DRAFT REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **102000025743**

Product name(s): **Foramsulfuron + Thiencarbazone-methyl**

(Active substance(s)) **OD 80 (50+30 g/L)**

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-Authorisation)

Applicant: **Bayer Crop Science Division**

Submission date: **31/08/2020**

MS Finalisation date: **06/2021; 12/2021**

Version history

When	What
31/08/2020	Initial Bayer CropScience submission (Regulation 1107/2009 - Art. 43) Foramsulfuron
06/2021	ZRMs evaluated dRR submitted by Applicant
12/2021	Updated assessment following commenting period

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7.1 Summary and zRMS Conclusion

zRMS comments are market in grey.

Foramsulfuron

Stability of Residues

Storage stability studies conducted on maize were considered as non-acceptable during the EU re-approval review of foramsulfuron (EFSA Journal 2016; 14(3).

New studies were provided. Studies are accepted.

The results of these studies showed that Foramsulfuron and its metabolite AE F153745 are stable in Sugar beet (body, leaf with root collar), Wheat (shoot, grain, straw) samples when stored at ≤ -18°C for period of up to 24 months. Metabolite AE F092944 are stable in wheat matrices (grain, green material, straw) for 24 months.

Sufficient stability has been demonstrated to support the residue data presented in this submission.

No further data are required to support the proposed uses.

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis.

Note concerning Metabolite AE F092944:

According to OECD 506 guideline for High water content category matrices:

If the stability of test substance in three diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

And for High starch content category:

If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other commodities that belong to this category is unnecessary.

Extrapolation is not possible. Only for wheat shoot (High water content category) and for wheat grain (High starch content category) data are available.

However, the AE F092944 metabolite is a provisional candidate for inclusion in the risk assessment definition. Metabolism studies in beet do not indicate the possibility of residues this compounds above the LOQ. The stability of parent compound has been confirmed by storage stability data. Additionally, this metabolite is common to a number of pyrimidinylsulfonylurea substances. The absence of studies on this metabolite does not constitute an inability to register the product. PL proposes that the applicant should provide the missing data after registration of the product.

Metabolism in plants

Two metabolism studies in sugar beets (primary crops) were conducted with [pyrimidine-2-^{14}C]- and [phenyl-UL-^{14}C]-foramsulfuron and have been submitted by the applicant to support the 1st registration of the product in the zone. Version 01 were submitted in 2015. Version 2 are the amended reports (correction of mistakes, names of person and test facilities).

A new confined rotational crop study is submitted in the framework of this application.

Sufficient data have been provided to acknowledge the metabolism of foramsulfuron in rotational crops.

The metabolism of foramsulfuron in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

EU end points:

Plant residue definition for monitoring and risk assessment: Foramsulfuron

Metabolite AE F092944 is provisionally a candidate for inclusion in the risk assessment definition (EFSA Journal 2016;14(3):4421).

AE F092944 is a common metabolite to a number of pyrimidinylsulfonylurea herbicides. A final decision on the risk assessment definition is therefore pending a comprehensive consumer risk assessment, considering the different possible sources of exposure including the potential transfer to livestock matrices and the full clarification with regard to the toxicological properties of AE F092944.

The results of the new studies are consist wiith the EFSA conclusions.

The above new studies should be assessed at the EU level.

Magnitude of residues in plants

Applicant provided trials which were already submitted and therefore reviewed in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South), GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as they are considered to be reviewed via a zonal process but not via an EU peer reviewed process. Foramsulfuron and its metabolite AE F153745 were analysed. These studies are acceptable to support the application.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application to support the proposed cGAP. A package of field trials was performed to determine the magnitude of the Foramsulfuron and metabolite AE F092944 residues in sugar beet and to clarify the consumer risk assessment including potential transfer to livestock matrices (see EFSA 2016; 14(3):4421 and §7.1.2.1)

The results of the new trials showed that no AE F092944 residues above the LOQ were observed in any parts of the plant, whether in body or in leaves. Significant exposure of consumers to AE F092944 is not expected.

The residues arising from the proposed uses will not exceed the MRLs established for sugar beets (0.01 mg/kg, Regulation (EC) No 289/2014). Extrapolation from sugar beets to fodder beets is possible.

Uses are accepted.

Note concerning independency of the trials:

The 8 residue trials from 12-2139 and 13-2009 can be considered as replicates to trials 12-2138 and 13-2000. Nevertheless, the number of trials provided is still sufficient (13) to support the intended use.

Magnitude of residues in livestock

The use of foramsulfuron in sugar beet/fodder beet according to the recommended GAP is not likely to result in significant residues in any of these animal commodities. Moreover, the assessment of the guanidine metabolite for the use on sugar beet and fodder beet demonstrated that livestock are not significantly exposed to the this metabolite.

Based on the previous model of the dietary burden calculation, EFSA 2016 stated that the livestock feeding studies are not triggered for foramsulfuron (dietary burden <0.004 mg/kg bw/day). By considering the new model, the results were slightly different. For the reasons exposed above, residue levels in ruminant commodities are expected to remain below the LOQ of 0.01 mg/kg in milk and other edible tissues. Therefore, it can be concluded that no livestock feeding study is needed.

Magnitude of residues in processed commodities

No further data are required to support the proposed uses. The use of FSN+TCM OD 80 in sugar beet/fodder beet according to the intended GAP does not result in significant residues (i.e. > 0.1 mg/kg)

of foramsulfuron in sugar beet root/fodder beet at harvest; residues were below the limit of quantification (0.01 mg/kg).

Magnitude of residues in representative succeeding crops

As stated by EFSA 2016, field rotational crop studies are not required as no residues are expected in succeeding crops according to confined rotational studies. No new data submitted in the frame-work of this application.

Other / special studies

Not required.

Estimation of exposure through diet and other means

TMDI calculations demonstrate a wide margin of safety

The proposed uses of foramsulfuron in the formulation FSN+TCM OD 80 do not represent unacceptable chronic risks for the consumer.

~~**Thiencarbazone-methyl**~~

~~No new data submitted in the framework of this application with the exception of Hoffmann, M.; Barrière, I., 2020. *EU approval renewal of the active substance thiencarbazone-methyl – Waiver for studies investigating residues in honey*. The presented arguments were accepted.~~

~~**Stability of Residues**~~

~~Available storage stability data in plant matrices cover the intended uses of FSN+TCM OD 80 on sugar beet.~~

~~Thiencarbazone-methyl (BYH 18636) and its metabolite BYH18636-N-desmethyl and BYH18636-MMT-glucoside are stable in high starch content, high water content, high oil content and dry matrices for 26 months.~~

~~**Metabolism in plants**~~

~~Plant residue definition for monitoring Thiencarbazone-methyl (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)~~

~~Plant residue definition for risk assessment Sum of thiencarbazone-methyl, BYH18636-N-desmethyl and BYH18636-MMT-glucoside, expressed as thiencarbazone-methyl (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)~~

~~Conversion factor from enforcement to RA Not necessary (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)~~

~~Available data are sufficient to cover the proposed uses.~~

~~**Magnitude of residues in plants**~~

~~Trials: data were evaluated in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South) and GER (zRMS, Cen tral) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as being EU data as they were submitted to RMS (FRA) to support Art. 12.1 of EU Regulation No 396/2005 (refer to Evaluation Report prepared by RMS France – 2019 and EFSA Journal 2020;18(1):5957).~~

~~According to the available data, the intended uses on sugar beet are considered acceptable, for out-door uses.~~

~~**Magnitude of residues in livestock**~~

~~EFSA Journal 2020;18(1):5957: *The dietary burdens calculated were found to be below the trigger value of 0.1 mg/kg DM for each group and further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.*~~

~~**Magnitude of residues in processed commodities**~~

~~For thiencarbazone-methyl processing trials are not required~~

~~**Magnitude of residues in representative succeeding crops**~~

~~Residues in rotational crops at the proposed application rate in the EU are unlikely to exceed 0.01 mg/kg and therefore rotational crop field trials are not required.~~

~~**Other / special studies**~~

~~Not required.~~

~~**Estimation of exposure through diet and other means**~~

~~TMDI calculations demonstrate a wide margin of safety~~

~~The proposed uses of Thiencarbazone-methyl in the formulation FSN+TCM OD 80 do not represent unacceptable chronic risks for the consumer.~~

~~**Combined exposure and risk assessment**~~

~~The product is a mixture of two active substances for which no acute reference dose has been allocated.~~

~~The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues.~~

~~**Use of an application together with a safener is acceptable.**~~

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 **FSN+TCM OD 80** are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for sugar beet/fodder beet. A list of all intended uses within the zones given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current EU MRL of 0.01 mg/kg for foramsulfuron and 0.01 mg/kg thiencarbazone-methyl as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of foramsulfuron and thiencarbazone-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.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- ~~None~~ Storage stability data for metabolite AE F092944

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season BBCH**	**number min max**	**interval between applications (min)**	**kg a.s./hL min max**	**water L/ha min max**	**kg a.s./ha min max**		
~~**From 22 to 27.**~~ ~~**31 IRE**~~	~~Sugar beet* (BEAVA)~~	~~Central-zone~~	~~FSS + TCM OD 80~~	~~F~~	~~(a)~~	~~OD~~	~~80~~	~~Spraying /broadcast~~	~~10-18~~	~~1~~	~~-~~	~~FSN: 0.017-0.050 TCM: 0.010-0.030~~	~~100-300~~	~~FSN: 0.050 TCM:0.030~~	~~-~~	~~(*) Fodder beet is registered in addition to sugar beet for Belgium and Ireland only~~ ~~A~~
~~**28 GBR**~~	~~Sugar beet (BEAVA)~~ ~~Fodder beet (BEAVC)~~	~~Central-zone~~	~~FSS + TCM OD 80~~	~~F~~	~~(a)~~	~~OD~~	~~80~~	~~Spraying /broadcast~~	~~14-18~~	~~1~~	~~-~~	~~FSN: 0.017-0.033 TCM: 0.010-0.020~~	~~150-300~~	~~FSN: 0.050 TCM:0.030~~		~~A~~
29 NLD	Sugar beet (BEAVA) Fodder beet (BEAVC)	Central-zone	FSS + TCM OD 80	F	(a)	OD	80	Spraying /broadcast	10-18	1	-	FSN: 0.017-0.062 TCM: 0.010-0.037	80-300	FSN: 0.050 TCM:0.030		A
~~**30 ROM**~~	~~Sugar beet (BEAVA)~~	~~Central-zone~~	~~FSS + TCM OD 80~~	~~F~~	~~(a)~~	~~OD~~	~~80~~	~~Spraying /broadcast~~	~~10-18~~	~~1~~	~~-~~	~~FSN: 0.017-0.025 TCM: 0.010-0.015~~	~~200-300~~	~~FSN: 0.050 TCM:0.030~~		~~A~~
~~**From 32 to 36**~~ ~~**40 IRE**~~	~~Sugar beet* (BEAVA)~~	~~Central-zone~~	~~FSS + TCM OD 80~~	~~F~~	~~(a)~~	~~OD~~	~~80~~	~~Spraying /broadcast~~	~~10-18 (B1 10-14 B2 : 12-18)~~	~~2~~	~~10~~	~~FSN: 0.008-0.025 TCM: 0.005-0.015~~	~~100-300~~	~~FSN: 0.025 TCM: 0.015~~	~~-~~	~~(*) Fodder beet is registered in addition to sugar beet for Belgium and Ireland only~~ ~~A~~
37 NLD	Sugar beet (BEAVA)	Central-zone	FSS + TCM OD 80	F	(a)	OD	80	Spraying /broadcast	10-18 (B1 10-14 B2 : 12-18)	2	10	FSN: 0.008-0.031 TCM: 0.005-0.019	80-300	FSN: 0.025 TCM: 0.015		A

	Fodder beet (BEAVC)															
~~**38 ROM**~~ ~~**39 HUN**~~	~~Sugar beet (BEAVA)~~	~~Central zone~~	~~FSS + TCM OD 80~~	~~F~~	~~(a)~~	~~OD~~	~~80~~	~~Spraying /broadcast~~	~~10-18 (B1 10-14 B2 : 12-18)~~	~~2~~	~~10~~	~~FSN: 0.008-0.012 TCM: 0.005-0.0075~~	~~200-300~~	~~FSN: 0.025 TCM: 0.015~~		~~A~~

(a): See in Part B, Section 0 for more details related to the weeds
* 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 14 “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

Thiencarbazone-methyl (non renewed active ingredient)

In agreement with the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170), for products containing two or more active substances and when the 1st substance is renewed, there is no need to evaluate data related to the 2nd substance.
Thiencarbazone-methyl (TCM) is the active ingredient not being renewed and therefore data pertaining to TCM should not be evaluated in this application unless they are required for mixture toxicity risk assessment.

It is worth mentioning that most TCM data relied upon in this dossier were already evaluated au EU level either during the EU approval of TCM review (UK, DAR, 2012) or during the EFSA review to support Art. 12.1 of EU Regulation No 396/2005 (refer to Evaluation Report prepared by RMS France – 2019 and EFSA Journal 2020;18(1):5957). Such TCM data are therefore not summarised in Appendix 2.
Moreover, all metabolism and residue TCM data referred to in this document were already submitted to and therefore evaluated in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South) and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone

The preparation FSN+TCM OD 80 is composed of the active substances foramsulfuron and thiencarbazone-methyl.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Foramsulfuron - Parent compound					
ADI	EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance foramsulfuron. EFSA Journal 2016;14(3):4421	2016	0.25 mg/kg bw per day	2-year rat	100
ARfD		2016	Not established	-	-
Thiencarbazone-methyl - Parent compound					
ADI	EFSA Journal 2013; 11(7): 3270	2013	0.23 mg/kg bw/day	Rat, chronic study	100
ARfD	EFSA Journal 2013; 11(7): 3270	2013	Not established	-	-

7.1.2.1 Summary for foramsulfuron

Table 7.1-3: Summary for foramsulfuron

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?
From 22 to 39	Sugar beet & Fodder beet	Yes	Yes (21 trials in Central Europe)	Not relevant	Yes	Yes	No Assessment of AE F 092944 (EFSA Journal 2016; 14(3):4421)	No

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

According to the EFSA Conclusions (doi:10.2903/j.efsa.2016.4453) on the foramsulfuron risk assessment linked with the aminopyridine metabolite AE F092944, a recent DEREK analysis was performed for foramsulfuron itself and several metabolites (E. Shipp, 2019, M-654051-01-1)[1]. It is concluded that "Based on the alerts from in silico evaluation of AE F092944 and on the lack of any effect in the rat or mouse long-term studies conducted with amidosulfuron, in which AE F092944 was an impurity at 3 g/kg, there is no toxicological hazard to be expected from this metabolite. This is especially true as there is no consumer exposure to be expected, as AE F092944 does not exceed the groundwater trigger value nor was it detected in plant metabolism studies." Since the metabolites are smaller degradation products a quicker elimination and thus shorter systemic bioavailability of them is normally expected and thus a lower toxicity potential. Also AE F092944 is a small degradation product of the parent containing the pyrimidine portion of the parent. Therefore, no higher toxicity for this metabolite than for parent has to be expected. Furthermore, AE F092944 was included as impurity in many batches which were tested in apical toxicology studies. A summary is given in a position paper (B. Mallyon, 2003, M-210912-01-1[1]) in which the concentrations of AE F092944 in different toxicology batches are given. Thus, AE F092944 was included in batches used in apical studies, like acute toxicity, irritation, sensitization and genotoxicity tests, reproduction and developmental toxicity studies and in rat, dog and mouse long-term studies and thus can be considered as sufficiently tested toxicologically. In addition to the explanations for AE F092944 further support for the lower toxicity than parent can be derived from bensulfuron data. In the monograph Vol 1, May 2006 it is shown that this metabolite is also a rat metabolite following bensulfuron administration ('IN-J0290, pyrimidine-amine'). Therefore this compound was tested in the rat studies with bensulfuron.

Furthermore, in RAR Vol 1, a 10-day study with this metabolite is reported, in which this metabolite was dosed 10 times over a 2-week period at a dose rate of 450 mg/kg bw/day. In this test, the no-observed-adverse-effect level (NOAEL) was greater than 450 mg/kg bw/day for male rats. Thus, with a NOAEL greater than 450 mg/kg bw/d this metabolite is less toxic than parent with an overall NOAEL of the short-term studies of 144.1 mg/kg bw (3-month dog study)".

New residue trials were performed to determine the magnitude of AE F092944 residues. The applications were made at the EU critical GAP on maize (application rate at 1 x 60 g foramsulfuron/ha and BBCH 12-18 or 12-16) with different formulations and on sugar beet, with an OD formulation (application rate at 1

[1] Refer to dRR Part B6 Core.

x 50 g foramsulfuron/ha and BBCH 10-18) in order to cover the various in-tended uses in the EU. For maize, the results showed that no AE F092944 residues were observed in any parts of the plant, whether in grain, in forage or in the rest of the plant. For sugar beet, the results also showed that no AE F092944 residues above the LOQ were observed in any sites of the plant, whether in body or in leaf with root collar. Thus, as no AE F0092944 residues are expected in food or animal feeds, there is no impact on the consumer risk. Only results on sugar beet are presented in this report.

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

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

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

7.1.2.2 Summary for thiencarbazone-methyl

Table 7.1-4: Summary for thiencarbazone-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?
From 22 to 39	Sugar beet Fodder beet	Yes	Yes (17 trials in Northern Europe)	Not relevant	Yes	Yes	No	No

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

As residues of thiencarbazone-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.

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

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

7.1.2.3 Summary for FSN+TCM OD 80

Table 7.1-5: Information on FSN+TCM OD 80 (KCA 6.8)

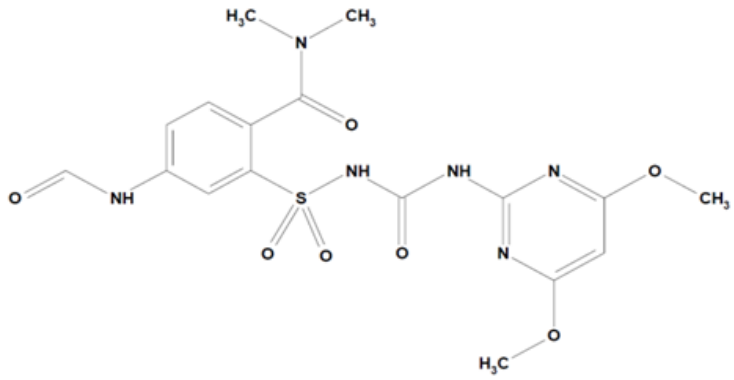
Crop	PHI for FSN+TCM OD 80 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for FSN+TCM OD 80 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Foramsulfuron	Thiencarbazone-methyl		
Sugar beet Fodder beet	Not needed	NR	NR	-	

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).

7.2 Foramsulfuron

General data on foramsulfuron are summarized in the table below

Table 7.2-1: General information on foramsulfuron

Active substance (ISO Common Name)	Foramsulfuron
IUPAC	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea
Chemical structure	
Molecular formula	$C_{17}H_{20}N_6O_7S$
Molar mass	452.44 g/mol
Chemical group	Sulfonylurea
Mode of action (if available)	Inhibition of acetolactate synthase ALS (acetohydroxyacid synthase AHAS)
Systemic	Yes
Company (ies)	Bayer Crop Science Division
Rapporteur Member State (RMS)	Germany (Original) Finland / Slovakia (EU Renewal)
Approval status	Approved Commission Directive 2003/23/EC dated 25 March 2003 (entry into

	force 1st of July 2003) Regulation for EU re-approval: Commission Implementing Regulation (EU) 2020/616 of 5th of May 2020 (entry into force: 01st of June 2020).
Restriction (e.g. is restricted to use as "...")	see Approval Directive / Regulation
Review Report	SANTE-2016-11214 Rev. 2 (24th of March 2020)
Current MRL regulation	Regulation (EC) No 289/2014
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Journal 2016; 14(3):4421
EFSA Journal: conclusion on article 12	EFSA Journal 2012; 10(11):2962
Current MRL applications on intended uses	none

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

Throughout the document, unless otherwise stated:
EFSA, 2012: EFSA Journal 2012;10(11):2962
EFSA, 2016: EFSA Journal 2016; 14(3):4421

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Storage stability studies conducted on maize were considered as non-acceptable during the EU re-approval review of foramsulfuron (EFSA Journal 2016; 14(3): One new stability study performed on sugar beet has been submitted by the applicant in the framework of this application as well as a stability study in wheat (grain, green material, straw) for 24 months. Results are summarized in the table below. The detailed assessment are presented in Appendix 2.

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			
Corn grain	High starch content	At least 20 months	Cole, M.G., 2001, M-238787-01-1 EFSA Journal 2016;14(3):4421 DAR 2001 (RMS: GER) RAR 2016 (RMS: FIN) EU peer reviewed
Corn stover	High water content	At least 20 months	Cole, M.G., 2001, M-238787-01-1 EFSA Journal

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			2016;14(3):4421 DAR 2001 (RMS: GER) RAR 2016 (RMS: FIN) EU peer reviewed
Corn forage	Other	At least 20 months	Cole, M.G., 2001, M-238787-01-1 EFSA Journal 2016;14(3):4421 DAR 2001 (RMS: GER) RAR 2016 (RMS: FIN) EU peer reviewed
Animal Products	Not triggered as calculated dietary burden does not exceed the trigger value of 0.004 mg/kg bw per day or any residues above LOQ is expected on basis of metabolism study.		EFSA Journal 2016;14(3):4421
New data			
Plant products			
Wheat, grain and Potato, tuber	High starch content	for 8 hours at +1°C following 7 days at -7°C (Foramsulfuron and its metabolite AE F153745)	Lakaschus, S., Gizler, A., 2015; M-480441-06-1 report Nr S13-03307 Not EU peer reviewed, Appendix 2
Sugar beet body	High starch content	At least 24 months (Foramsulfuron and its metabolite AE F153745)	Thies, S., 2015, M-503516-02-1 report Nr 2013/0037/01 Not EU peer reviewed Appendix 2
Sugar beet leaf with root collar	High water content	At least 24 months (Foramsulfuron and its metabolite AE F153745)	
Wheat shoot	High water content	24 months (Foramsulfuron and its metabolites AE F092944 and AE F153745)	Kaussmann M.; 2019 M-635482-02-1 Not EU peer reviewed Appendix 2
Wheat grain	High starch content	24 months (Foramsulfuron and its metabolites AE F092944 and AE F153745)	Kaussmann M.; 2019 M-635482-02-1 Not EU peer reviewed Appendix 2
Wheat straw	Other	24 months (Foramsulfuron and its metabolites AE F092944 and AE F153745)	Kaussmann M.; 2019 M-635482-02-1 Not EU peer reviewed Appendix 2

Conclusion on stability of residues during storage

The maximum storage period of deep-frozen samples before analysis was of 385 days and is completely covered by the storage stability study.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

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

Conclusion on stability of residues in sample extracts

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis. Every analytical batch does contain at least one freshly fortified sample for concurrent recovery determination. The extracts of the fortified samples and of the study samples are handled and stored in parallel. If the recoveries in the fortified samples are within acceptable ranges, the stability of the sample extracts is considered as sufficiently proven.

