	UK adult	0,02	0,2%	Wheat	0,0%	Barley	0,0%	Oat	0,2%	0,2%
0,2%	DK adult	0,02	0,1%	Wheat	0,1%	Rye	0,0%	Oat	0,2%	0,2%
0,1%	IE child	0,01	0,1%	Wheat	0,0%	Oat	0,0%	Barley	0,1%	0,1%
0,1%	FI adult	0,01	0,1%	Rye	0,0%	Wheat	0,0%	Oat	0,1%	0,1%
0,1%	FR infant	0,01	0,1%	Wheat	0,0%	Oat	0,0%	Rye	0,1%	0,1%
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

A 3.2.2 IEDI calculations

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

A 3.2.3 IESTI calculations - Raw commodities for Tribenuron methyl

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,07%	Wheat	0,01 / 0,01	0,14
0,03%	Rye	0,01 / 0,01	0,06
0,03%	Barley	0,01 / 0,01	0,06
0,01%	Oat	0,01 / 0,01	0,01

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,04%	Wheat	0,01 / 0,01	0,08
0,02%	Rye	0,01 / 0,01	0,05
0,02%	Barley	0,01 / 0,01	0,05
0,00%	Oat	0,01 / 0,01	0,01

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,07%	Wheat	0,01 / 0,01	0,14
0,03%	Rye	0,01 / 0,01	0,06
0,03%	Barley	0,01 / 0,01	0,06
0,01%	Oat	0,01 / 0,01	0,01

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,04%	Wheat	0,01 / 0,01	0,08
0,02%	Rye	0,01 / 0,01	0,05
0,02%	Barley	0,01 / 0,01	0,05
0,00%	Oat	0,01 / 0,01	0,01

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

A 3.2.4 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 (wholemeal)	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%	Oat / boiled	0,01 / 0,01	0,04	0,02%	Wheat / bread (wholemeal)	0,01 / 0,01	0,03
0,0%	Barley / cooked	0,01 / 0,01	0,04	0,01%	Oat / boiled	0,01 / 0,01	0,02
0,0%	Rye / milling (wholemeal)-b	0,01 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,0%	Oat / milling (flakes)	0,01 / 0,01	0,03	#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!
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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%	Oat / boiled	0,01 / 0,01	0,04	0,02%	Wheat / bread (wholemeal)	0,01 / 0,01	0,03
0,02%	Barley / cooked	0,01 / 0,01	0,04	0,01%	Oat / boiled	0,01 / 0,01	0,02
0,02%	Rye / milling (wholemeal)-	0,01 / 0,01	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,02%	Oat / milling (flakes)	0,01 / 0,01	0,03	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0,01%	Barley / milling (flour)	0,01 / 0,01	0,02	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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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 3.2.5 NTMDI calculations

NTMDI calculations are not required

A 3.2.6 NESTI calculations

NESTI calculations are not required

Appendix 4 Additional information provided by the applicant

No information has been provided.