As stated in the dRAR from January 2016, during the development of the enforcement method [method number 01360 (Report MR-13/007)] for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl and foramsulfuron in samples from plant origin by HPLC-MS/MS, the stability in final plant extracts was checked for the tested sample materials over a period of 16 to 43 days. In addition in the Independent Laboratory Validation (ILV) the stability in extracts was rechecked over a shorter time period. The stability results from both studies show significant deviations between initial and re-analysis especially for the matrices lemon fruit and oilseed rape. Therefore the analysis of the samples has to be conducted within 1 day. Details of the method and the ILV are presented in the method section (Section 4) of the active substance dossier (Stuke, S.; Ballmann, C. 2013; M-455564-01-1; KCA 4.2/20 and Konrad, S.; 2013; M-470160-01-1; KCA 4.2/21).

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

Two metabolism studies in sugar beets were conducted with [pyrimidine-2-^{14}C]- and [phenyl-UL-^{14}C]-foramsulfuron and have been submitted by the applicant to support the 1st registration of the product in the zone. These studies are summarized below. The detailed assessment of these studies is presented in Appendix 2 as they were submitted at zonal level but not at EU level.

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Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	[U-^{14}C]-phenyl	Foliar, G (BBCH 17-	0.06 (1X) 0.24 (4X)	1	Immature plant:	Foramsulfuron formu-	Huang, M. N. (2000);

			31)			0, 14, 27, 42 Forage: 60 Stover and grain: 77	lated with safener isoxadifen ethyl (1:1)	M-185906-01-1 EFSA, 2012, 2016 EU peer re-viewed
		[2-^{14}C]-pyrimidinyl				Immature plant: 0, 14, 42 Forage: 85 Stover and grain: 106		
Data (submitted and reviewed at zonal level)*								
Root and tuber vegetables	Sugar beet	[U-^{14}C]-phenyl	Foliar, G BBCH12-14 BBCH 14-18 (2 weeks after)	0.0288 (1X) 0.055 (2X)	2	98 (Sugar beets, leaves and root tops)	A sugar beet *(Beta vulgaris)* variety being in the state of develop-ment for resistance to sulfonyl urea herbi-cides was used.	Schallau, K., Klempner, A. (2013); M-454861-02-1 Not EU peer reviewed Appendix 2
		[2-^{14}C]-pyrimidinyl	Foliar, G BBCH12-14 BBCH 14-18 (2 weeks after)	0.0288 (1X) 0.055 (2X)	2	98 (Sugar beets, leaves and root tops)		Schallau, K., Klempner, A. (2013); M-454046-02-1 Not EU peer reviewed Appendix 2

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
Data (reviewed at zonal level)*: data already submitted and therefore reviewed in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South) and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as they are considered to be reviewed via a zonal process but not via an EU peer reviewed process.

Summary of plant metabolism studies reported in the EU

As stated in EFSA Journal 2016;14(3):4421:

"Metabolism was investigated in maize (cereal crop group) following foliar application using 14C-Phenyl and 14C-Pyrimidyl labelled foramsulfuron. At a comparable application rate; the pyrimidyl label lead to higher proportions and levels of identified residues due to the better extractability of pyrimidyl label residues when compared to phenyl label study. The parent compound was a major residue in the maize commodities (7–10% TRR phenyl label and 16-55% TRR pyrimidyl label). The presence of label specific metabolites AE F092944 (3–4% TRR) and AE F153745 (4–9% TRR) resulting into compounds of either pyrimidine amine or sulphonamide structure indicated the cleavage of the sulfonylurea bridge is taking place. Very little identification was made in grain for both labels that could be justified by the low recovered TRR in grain (0.004–0.01 mg/kg) at an exaggerated rate (4N). Despite some shortcomings with regard to the full investigation of residues in feed commodities, it was considered that for the purpose of the assessment of the representative use in maize the study is acceptable.
Considering the representative use in maize (cereals), the relevant residue for both enforcement and risk assessment on this crop group was proposed as parent foramsulfuron by default."

Summary of plant metabolism studies (submitted and reviewed at zonal level)

The metabolism of [pyrimidine-2-^{14}C]- and [phenyl-UL-^{14}C]-foramsulfuron in sugar beets was investigated according to the envisaged use pattern. The formulated test compound was applied to the sugar beets by post-emergence spray-application. A 2X target rate experiment was performed to increase the TRR values. However, the TRR values in the RACs of the 2X target rate experiment as measured by LSC following combustion did not reflect the doubled application rate.
The TRR levels were generally very low. In the beets, only 0.013-0.019 mg/kg were detected. The leaves showed a slightly higher TRR of 0.020-0.034 mg/kg. The radioactive residues were extracted with acetonitrile/water mixtures. The conventional extraction was sufficient for neither leaves nor beets, but combined with a subsequent microwave extraction, the extraction efficiencies were sufficient.
• Foramsulfuron was extensively metabolised in sugar beets.
• Besides parent compound, eight metabolites were identified and the majority of them were label-specific.
• Parent compound foramsulfuron was a minor component in the leaves and beets.

The metabolic reactions observed were:
• cleavage of the sulfonylurea bridge to 1-(4,6-dimethoxypyrimidin-2-yl)urea, followed by hydrolysis of the amide bond and further hydrolytic degradation,
• cleavage of the sulfonylurea bridge to 4,6-dimethoxypyrimidin-2-amine, followed by further hydrolytic degradation
• *O*-demethylation
• a ring closure and deformylation (in random order)

<u>For the phenyl label:</u>
• The major compounds (>10%) in beets were the metabolites AE0001082 and AEF153745, in leaves the metabolites AE0014940 and AE0338795.
• In beets, the metabolite AE0001082 was the most prominent compound, representing about 15% of the TRR. In leaves, the metabolite was only a minor compound.
• The only not-label-specific metabolite AE0338795 was the most prominent metabolite in leaves, representing about 20% of the TRR, but was only a minor compound in beets.

<u>For the pyrimidinyl label:</u>
• In beets, the metabolite AEF092944 was the most prominent compound, representing about 29% of the TRR. This metabolite was also the main hydrolysis product of the parent compound. In leaves, the metabolite was only a minor compound.
• The metabolite guanidine was the most prominent metabolite in leaves, representing about 40% of the TRR. Guanidine is known to be a natural compound in sugar beets.
• The only not-label-specific metabolite AE0338795 was detected in leaves with about 10% of the TRR (0.003 mg/kg).
• AEF099095 was a minor metabolite detected in leaves only.

Conclusion on metabolism in primary crops

Sufficient data have been provided to acknowledge the metabolism of foramsulfuron in maize and sugar beet.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

A new confined rotational crop study is submitted in the framework of this application. This study is summarized in the table below and a detailed assessment is presented in Appendix 2 (M-625836-02-1).

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								
Root and tuber vegetables	Radish	U-^{14}C]-phenyl and [2-^{14}C]-pyrimidinyl	Soil, G	0.06 and 0.09	59, 119, 269	90, 152	-	Huang, M. N.; Faulkner, T. D. (1999); M-185898-01-1 EFSA, 2012, 2016 EU peer reviewed
Pulses and oilseeds	Soya bean				30, 119, 269	140, 228, 265, 330, 353, 413	-	
Cereals	Wheat				59, 119, 269	93, 139, 153, 206, 317, 398	-	
New data								
Leaf, vegetables, herbs & edible flowers	Sweet chard	[2-^{14}C]-pyrimidinyl	Soil, G	0.064	30, 149, 365	72, 113, 262, 276, 408, 441	-	Rieder, B.; (2019) M-625836-02-1 Not EU peer reviewed Appendix 2
Root and tuber vegetables	Turnip				30, 149, 365	113, 255, 441	-	
Cereals	Wheat				30, 149, 365	55, 80, 102, 196, 230, 246, 395, 429; 441	-	

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

Summary of metabolism in rotational crops reported in the EU

As stated in EFSA Journal 2012; 10(11):2962 (and EFSA Journal 2016;14(3):4421):

"Total residues were very low and declined with longer soil ageing. Residues were higher in plants from plots treated with pyrimidyl labelled foramsulfuron than with phenyl labelled foramsulfuron. The only residues above 0.01 mg/kg resulting from the phenyl labelled foramsulfuron treatment were seen in wheat straw from each rotation (0.011 to 0.014 mg/kg). Treatment with pyrimidyl labelled active substance resulted in residues above 0.01 mg/kg only in soya bean forage and hulls (0.019 and 0.016 mg/kg) and in wheat forage and grain (0.014 mg/kg both) from the earliest rotation and in wheat straw from later rotations 0.083 and 0.022 mg/kg. Extracts from crops with TRR above 0.01 mg/kg contained insignificant organic soluble residues (less than 0.01 mg/kg) and aqueous soluble residues were also very low. Only wheat straw from the 59 and 119 day treatment with pyrimidyl labelled foramsulfuron contained aqueous extractable residues slightly above 0.05 mg/kg TRR (0.053 to 0.054 mg/kg). The non-extractable residue was low in all crops (<0.03 mg/kg).

No relevant metabolite was found in any commodity. The largest single component (at <0.03 mg parent

eq/kg) was a metabolite in 59 and 119 day rotation wheat straw from the pyrimidyl labelled treatment only. Identification, however, was not feasible due to the low level of radioactivity involved, but it was extensively characterised as being highly polar."

A new study to further identify the metabolism in succeeding crops was performed. The results were consistent with the already evaluated study. Foramsulfuron was completely degraded and guanidine was detected as the main metabolite in all RACs but was never observed at levels above 0.003 mg/kg.

Conclusion on metabolism in rotational crops

Sufficient data have been provided to acknowledge the metabolism of foramsulfuron in rotational crops. The metabolism of foramsulfuron in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed 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.

As stated in EFSA 2012 (and 2016):
"Quantifiable residues of foramsulfuron are not expected in maize grains and as the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing."

This is also true for sugar beets/fodder beet, where no quantifiable residues of foramsulfuron are expected and the chronic exposure does not exceed 10 % of the ADI.

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 (maize) Root and tuber vegetables (sugar beet)
Rotational crops covered	Radish, soybean and wheat Sweet chard, turnip, wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not applicable
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Foramsulfuron (EFSA, 2012, 2016)
Plant residue definition for risk assessment	Foramsulfuron (EFSA, 2012, 2016)
Conversion factor from enforcement to RA	1 (EFSA, 2012, 2016)

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[U-^{14}C]-phenyl	1	0.389[(a)]	7	Milk and blood	twice daily	xxx (1999); M-191251-01-1 EFSA, 2012, 2016 EU peer reviewed
						Urine and faeces	daily	
						Tissues	After sacrifice	
Laying poultry	Hens	[U-^{14}C]-phenyl	6	0.75[(b)]	14	Eggs	twice daily	xxx. (1999); M-191323-01-1 EFSA, 2012, 2016 EU peer reviewed
						Excreta	daily	
						Tissues	After sacrifice	

[(a)]dose corresponding to 16 mg/kg DM feed, [(b)]dose corresponding to 10 mg/kg DM feed.

Summary of animal metabolism studies reported in the EU

As stated in EFSA Journal 2012; 10(11):2962:

"Laying hens were dosed with 0.75 mg/kg bw per d of foramsulfuron, corresponding to approximately 375 times the exposure of poultry. This study demonstrates that transfer of residues to egg white, muscle and fat is insignificant. Highest residue levels were found in liver (0.023 mg/kg) and egg yolk (0.014 to 0.018 mg/kg).

In the metabolism study on poultry, extraction in liver was insufficient, releasing only 55% TRR. Parent compound and its metabolite AE F153745 were identified in this organ at 7.32 % and 4.54 % respectively, 28.51 % accounting for unidentified compounds. In egg yolks, extraction was insufficient, releasing up to 63.24 % TRR. Parent compound and its metabolite AE F153745 were identified, each being not present in the same sample. Parent was quantified at 11.5 %, AE F153745 at 36.25 %. No other compound was identified in any fraction.

Lactating cow was dosed with 0.39 mg/kg bw per d of foramsulfuron corresponding to approximately 39 times the exposure of meat ruminant. This study demonstrates that transfer of residues to milk and muscle is insignificant at the investigated dose. Highest TRR levels were found in kidney (0.036 mg/kg), liver (0.025 mg/kg) and renal fat (0.024 mg/kg).

In the metabolism study on ruminants, extraction rates are sufficient (>90%TRR) in omental and renal fat and deemed acceptable in renal fat and kidney (>70%TRR). Only 63 % TRR was extracted from liver. Even if further characterisation was not deemed necessary, TRR was extracted and analysed in muscle (58.8% TRR extracted) and milk (107.4% TRR extracted). Parent compound and its metabolite AE F153745 were identified in all these fractions. Parent was the major compound in subcutaneous fat

(61.6%), liver (49.3%), muscle (34.4%) and omental fat (11.1%). Metabolite AE F153745 was the major compound in milk (61.7 %), kidney (53%) and renal fat (35.2%). No other compound was identified in any fraction."

And in EFSA Journal 2016;14(3):4421:
"*Although not triggered as the level of 0.004 mg/kg bw/day was not reached for any livestock species, two metabolism studies were conducted.*"
"Metabolism studies are available in cow and hen with phenyl labelled foramsulfuron only. The two major residues identified were parent (11–62% TRR) and AE F153745 (21–62% TRR), indicating that cleavage of the sulfonylurea bridge occurred to a considerable extent in the animals. Although a pyrimidinyl radiolabel study with foramsulfuron is not available it can be assumed that also AE F092944 might have formed a significant proportion of the residue in animal commodities under these conditions. A data gap was not triggered for a pyrimidinyl radiolabel study in livestock, and therefore the adequacy of the animal residue definitions proposed by the RMS was not further discussed in the peer review."

Conclusion on metabolism in livestock

Sufficient data have been provided to acknowledge the metabolism of foramsulfuron in ruminant and poultry.

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	Ruminants
	Poultry
Time needed to reach a plateau concentration	120 h in milk
	10 days for egg yolk, 8 days for egg white
Animal residue definition for monitoring	Foramsulfuron (EFSA, 2016)
Animal residue definition for risk assessment	Foramsulfuron and AE F153745 for milk, kidney and eggs (EFSA, 2016)
Conversion factor	Variable depending on commodity (tissue), ranging from 1.4 to 17* based on metabolism studies. (EFSA, 2016)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

*The applicant has calculated the CF based on the metabolism studies and found values of 2.8 (milk), 4.2 (egg) and 4.8 (kidney).

7.2.3 Magnitude of residues in plants (KCA 6.3)

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application to support the proposed cGAP. A package of field trials was performed to determine the magnitude of the metabolite AE F092944 residues in sugar beet and to clarify the consumer risk assessment including potential transfer to livestock matrices (see EFSA 2016; 14(3):4421 and §7.1.2.1)

These studies are summarized in the table below. The detailed assessment of these studies is presented in Appendix 2.

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of FSN+TCM OD 80 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
Sugarbeet	Trials* 12-2138 13-2000	N-EU	Trials GAP: 1 x 50 g a.s./ha, BBCH 14-18, sampling at harvest, outdoor, formulation type OD E: 9 x <0.01 RA: 9 x <0.01 Studies M-480852-01-1, M-494921-01-1		E: 0.01 RA: 0.01			
	Trials* 12-2139 13-2009	N-EU	Trials GAP: 2 x 25 g a.s./ha, BBCH 14-15 & 18-19, sampling at harvest, outdoor, formulation type OD E: 8 x <0.01 RA: 8 x <0.01 Studies M-480864-01-1, M-496362-01-1		E: 0.01 RA: 0.01			
	New trials 17-2033**	N-EU	Trials GAP: 50 g a.s./ha, BBCH 18, sampling at harvest, outdoor, formulation type OD E: 4 x <0.01 RA: 4 x <0.01 Study M-642771-01-1		E: 0.01 RA: 0.01			
	Overall supporting data for cGAP	N-EU	cGAP: 1x 50 or 2 x 25 g a.s./ha, BBCH 10-18, PHI not needed, outdoor, formulation type OD E: 21 x <0.01 RA: 21 x <0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.01	Yes

* Source of EU MRL: Commission Regulation (EU) No 289/2014 of 21 March 2014

Trials*: these trials were already submitted and therefore reviewed in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South), GER (zRMS, Central) in 2015 in

order to support the 1st registration of the product in each zone. They are reported in this document as they are considered to be reviewed via a zonal process but not via an EU peer reviewed process.

** Analysis of metabolite AEF 092944.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on sugar beet and fodder beet are considered acceptable, for the outdoor uses. The data submitted show that no exceedance of the EU MRL will occur. The uses are considered acceptable.

Moreover, regarding AE F092944, the results of the new trials showed that no residues above the LOQ were observed in any parts of the plant, whether in body or in leaves. Thus, as no AE F092944 residues are expected in food (such as grain) or animal feeds (such as forage), there is no significant consumer exposure to be expected, as AE F092944.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

In the following table the results of the dietary burden calculation which may arise from all authorised uses for foramsulfuron are summarised following the guidance given in pesticides_mrl_guidelines_animal_intake_mrl_2015_en.pdf and using the official spreadsheet pesticides_mrl_guidelines_animal_model_2017_en.xls published on the DG SANTE website.

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorised within the zone and/or evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : foramsulfuron				
Corn, field forage/silage	0.01	Median residue (EFSA Journal 2016;14(3):4421)	0.01	Median residue (EFSA Journal 2016;14(3):4421)
Sugar beet tops	0.01	Median residue (new data submitted in this dRR)	0.016	Highest residue (new data submitted in this dRR)*
Beet, mangel fodder	0.01	Median residue (new data submitted in this dRR)	0.016	Highest residue (new data submitted in this dRR)*
Corn, field grain	0.01	Calculation with default PF	-	-
Corn, pop grain	0.01	Calculation with default PF	-	-
Sugar beet, dried pulp	0.01	Calculation with default PF	-	-
Sugar beet, ensiled pulp	0.01	Calculation with default PF	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet, molasses	0.01	Calculation with default PF	-	-
Corn, field Milled by-pdts	0.01	Calculation with default PF	-	-
Corn, field hominy mial	0.01	Calculation with default PF	-	-
Corn, field Gluten feed	0.01	Calculation with default PF	-	-
Corn, field grain Gluten meal	0.01	Calculation with default PF	-	-
Distiller's grain dried	0.01	Calculation with default PF	-	-

[1] input value for mais forage=0.01 mg/kg based on 4 residue trials 13-2160 performed after EFSA 2012 and included in the AIR submission as additional data validated by EFSA 2016
*ref study: M-641993-01-1 (residue trials: 17-2142)

Table 7.2-10: Results of the dietary burden calculation (model 2017)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,004	0,004	0,10	0,11	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Cattle (dairy only)	0,004	0,004	0,10	0,11	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Sheep (all diets)	0,004	0,004	0,09	0,10	Lamb	Beet, sugar	dried pulp	Yes
Sheep (ewe only)	0,001	0,003	0,03	0,10	Ram/Ewe	Beet, sugar	dried pulp	No
Swine (all diets)	0,001	0,001	0,06	0,06	Swine (breeding)	Beet, sugar	dried pulp	No
Poultry (all diets)	0,002	0,002	0,02	0,03	Poultry layer	Beet, sugar	tops	No
Poultry (layer only)	0,002	0,002	0,02	0,03	Poultry layer	Beet, sugar	tops	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The calculated residue burdens for different groups of livestock do not exceed the trigger value of 0.004 mg/kg bw/day, except for lamb with a value slightly higher (with a maximum at 0.00421 mg/kg bw/day) and for cattle (with a maximum at 0.00423 mg/kg bw/day). According to the ruminant metabolism study (M-191251-01-1), foramsulfuron and its metabolites are very poorly absorbed. The residue levels (Total Residue) in all edible tissues were found at concentrations which ranged between 0.004 to 0.036 mg eq/kg tissue. Taking into account that the dose level of the metabolism study is about 100 higher than the maximum dietary burden, we do not expect to find measurable residue levels in milk and other edible tissues. Moreover for processed items, the calculation of the dietary burden was performed by considering

the default PF (processing factor) which are regarded as worst cases. Hence, no livestock feeding study is needed.

Further information: Livestock exposure to guanidine via the sugar beet leaves
The metabolism study on sugar beet (M-454046-02-1) showed that the major metabolite guanidine was recovered at 39.6 % of the TRR. Even if the pourcentage is relatively high, the concentration is very low, equivalent to 0.013 mg/kg expressed as foramsulfuron or 0.0017 mg/kg expressed as guanidine. In order to evaluate the livestock exposure to this metabolite, a dietary burden has been calculated for guanidine (for more details, refer to the position paper, M-636830-01-1,"Conviso One : use of fodder and sugar beet leaves for animal feeding" in Appendix 2). As there are no experimental residue data for guanidine, the calculation was based on the metabolism of pyrimidinyl-2-14C]-foramsulfuron with an OD 050 formulation, with 2 applications: 28.8 g a.s./ha at BBCH 12-14 and 28.8 g a.s./ha at BBCH 14-18 in sugar beet. In fact, we can consider that the GAP is consistent with the intended cGAP, 2 x 25g/ha FSN at BBCH 10-14 & 12-18 and also with the single application cGAP, 50g/ha FSN at BBCH 10-18 due to the short interval between the 2 applications (14 days) in comparison with the interval between the last treatment and the harvest (98 days).The results showed that the dietary burden is very low compared to the trigger value of 0.004 mg/kg. Therefore after the use of foramsulfuron, it is expected that livestock will not be significantly exposed to guanidine. Consequently a transfer of residue of guanidine in animal commodity is deemed unlikely

Conclusion on the magnitude of residues in livestock
Therefore the use of foramsulfuron in sugar beet/fodder beet according to the recommended GAP is not likely to result in significant residues in any of these animal commodities. Moreover, the assessment of the guanidine metabolite for the use on sugar beet and fodder beet demonstrated that livestock are not significantly exposed to the guanidine metabolite.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Based on the previous model of the dietary burden calculation, EFSA 2016 stated that the livestock feeding studies are not triggered for foramsulfuron (dietary burden <0.004 mg/kg bw/day). By considering the new model, the results were slightly different. For the reasons exposed above, residue levels in ruminant commodities are expected to remain below the LOQ of 0.01 mg/kg in milk and other edible tissues. Therefore, it can be concluded that no livestock feeding study is needed.

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

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

The use of FSN+TCM OD 80 in sugar beet/fodder beet according to the intended GAP does not result in significant residues (i.e. > 0.1 mg/kg) of foramsulfuron in sugar beet root/fodder beet at harvest; residues were below the limit of quantification (0.01 mg/kg). In addition, dietary risk assessments show that the TMDI for sugar beet is <10% of the ADI. Therefore, studies on industrial processing and/or household preparation are not necessary.

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

Investigations of the effect of industrial and/or household processing were not conducted and are not obligatory in view of the very low residues in sugar beet roots.

7.2.6 Magnitude of residues in representative succeeding crops

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

As stated by EFSA 2016, field rotational crop studies are not required as no residues are expected in succeeding crops according to confined rotational studies. No new data submitted in the framework of this application.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FSN+TCM OD 80. Therefore, other special studies are not needed.

Question regarding the potential residues in honey: a position paper (M-683705-01-1) giving an overview on the potential occurrence of residue on honey following the use Conviso One in sugar beet is presented in Appendix 2.

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).

Reference value	Source	Year	Value	Study relied upon	Safety factor
Foramsulfuron - Parent compound					
ADI	EFSA Journal 2016; 14(3):4421	2016	0.25 mg/kg bw/day	2-year rat study	100
ARfD	EFSA Journal 2016; 14(3):4421	2016	Not allocated	-	-

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Calculation was performed taking into account all the food items for which European MRLs have been set, including a number of crops that are not likely to be treated with foramsulfuron (as this compound is not registered for use in these crops). TMDI calculation was performed using the MRLs given in the following table.

Table 7.2-11: input values used for TMDI calculation of foramsulfuron

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Foramsulfuron		
Citrus	0.01	MRL*
Tree nuts	0.02	MRL*
Pome fruit	0.01	MRL*
Stone fruit	0.01	MRL*
Berries & small fruit	0.01	MRL*
Miscellaneous fruit	0.01	MRL*
Root and tuber vegetables	0.01	MRL*
Bulb vegetables	0.01	MRL*
Fruiting vegetables	0.01	MRL*
Brassica vegetables	0.01	MRL*
Lettuce and other salad plants including Brassicacea	0.01	MRL*
Spinach & similar	0.01	MRL*
Vine leaves	0.01	MRL*
Water cress	0.01	MRL*
Witloof	0.01	MRL*
Herbs	0.02	MRL*
Legume vegetables	0.01	MRL*
Stem vegetables	0.01	MRL*
Fungi	0.01	MRL*
Sea weeds	0.01	MRL*
Pulses, dry	0.01	MRL*
Oilseeds and oilfruits	0.02	MRL*
Cereals (including maize)	0.01	MRL*
Tea, coffee, herbal infusion and cocoa	0.05	MRL*
Hops	0.05	MRL*
Spices seeds, fruits and berries, bark	0.05	MRL*
Spices roots or rhizome liquorice, ginger, turmeric, others	0.05	MRL*
Spices buds, flower stigma, aril	0.05	MRL*
Sugar plants (including sugar beet root)	0.01	MRL*
Tissue of animal origin, milk, bird eggs	0.01	MRL*
Honey	0.05	MRL*
Amphibians and reptiles	0.01	MRL*
Terrestrial invertebrate animals	0.01	MRL*
Other terrestrial animal products	0.01	MRL*

* MRL according to Regulation (EC) No 289/2014 (22 March 2014). All MRLs at Limit of Quantification.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
As shown in the following table, the highest TMDI calculated for foramsulfuron represented 0.5% of the ADI, which denotes considerable margins of safety.

Table 7.2-12: Consumer risk assessment0

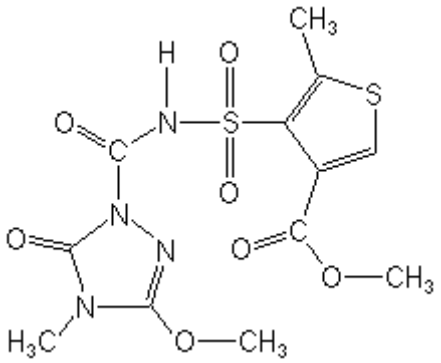
TMDI (% ADI) according to EFSA PRIMo. V3.1	0.5 % (based on NL toddler)

The proposed uses of foramsulfuron in the formulation FSN+TCM OD 80 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Thiencarbazone-methyl

General data on thiencarbazone-methyl are summarized in the table below (last updated April 2020)

Table 7.3-1: General information on thiencarbazone-methyl

Active substance (ISO Common Name)	thiencarbazone-methyl
IUPAC	methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate
Chemical structure	
Molecular formula	$C_{12}H_{14}N_4O_7S_2$
Molar mass	390.44 g/mol
Chemical group	Sulfonyl-amino-carbonyl-triazolinone
Mode of action (if available)	ALS inhibitor, systemic, absorbed by roots and leaves, contact and residual action
Systemic	Yes
Company (ies)	Bayer Crop Science Division
Rapporteur Member State (RMS)	United Kingdom (former RMS) France (newly appointed RMS)
Approval status	Approved Commission Implementing Regulation (EU) No. 145/2014 dated 14th February 2014. The entry into force is 1st July 2014.
Restriction (e.g. is restricted to use as "...")	None
Review Report	SANCO/12602/2013-Final
Current MRL regulation	Default MRL of 0.01 mg/kg according to Art. 18(1)(b) Reg. 396/2005
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Journal 2013;11(7):3270
EFSA Journal: Conclusion on article 12	EFSA Journal 2020; 18(1):5957
Current MRL applications on intended uses	Default MRL of 0.01 mg/kg (Reg. (EU) 396/2005) Cereal grain, sugar beet root

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			
Thiencarbazone-methyl (BYH 18636) and its metabolite BYH18636-N-desmethyl and BYH18636-MMT-glucoside			
Corn/maize kernels, potato tuber	High starch content	26 months	Storage up to 12 months: MR-186/05 Brumhard, B.; Wolters, A, 2007 (M-284222-01-2); storage up to 24 months (nominal): MR-07/229 Brumhard, B.; Wolters, A., 2008 (M-304143-01-1) DAR, UK, April 2012 EFSA Journal 2013;11(7):3270 EU peer reviewed
Lettuce, tomato, maize forage	High water content		
Soybean seed	High oil content		
Corn/maize stover	Dry matrices		
Lettuce, tomato, maize forage	High water content		
Soybean seed	High oil content		
Corn/maize stover	Dry matrices		
Animal Products			
BYH18636-sulfonamide			
Ruminant	Milk, fat	2 months	xxx; 2007; MR-06/095 (M-286140-01-2*) DAR, UK, April 2012 EFSA Journal 2013;11(7):3270 EU peer reviewed

*Investigations of storage stability were done as a part of the cattle feeding study. Samples of liver, kidney and muscle were analysed for BYH 18636-sulfonamide within 23 days of collection. Therefore, freezer storage stability data were not required for these matrices

Conclusion on stability of residues during storage

The maximum storage period of deep-frozen samples before analysis was of 174 days and is covered by the storage stability study. Storage stability data in plant matrices cover the intended uses of FSN+TCM OD 80 on sugar beet.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The storage stability of residues of BYH 18636 in extracts was tested during methods. Since the validity of the methods depends on factors, such as reproducibility for interruption during the work up process, it has to be concluded that the storage of samples in extracts is always guaranteed. Additionally, when conducting analyses of regular samples, the whole analytical procedure is routinely monitored by recoveries with each sample set (DAR, RMS UK, December 2008).

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

The available studies are summarized in the table below. The detailed assessment of these studies is presented in the table below.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G*	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Corn/ maize	[dihydrotriazole-3-^{14}C] and [thiophene-4-^{14}C]	Foliar treatment, F	0.048 pre emergence	1	forage: 104 stover & kernels: 153	With the safener cyprosulfamide	Bongartz, R.; 2005, M-263042-01-2, report MEF-05/004 Bongartz, R.; 2005, M-263405-01-2, report MEF-05/003 DAR, UK, April 2012 EU peer reviewed
Cereals	Corn/ maize	[dihydrotriazole-3-^{14}C] and [thiophene-4-^{14}C]	Foliar treatment, F	0.012 early post emergence	1	forage: 70 and 71 stover & kernels: 109 and 110		Bongartz, R.; 2005, M-266796-02-2, report MEF-04/182 Bongartz, R.; 2005; M-256647-01-2, report MEF-04/181 DAR, UK, April 2012 EU peer reviewed
Cereals	Corn/ maize	[dihydrotriazole-3-^{14}C] and [thiophene-4-^{14}C]	Foliar treatment, F + 1 soil treatment	0.032 + 0.016 early post emergence	1	forage: 46 stover & kernels: 95	With the safener isoxadifen-ethyl	Bongartz, R.; 2005, M-267247-01-2, report MEF-05/006 Bongartz, R., 2006, M-268530-01-2, report MEF-05/005 DAR, UK, April 2012 EFSA Journal 2013;11(7):3270 EU peer reviewed
Cereals	Wheat	[dihydrotriazole-3-^{14}C] and [thiophene-4-^{14}C]	Foliar treatment, F	0.016/0.017 early post emergence	1	Forage: 16, hay: 54, straw &	With the safener mefenpyr-diethyl	Sur, R., 2005, M-267443-01-2, report MEF-05/041

						grain: 89		Sur, R., 2005, M-268145-01-2, report MEF-05/042 DAR, UK, April 2012 EFSA Journal 2013;11(7):3270 EU peer reviewed
Root and tuber vegetables	Sugar beet	[thiophene-4-^{14}C]	foliar treatment, F	16 (1X) 31 (2X) early post emergence	2	Roots & leaves: 96 (1X) 97 (2X)	two experiments conducted: at 1X rate and at 2X overdose rate	Justus, K., 2012, M-442848-02-1, report MEF-11/905 France, 2019 EFSA Journal 2020;18(1):5957 EU peer-reviewed
		[dihydrotriazole-3-^{14}C]	foliar treatment, F	16 (1X) 32 (2X) early post emergence	2	Roots & leaves: 97 (1X) 98 (2X)	two experiments conducted: at 1X rate and at 2X exaggerated rate	Justus, K., 2012, M-442854-02-1, report MEF-11/872 France, 2019 EFSA Journal 2020;18(1):5957 EU peer-reviewed

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

The two metabolism studies (sugar beets) were conducted with [thiophene-4-^{14}C]thiencarbazone-methyl and [dihydrotriazole-3-^{14}C]thiencarbazone-methyl and were submitted in 2015 at zonal level to support the 1st registration the product.
These data are reported in this document as being EU data (EU peer reviewed) as they were submitted to RMS (FRA) to support Art. 12.1 of EU Regulation No 396/2005 by EFSA (refer to Evaluation Report prepared by RMS France – 2019 and EFSA Journal 2020;18(1):5957).

Summary of plant metabolism studies reported in the EU

Conclusion (RMS), DAR, April 2012:
The metabolism of BYH18636 has been fully investigated in plants using labelling in both the dihydrotriazole and thiophene parts of the molecule. The metabolic pathway is identical in corn, wheat and in the rotational crops wheat, turnip, soybean and Swiss chard, and proceeds through oxidative N-demethylation of the parent compound and hydrolysis steps. The identified metabolites are present at very low levels. Maximum residues in edible plant commodities were 0.004 mg/kg for BYH18636 and BYH18636-MMT-glucoside (M22) in soybean seeds and 0.003 mg/kg for BYH18636-N-desmethyl (M07) in primary wheat grain. All other metabolites in any edible plant commodity were ≤ 0.001 mg/kg, including corn kernels and wheat grain. Maximum residues in non-edible plant commodities were 0.17 mg/kg for BYH18636-N-desmethyl (M07) in primary wheat forage and 0.06 mg/kg for BYH18636-MMT (M21) in wheat straw. All other metabolites were ≤ 0.04 mg/kg in any non-edible commodity of corn and wheat. The nature of the residue as a result of primary crop treatment with thiencarbazone-methyl (BYH18636) has been investigated in maize. BYH18636 was applied pre and post emergence. All compounds in the RAC consumed directly by humans (grain and corn) and in the RAC consumed only by livestock (forage and stover) were < 0.01 mg/kg.*

* comment by the applicant: This is obviously a typo and BYH18636-MMT-glucoside (M22) is meant (see DAR, RMS UK, April 2012, study evaluations part of residues)

EFSA Journal 2013;11(7):3270

Metabolism in plants was investigated in cereal only, on maize and wheat, using ^{14}C-thiencarbazone-methyl either labelled on dihydrotriazole or the thiophene moiety. Three different application patterns were investigated on maize; a single pre-emergence application at 48 g/ha, an early post-emergence application at stage BBCH 13-16 at 12 g/ha (equivalent to field treatment at ca 48 g/ha) and a post-emergence application at stage BBCH 16 with an additional soil application at the 12 leaf stage, amounting to a total rate of 48 g/ha. A single post-emergence application at 15 g/ha at BBCH stage 13-15 was studied on wheat.

Low radioactive residue levels (TRR) were detected in all maize matrices, in the range of 0.001 to 0.083 mg/kg and therefore metabolites were all detected at very low levels, below 0.010 mg/kg. Following pre-emergence application, the metabolic profile was dominated by the metabolites resulting from the cleavage of the parent molecule and containing either the dihydrotriazole or the thiophene moiety. The dihydrotriazole metabolite BYH 18636-MMT was characterised up to 60 % TRR in maize forage and stover (0.003-0.010 mg/kg) and the thiophene metabolite BYH 18636-hydroxy-sulfonamide-carboxylic acid, up to 23 % TRR in stover (0.003 mg/kg). Following post-emergence application, the radioactivity in maize was distributed between the dihydrotriazole and thiophene metabolites identified under pre-emergence application and metabolites containing the initial parent structure, such as BYH 18636-N-desmethyl and BYH 18636-carboxylic acid, all accounting individually for less than 12 % TRR and less than 0.009 mg/kg. Thiencarbazone-methyl was only detected in the forage and stover samples, at the maximum level of 0.007 mg/kg.*

Higher TRRs were observed in wheat following post-emergence application, up to 0.014 mg/kg in grain and 0.39 mg/kg in the other matrices. Parent thiencarbazone-methyl was only detected in significant proportions and levels in the forage samples collected shortly after application (ca 15 % TRR, 0.05 mg/kg). In contrast to maize, the metabolism was dominated by the compounds containing the entire structure of the parent compound, especially the BYH 18636-N-desmethyl metabolite that accounted for 45 % TRR in forage (0.17 mg/kg), 15 % TRR in straw (0.05 mg/kg) and 13-30 % TRR in grain (0.003 mg/kg). In addition, the dihydrotriazole and thiophene metabolites were also identified in wheat, up to 22 % TRR (0.06 mg/kg) for the BYH 18636-MMT-glucoside metabolite and up to 10 % TRR (0.04 mg/kg) for the BYH 18636-hydroxy-sulfonamide-carboxylic acid metabolite in straw. Similar metabolic profile was observed in the rotational crop studies where thiencarbazone-methyl, BYH 18636-N-desmethyl-hydroxy, BYH 18636-MMT and BYH 18636-MMT-glucoside were identified as the major components of the radioactive residues.

Considering that BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were observed in significant proportions and levels in the wheat matrices, the residue definition for risk assessment was proposed as the sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside expressed as thiencarbazone-methyl. For monitoring, the residue definition was limited to the parent compound only.

* comment by the applicant: This is obviously a typo and BYH18636-MMT-glucoside (M22) is meant (see DAR, RMS UK, April 2012, study evaluations part of residues)

EFSA Journal 2020;18(1):5957

In sugar beet and for each label, two experiments with two foliar applications each at BBCH 12–14 and BBCH 14–18 were performed. The first experiment was performed with two applications of 16 g a.s./ha (just above 1N the cGAP for sugar beet and fodder beet) and the second one with two applications of 31–32 g a.s./ha. Proportions of TRR were similar for both application rates, with highest absolute levels of residues found in the 2N rate experiment.
After two foliar applications, thiencarbazone-methyl was moderately metabolised and remained the major component identified in both labels, representing 38–59% TRR (0.01–0.026 mg eq/kg) in the roots

and 12–14% TRR (0.016–0.045 mg eq/kg) in the leaves. In the dihydrotriazole label studies, BYH 18636-MMT and BYH 18636-MMT-glucoside were significant in leaves, with BYH 18636-MMT-glucoside being the major compound accounting for 39–41% TRR (0.046–0.083 mg eq/kg). In the thiophene label, the major metabolites in roots and leaves were BYH 18636-hydroxy-sulfonamideglucoside and BYH 18636-hydroxy-sulfonamide-carboxylic acid-glucoside, representing up to 16% TRR (0.02 mg eq/kg) and 29% TRR (0.10 mg eq/kg), respectively (France, 2019). No new metabolites were identified with respect to the ones found in the metabolism studies performed in cereals.
The metabolic pathway of thiencarbazone-methyl was sufficiently elucidated, and it is concluded that the metabolic pattern of tuber and root vegetables (sugar beet) is covered by that in cereals (wheat and maize).

Conclusion on metabolism in primary crops

All metabolites and metabolic pathways identified in the sugar beet studies were also observed in the already evaluated cereals metabolism studies on corn and wheat. Translating the results of the sugar beet metabolism studies to the results of the residue field trials (see chapter 7.2.3 Magnitude of residues in plants), all metabolites except BYH 18636-MMT-glucoside (one result at 0.012 mg/kg in leaves) are calculated to occur at levels below 0.01 mg/kg following the application rates of the GAPs. Therefore it is concluded that the residue definitions established for cereals (EFSA Journal 2013;11(7):3270), namely the sum of thiencarbazone-methyl, BYH 18636-N-desmethyl, and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl, for risk assessment; and thiencarbazone-methyl for monitoring, are also applicable for the root and tuber vegetables group.

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

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	Turnips	[dihydrotriazole-3-^{14}C]-BYH 18636 and [thiophene-4-^{14}C]-BYH 18636	F	0.045 on bare soil	180, 270	Leaves & roots: 266 and 340		Justus, K., 2006, M-277504-01-2, report MEF-06/215 Justus, K., 2006, M-275070-01-2, report MEF-05/297 DAR, UK, April 2012 EU peer reviewed
Pulses and oilseeds	Soybean				90, 270	Forage: 125 and 307, hay: 155 and 337, seeds: 202 and 368		
Cereals	Wheat				90, 270	Forage: 116 and 299, hay: 155		

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	
						and 350, straw & grain: 221 and 398		
Root and tuber vegetables	Turnips	[dihydrotriazole-3-^{14}C]-BYH 18636 and [thiophene-4-^{14}C]-BYH 18636	F	0.030 on bare soil	90, 269	Leaves & roots: 202 and 337		Justus, K., 2006, M-278990-01-2; report MEF-06/258 Justus, K., 2006, M-277462-01-2, report MEF-05/539 DAR, UK, April 2012 EU peer reviewed
Pulses and oilseeds	Soybean				90, 269	Forage: 128 and 304, hay: 156 and 328, seeds: 196 and 364		
Cereals	Wheat				90, 269	Forage: 118 and 303, hay: 171 and 338, straw & grain: 230 and 384		
Root and tuber vegetables	Turnips	[dihydrotriazole-3-^{14}C]-BYH 18636 and [thiophene-4-^{14}C]-BYH 18636	F	0.015 on bare soil	29,118, 247	Leaves & roots: 111, 184 and 317		Reiner, H., 2005, M-261209-02-2, report MEF-05/023 Reiner, H., 2005, M-260471-01-2, report MEF-05/024 DAR, UK, April 2012, EFSA 2013** EU peer reviewed
Leafy vegetables	Swiss chard				29,118, 247	92, 161 and 307		
Cereals	Wheat				29,118, 247	Forage: 71/72, 160 and 303, hay: 94, 198 and 338, straw & grain: 118, 247 and 373		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)
** Studies were summarized but not evaluated in the DAR (RMS UK, April 2012). However, the data of the studies were included in the evaluation of the EFSA conclusion on the peer review (2013).
† Sampling DAT data taken from the study report

Summary of plant metabolism studies reported in the EU

DAR, RMS UK, April 2012
Many metabolites are present in both primary crops and rotational crops. An exception are six metabolites that were not detected in edible parts of rotational crops but were present in edible parts of primary crops (BYH 18636-hydroxy-glycoside, BYH 18636-hydroxy-sulfonamide-glyceric acid ester, BYH 18636-N-desmethyl-glycoside, BYH 18636-N-desmethyl-hydroxy-glycoside, BYH 18636-OMT and BYH 18636-OMT-glycoside, and BYH 18636-thienosaccharine). However, the levels of these metabolites in edible parts of primary crops are extremely low (≤ 0.001 mg/kg) and at the limit of detection. One of these metabolites is present in non-edible commodities of rotational crops.

On the other hand, only one metabolite (BYH 18636-hydroxy-sulfonamide) was detected in edible parts of some rotational crops but not at all in edible parts of primary crops. However, this metabolite was found in non-edible parts of primary crops and levels in rotational wheat grain and turnip roots were < 0.001 mg/kg. Thus, all metabolites that were detected in rotational crops were also seen in primary corn and/or wheat.

Concentrations of metabolites in edible parts of primary and rotational crops were very similar, mostly ≤ 0.001 mg/kg. BYH 18636-MMT-glucoside was present at 0.004 mg/kg in rotational soybean seeds and at a maximum of < 0.001 mg/kg in primary wheat grain and corn kernels. However, because both levels are extremely low and close to the detection limit, this difference is not significant. In nonedible commodities, levels of metabolites are typically lower in rotational crops than primary crops. For example, residues of BYH 18636-N-desmethyl are much lower in rotational wheat (maximum 5.1 % TRR and 0.001 in wheat forage; ≤ 0.001 in any wheat RAC) than in target wheat crops (maximum 47.2 %, 0.17 mg/kg in wheat straw). As a summary, levels of metabolites in rotational crops are in the same order of magnitude or lower than in primary crops.

Primary crops are exposed to BYH 18636 on the leaves and to parent compound plus metabolites in the soil. For rotational crops, the only way of uptake is via soil. Major soil metabolites are BYH 18636-carboxylic acid, BYH 18636-MMT, BYH 18636-sulfonamide and BYH 18636-sulfonamide-carboxylic acid. None of these metabolites is present in rotational crops at elevated levels compared to primary crops (neither in edible nor in non-edible commodities). In fact, all major soil metabolites are present in both rotational and primary crops.

Although the only way of uptake in rotational crops is via soil, the metabolic pathway and the levels of metabolites are not determined by the levels in soil but by quick and comprehensive metabolic processes in plants.

In terms of pathway and concentrations, plant metabolism is identical in primary and rotational crops.

The plant residue definition (including BYH 18636, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside) is valid for primary crops and rotational crops.

EFSA Journal 2013;11(7):3270
Confined rotational crops: Maximum residue of a metabolite in edible matrices 0.004 mg eq/kg for BYH 18636-MMT-glucoside in soya seeds. All other metabolites ≤ 0.001 mg/kg. In non-edible commodities, the maximum concentration 0.043 mg eq/kg for BYH 18636-MMT-glucoside. All other metabolites ≤ 0.011 mg/kg.
A similar (comment by the applicant: as compared to primary wheat and maize) *metabolic profile was observed in the rotational crop studies where thiencarbazone-methyl, BYH 18636-N-desmethyl-hydroxy, BYH 18636-MMT and BYH 18636-MMT-glucoside were identified as the major components of the radioactive residues.*

Conclusion on metabolism in rotational crops

Based on the similar metabolism observed in the primary and the rotational crops, it is concluded that the

residue definitions for the primary crops are also applicable for rotational crops.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data are submitted in the framework of this application.
Studies on the effects of industrial processing and household preparations on the nature and levels of the residue are not required, as residue levels in sugar beet are below the LOQ (<0.01 mg/kg for each analyte, or <0.03 mg/kg of total residues in parent equivalents), thus also below the trigger value of 0.1 mg/kg. In addition, dietary risk assessment shows that the TMDI is <10% of the ADI (EFSA Journal 2020;18(1):5957).

Conclusion on nature of residues in processed commodities

Data on nature of the residues in processed commodities are not required.

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	Root and tuber vegetables (sugar beet) Cereals (Wheat, corn/maize)
Rotational crops covered	Turnips, soybean, wheat, Swiss chard
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	Thiencarbazone-methyl (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)
Plant residue definition for risk assessment	Sum of thiencarbazone-methyl, BYH18636-N-desmethyl and BYH18636-MMT-glucoside, expressed as thiencarbazone-methyl (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)
Conversion factor from enforcement to RA	Not necessary (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)

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 sampling	
EU data								
Lactating ruminants	Goat	[dihydrotriazole-3-^{14}C]-BYH 18636 and [thiophene-4-^{14}C]-BYH 18636	1	2	5	Milk	twice daily	xxx., 2006, M-278516-01-2, report MEF-05-261 xxx., 2006, M-276289-01-2, report MEF-05/307 DAR, UK, April 2012 EU peer reviewed
						Urine and faeces*	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[dihydrotriazole-3-^{14}C]-BYH 18636 and [thiophene-4-^{14}C]-BYH 18636	6	2	14	Eggs	daily	xxx., 2006, M-279414-03-2, report MEF-05/260 xxx, 2006, M-279676-03-2, report MEF-05/259 EU agreed DAR, UK, April 2012 EU peer reviewed
						Excreta*	daily	
						Tissues	at sacrifice	

* Urine, faeces and excreta were collected and analysed, however, these matrices are not commodities.

Summary of animal metabolism studies reported in the EU

DAR, RMS UK, April 2012

The metabolism of thiencarbazone-methyl has been fully investigated in livestock and proceeds mainly through cleavage of the parent compound, oxidative N-demethylation and hydrolysis steps. The identified metabolites are present at very low levels.

The metabolism in laying hens and lactating goat is very similar. Following the administration of dihydrotriazole-labelled parent compound, the most abundant metabolites and the key metabolites in the pathway, BYH 18636-MMT (M21) and BYH 18636-methyl carbamate (M23), were present in both hen and goat. Following the administration of thiophene-labelled parent compound, BYH 18636-sulfonamide (M15) and BYH 18636-sulfonamide-carboxylic acid (M04) were major residues after cleavage of the parent molecule. The key metabolites in the pathway are also present in the rat, i.e. BYH 18636-carboxylic acid (M01), BYH 18636-sulfonamide-carboxylic acid (M03), BYH 18636-thienosaccharine (M05), BYH 18636-MMT (M21) and methyl carbamate (M23). It can be expected that the metabolism in other farm animals does not differ and a study in pigs is not required.

Residues of BYH 18636 are expected to be extremely low in animal tissues, milk and eggs when livestock is fed with feed produced according to the GAP proposed in the EU. Metabolism studies in poultry and

ruminants demonstrate that residues above 0.01 mg/kg will not occur in edible tissue from the dietary burden resulting from the proposed application rate in the EU.

Conclusion on metabolism in livestock

EFSA Journal 2013;11(7):3270
Animal metabolism studies were provided although the intakes by livestock were calculated to be far below the trigger value of 0.1 mg/kg DM. Studies were conducted on poultry and goat at the dose rate of 2 mg/kg bw and using the two labelled forms of ^{14}C-thiencarbazone-methyl. The parent thiencarbazone-methyl was extensively metabolised and residues in all matrices mainly composed of the triazole and thiophene metabolites resulting from the cleavage of the parent at the sulfonamide bond. TRRs in the edible material were significantly higher for the triazole label, indicating that after cleavage of the parent the metabolites containing the thiophene moiety were more intensively eliminated. Since the metabolite BYH 18636-MMT was identified as the major component of the radioactive residues, accounting for 49-70 % and 23-49 % TRR in all poultry and goat matrices respectively, the residue definition for monitoring and risk assessment was proposed as the sum of thiencarbazone-methyl and BYH 18636-MMT expressed as thiencarbazone-methyl. Having regard to the insignificant intakes by livestock, no MRLs were proposed for products of animal origin.

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	3 days in milk
	7 days in eggs
Animal residue definition for monitoring	Sum of thiencarbazone-methyl and BYH18636-MMT expressed as thiencarbazone-methyl (EFSA Journal 2013;11(7):3270)
Animal residue definition for risk assessment	Sum of thiencarbazone-methyl and BYH18636-MMT, expressed as thiencarbazone-methyl (EFSA Journal 2013;11(7):3270)
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat-soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

Table 7.3-8: Comparison of intended GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between applications	Growth stage at last application	PHI (days)
Intended cGAP (from 22 up to 31*) Sugar/fodder beet, N-EU	1	0.030	N/A	BBCH 10-18	N/A
Intended cGAP (from 32 p to 40*) Sugar/fodder beet, N-EU	2	0.015	10 days	BBCH 12-18	N/A

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

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

No new studies on the magnitude of residue have been submitted by the applicant in the framework of this application. The studies, already evaluated at EU level, are summarized in the table below.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of FSN+TCM OD 80 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
Sugar beet	EU data Trials* 12-2138 13-2000	N-EU	Trials GAP: 1 × 0.03 kg a.s./ha, BBCH 14-18, sampling at harvest, outdoor E: 9× <0.01 RA: 9× <0.03 Studies M-480852-01-1 and M-494921-02-1	N/A				
	EU data Trials* 12-2139 13-2009	N-EU	Trials GAP: 2 × 0.015 kg a.s./ha, BBCH 14-15 & 18-19, sampling at harvest, outdoor E: 8× <0.01 RA: 8× <0.03 Studies M-480864-01-1 and M-496362-01-1					
	Overall supporting data for cGAP	N-EU	cGAP: 1 × 30 or 2 × 15 g thiencarbazone-methyl/ha, BBCH 10-18, PHI not needed, outdoor E : 17× <0.01 RA: 17× <0.03	E: <0.01 RA: <0.03	E: <0.01 RA: <0.03	0.010	0.01	Yes

* Source of EU MRL: Reg. (EC) No. 396/2005 (default MRL according to Art. 18[1] [b])

Trials*: data already submitted and therefore evaluated in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South) and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as being EU data as they were submitted to RMS (FRA) to support Art. 12.1 of EU Regulation No 396/2005 (refer to Evaluation Report prepared by RMS France – 2019 and EFSA Journal 2020;18(1):5957). They are therefore not summarised in Appendix 2.

7.3.3.2 Conclusion on the magnitude of residues in plants

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

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

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

In the following table the results of the dietary burden calculation which may arise from all authorised uses for thiencarbazone-methyl are summarised following the guidance given in the EFSA document 'Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin' (September 2015, issued on the DG SANTE website) and using the official spreadsheet pesticides_mrl_guidelines_animal_model_2017.xls published on the DG SANTE website. Due to the no-residue situation, EFSA considers the setting of a conversion factor for risk assessment unnecessary (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957). In addition, since the residues of thiencarbazone-methyl are < LOQ in corn grain, wheat grain and sugar beet, the default processing factor PF used for their respective by-products (milled by-products, hominy meal, gluten feed, gluten meal and distiller's grain for corn grain, gluten meal, milled by-products for wheat grain and dried pulp, ensiled pulp and molasses for sugar beet) can be replaced by PF=1.

In the OECD feedstuff tables, new feed items such as immature cereals (forage, hay, silage) have been introduced. Following the recommendation in the EFSA document 'Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin' (September 2015, issued on the DG SANTE website) uses on cereals are – by default – understood as 'uses on cereals for grain production' and therefore, only residues in grains and straw from cereals are considered for the animal dietary burden calculation below

Table 7.3-10: Input values for the dietary burden calculation (considering the uses authorised within the zone and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg) (1)	Comment	Input value (mg/kg) (1)	Comment
Risk assessment residue definition: Thiencarbazone-methyl (BYH 18636), BYH 18636-N-desmethyl, and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl				
Sugar beet tops	0.01	Median residue (EFSA, 2020)	0.01	Highest residue (EFSA, 2020)
Sugar beet, dried pulp	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	
Sugar beet, ensiled pulp	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	
Sugar beet, molasses	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg) (1)	Comment	Input value (mg/kg) (1)	Comment
Corn/maize forage/silage	0.01	Median residue (DAR, UK, 2012)	0.01	Highest residue (DAR, UK, 2012; EFSA, 2013)
Corn/maize stover	0.01	Median residue (DAR, UK, 2012)	0.01	Highest residue (DAR, UK, 2012)
Corn/maize grain	0.01	Median residue (EFSA, 2013)	0.01	Median residue (EFSA, 2013)
Wheat/rye/triticale grain	0.01	Median residue (EFSA, 2020)	0.01	Highest residue (EFSA, 2020)
Wheat/rye/triticale straw	0.01	Median residue (EFSA, 2020)	0.02	Highest residue (EFSA, 2020)
Corn, milled by-products, hominy meal, gluten feed, gluten meal	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	-
Wheat gluten meal, milled by-products	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	-
Distiller´s grain, dried	0.01	Median residue x PF(1) (EFSA, 2020, PF = 1)	-	-

(1) Although the usual procedures would suggest the usage of a value of 0.03 mg/kg for the plant matrices (0.01 mg/kg each for the three analytes of the risk-assessment residue definition), EFSA used the default MRL value of 0.01 mg/kg in all risk assessments (EFSA 2013, EFSA 2020). EFSA stated, "Having regard to the no-residue situation, the setting of a conversion factor for risk assessment was considered unnecessary."
(2) Since the residues of thiencarbazone-methyl are < LOQ in corn grain, wheat grain and sugar beet, the default PF used for their respective by-products can be replaced by PF=1 (EFSA 2013, EFSA 2020).

Table 7.3-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Beet, mangel	fodder	No
Cattle (dairy only)	0.002	0.002	0.05	0.05	Dairy cattle	Beet, mangel	fodder	No
Sheep (all diets)	0.001	0.001	0.02	0.02	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0.001	0.001	0.02	0.02	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0.000	0.000	0.02	0.02	Swine (breeding)	Beet, mangel	fodder	No
Poultry (all diets)	0.001	0.001	0.01	0.01	Poultry layer	Corn, field	forage/silage	No
Poultry (layer only)	0.001	0.001	0.01	0.01	Poultry layer	Corn, field	forage/silage	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

According to the dietary burden calculation, livestock studies are not triggered.

EFSA Journal 2020;18(1):5957
The dietary burdens calculated were found to be below the trigger value of 0.1 mg/kg DM for each group and further investigation of residues as well as the setting of MRLs in commodities of animal origin is not

necessary.
* comment by the applicant: the dietary burdens reported by EFSA were also below the more restrictive trigger value of 0.004 mg/kg bw/day.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

One feeding study on ruminant was conducted in the USA and submitted on EU level (M-286140-01-2; DAR, UK, 2012; EFSA, 2013) although not requested according to EU guidelines. The results of this study performed at a dose rate equivalent to 8N confirmed that no residues are expected in animal matrices (EFSA, 2020).

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

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

For thiencarbazone-methyl in the EU, processing trials are not required, as residue levels in all relevant sugar beet commodities are below the LOQ (<0.01 mg/kg for each analyte, or <0.03 mg/kg of total residues in parent equivalents). In addition, dietary risk assessment shows that the TMDI for plants is <10% of the ADI.

7.3.5.1 Available data for all crops under consideration

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

7.3.5.2 Conclusion on processing studies

Processing studies are not required.

7.3.6 Magnitude of residues in representative succeeding crops

The uptake of residues in rotational crops was investigated after application of dihydrotriazole- and thiophene-labelled thiencarbazone-methyl to bare soil at 15, 30, and 45 g/ha. Following plant-back intervals of 90 days (1st rotation) and 270 days (2nd rotation), soybeans, turnips, and wheat were sown. The two studies conducted at 15 g/ha were not evaluated by UK-CRD, as the dose rate represented 0.3N of the maximum application rate in the EU, and thus was considered to be grossly under dosed in relation to the proposed use. However, the data from the two studies were included in the evaluation of the EFSA conclusion on the peer review (2013).
In summary, the metabolic pathway is identical in corn (maize), wheat, sugar beet and in the rotational crops wheat, turnip, soybean, and Swiss chard. The identified metabolites are present at very low levels.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Residues in rotational crops at the proposed application rate in the EU are unlikely to exceed 0.01 mg/kg and therefore rotational crop field trials are not required.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FSN+TCM OD 80. Therefore, other special studies are not needed.

Question regarding the potential residues in honey: a position paper giving an overview on the potential occurrence of residues of thiencarbazone-methyl in honey is presented in Appendix 2.

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).
As an ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-12: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition (products of plant origin): Sum of thiencarbazone-methyl, BYH 18636-N-desmethyl, and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl		
Sugar beet root	0.01*	Default MRL
Maize grain	0.01*	Default MRL
Wheat/triticale/rye grain	0.01*	Default MRL
All other crops	0.01*	Default MRL
Risk assessment residue definition (products of animal origin): Sum of thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl		
Tissue of animal origin, milk, bird eggs	0.01*	Default MRL
Honey and other apiculture products	0.05*	Default MRL

* Although the usual procedures would suggest the usage of a value of 0.03 mg/kg for the plant matrices (0.01 mg/kg each for the three analytes of the risk-assessment residue definition) and, similarly, 0.02 mg/kg for animal matrices, EFSA used the default MRL value of 0.01 mg/kg in all risk assessments (EFSA 2013, EFSA 2020). EFSA stated, "Having regard to the no-residue situation, the setting of a conversion factor for risk assessment was considered unnecessary."

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets (PRIMo rev 3.1) are presented in **Błąd! Nie można odnaleźć źródła odwołania.**

Table 7.3-13: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	0.5% (based on critical consumer group NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not relevant
IESTI (% ARfD) according to EFSA PRIMo 3.1	No ARfD derived, not necessary

The proposed uses of thiencarbazone-methyl in the formulation FSN+TCM OD 80 (50+30) G do not represent unacceptable acute and chronic risks for the consumer.

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.

7.4.1 Acute consumer risk assessment from combined exposure

The product is a mixture of two active substances for which no acute reference dose has been allocated.

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

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance foramsulfuron. EFSA Journal 2016;14(3):4421, 119 pp. doi:10.2903/j.efsa.2016.4421.

EFSA (European Food Safety Authority), 2012. Review of the existing maximum residue levels (MRLs) for foramsulfuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(11):2962. [28 pp.] doi:10.2903/j.efsa.2012.2962. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance thiencarbazone-methyl. EFSA Journal 2013;11(7):3270, 77 pp. doi:10.2903/j.efsa.2013.3270.

Evaluation report prepared under article 12.1 of Regulation (EC) no. 396/2005 - Review of the existing MRLs for thiencarbazone-methyl - Rapporteur member state: France; M-677915-01-1

EFSA (European Food Safety Authority), 2020. Scientific Opinion on the review of the existing maximum residue levels for thiencarbazone-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5957, 39 pp. https://doi.org/10.2903/j.efsa.2020.5957

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No. 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007.

Finland, 2015. Renewal assessment report (RAR) on the active substance foramsulfuron prepared by the rapporteur member state, Finland, in the framework of Commission Implementing Regulation (EU) No 844/2012, March 2015. Available online: www.efsa.europa.eu.

Finland, 2016. Revised renewal assessment report (RAR) on foramsulfuron, compiled by EFSA, January 2016. Available online: www.efsa.europa.eu.

France, 2019. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for thiencarbazone-methyl, 25 April 2019, revised on 27 July 2019. Available online: www.efsa.europa.eu

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCA 6.1 / 01	Lakaschus, S.; Gizler, A.	2017	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil) Report No.: S13-03307, Edition Number: M-480441-06-1 Eurofins Agroscience Services Chem GmbH (EAS Chem), Hamburg, Germany ... amended: 2017-08-16 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.1 / 02	Thies, S.	2015	Storage stability testing of foramsulfuron and AE F153745 on sugar beet, leaf and sugar beet, body (final report after 24 months at <= 20 degree centigrade) Report No.: 2013/0037/01, Edition Number: M-503516-02-1 Currenta GmbH & Co. OHG, Leverkusen, Germany ... amended: 2015-06-02 GLP/GEP: Yes unpublished	No	Bayer

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.1 / 03	Kaussmann, M.	2019	Storage stability of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in wheat (grain, green material, straw) for 24 months - Final report Report No.: P642176501, Edition Number: M-635482-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2019-04-23 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.2.1 / 01	Klempner, A.	2019	Amendment no. 1: Metabolism of [phenyl-UL-14C] foramsulfuron in sugar beets Report No.: EnSa-12-0375, Edition Number: M-454861-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2019-09-25 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.2.1 / 02	Klempner, A.	2018	Amendment no. 1: Metabolism of [pyrimidine-2-14C]foramsulfuron in sugar beets Report No.: EnSa-12-0511, Edition Number: M-454046-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2018-07-02 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3 / 01	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3 / 02	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2139, Edition Number: M-480864-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.3 / 03	Stuke, S.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the Netherlands and United Kingdom Report No.: 13-2000, Edition Number: M-494921-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-11-10 GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3 / 04	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany and The Netherlands Report No.: 13-2009, Edition Number: M-496362-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3 / 05	Kaussmann, M.; Houtermans, M.	2018	Determination of the residues of foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the United Kingdom and northern France Report No.: 17-2033, Edition Number: M-642771-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCA 6.3 / 06	xxx	2018	Conviso One - Use of fodder and sugar beet leaves for animal feeding Report No.: M-636830-01-1 xxx GLP/GEP: n.a. unpublished	No	Bayer
KCA 6.6.1 / 01	Rieder, B.	2019	Report amendment no.1 to final report - Metabolism of [pyrimidine-2-14C] foramsulfuron in rotational crops Report No.: S16-01039, Edition Number: M-625836-02-1 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany ... amended: 2019-01-28 GLP/GEP: Yes unpublished	No	Bayer

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source** **GLP or GEP status** **published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.10.1 / 01	Wegener, M.; Pourcelot, A.; Hoffmann, M.	2020	Overview on the potential occurrence of residues in honey following application of Conviso One (FSN + TCM 0D 80) in herbicide tolerant sugar beets Report No.: M-683705-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCA 6.10.1 / 02	Hoffmann, M.; Barrière, I.	2020	EU approval renewal of the active substance thiencarbazone-methyl - Waiver for studies investigating residues in honey Report No.: M-679156-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer

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

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied upon.

Bayer is the owner of the data package peer-reviewed for the EU re-approval of the active substance **foramsulfuron**.
Bayer is the owner of the data package peer-reviewed for the EU approval of the active substance **thiencarbazone-methyl.**

Data protection will be requested when relevant at MS level in the Part A

Foramsulfuron

The following studies are considered as already evaluated at EU peer review as they were submitted during the EU re-approval process of foramsulfuron. They are referenced in the document entitled: "Draft Renewal Assessment Report under Regulation (EC) 1107/2009; FORAMSULFURON; Volume 3 Annex B.7 (AS). Rapporteur Member State: Finland Co- Rapporteur Member State: Slovakia; March 2015". The data point refers to the data point as referenced in the EU re-approval dossier.

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 /02	Cole, M. G.	2001	Stability of AE F130360 and AE F153745 Residues in Corn (forage, stover and grain) During Frozen Storage, USA, 1998 (Minimum Storage Interval of 616 Days) Aventis CropScience USA LP, Residue Chemistry, USA Report No.: B003134, Report includes Trial Nos.: CF98R004 , Edition Number: M-238787-01-1 GLP/GEP: yes unpublished	No	Bayer
KCA 6.2.1 / 01	Huang, M. N.	2000	Metabolism of (U-14C-phenyl)-AE F130360 and (2-14C-pyrimidyl)-AE F130360 in corn grown under field conditions Code: AE F130360 Report No.: C003293, Edition Number: M-185906-01-1 Aventis CropScience USA LP, Pikeville, NC, USA GLP/GEP: Yes, unpublished	No	Bayer

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 6.2.2 / 01	xxx	1999	AE F130360: Poultry - Metabolism and nature of the residues in the eggs and edible tissues in the laying hen Report No.: C005081, Edition Number: M-191323-01-1, MRID#: 45109624 xxx GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 6.2.3 / 01	xxx	1999	Cow - metabolism, distribution and nature of the residues in milk and edible tissues AE F130360 Code: AE F130360 00 ZE Report No.: C005046, Edition Number: M-191251-01-1, MRID#: 45109625 xxx GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 6.6.1 / 01	Huang, M. N.; Faulkner, T. D.	1999	Uptake of residues of (U-phenyl-14C)-AE F130360 and (2-pyrimidyl-14C)-AE F130360 in soil by rotational crops under confined conditions Report No.: C003287, Edition Number: M-185898-01-1, MRID#: 45109708 AgrEvo USA Company, Pikeville, NC, USA GLP/GEP: Yes, unpublished	No	Bayer

Thiencarbazone-methyl

The following studies are considered as already evaluated at EU peer review as they are referenced in the document entitled ("Council Directive 91/414/EEC. Thiencarbazone-methyl (BYH 18636) - Volume 2 - Annex A to the Draft Report and Proposed Decision - List of tests and studies submitted and information available (by Annex point). 2012).

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate Study	Owner
KIIA 6.1.1 /01	Brumhard, B.; Wolters, A.	2007	Storage stability of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 18 months - results for an interval of 0 to 12 months Report No.: MR-186/05, Edition Number: M-284222-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.1.1 /02 also filed: KIIA 6.4.2 /01	xxx	2007	BYH 18636: Dairy cattle feeding study Report No.: MR-06/095, Edition Number: M-286140-01-2 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KIIA 6.1.1 /03 Study referenced in DAR Addendum (March 2013) also filed: KIIA 6.4.2 /01)	Brumhard, B., Wolters, A	2008	Storage stability of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 24 months Report No.: MR-07/229, Document No.: M-304143-01-1 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /01	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn in combination with the safener AE 0001789 as a pre-emergence application Report No.: MEF-05/004, Edition Number: M-263042-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate Study	Owner
KIIA 6.2.1 /02	Bongartz, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in corn in combination with the safener AE 0001789 as a pre-emergence application Report No.: MEF-05/003, Edition Number: M-263405-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate Study	Owner
KIIA 6.2.1 /03	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn Report No.: MEF-04/182, Edition Number: M-266796-02-2 Bayer CropScience AG Amended: 15.02.2007 GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /04	Bongartz, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in corn Report No.: MEF-04/181, Edition Number: M-256647-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /05	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn in combination with the safener isoxa-difen-ethyl following two post-emergence applications at growth stages V6 and V12 Report No.: MEF-05/006, Edition Number: M-267247-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /06	Bongartz, R.	2006	Metabolism of [thiophene-4-14C]BYH18636 in corn in combination with the safener isoxadifen-ethyl following two post-emergence applications at growth stages V6 and V12 Report No.: MEF-05/005, Edition Number: M-268530-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /07	Sur, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in wheat Report No.: MEF-05/041, Edition Number: M-267443-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.2.1 /08	Sur, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in wheat Report No.: MEF-05/042, Edition Number: M-268145-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate Study	Owner
KIIA 6.2.2 /01	xxx	2006	Metabolism of [thiophene-4-14C]BYH18636 in the laying hen Report No.: MEF-05/260, Edition Number: M-279414-03-2 xxx Amended: 27.12.2006 GLP/GEP: Yes unpublished	Yes	Bayer
KIIA 6.2.2 /02	xxx	2006	Metabolism of [dihydrotriazole-3-14C]BYH18636 in the laying hen Report No.: MEF-05/259, Edition Number: M-279676-03-2 xxx Amended: 27.12.2006 GLP/GEP: Yes unpublished	Yes	Bayer
KIIA 6.2.3 /01	xxx	2006	[Thiophene-4-14C]BYH 18636: Absorption, distribution, excretion, and metabolism in the lactating goat Report No.: MEF-05/261, Edition Number: M-278516-01-2 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KIIA 6.2.3 /02	xxx	2006	[Dihydrotriazole-3-14C]BYH 18636 - Absorption, distribution, excretion, and metabolism in the lactating goat Report No.: MEF-05/307, Edition Number: M-276289-01-2 xxx GLP/GEP: Yes unpublished	Yes	Bayer
KIIA 6.6.2 /01	Justus, K.	2006	Metabolism of [dihydrotriazole-3-14C]BYH18636 in confined rotational crops following co-application with safener AE 0001789 Report No.: MEF-06/215, Edition Number: M-277504-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate Study	Owner
KIIA 6.6.2 /02	Justus, K.	2006	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops following co-application with safener AE 0001789 Report No.: MEF-05/297, Edition Number: M-275070-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.6.2 /03	Justus, K.	2006	Metabolism of [dihydrotriazole-3-14C]BYH 18636 in confined rotational crops after an application rate of 30 g/ha in the presence of safener AE 0001789 Report No.: MEF-06/258, Edition Number: M-278990-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.6.2 /04	Justus, K.	2006	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops after an application rate of 30 g/ha in the presence of safener AE0001789 Report No.: MEF-05/539, Edition Number: M-277462-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.6.2 /05	Reiner, H.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in confined rotational crops Report No.: MEF-05/023, Edition Number: M-261209-02-2 Amended: 16.02.2007 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer
KIIA 6.6.2 /06	Reiner, H.	2005	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops Report No.: MEF-05/024, Edition Number: M-260471-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Bayer

The studies referenced in the table below were submitted to RMS (FRA) and EFSA to support Art. 12 of EU Regulation No 396/2005 (refer to Review of the existing maximum residue levels for thiencarbazone-methyl according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2020;18(1):5957).
These data are considered as being EU peer reviewed data.

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
Refer to 2019 Evaluation Report, FRA (RMS)	Justus, K.	2014	Amendment no 1 to metabolism of [thiophene-4-14C]thiencarbazone-methyl in sugar beets Report No.: MEF-11/905, Edition Number: M-442848-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-25 GLP/GEP: Yes unpublished	No	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Justus, K.	2014	Amendment No 1 to metabolism of [dihydrotriazole-3-14C]thiencarbazone-methyl in sugar beets Report No.: MEF-11/872, Edition Number: M-442854-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-25 GLP/GEP: Yes unpublished	No	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the Netherlands and United Kingdom Report No.: 13-2000, Edition Number: M-494921-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-11-10 GLP/GEP: Yes unpublished	No	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany and The Netherlands Report No.: 13-2009, Edition Number: M-496362-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Foramsulfuron

A 2.1.1 7.2.1 Stability of residues

A 2.1.1.1 7.2.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study report S13-03307

Comments of zRMS:	Study is accepted

Reference:	**KCA 6.1/01**
Title:	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil)
Report:	Lakaschus, S.; Gizler, A.; 2017; S13-03307; M-480441-06-1
Authority registration No:	
Guideline(s):	Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances US EPA Residue Chemistry Test Guideline OPPTS 860.1380: Storage Stability Data OECD Test Guideline 506, adopted 16 October 2007
Deviations:	see report
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The study was initiated to evaluate the stability of 61 analytes (parent and metabolite molecules) after storage for a period of 8 hours at +1°C followed by 7 days of storage at -7°C in tomato fruit, wheat green material, onion bulbs (high water content), grape bunches (high acid content), wheat grain, potato tuber (high starch content), dry peas (high protein content) and oilseed rape seeds (high oil content).

Only foramsulfuron and its metabolite AE F153745 data will be presented here in wheat grain and potato tuber (high starch content commodities).

Prior to the storage stability tests a method validation was performed. For this purpose one control sample and five fortified samples were analysed for each matrix. In case of successful validation results the storage stability was started.

For the storage stability, aliquots of typically 5 g of each homogenised matrix were fortified with foramsulfuron and its metabolite AE F153745 at a fortification level of 1.0 mg/kg. Spiking solutions of both compounds were prepared in acetone, diluted with acetonitrile.(1/20), for a final concentration of 20 µg/L.

The samples, fortified (procedural recoveries) or not (control material), were stored in plastic containers (50 mL centrifuge tubes with screw caps) at an average temperature of +1 °C for 8 hours and -7°C for the following 7 days and were analysed at the nominal storage intervals of 0 and 7 days. The storage temperature was recorded with a calibrated data logger.

Concurrent recoveries were conducted at 1.0 mg/kg in both matrices at 7 days.

For analysis using method BSC 01207, samples were mixed with acetonitrile-water at a ratio of (4/1, v/v) and shaken. Then, a salt mixture of mg2SO4/NaCl/Na3 citrate 2 H2O/Na2H citrate 6 H2O (4/1/1/0.5, w/w/w/w) was added, the extract was shaken the phases were separated by centrifugation. An aliquot of the acetonitrile phase was filled up with methanol-water (1/1, v/v). Final analysis was performed by LC-MS/MS with and LOQ of 0.01 mg/kg per analyte.

The residues of foramsulfuron and its metabolite AE F153745 were analytically determined according to method BCS 01207 as validated in S10-00279, 2013-12-11 by LC-MS/MS using two MRM transitions.

Compound	Mass Quantification Transition	Mass Confirmation Transition
foramsulfuron	m/z 453→ 182	m/z 453→ 272
AE F153745	m/z 272→ 227	m/z 272→ 80

Results and discussions

Residues of foramsulfuron and its metabolite AE F153745 in the control samples of wheat (grain) and potato (tuber) were ≤ 30% (0.30 mg/kg) of the fortification level (1.0 mg/kg) and no correction for control residues was necessary. The fortification level was defined as 1.0 mg/kg in the study plan in order to avoid possible blank subtraction.

Five control samples wheat (grain) and potato (tuber) were spiked at 1.0 mg/kg with a mixture containing foramsulfuron and its metabolite AE F153745. The mean recoveries were 70-120% for wheat (grain) and potato (tuber), with an RSD < 20%, each. The validation recovery data are summarised below.

Table A 1: Validation recoveries of foramsulfuron and its metabolite AE F153745 from wheat grain and potato tuber (high starch content).

Matrix	Spike level (mg/kg)	Number of replicates	Mean	RSD (%)*	Remark
foramsulfuron					
Wheat grain	1.0	5	96	1.1	Q:m/z 453→ 182
		5	96	1.7	C:m/z 453→ 272
Potato tuber	1.0	5	90	3.7	Q:m/z 453→ 182
		5	91	2.7	C:m/z 453→ 272
AE F153745					
Wheat grain	1.0	5	99	3.7	Q:m/z 272→ 227
		5	99	4.8	C:m/z 272→ 80
Potato tuber	1.0	5	102	2.8	Q:m/z 272→ 227
		5	99	4.3	C:m/z 272→ 80

* Standard deviation not reported. Recalculated from individual recoveries.

The recoveries in the freshly fortified samples proved also the method performance using the quantification transition. Foramsulfuron mean recoveries ranged between 90% and 93% with RSD below 20% and AE F153745 mean recoveries ranged between 91% and 93% with RSD below 20%. In addition, 2 concurrent recoveries per commodity were conducted at the nominal storage intervals of 7 days for matrices wheat grain and potato tuber. Mean recoveries were between 84% and 95% for foramsulfuron and between 99% and 103% for AE F153745. Procedural recoveries are summarised below.

Table A 2: Summary of concurrent recoveries of foramsulfuron and its metabolite AE F153745 from wheat grain and potato tuber (high starch content)

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± /RSD (%)
foramsulfuron					
Wheat grain	1.0	0	5	93; 91; 91; 93; 97	93 ± 2.6
	1.0	7	2	81; 86	84 ±-
Potato tuber	1.0	0	5	89; 89; 88; 88; 94	90 ± 2.8
	1.0	7	2	96; 93	95 ± -
AE F153745					
Wheat grain	1.0	0	5	92; 81; 90; 96; 97	91 ± 7.0
	1.0	7	2	100; 97	99 ± -
Potato tuber	1.0	0	5	92; 94; 92; 93; 93	93± 0.9

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± /RSD (%)
	1.0	7	2	105; 101	103 ± -

In all the control samples, residues of foramsulfuron and AE F153745 were below the LOQ (0.01 mg/kg). The recoveries of the stored samples showed that the residues of foramsulfuron and AE F153745 were stable in plant matrices (wheat grain and potato tuber), for at least 8 hours at +1°C following 7 days at -7°C. The residues of foramsulfuron and AE F153745 in the stored spiked samples of the investigated matrices were summarised below.

Table A 3: Storage Stability Data of foramsulfuron and its metabolite AE F153745 in wheat grain and potato tuber (high starch content).

Matrix	Nominal spike level (mg/kg)	Storage interval (days)	Sample size (n)	Individual recovered residues (mean) (mg/kg)	Individual recoveries (%)	mean ± RSD (%)	Normalisation to Day 0 (%)[a]
foramsulfuron							
Wheat, grain	1.0	0	5	0.929, 0.911, 0.913, 0.926, 0.973	93, 91, 91, 93, 97	93 ± 2.6	100
		7	5	0.858, 0.860, 0.856, 0.872, 0.865	86, 86, 86, 87, 86	86 ± 0.5	93
Potato, tuber	1.0	0	5	0.889, 0.893, 0.884, 0.878, 0.938	89, 89, 88, 88, 94	90 ± 2.8	100
		7	5	0.901, 0.940, 0.917, 0.899, 0.982	90, 94, 92, 90, 98	93 ± 3.6	104
AE F153745							
Wheat, grain	1.0	0	5	0.917, 0.814, 0.903, 0.958, 0.969	92, 81, 90, 96,97	91 ± 7.0	100
		7	5	1.031, 0.997, 0.972, 0.994, 0.952	103, 100, 97, 99, 95	99 ± 3.1	108
Potato, tuber	1.0	0	5	0.921, 0.945, 0.932, 0.932, 0.924	92, 94, 93, 93, 92	93 ± 0.9	100
		7	5	1.061, 1.006, 1.035, 1.006, 1.000	106, 101, 103, 101, 100	102 ± 2.3	110

[a]Normalisation to Day 0 Recovery = (Mean recovery / Mean recovery at day 0) x 100%

Conclusion

The study results demonstrate that foramsulfuron and its metabolite AE F153745 are stable in wheat grain and potato tuber for 8 hours at +1°C following 7 days at -7°C.
Mean uncorrected recoveries ranged between 70% and 120% in the tested plant commodities (high starch content commodities).

A 2.1.1.1.1.2 Study report 2013/0037/01

Comments of zRMS:	Study is accepted

Reference:	**KCA 6.1/02**
Title:	Storage stability testing of foramsulfuron and AE F153745 on sugar beet, leaf and sugar beet, body (final report after 24 months at <= 20 degree centigrade)
Report:	Thies, S.; 2015; 2013/0037/01; M-503516-02-1
Authority registration No:	
Guideline(s):	Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances (reference to document no. 7032/VI/95 rev.5 Appendix H) US EPA Residue Chemistry Test Guideline OCSPP 860.1380: Storage Stability Data OECD Test Guideline 506, adopted 16 October 2007 PMRA Ref.: DACO 7.3, Storage Stability
Deviations:	not specified
GLP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The stability of foramsulfuron and its metabolite AE F153745 was investigated in/on sugar beet body and leaf (high starch and high water commodities respectively) for about 24 months (707 days) under frozen storage (24 months at ≤ -20 °C).
Individual aliquots of homogenised sugar beet body and sugar beet leaf with root collar were fortified with foramsulfuron and its metabolite AE F153745 separately. The fortification level was 0.10 mg/kg for foramsulfuron and the metabolite AE F153745 respectively. The spiking solution was prepared by dissolving foramsulfuron in acetonitrile/water (99/1, v/v) + 0.1 mL/L NH_3 solution (25%) and dissolving AE F153745 in acetonitrile; the solutions were further diluted with water + 0.1 mL/L NH_3 solution (25%) to give a final concentration of 1000 µg/L. The fortified samples were stored in amber glass bottles at -20°C or below until analysis. The samples were analysed at the actual storage intervals of 0, 30, 62-64, 90-92, 184, 372-377, 525 and 707 days.
The residues of foramsulfuron and its metabolite AE F153745 were determined according to method 01340 by LC-MS/MS. The analytes were extracted from sugar beet leaves twice and from sugar beet body three times, using a mixture of acetonitrile/water and a microwave. After centrifugation and filtration the solution was made up to volume. An aliquot of the extract was diluted and filtrated for measurement by reversed phase HPLC-MS/MS in positive ion mode without further clean-up. Residues were quantified using matrix matched standards. Validation recoveries were conducted at 0.01 mg/kg and 0.10 mg/kg.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg for all analytes in both matrices.
In the control samples used for fortification the residues were always below 30% of the LOQ.

Results and discussions

After a deep-freezer storage period of about 24 months, the mean recovery rate for foramsulfuron from the stored samples of sugar beet body was 83% (100% normalized to day 0). In samples of sugar beet leaf with root collar the mean recovery was 94% (98% normalized to day 0).

The results of the concurrent recovery experiments are shown in Table A 1. In order to assess the accuracy of the residue analyses, concurrent recoveries were determined by analysing freshly fortified samples

alongside with the stored fortified samples. At all storage intervals concurrent recoveries were determined at the 10-fold LOQ level (0.10 mg/kg). The samples for the determination of concurrent recoveries were fortified with a mixture of foramsulfuron and AE F153745. All the mean concurrent recoveries were within the acceptable interval of 70-110%, except for sugar beet leaf with root collar at 30 days of storage with 66%. Means of concurrent recoveries from freshly fortified samples analysed along with the stored samples for sugar beet body ranged from 73% to 105% for foramsulfuron and from 84% to 106% for the metabolite AE F153745 mix. In samples of sugar beet leaf with root collar the means of concurrent recoveries ranged from 66% to 106% for foramsulfuron and from 75% to 109% for the metabolite AE F153745. Procedural recoveries from freshly fortified samples were at the same level as the recoveries from the stored samples.

Table A 4: Summary of concurrent recoveries of foramsulfuron and its metabolite AE F153745 from Sugar Beet leaf with root collar and Sugar Beet body at 24 months.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± /RSD (%)
foramsulfuron					
Sugar Beet leaf with root collar	0.10	0	2	95, 98	96 ± -
		30	2	69, 63	66 ± -
		64	2	105, 107	106 ± -
		92	2	98, 103	101 ± -
		184	2	97, 99	98 ± -
		372	2	96, 94	95 ± -
		525	2	99, 99	99 ± -
		707	2	91, 89	90 ± -
Sugar Beet body	0.10	0	2	71, 79	75 ± -
		30	2	76, 70	73 ± -
		62	2	81, 83	82 ± -
		90	2	81, 81	81 ± -
		184	2	88, 88	88 ± -
		377	2	104, 105	105 ± -
		525	2	76, 82	79 ± -
		707	2	78, 84	81 ± -

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± /RSD (%)
AE F153745					
Sugar Beet leaf with root collar	0.10	0	2	102, 96	99 ± -
		30	2	79, 71	75 ± -
		64	2	95, 94	94 ± -
		92	2	82, 79	81 ± -
		184	2	103, 106	105 ± -
		372	2	108, 109	109 ± -
		525	2	97, 91	94 ± -
		707	2	94, 93	93 ± -
Sugar Beet body	0.10	0	2	101, 105	103 ± -
		30	2	91, 82	87 ± -
		62	2	103, 103	103 ± -
		90	2	104, 102	103 ± -
		184	2	104, 108	106 ± -
		377	2	85, 83	84 ± -
		525	2	97, 100	99 ± -
		707	2	98, 106	102 ± -

* Standard deviation not reported. Recalculated from individual recoveries.

Table A5 summarizes the levels of foramsulfuron and its metabolite AE F153745 recovered in the fortified samples stored at – 20°C or below.

Table A 5: Storage stability data of foramsulfuron and its metabolite AE F153745 in sugar beet leaf with root collar and sugar beet body at 24 months at ≤ -20°C

Matrix	Nominal spike level (mg/kg)	Storage interval (days)	Sample size (n)	Individual recovered residues (mean) (mg/kg)	Individual recoveries (%) *	Mean ± RSD (%)	Normalisation to Day 0 (%)[a]
foramsulfuron							
Sugar beet	0.10	0	5	0.096, 0.099, 0.098, 0.097, 0.096	96, 99, 98, 97,96	97±1.3	100

Matrix	Nominal spike level (mg/kg)	Storage interval (days)	Sample size (n)	Individual recovered residues (mean) (mg/kg)	Individual recoveries (%) *	Mean ± RSD (%)	Normalisation to Day 0 (%)[a]
leaf with root collar		30	3	0.068, 0.064, 0.069	68, 64, 69	67±3.9	69
		64	3	0.102, 0.100, 0.103	102, 100, 103	102±1.5	105
		92	3	0.098, 0.099, 0.095	98, 99, 95	97±2.1	100
		184	3	0.102, 0.098, 0.100	102, 98,100	100±2.0	103
		372	3	0.098, 0.091, 0.098	98, 91, 98	96±4.2	98
		525	3	0.102, 0.102, 0.101	102, 102, 101	102±0.6	105
		707	3	0.109, 0.109, 0.095	109, 109, 95	104±7.7	107
Sugar beet body	0.10	0	5	0.083, 0.082, 0.082, 0.078, 0.078	83, 82, 82, 78, 78	81±3.0	100
		30	3	0.065, 0.063, 0.070	65, 63, 70	66±5.5	82
		62	3	0.090, 0.087, 0.086	90, 87, 86	88±2.4	109
		90	3	0.078, 0.082, 0.075	78, 82, 75	78±4.5	97
		184	3	0.092, 0.092, 0.089	92, 92, 89	91±1.9	113
		377	3	0.080, 0.084, 0.102	80, 84, 102	89±13.2	110
		525	3	0.076, 0.078, 0.079	76, 78, 79	78±2.0	96
		707	3	0.075, 0.079, 0.079	75, 79, 79	78±3.0	96
AE F153745							
Sugar beet leaf with root collar	0.10	0	5	0.093, 0.098, 0.094, 0.095, 0.094	93, 98, 94, 95, 94	95±2.0	100
		30	3	0.083, 0.081, 0.088	83, 81, 88	84±4.3	88
		64	3	0.097, 0.091, 0.091	97, 91, 91	93±3.7	98
		92	3	0.082, 0.083, 0.073	82, 83, 73	79±6.9	84
		184	3	0.096, 0.094, 0.094	96, 94, 94	95±1.2	100
		372	3	0.110, 0.106, 0.085	110, 106, 85	100±13.4	106
		525	3	0.098, 0.095, 0.094	98, 95, 94	96±2.2	101
		707	3	0.088, 0.091, 0.088	88, 91, 88	89±1.9	94

Matrix	Nominal spike level (mg/kg)	Storage interval (days)	Sample size (n)	Individual recovered residues (mean) (mg/kg)	Individual recoveries (%) *	Mean ± RSD (%)	Normalisation to Day 0 (%)[a]
Sugar beet body	0.10	0	5	0.101, 0.105, 0.104, 0.107, 0.107	101, 105, 104, 107, 107	105±2.4	100
		30	3	0.077, 0.076, 0.079	77, 76, 79	77±2.0	74
		62	3	0.089, 0.090, 0.094	89, 90, 94	91±2.9	87
		90	3	0.093, 0.089, 0.089	93, 89, 89	90±2.6	86
		184	3	0.095, 0.089, 0.093	95, 89, 93	92±3.3	88
		377	3	0.088, 0.094, 0.074	88, 94, 74	85±12.0	81
		525	3	0.084, 0.089, 0.095	84, 89, 95	89±6.2	85
		707	3	0.099, 0.090, 0.092	99, 90, 92	94±5.0	89

Conclusion

The study results demonstrate that foramsulfuron and its metabolite AE F153745 are stable for at least 24 months in frozen storage at ≤ -20°C in the tested plant commodities (high water content and high starch content commodities).

A 2.1.1.1.1.3 Study P642176501

Comments of zRMS:	Study is accepted

Reference:	**KCA 6.1/03**
Title:	Storage stability of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in wheat (grain, green material, straw) for 24 months - Final report
Report:	Kaussmann, M.; 2019; P642176501; M-635482-02-1
Authority registration No:	
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16 US EPA OCSPP 860.1380, Storage Stability Data
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The study was conducted to determine the stability of residues of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in fortified control samples of material of plant origin (wheat grain, green material and straw) for about 24 months under frozen storage conditions. In the following summary only results for foramsulfuron and its metabolites (AE F153745 and AE F092944) are shown.
Control samples were fortified individually with the spiking solutions of foramsulfuron, AE F153745 and AE F092944 at intended fortification level of 0.1 mg/kg. The fortification level of AE F153745 and AE F092944 are expressed as parent equivalents. Subsequently, the tubes were closed and deep-frozen at -18 °C until analysis, except for the day-0 samples. In addition, untreated samples of each sample material were prepared for control and recovery experiments.
The spiking solutions of foramsulfuron and AE F153745 were prepared in a mixture acetonitrile:0.02 N triethylamin (4:1; *v:v*) , whereas the spiking solutions of AE F092944 were prepared in acetonitrile and further diluted in a mixture of acetonitrile:water (1:1, *v:v*).
Residues of foramsulfuron and AE F153745 were determined in/on wheat matrices according to the method 01376/M002 and quantified using external calibration with matrix-matched standards.
Residues of AE F092944 were determined in/on wheat matrices according to the method 01516 and quantified using external calibration with matrix-matched standards.
In the method 01376/M002, residues of foramsulfuron were extracted twice from 5-g specimen with a 100-mL with a mixture of acetonitrile/ 0.02 M trimethylamine in water (80:20; *v:v*). Residues of all compounds were determined without any further clean-up by reversed phase HPLC-MS/MS.
In the method 01514 residues of AE F092944 were extracted twice from 5-g specimen with a 100-mL mixture of acetonitrile:water (50:50, *v:v*). Residues of AE F092944 were determined without any further clean-up by HILIC HPLC-MS/MS.
In both methods, all compounds were detected in positive electrospray ionization mode, quantified using matrix-matched calibration standards and metabolites were expressed as parent equivalents.
The Limits of Quantification (LOQ) for all compounds was 0.5 µL/L corresponding to 0.01 mg/kg in plant material (expressed as parent equivalents).
During each set of analysis, a calibration curve (*1/x* weighted linear regression) was established with at least five concentration levels and used for the quantitation of each analyte in each sample material. For each calibration curve, the correlation coefficient R was above 0.99.
For each sample material, five spiked samples and one control sample were analyzed on day 0 (zero time analysis). In addition, three recoveries at the respective LOQ level and three recoveries at the respective 10-fold LOQ level were determined to validate the use of the method for analysis of the respective sample materials.
The remaining samples were stored in a deep-freezer at ≤-18°C. At each storage period except day 0, three fortified and three control samples of each tested plant material were removed from the deep-freezer and allowed to reach room temperature. Subsequently, two of the control samples of each sample material were fortified with the analytes to determine the concurrent recoveries (fortification levels were at the same magnitude as the spiked storage samples). All samples were extracted and analyzed concurrently.

Results and discussions

The performance of the analytical method was tested during the conduct of the whole study. Concurrent recoveries were deemed acceptable (between 70 and 110%) as shown in the tables below, except for AEF092944 in wheat green material (at 587 days) for which concurrent recovery was sliglty above 110%. For both untreated and treated samples, a sufficient number of samples was tested for each storage period.

In the control samples, the apparent residues were below 30% of the LOQ. The results of the spiked stored samples are summarised in the table below.
Foramsulfuron and its metabolites AE F153745 and AE F092944 are stable in all tested matrices for at least 24 months under deep-freezer storage conditions (≤-18°C).

Table A 6: Summary of concurrent recoveries of foramsulfuron and its metabolites (AE F153745 and AE F092944) in different matrices

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ±RSD (%)
Foramsulfuron					
Wheat (grain)	0.1	29	2	90, 92	91
		90	2	96, 96	96
		182	2	104, 108	106
		456	2	101, 98	100
		587	2	103, 97	100
		721	2	104, 111	108
Wheat (green material)	0.1	29	2	92, 93	93
		90	2	95, 98	97
		182	2	97, 91	94
		456	2	100, 95	98
		587	2	102, 102	102
		721	2	98, 100	99
Wheat (straw)	0.1	29	2	95, 96	96
		90	2	100, 104	102
		182	2	107, 104	106
		456	2	100, 94	97
		587	2	106, 107	107
		721	2	100, 101	101
AE F153745					
Wheat (grain)	0.1	29	2	98, 98	98
		90	2	110, 110	110
		182	2	101, 99	100
		456	2	102, 98	100
		587	2	103, 99	101
		721	2	105, 106	106
Wheat (green material)	0.1	29	2	106, 109	108
		90	2	103, 105	104
		182	2	98, 95	97
		456	2	99, 96	98
		587	2	104, 101	103
		721	2	105, 104	105
Wheat (straw)	0.1	29	2	97, 95	96
		90	2	105, 102	104
		182	2	108, 106	107

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ±RSD (%)
		456	2	96, 97	97
		587	2	103, 107	105
		721	2	100, 103	102
AE F092944					
Wheat (grain)	0.1	29	2	78, 73	76
		90	2	102, 102	102
		182	2	101, 100	101
		456	2	107, 112	110
		587	2	76, 72	74
		721	2	103, 99	101
Wheat (green material)	0.1	29	2	108, 110	109
		90	2	89, 91	90
		182	2	96, 94	95
		456	2	94, 100	96
		587	2	110, 113	112
		719	2	101, 103	102
Wheat (straw)	0.1	29	2	88, 87	88
		90	2	89, 90	90
		182	2	80, 83	82
		456	2	97, 91	94
		587	2	89, 88	89
		721	2	106, 110	108

** RSD : not appropriated for a sample size below 3

Table A 7: Stability of residues of foramsulfuron and its metabolites (AE F153745 and AE F092944) in different matrices following storage at -18°C.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ±RSD (%)
Foramsulfuron					
Wheat (grain)	0.1	0	5	106, 104, 102, 108, 103	105 ±2.3
		29	3	93, 87, 98	93 ±5.9
		90	3	99, 93, 97	96±3.2
		182	3	111, 100, 101	104±5.9
		456	3	104, 105, 104	104±0.6
		587	3	114, 106, 108	109±3.8
		721	3	117, 108, 117	114±4.6
Wheat (green	0.1	0	5	104, 103, 102, 102, 101	102±1.1

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ±RSD (%)
material)		29	3	92, 91, 94	92±1.7
		90	3	99, 102, 108	103±4.5
		182	3	103, 107, 107	106±2.2
		456	3	102, 108, 103	104±3.1
		587	3	97, 100,100	99±1.8
		721	3	103, 104,108	105±2.5
Wheat (straw)	0.1	0	5	99, 99, 100, 98, 97	99±1.2
		29	3	97, 96, 96	96±0.6
		90	3	101, 104, 105	103±2.0
		182	3	107, 109, 106	107±1.4
		456	3	101, 102, 107	103±3.1
		587	3	108, 109, 108	108±0.5
		721	3	106, 108, 109	108±1.4
AE F153745					
Wheat (grain)	0.1	0	5	100, 104, 102, 103, 104	103±1.6
		29	3	98, 98, 96	97±1.2
		90	3	98, 104, 102	101±3.0
		182	3	102, 104, 103	103±1.0
		456	3	104, 106, 105	105±1.0
		587	3	103, 103, 106	104±1.7
		721	3	106, 107, 106	106±0.5
Wheat (green material)	0.1	0	5	99, 99, 99, 100, 98	99±0.7
		29	3	93, 93, 93	93±0.0
		90	3	107, 110, 107	108±1.6
		182	3	91, 88, 91	90±1.9
		456	3	98, 95, 94	96±2.2
		587	3	82, 82, 83	82±0.7
		721	3	78, 76, 78	77±1.5
Wheat (straw)	0.1	0	5	98, 98, 98, 98, 94	97±1.8
		29	3	99, 95, 95	96±2.4
		90	3	108, 111, 109	109±1.4
		182	3	107, 110, 109	109±1.4
		456	3	100, 99, 101	100±1.0
		587	3	103, 103, 102	103±0.6
		721	3	102, 103, 103	103±0.6
AE F092944					
Wheat (grain)	0.1	0	5	89, 88, 91, 82, 82	86±4.8

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ±RSD (%)
		29	3	78, 82, 77	79±3.4
		90	3	73, 83, 75	77±6.9
		182	3	84, 77, 89	83±7.2
		456	3	102, 101, 98	100±2.1
		587	3	72, 73, 71	72±1.4
		721	3	85, 80, 80	82±3.5
Wheat (green material)	0.1	0	5	93, 95, 93, 90, 93	93±1.9
		29	3	97, 103, 106	102±4.5
		90	3	83, 80, 85	83±3.0
		182	3	73, 90, 87	83±10.9
		456	3	74, 67, 71	71±5.0
		587	3	77, 83, 73	78±6.5
		719	3	97, 98, 96	97±1.0
Wheat (straw)	0.1	0	5	90, 90, 92, 90, 94	91±2.0
		29	3	81, 85, 84	83±2.5
		90	3	84, 91, 89	88±4.1
		182	3	82, 85, 83	83±1.8
		456	3	91, 89, 88	89±1.7
		587	3	74, 74, 74	74±0.0
		721	3	95, 84, 79	86±9.5

Conclusion

The study results demonstrate that the residues of foramsulfuron and its metabolites are stable in wheat grain, straw, and green material for at least 24 months under deep-freezer storage conditions (≤-18°C

A 2.1.1.1.2 Storage stability of residues in animal products

Not new study submitted.

A 2.1.1.2 7.2.1.2 Stability of residues in sample extracts

No new study submitted.

A 2.1.2 7.2.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 7.2.2.1 Nature of residue in primary crops

Additional studies have been submitted.

A 2.1.2.1.1 Study EnSa-12-0375

Comments of zRMS:	Study is accepted

Version 01 was submitted in 2015. Version 2 is the amended report (correction of mistakes, names of person and test facilities)

Reference:	**KCA 6.2.1/01**
Title:	Amendment no. 1: Metabolism of [phenyl-UL-14C] foramsulfuron in sugar beets
Report:	Klempner, A.; 2019; EnSa-12-0375; M-454861-02-1
Authority registration No:	
Guideline(s):	OECD Guideline for the Testing of Chemicals 501: Metabolism in Crops US EPA OCSPP Residue Chemistry Test Guideline OPPTS 860.1300: Nature of the Residue - Plants, Livestock Japanese MAFF, 12 Nousan 8147 European Parliament and Council Regulation (EC) No 1107/2009
Deviations:	not applicable
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The metabolism of [phenyl-UL-^{14}C]-foramsulfuron in sulfonyl urea resistant sugar beets (in development) was investigated according to the envisaged use pattern. Two different application rates (1X and 2X target rate) with two applications (1st application at BBCH 12-14 (= two leaves [first pair of leaves] unfolded till four leaves [second pair of leaves] unfolded) and 2nd application at BBCH 14-18 (= four leaves unfolded till eight leaves unfolded)) were covered by this study. In both experiments, [phenyl-UL-^{14}C]-foramsulfuron was formulated as an OD 050 diluted in water at an application rate of 28.8 g a.s./ha for the 1X target rate experiment (including 15% for losses) and 55 g a.s./ha for the 2X target rate experiment (including 10% for losses). At maturity the sugar beets were harvested. Concurrently, the leaves and beets were sampled.

Each experiment was conducted with sugar beets in a planting container with a surface area of approx. 1 m^2 with 11 plants per square metre. The two planting containers were filled with sandy loam soil. The plants were cultivated in the glass-roofed vegetation hall of the test facility. The plants were grown similar to natural temperature and light conditions, but protected from rainfall. The plants were watered by pouring onto the soil in the planting containers.

The sugar beets were harvested at BBCH 49 (harvestable size). The beets were dug out of the soil. Adhering soil was removed. Leaves were cut off ca. 5-10 cm above the beet top. The beets were washed, the beet tops cut of and sampled with the leaves. Beets were ground, leaves and beet tops were cut into ca. 1 cm long pieces and all samples were homogenised under liquid nitrogen using a high speed blender (Polytron). The samples were stored in a freezer (≤ -18°C) until extraction. Aliquots of the homogenised sample materials were used to determine the TRR by combustion analysis. Aliquots of the washing water were analysed by LSC.

Only RACs of the 1X application rate experiment were extracted.

The leaves of the 1X target rate experiment were extracted three times with a mixture of acetonitrile/water (8/2, v/v) using a high speed blender (Polytron PT3100 or Ultraturrax). After each extraction step, extracts and solids were separated by filtration. The remaining solids were further extracted by microwave treatment. The profiles were compared. The beets of the 1X target rate experiment were extracted with a mixture of ACN/1% formic acid (8/2; v/v) and a second time with a mixture of ACN/water (8/2; v/v) using a high speed blender (Polytron). After each extraction step, extracts and solids were separated by filtration. The remaining solids were extracted by microwave treatment. All

combined extracts of the conventional extractions were subjected to a clean-up step using an SPE RP 18 cartridge (Phenomenex, Strata C18-E, 10 - 20 g), which was conditioned with an ACN/water mixture (8/2; v/v) beforehand. The flow-through fraction (effluent) was collected and the cartridge was rinsed with 100 mL of acetonitrile/water (8/2; v/v). The cartridge used for the sugar beet extract was additionally rinsed with tetrahydrofurane/methanol (1/1, v/v). The percolate and the acetonitrile/water fraction were combined and concentrated by rotary evaporation in vacuo for HPLC analysis. The extracts were stored in a freezer (≤ -18°C).
The remaining solids from leaves extraction were further extracted one time with ACN/water (8/2; v/v) and one time with ACN/water (1/1; v/v), both times with microwave treatment (5 min heating to 120°C, keeping the temperature for 15 min), while the remaining solids from beets extraction were further extracted two times with ACN/water (1/1; v/v) and microwave treatment (5 min heating to 120°C, keeping the temperature for 20 min). The combined MW extracts of both microwave extractions were concentrated by evaporation and cleared by subsequent centrifugation. The extracts were stored in a freezer (≤ -18°C).
The extracts of the beets and leaves were analysed by HPLC with radiodetection using reversed phase methods AEF360-2, AEF360-2A and the ion pair method AEF360-TBA1, which has a completely different selectivity than the reversed phase methods
Parent compound and metabolites were identified
• by HPLC and TLC co-chromatography of the conventional and microwave extracts with radiolabelled and non-radiolabelled reference compounds
• by HPLC and TLC co-chromatography of isolated compounds or fractions of various conventional extracts with radiolabelled and non-radiolabelled reference compounds
• by comparison of the HPLC profiles of the conventional and microwave extracts from leaves and beets with each other.

Results and discussion

The TRR values detected in beets and leaves were very low. Low TRR values were expected in this study due to low application rates applied at very early plant growth stages. Therefore, a second experiment with 2X application rate was performed. However, the TRR values in the RACs of the 2X target rate experiment as measured by LSC following combustion did not reflect the doubled application rate. Therefore, the samples from these experiments were not extracted. The leaves and beets of the 1X target rate experiment were extracted conventionally as well as with microwave support with acetonitrile/water mixtures or acetonitrile/formic acid mixtures releasing in total 74% and 62.5% of the TRR.

Table A 8: Total Radioactive Residues (TRRs) in sugar beet matrices.

Matrix	Timing and Applic. No.	PHI* (days)	TRR (ppm a.s. equivalent)
			[phenyl-UL-^{14}C]-foramsulfuron
Sugar beets	1X target rate experiment 1st application (BBCH 12-14), 28.0 g a.s./ha 2nd application (BBCH 14-18), 28.2 g a.s./ha	98	0.019
Leaves and tops		98	0.020
Sugar beets	2X target rate experiment 1st application (BBCH 12-14), 52.1 g a.s./ha 2nd application (BBCH 14-18), 54.0 g a.s./ha	98	0.026#
Leaves and tops		98	0.030#

* PHI: preharvest interval (corresponds to days after last treatment (DAT) at harvest/sampling)
# The TRR values given were determined by combustion followed by LSC.

Parent compound and metabolites in the extracts of leaves and beets were analysed by HPLC. Identification was performed by HPLC and/or TLC co-chromatography with reference compounds as well as by comparison of HPLC profiles. The major components and several minor components were identified.

Foramsulfuron was extensively metabolised in sugar beets into thirteen metabolites, most of them specific for the phenyl-label. Parent compound foramsulfuron was a minor component and represented 8.7% and 1.8% of the TRR. The metabolites AE0014940 and AE0338795 in leaves and AE0001082 and AEF153745 in beets were the major components and represented 11.0%, 19.0%, 13.9% and 11.3% of the TRR (0.002 mg/kg, 0.004 mg/kg, 0.003 mg/kg and 0.002 mg/kg). Minor metabolites identified were AE0001082 and AEF153745 in leaves, AE0014940 and AE0338795 in beets and AEF148003 in both matrices. Eight minor metabolites were not identified, but characterised by behaviour during extraction, clean up and chromatography. Additional details about the amounts of parent compound and metabolites are shown in the following table.

Table A 9: Summary of characterization and identification of Radioactive Residues in sugar beet matrices following application of [phenyl-UL-^{14}C]-foramsulfuron at 2x28 g/ha.

Compound Report name of compound (Foramsulfuron-)	**Leaves TRR = 0.020 ppm**		**Beets TRR = 0.019 ppm**	
	% TRR	**ppm**	**% TRR**	**ppm**
AE0014940	11.0	0.002	4.8	0.001
AE0001082	1.6	<0.001	13.9	0.003
AEF148003	8.8	0.002	6.7	0.001
AEF153745	9.0	0.002	11.3	0.002
AE0338795	19.0	0.004	0.9	<0.001
Parent compound	8.7	0.002	1.8	<0.001
Total identified	**58.0**	**0.011**	**39.4**	**0.007**
Unknown 1	1.3	<0.001	-	-
Unknown 2	1.9	<0.001	-	-
Unknown 3	-	-	2.9	0.001
Unknown 4	-	-	1.4	<0.001
Unknown 5	2.4	<0.001	-	-
Unknown 6	7.2	<0.001	4.2	0.001
Unknown 7	1.4	<0.001	-	-
Unknown 8	1.7	<0.001	-	-
Total characterized	**16.0**	**0.003**	**9.1**	**0.002**
Total extracted	**74.0**	**0.014**	**62.5**	**0.012**
Unextractable (PES)*	26.0	0.005	37.5	0.007
Accountability**	100.0	0.020	100.0	0.019

* Residues remaining after exhaustive extractions.
** Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.

Table A 10: Identification of compounds from metabolism study

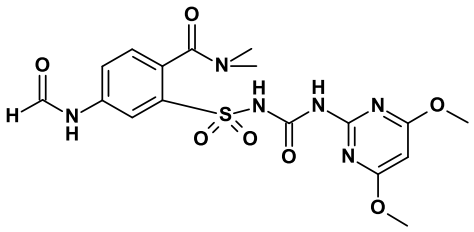
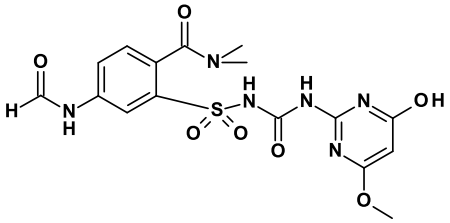
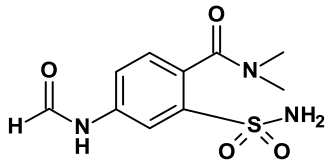
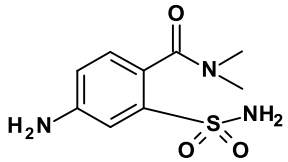
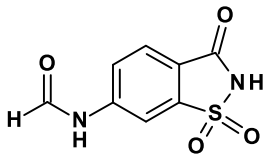
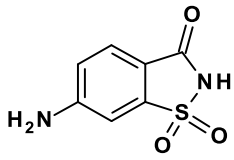
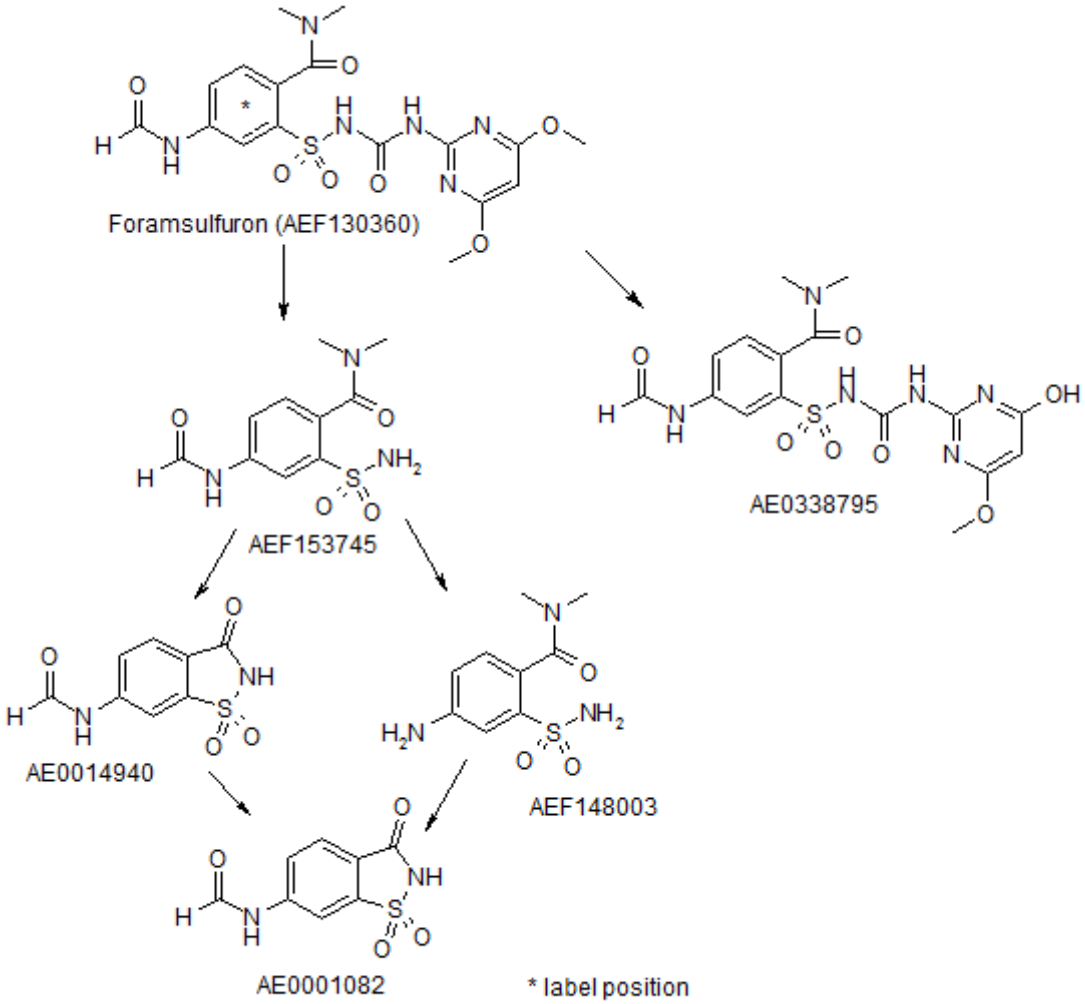
Common name/code	Chemical name	Chemical structure
Foramsulfuron AE130360	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea	
AE0338795	4-formamido-2-{[(4-hydroxy-6-methoxypyrimidin-2-yl) carbamoyl]sulfamoyl}-*N*,*N*-dimethylbenzamide	
AEF153745	4-formamido-*N*,*N*-dimethyl-2-sulfamoylbenzamide	
AEF148003	4-amino-*N*,*N*-dimethyl-2-sulfamoylbenzamide	
AE0014940	*N*-(1,1-dioxido-3-oxo-2,3-dihydro-1,2-benzothiazol-6-yl)formamide	
AE0001082	6-amino-1,2-benzothiazol-3(2H)-one 1,1-dioxide	

Figure A 1: Proposed Metabolic Profile of foramsulfuron in sugar beet ([phenyl-UL-^{14}C] label)



Conclusions

The metabolism of [phenyl-UL-^{14}C]-foramsulfuron in sugar beets was investigated according to the envisaged use pattern. The formulated test compound was applied to the sugar beets by post-emergence spray-application. A 2X target rate experiment was performed to increase the TRR values. However, the TRR values in the RACs of the 2X target rate experiment as measured by LSC following combustion did not reflect the doubled application rate.

The TRR levels were generally very low. In beets, only 0.019 mg/kg were detected, in leaves a comparable value of 0.020 mg/kg. The radioactive residues were extracted with acetonitrile/water mixtures. The conventional extraction was sufficient for neither leaves nor beets, but combined with a subsequent microwave extraction, the extraction efficiencies were sufficient (74% for leaves, 62.5% for beets). The residues remaining in the solids were very low (≤0.007 mg/kg).

The extraction efficiency in the samples from the hot water extraction, which was performed to analyse extraction behaviour during sugar production, was distinctly lower than in the extraction used for metabolic analysis.

The identification rate for leaves was about 58% of the TRR. Due to the very low TRR values in beets and losses during the clean up separation procedures (representing 14.6% of the TRR, but only 0.003 mg/kg), the identification rate in beets was lower than in leaves and amounted to about 40% of the TRR.
• Foramsulfuron was extensively metabolised in sugar beets into thirteen metabolites.
• Besides parent compound, five metabolites were identified and the majority of them were label-specific.
• Parent compound foramsulfuron was a minor component in the leaves and beets and was only found in the conventional extract.
• The major compounds (>10%) in beets were the metabolites AE0001082 and AEF153745, in leaves the metabolites AE0014940 and AE0338795.
• In beets, the metabolite AE0001082 was the most prominent compound, representing about 15% of the TRR. In leaves, the metabolite was only a minor compound.
• The only not-label-specific metabolite AE0338795 was the most prominent metabolite in leaves, representing about 20% of the TRR, but was only a minor compound in beets.
• Additionally, eight minor metabolites were not identified, but characterised by their chromatographic behaviour. All of them were minor or trace metabolites (≤0.001 mg/kg).

The following metabolic reactions were observed:
• cleavage of the sulfonylurea bridge or *O*-demethylation followed by cleavage of the sulfonylurea bridge followed by • a ring closure and deformylation (in random order).

A 2.1.2.1.2 Study EnSa-12-0511

Comments of zRMS:	Study is accepted

Version 01 was submitted in 2015. Version 2 is the amended report (correction of mistakes, names of person and test facilities)

Reference:	**KCA 6.2.1/02**
Title:	Amendment no. 1: Metabolism of [pyrimidine-2-14C]foramsulfuron in sugar beets
Report:	Klempner, A.; 2018; EnSa-12-0511; M-454046-02-1
Authority registration No:	
Guideline(s):	OECD Guideline for the Testing of Chemicals 501: Metabolism in Crops US EPA OCSPP Residue Chemistry Test Guideline OPPTS 860.1300: Nature of the Residue – Plants, Livestock PMRA Regulatory Directive Dir98-02: Residue Chemistry Guidelines Section 2: Nature of the Residue – Plants, Livestock Japanese MAFF, 12 Nousan 8147 European Parliament and Council Regulation (EC) No 1107/2009
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The metabolism of [pyrimidinyl-2-^{14}C]-foramsulfuron in sulfonyl urea resistant sugar beets (in development) was investigated according to the envisaged use pattern. Two different application rates (1X and 2X target rate) with two applications (1st application at BBCH 12-14 (= two leaves [first pair of leaves] unfolded till four leaves [second pair of leaves] unfolded) and 2nd application at BBCH 14-18 (= four leaves unfolded till eight leaves unfolded)) were covered by this study. In both experiments, [pyrimidinyl-2-^{14}C]-foramsulfuron was formulated as an OD 050 diluted in water at an application rate of 28.8 g a.s./ha

for the 1X target rate experiment (including 15% for losses) and 55 g a.s./ha for the 2X target rate experiment (including 10% for losses). At maturity the sugar beets were harvested. Concurrently, the leaves and beets were sampled.
Each experiment was conducted with sugar beets in a planting container with a surface area of approx. 1 m^2 with 11 plants per square metre. The two planting containers were filled with sandy loam soil. The plants were cultivated in the glass-roofed vegetation hall of the test facility. The plants were grown similar to natural temperature and light conditions, but protected from rainfall. The plants were watered by pouring onto the soil in the planting containers.
The sugar beets were harvested at BBCH 49 (harvestable size). The beets were dug out of the soil. Adhering soil was removed. Leaves were cut off ca. 5-10 cm above the beet top. The beets were washed, the beet tops cut of and sampled with the leaves. Beets were ground, leaves and beet tops were cut into ca. 1 cm long pieces and all samples were homogenised under liquid nitrogen using a high speed blender (Polytron). The samples were stored in a freezer (≤ -18°C) until extraction. Aliquots of the homogenised sample materials were used to determine the TRR by combustion analysis. Aliquots of the washing water were analysed by LSC.
Only RACs of the 1X application rate experiment were extracted. The leaves of the 1X target rate experiment were extracted three times with a mixture of acetonitrile/water (8/2, v/v) using a high speed blender (Polytron PT3100). After each extraction step, extracts and solids were separated by filtration. The remaining solids were further extracted by microwave treatment. The beets of the 1X target rate experiment were extracted three times with a mixture of ACN/water (1/1; v/v) using ahigh speed blender (Polytron). After each extraction step, extracts and solids were separated by filtration and, in case of filter blockage, by centrifugation. The remaining solids were extracted by microwave treatment. All combined extracts of the conventional extractions were subjected to a clean-up step using an SPE RP 18 cartridge (Phenomenex, Strata C18-E, 10 g, 20 g or 50 g), which was conditioned with ACN/water mixtures (1/1 or 8/2; v/v) or MeOH followed by water beforehand. The flowthrough fraction (effluent) was collected and the cartridge was rinsed with an ACN/water mixture (8/2; v/v) and tetrahydrofurane/methanol (1/1, v/v) or with water, followed by an ACN/water mixture (1/1; v/v) and ACN. The percolate and the first rinsing fraction were combined and concentrated by rotary evaporation in vacuo for HPLC analysis. The extracts were stored in a freezer (≤ -18°C).
The remaining solids from leaves and beets extraction were further extracted two times with ACN/water (1/1; v/v) and microwave treatment (5 min heating to 120°C, keeping the temperature for 20 min). The combined MW extracts of both microwave extractions were concentrated by evaporation and cleared by subsequent centrifugation. The extracts were stored in a freezer (≤ -18°C).

The extracts of the beets and leaves were analysed by HPLC with radiodetection using reversed phase methods AEF360-2 and AEF360-2A (see chapter 3.5.2) and the HPLC chromatograms were integrated.
Parent compound and metabolites were identified
• by HPLC and TLC co-chromatography of the conventional and microwave extracts with radiolabelled and non-radiolabelled reference compounds
• by HPLC and TLC co-chromatography of isolated compounds or fractions of various conventional extracts with radiolabelled and non-radiolabelled reference compounds
• by comparison of the HPLC profiles of the conventional and microwave extracts from leaves and beets with each other.

Results and discussion

The TRR values detected in beets and leaves were very low. Low TRR values were expected in this study due to low application rates applied at very early plant growth stages. Therefore, a second experiment with 2X application rate was performed. However, the TRR values in the RACs of the 2X target rate ex-

periment as measured by LSC following combustion did not reflect the doubled application rate. Therefore, the samples from these experiments were not extracted. The leaves and beets of the 1X target rate experiment were extracted with acetonitrile/water mixtures releasing 91.9% and 86.3% of the TRR.

Table A 11: Total Radioactive Residues (TRRs) in sugar beet matrices.

Matrix	Timing and Applic. No.	PHI* (days)	TRR (ppm a.s. equivalent)
			[pyrimidinyl-2-^{14}C]-foramsulfuron
Sugar beets	1X target rate experiment 1st application (BBCH 12-14), 28.2 g a.s./ha 2nd application (BBCH 14-18), 28.2 g a.s./ha	98	0.013
Leaves and tops		98	0.034
Sugar beets	2X target rate experiment 1st application (BBCH 12-14), 51.7 g a.s./ha 2nd application (BBCH 14-18), 54.0 g a.s./ha	98	0.025#
Leaves and tops		98	0.036#

* PHI: preharvest interval (corresponds to days after last treatment (DAT) at harvest/sampling)
# The TRR values given were determined by combustion followed by LSC.

Parent compound and metabolites in the extracts of leaves and beets were analysed by HPLC. Identification was performed by HPLC and/or TLC co-chromatography with reference compounds as well as by comparison of HPLC profiles. The major components and several minor components were identified. Foramsulfuron was extensively metabolised in sugar beets into sixteen metabolites. Parent compound foramsulfuron was a minor component and represented 9.3% and 2.8% of the TRR (0.003 mg/kg and <0.001 mg/kg). The metabolite guanidine, a natural compound in sugar beets, was a major component (>10% of the TRR) in leaves and beets, representing 39.6% of the TRR (0.013 mg/kg) in leaves and 10.7% (0.001 mg/kg) in beets. The metabolites AE0338795 in leaves and AEF092944 in beets were other major components and represented 10.0% of the TRR (0.003 mg/kg) and 28.9% (0.004 mg/kg). All other metabolites were minor. Each minor metabolite represented less than 10% of the TRR and was below 0.01 mg/kg. Minor metabolites identified were AEF092944 and AE099095 in leaves. Twelve minor metabolites were not identified, but characterised by their behaviour during extraction, clean up and chromatography.

Additional details about the amounts of parent compound and metabolites are shown in the following table.

Table A 12: Summary of characterization and identification of Radioactive Residues in sugar beet matrices following application of [pyrimidinyl-2-^{14}C]-foramsulfuron at 2x28 g/ha.

Compound Report name of compound (Foramsulfuron-)	Leaves TRR = 0.034 ppm		Beets TRR = 0.013 ppm	
	% TRR	ppm	% TRR	ppm
Guanidine	39.6	0.013	10.7	0.001
AEF092944	7.6	0.003	28.9	0.004
AE0338795	10.0	0.003	-	-
AEF099095	2.5	0.001	-	-
Parent compound	9.3	0.003	2.8	<0.001
Total identified	**69.0**	**0.023**	**42.3**	**0.005**
Unknown 1	-	-	0.6	<0.001
Unknown 2	3.3	0.001	2.8	<0.001
Unknown 3	-	-	1.5	<0.001
Unknown 4	4.8	0.002	1.5	<0.001
Unknown 5	-	-	1.5	<0.001
Unknown 6	3.2	0.001	0.6	<0.001
Unknown 7	2.7	0.001	0.8	<0.001
Unknown 8	-	-	1.2	<0.001
Unknown 9	1.1	<0.001	0.8	<0.001
Unknown 10	1.0	<0.001	0.7	<0.001
Unknown 11	0.9	<0.001	0.6	<0.001
Unknown 12	0.6	<0.001	-	-
Total characterized	**17.6**	**0.006**	**12.6**	**0.002**
Total extracted	**91.9**	**0.031**	**86.3**	**0.011**
Unextractable (PES)*	8.1	0.003	13.7	0.002
Accountability**	100.0	0.033	100.0	0.013

* Residues remaining after exhaustive extractions.
** Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.

Table A 13: Identification of compounds from metabolism study

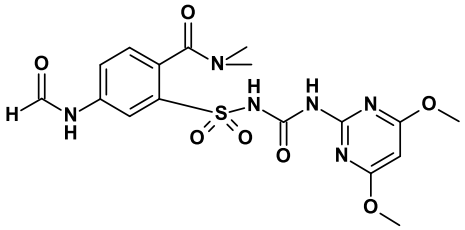
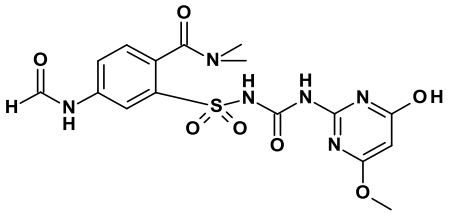
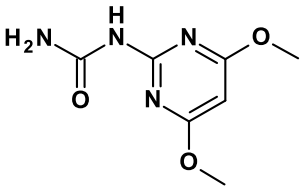
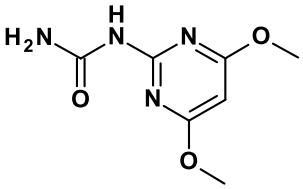
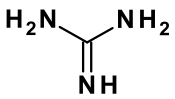
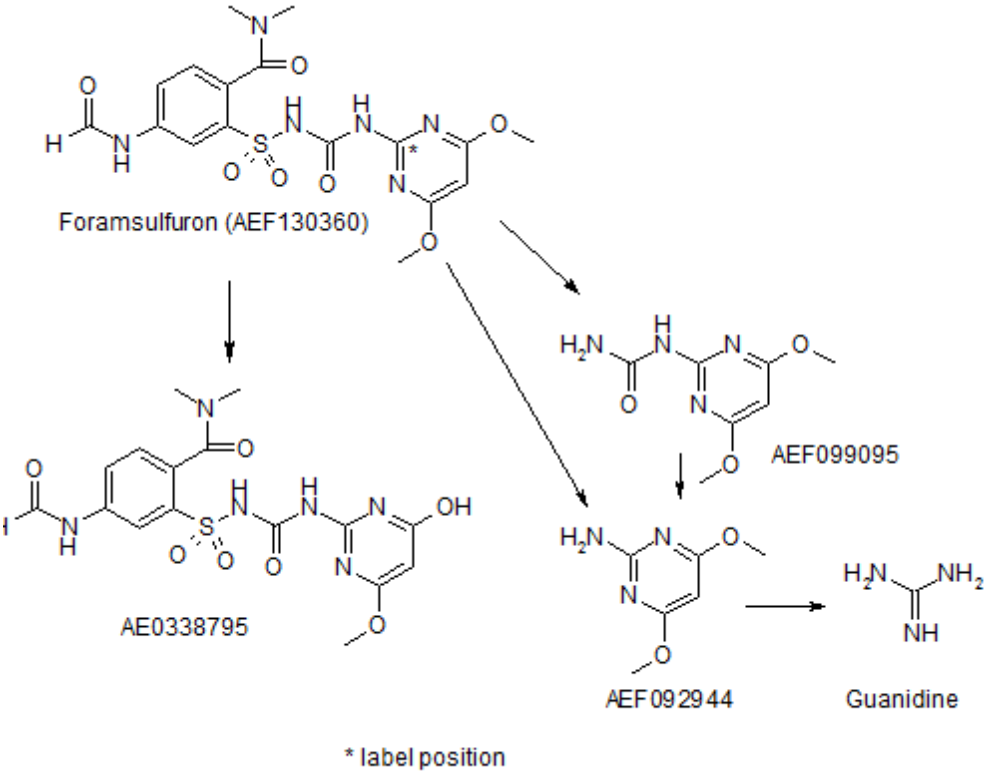
Common name/code	Chemical name	Chemical structure
Foramsulfuron AE130360	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea	
AE0338795	4-formamido-2-{[(4-hydroxy-6-methoxypyrimidin-2-yl) carbamoyl]sulfamoyl}-*N,N*-dimethylbenzamide	
AEF092944	4,6-dimethoxypyrimidin-2 amine	
AEF099095	1-(4,6-dimethoxypyrimidin-2-yl)urea	
Guanidine	Guanidine	

Figure A 2: Proposed Metabolic Profile of foramsulfuron in sugar beet ([pyrimidinyl-2-^{14}C] label)



Conclusions

The metabolism of [pyrimidinyl-2-^{14}C]-foramsulfuron in sugar beets was investigated according to the envisaged use pattern. The formulated test compound was applied to the sugar beets by post-emergence spray-application. A 2X target rate experiment was performed to increase the TRR values. However, the TRR values in the RACs of the 2X target rate experiment as measured by LSC following combustion did not reflect the doubled application rate.

The TRR levels were generally very low. In the beets, only 0.013 mg/kg were detected. The leaves showed a slightly higher TRR of 0.034 mg/kg. The radioactive residues were extracted with acetonitrile/water mixtures. The conventional extraction was sufficient for neither leaves nor beets, but combined with a subsequent microwave extraction, the extraction efficiencies were good (>86%). The residues remaining in the solids were very low (≤0.003 mg/kg). The extraction efficiency using sugar production methods with hot water were even lower than the extraction efficiencies of the extraction procedures used for metabolic profiling.

The identification rate for leaves was good and amounted to about 70% of the TRR. The identification rate in beets was lower than in leaves and amounted to about 42% of the TRR due to the very low TRR values in beets, losses during the clean-up procedure (representing 21.1% of the TRR, but only 0.003 mg/kg) and numerous minor metabolites, each with less than 3% of the TRR and less than 0.001 mg/kg, which were characterised.

• Foramsulfuron was extensively metabolised in sugar beets into sixteen metabolites.
• Besides parent compound, four metabolites were identified and the majority of them were label-specific.
• Parent compound foramsulfuron was a minor component in the leaves and beets.

• In beets, the metabolite AEF092944 was the most prominent compound, representing about 29% of the TRR. This metabolite was also the main hydrolysis product of the parent compound. In leaves, the metabolite was only a minor compound.
• The metabolite guanidine was the most prominent metabolite in leaves, representing about 40% of the TRR. Guanidine is known to be a natural compound in sugar beets.
• The only not-label-specific metabolite AE0338795 was detected in leaves with about 10% of the TRR (0.003 mg/kg).
• AEF099095 was a minor metabolite detected in leaves only.
• Additionally, twelve minor metabolites were not identified, but characterised by their chromatographic behaviour.
Three metabolic routes were observed:
• cleavage of the sulfonylurea bridge to 1-(4,6-dimethoxypyrimidin-2-yl)urea, followed by hydrolysis of the amide bond and further hydrolytic degradation,
• cleavage of the sulfonylurea bridge to 4,6-dimethoxypyrimidin-2-amine, followed by further hydrolytic degradation
• *O*-demethylation.

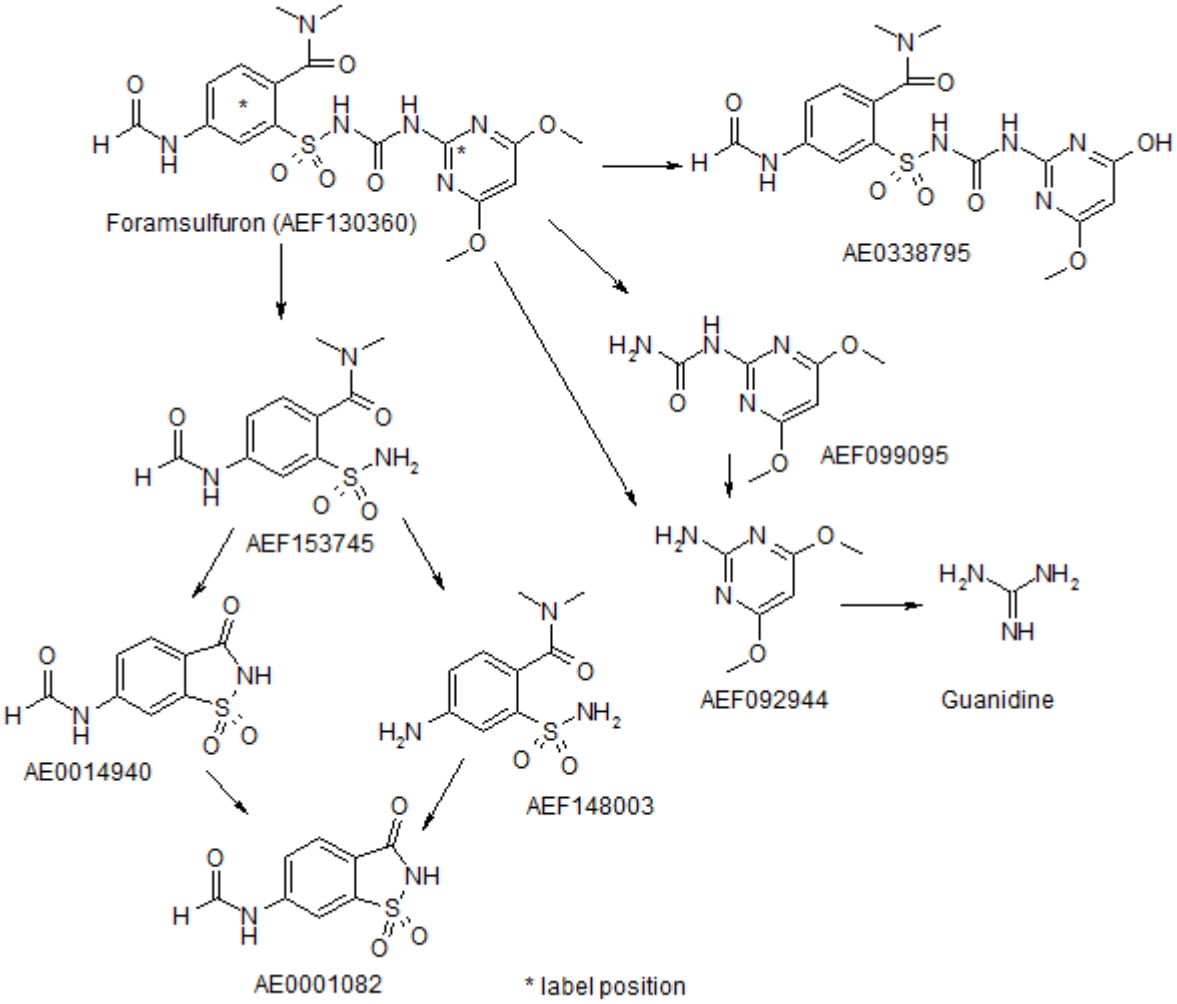
Overall conclusion

The metabolism of [pyrimidinyl-2-^{14}C]-foramsulfuron and of [phenyl-UL-^{14}C]-foramsulfuron in sugar beets was investigated according to the envisaged use pattern. The formulated test compound was applied to the sugar beets by post-emergence spray-application. A 2X target rate experiment was performed to increase the TRR values. However, the TRR values in the RACs of the 2X target rate experiment as measured by LSC following combustion did not reflect the doubled application rate.
The TRR levels were generally very low. In the beets, only 0.013-0.019 mg/kg were detected. The leaves showed a slightly higher TRR of 0.020-0.034 mg/kg. The radioactive residues were extracted with acetonitrile/water mixtures. The conventional extraction was sufficient for neither leaves nor beets, but combined with a subsequent microwave extraction.
The identification rate for leaves was 58- 70% of the TRR. The identification rate in beets was lower than in leaves and amounted to about 40-42% of the TRR due to the very low TRR values in beets, losses during the clean-up procedure and numerous minor metabolites.

• Foramsulfuron was extensively metabolised in sugar beets
• Besides parent compound, one non-label-specific and seven label-specific metabolites were identified
• Parent compound foramsulfuron was a minor component in the leaves and beets.

The metabolic reactions were:
• cleavage of the sulfonylurea bridge to 1-(4,6-dimethoxypyrimidin-2-yl)urea, followed by hydrolysis of the amide bond and further hydrolytic degradation,
• cleavage of the sulfonylurea bridge to 4,6-dimethoxypyrimidin-2-amine, followed by further hydrolytic degradation
• ring closure and deformylation
• *O*-demethylation.

Figure A 3: Proposed Overall Metabolic Profile of foramsulfuron in sugar beet ([phenyl-UL-^{14}C] label and [pyrimidinyl-2-^{14}C] label)



A 2.1.2.2 7.2.2.2 Nature of residue in rotational crops

A 2.1.2.2.1 Study S16-01039

Comments of zRMS:	Study is accepted

Reference:	**KCA 6.6.1/01**
Title:	Report amendment no.1 to final report - Metabolism of [pyrimidine-2-14C] foramsulfuron in rotational crops
Report:	Rieder, B.; 2019; S16-01039; M-625836-02-1
Authority registration No:	
Guideline(s):	OECD Test Guideline No. 502, (2007) Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 1107/2009 US EPA OCSPP Test Guideline No. 860.1850 (1996)
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

The test compound [pyrimidine-2-^{14}C]foramsulfuron was ^{14}C-radiolabelled in the [pyrimidine-2] ring. An adequate amount of the test compound was formulated as an OD 45 for the experiment. The test compound was dissolved in acetonitrile, evaporated to dryness and dissolved in the respective blank formulation (containing safener Isoxadifen-Ethyl). The resulting treating solution was applied onto the soil surface in a planting container (1 m^2 surface area) using a computer controlled track sprayer with a flat fan nozzle at a nominal application rate of 60 g a.s/ha. After subtraction of losses, the actual application rate was 64 g a.s./ha. The container was divided into three sectors and the rotational crops spring wheat (variety Kadrilij), Swiss chard (variety Feurio) and turnips (variety Rondo) were sown separately on each of these sectors. Sowing was done 30, 149 and 365 days after the application. Plants were cultivated in the greenhouse of the test facility (controlled temperature, humidity and light conditions).

The following plant matrices were sampled at each rotation: Swiss chard, turnip (leaves and roots), wheat (forage, hay, straw and grain).
From the first rotation, Swiss chard leaves were sampled in immature stage 72 days and as mature plants 113 days after application. Mature turnip matrices were sampled 113 days after application. Wheat was sampled in immature stage (forage) 55 days, as hay 80 days and as mature plants 102 days after the application.
From the second rotation, mature Swiss chard leaves were sampled in immature stage 262 days and as mature plants 276 days after application. Mature turnip matrices were sampled 255 days after application. Wheat was sampled in immature stage (forage) 196 days, as hay 230 days and as mature plants 246 days after the application.
From the third rotation, mature Swiss chard leaves were sampled in immature stage 408 days and as mature plants 441 days after application. Mature turnip matrices were sampled 441 days after application. Wheat was sampled in immature stage (forage) 395 days, as hay 429 days and as mature plants 441 days after the application.
Wheat forage was sampled at the end of tillering stage and wheat hay was sampled between the late milk state and the end the early dough state. To yield hay, the sample material was dried at room temperature for at least six days. At maturity, wheat plants were cut off shortly above soil surface. The grains were collected by hand and the remaining ears and chaffs were combined with straw.
Swiss chard (immature and at maturity) was cut from the roots, which remained in the soil. At maturity, the turnips were pulled out of the soil and the leaves were separated from roots. The roots were cut into slices and the leaves into small pieces.

All samples were homogenised with liquid nitrogen and stored at approx. ≤ -18 °C. All RACs of the respective rotations were extracted and first analytical profiles were obtained by HPLC analysis within less than 6 months after sampling. Exhaustive extracts were also extracted after 6 months.
Analytical profiles of exhaustive extractions of wheat forage and hay of the first rotation were obtained within 235-249 days after sampling. The partitioning of the dioxane extract was completed 198-649 days after sampling for wheat feed matrices of the first rotation. The analytical profile of the wheat grain extract from enzymatic digestion of the second rotation was obtained 443 days after harvest.
The stability of the extract of enzymatic digestion of wheat grain of the first rotation was demonstrated by re-analysis of the extract by HPLC after 56 weeks of storage. Comparing the HPLC analyses of the conventional extracts and exhaustive extracts of the RACs, no significant alteration in the metabolites pattern were observed. Therefore, it was concluded that the results of this study were not negatively influenced by storage effects.

Aliquots of the homogenised wheat forage, hay, straw and grain of the first rotation, wheat hay, straw and grain of the second rotation and wheat straw of the third rotation were successively extracted with acetonitrile/water (80:20, v/v, 3x) using a high-speed blender. Dry matrices (wheat hay, straw and grain) of the first and second rotation were mixed with water beforehand to extraction for soaking for 30 min. Acetonitrile added for extraction using a high speed blender. After each extraction step, the extracts were separated from the solids by suction through a filter. All extracts were combined and the solids were air-dried. The combined acetonitrile/water extract of each matrix was subjected to a clean-up step using an equilibrated SPE RP 18 cartridge. The percolate and rinse were collected and the cartridge was eluted with acetonitrile water (80/20, v/v). Less polar fractions on the cartridge were eluted with methanol/tetrahydrofuran (1/1, v/v). The percolate and rinse fractions were combined, mixed with emulsifier and evaporated to the aqueous remainder. The aqueous remainder was measured for radioactivity and investigated by HPLC. Turnip and Swiss chard samples were not extracted due to low amounts of total radioactive residues (< 0.010 mg eq/kg).

An aliquot of solids of forage (first rotation), of hay (first and second rotation), straw (all rotations) and grain (first and second rotation) was further extracted exhaustively twice with acetonitrile/water/formic acid (50/50/1, v/v/v) for 20 min at 120°C using a microwave. The extracts were filtered by suction and centrifugation. After the extracts were combined, aliquots of these samples were subjected to a clean-up step using an equilibrated SPE RP 18 cartridge. The percolate and rinse was collected and the cartridge was eluted with acetonitrile/water (80/20, v/v). Less polar fractions on the cartridge were eluted with methanol/tetrahydrofuran (1/1, v/v). The percolate and rinse fractions were combined, mixed with emulsifier and evaporated to the aqueous remainder. The aqueous remainder was measured for radioactivity and investigated by HPLC.

Solids of wheat hay and wheat straw after exhaustive extraction of the first rotation were further investigated by extraction with dioxane/HCL (9/1, v/v, 2x) under microwave assistance (20 min at 120 °C). After each extraction step, extract and solids were filtrated by suction and centrifugation. The residual solids were dried at room temperature and the two filtrates were combined and further characterised by partitioning with water and n-heptane in a ratio of 1/1/1 in a separatory funnel. The resulting aqueous phase and organic phase were separated.

Solids of wheat grain after exhaustive extraction of the first and the second rotation were further investigated by enzymatic cleavage. The solids were treated with the enzyme amylase in a sodium acetate buffer for 24 hours at 37 °C. The sample was shaken several times and centrifuged for 5 min at 14500 rpm. The procedure was repeated one time using similar amounts of buffer and enzyme. The two filtrates were combined and the residual solids were dried at room temperature. After digestion, the respective extract was concentrated and further analysed by HPLC.

The radioactivity in the combined acetonitrile/water extracts, the microwave extracts as well as in the aqueous phases and organic phases, and in the amylase extract was determined by liquid scintillation counting (LSC). The solids were combusted. The CO2 produced by combustion was absorbed in a CO2 absorbent / scintillation cocktail mixture and the radioactivity was measured by LSC. The TRR in the RAC samples was calculated by summing up the radioactivity measured in the combined acetonitrile/water extract and remaining solids. Amounts of radioactive residues in the extracts were expressed as percentage of the TRR and also as mg eq/kg.

The conventional and exhaustive extracts as well as respective extracts after digestion were analysed by reverse –phased HPLC with radiodetection (generally by a MicroBeta counter after fractionation on luma plates) and by TLC using glass-coated Silica gel plates (0.25 mm thickness) with radiodetection (BioImaging Analyzer). Corresponding metabolites were assigned to each other by comparison of the metabolite profiles and retention times based on the HPLC profiling method.

The metabolite guanidine was identified by TLC and HPLC co-chromatography using a reference compound. One other metabolite ("unknown 1) had a similar retention time in the HPLC profiling method as the reference compound AE F0338795, but could not be assigned to the reference compound by HPLC and TLC co-chromatography.

Radioactive residues were only moderately extractable by conventional extraction but could be sufficiently extracted by use of exhaustive extraction methods using microwave assistance and specific extraction methods as enzymatic digestion with amylase or dioxane/HCl extraction, which is very typical
for samples with incorporated radioactivity.

The majority of the radioactivity in wheat RACs was bound to or incorporated into natural compounds like starch or lignin. This is supported by the findings that the radioactivity in post extraction solids of hay and straw was releasable by use of dioxane/HCl indicating a former binding to lignin structures and the released radioactivity was very polar as shown by partitioning of the extracts. And furthermore a distinct amount of the radioactivity in grain was assimilated into carbohydrates and released during enzymatic digestion of the carbohydrates with amylase.

Results and discussion

In the first rotation, the total radioactive residues (TRR) in food commodities amounted to 0.005 mg eq/kg for Swiss chard (immature and at maturity) and turnip roots and 0.032 mg eq/kg for wheat grains. The TRR level in feed commodities was slightly higher, amounting to 0.006 mg eq/kg for turnip leaves and 0.011-0.054 mg eq/kg for wheat feed matrices. In the second rotation, the total radioactive residues (TRR) in food commodities amounted to 0.004 mg eq/kg for Swiss chard (immature), 0.003 mg eq/kg for Swiss chard at maturity, 0.003 mg eq/kg for turnip roots and 0.017 mg eq/kg for wheat grains. The TRR level in feed commodities was slightly higher, amounting to 0.004-0.016 mg eq/kg. In the third rotation, the total radioactive residues (TRR) in food commodities was very low and amounted to 0.002 mg eq/kg for Swiss chard (immature), 0.001 mg eq/kg for Swiss chard at maturity, 0.001 mg eq/kg for turnip roots and 0.004 mg eq/kg for wheat grains. In feed commodities, the TRR values ranged from 0.001 to 0.012 mg eq/kg.

Comparing the TRRs from all three rotations a significant decline in the radioactive residues in all RACs can be observed. Throughout the study, the highest residues were found in the feed commodities of wheat (see the table a, below.). As the total radioactive residues in the current study were very low, only wheat RACs with a total radioactive residue > 0.01 mg eq/kg were extracted. Turnip and swiss chard samples

from all rotations were not extracted due to the low amounts of total radioactive residues (<0.010 mg eq/kg).

The parent compound foramsulfuron was completely metabolised within the current study and up to three metabolites were detected and further studied by chromatographic methods. Guanidine was the only metabolite identified in the different matrices. In all analysed sample materials of the first rotation, guanidine was the major radioactive component, accounting for 24.8–36.9% in feed commodities of wheat, and for 65.1% in wheat grain. In the second rotation, guanidine represented 18.5% and 14.4% in wheat hay and straw, respectively, and 67.8% in wheat grain. In the third rotation of wheat straw, guanidine was the only component accounting for 43.5% of the TRR. Although observed in levels >0.01 mg eq/kg in 4 wheat matrices (hay, straw, grain (1st rotation); grain (2nd rotation)), it was never observed at levels above 0.003 mg/kg when expressed as itself.
Two unknown metabolites were additionally characterised in in wheat feed commodities in the current study. Each of them was below below 0.01 mg eq/kg.

Turnip (leaves and roots) and Swiss chard (immature and mature) were not extracted due to very low residue amounts (< 0.010 mg eq/kg). Only wheat RACs with a total radioactive residue > 0.010 mg eq/kg were conventionally extracted in this study.

Wheat grain
Small portions of the radioactive residues in grain (first and second rotation) was extractable with acetonitrile/water (12.8-15.3% of the TRR, 0.002-0.005 mg eq/kg) and exhaustive extractions (7.3-11.3% of the TRR, 0.002 mg eq/kg); a larger portion of the TRR (55.0-56.6%, 0.009-0.018 mg eq/kg) was released by treatment with amylase. Non-extractable residues amounted to 20.8-20.9% of the TRR (0.004-0.007 mg eq/kg) (see the tables b, c & d below).

Wheat forage
Major amounts of the radioactivity (49.8% of the TRR, 0.005 mg eq/kg) in wheat forage of the first rotation were extractable with acetonitrile/water and 14.2% of the TRR (0.001 mg eq/kg) was exhaustively extracted. Non-extractable residues amounted to 36.0% of the TRR (0.004 mg eq/kg) (see the tables b, c & d below).

Wheat hay
Major amounts of the radioactivity (23.0-25.8% of the TRR, 0.004-0.010 mg eq/kg) were extractable with acetonitrile/water in the first and second rotation. Similar amounts were released by exhaustive extractions (15.1-18.8% of the TRR, 0.002-0.007 mg eq/kg). After dioxane-HCl extraction and partitioning of the first extraction, major amounts of residues were found in the aqueous phase (40.7% of the TRR, 0.016 mg eq/kg) and minor amounts in the organic phase (2.0% of the TRR, <0.001 mg eq/kg). Non-extractable residues amounted to 12.7 % of the TRR (0.005 mg eq/kg) in the first rotation, and to 61.9% of the TRR (0.010 mg eq/kg) in the second rotation (see the tables b, c & d below).

Wheat straw
Major amounts of the radioactivity (36.1-43.5% of the TRR, 0.005-0.020 mg eq/kg) were extractable with acetonitrile/water. Smaller amounts were released by exhaustive extractions (3.3-15.2% of the TRR, 0.002 mg eq/kg). After dioxane-HCl extraction and partitioning of the first extraction, major amounts of residues were found in the aqueous phase (37.5% of the TRR, 0.020 mg eq/kg) and minor amounts in the organic phases (8.7% of the TRR, 0.005 mg eq/kg). Non-extractable residues amounted to 14.5-46.5% of the TRR (0.005-0.008 mg eq/kg) (see the tables b, c & d below).

The results are summarised in the tables e, f and g, below The identified compound is listed in the table d,

below.

Table A 14: Total Radioactive Residues (TRRs) in in wheat, Swiss chard and turnip matrices (including soil).

Table a.	**Total Radioactive Residues (TRRs) in wheat, Swiss chard and turnip matrices (including soil).**				
Rotation/ Plant-back interval (days)	**Crop**	**Sampled commodity**	**Sampling (DAT*)**	**Growth stage**	**TRR (mg eq/kg)**
0	Soil (mean value from 10 filter papers)				304100 dpm/g (1.12 mg a.s. eq/kg)
1 / 30	Soil samples in 0-20 cm depth (mean value from 5 soil samples)				10028 dpm/g (0.037 mg a.s. eq/kg)
	Swiss chard	leaves	72	immature	0.005
			113	mature	0.005
	Turnip	leaves	113		0.006
		roots			0.005
	Spring wheat	forage	55	immature (hay: soft dough)	0.011
		hay	80		0.038
		grain	102	mature	0.032
		straw			0.054
2 / 149	Soil samples in 0-20 cm depth (mean value from 5 soil samples)				6473 dpm/g (0.0024 mg a.s. eq/kg)
	Swiss chard	leaves	262	immature	0.004
		leaves	276	mature	0.003
	Turnip	leaves	255		0.004
		roots			0.003
	Spring wheat	forage	196	immature (hay: soft dough)	0.004
		hay	230		0.016
		grain	246	mature	0.017
		straw			0.012
3 / 365	Soil samples in 0-20 cm depth (mean value from 5 soil samples)				6378 dpm/g (0.024 mg a.s. eq/kg)
	Swiss chard	leaves	408	immature	0.002
			441	mature	0.001
	Turnip	leaves	441		0.001
		roots			0.001
	Spring wheat	forage	395	immature (hay: soft dough)	0.002
		hay	429		0.009
		grain	441	mature	0.004
		straw			0.012

Table A 15: Distribution of the parent and the metabolites in rotational crop matrices when dosed with 14C-labeled foramsulfuron.

Table b	**Distribution of radioactivity in the extracts of the wheat matrices of rotational crops planted 30 days (first rotation) after pre-plant soil application of [pyrimidine-2-^{14}C]-Foramsulfuron**							
Metabolite Fraction	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.011		0.038		0.054		0.032	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Acetonitrile/water extracts	49.8	0.005	25.8	0.010	36.1	0.020	15.3	0.005
Exhaustive extracts	14.2	0.001	18.8	0.007	3.3	0.002	7.3	0.002
Dioxane/HCl extraction	---	---	42.7	0.016	46.2	0.025	---	---
Dioxane/HCl extract portioned in:								
aqueous phase	---	---	40.7	0.016	37.5	0.020	---	---
organic phase	---	---	2.0	<0.001	8.7	0.005	---	---
Digestion by amylase							56.6	0.018
Total extracted	64.0	0.007	87.3	0.033	85.5	0.046	79.1	0.025
Total bound residues (PES)	36.0	0.004	12.7	0.005	14.5	0.008	20.9	0.007
Accountability	100.0	0.011	100.0	0.038	100.0	0.054	100.0	0.032

--- not performed

Table c	**Distribution of radioactivity in the extracts of the wheat matrices of rotational crops planted 149 days (second rotation) after pre-plant soil application of [pyrimidine-2-^{14}C]-Foramsulfuron**							
Metabolite Fraction	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.004		0.016		0.012		0.017	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Acetonitrile/water extracts	23.0	0.004	38.5	0.005	23.0	0.004	12.8	0.002
Exhaustive extracts	15.1	0.002	15.0	0.002	15.1	0.002	11.3	0.002
Digestion by amylase	---	---	---	---	---	---	55.0	0.009
Total extracted	---	---	38.1	0.006	53.5	0.008	79.2	0.013
Total bound residues (PES)	---	---	61.9	0.010	46.5	0.004	20.8	0.004
Accountability	100.0	0.004	100.0	0.016	100.0	0.012	100.0	0.017

--- not performed

Table d	**Distribution of radioactivity in the extracts of the wheat matrices of rotational crops planted 365 days (third rotation) after pre-plant soil application of [pyrimidine-2-^{14}C]-foramsulfuron**							
Metabolite Fraction	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.002		0.009		0.012		0.004	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Acetonitrile/water extracts	---	---	---	---	43.5	0.005	---	---
Exhaustive extracts	---	---	---	---	15.2	0.002	---	---
Total extracted	---	---	---	---	58.7	0.007	---	---

Table d	**Distribution of radioactivity in the extracts of the wheat matrices of rotational crops planted 365 days (third rotation) after pre-plant soil application of [pyrimidine-2-^{14}C]-foramsulfuron**							
Total bound residues (PES)	---	---	---	---	41.3	0.005	---	---
Accountability	100.0	0.002	100.0	0.009	100.0	0.012	100.0	0.004

--- not performed

Table A 16: Summary of characterization and identification of Radioactive Residues in rotational crop matrices following application of radiolabeled formasulfuron at 64 g/ha.

Table e	**Summary of characterization and identification of Radioactive Residues in rotational crop matrices (first rotation) following application of radiolabeled [pyrimidine-2-^{14}C]-foramsulfuron at 64 g/ha.**							
Compound	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.011		0.038		0.054		0.032	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Guanidine	24.8	0.002 (0.0003*)	36.9	0.014 (0.0018*)	27.8	0.015 (0.0020*)	65.1	0.021 (0.0027*)
Total identified	24.8	0.002	36.9	0.014	27.8	0.015	65.1	0.021
Total characterised	39.2	0.004	48.2	0.018	57.3	0.031	7.3	0.002
Total extractable	64.0	0.007	87.3	0.033	85.5	0.046	79.1	0.025
Unextractable (PES)[1]	36.0	0.004	12.7	0.005	14.5	0.008	20.9	0.007
Accountability[2]	100.0	0.011	100.0	0.038	100.0	0.054	100.0	0.032

- ~~* Expressed as itself (x59.01/454.44)~~

1 Residues remaining after exhaustive extractions.

2 Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.

Table f.	**Summary of characterization and identification of Radioactive Residues in rotational crop matrices (second rotation) following application of radiolabeled [pyrimidine-2-^{14}C]-foramsulfuron at 64 g/ha.**							
Compound	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.004		0.016		0.012		0.017	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Guanidine	---	---	18.5	0.003 (0.0004*)	14.4	0.002 (0.0003*)	67.8	0.011 (0.0014*)
Total identified	---	---	18.5	0.003	14.4	0.002	67.8	0.011
Total characterised	---	---	19.6	0.003	39.1	0.006	11.3	0.002
Total extractable	---	---	38.1	0.006	53.5	0.008	79.2	0.013
Unextractable (PES)[1]	---	---	61.9	0.010	46.5	0.005	20.8	0.004
Accountability[2]	100.0	0.004	100.0	0.016	100.0	0.012	100.0	0.017

--- not performed

- ~~* Expressed as itself (x59.01/454.44)~~

Table g.	**Summary of characterization and identification of Radioactive Residues in rotational crop matrices (third rotation) following application of radiolabeled [pyrimidine-2-^{14}C]-foramsulfuron at 64 g/ha.**							
Compound	**Wheat forage**		**Wheat hay**		**Wheat straw**		**Wheat grain**	
	0.002		0.009		0.012		0.004	
	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg	% TRR	mg eq/kg
Guanidine	---	---	---	---	43.5	0.005	---	---
Total identified	---	---	---	---	43.5	0.005 (0.0007*)	---	---
Total characterised	---	---	---	---	15.2	0.002	---	---
Total extractable	---	---	---	---	58.7	0.007	---	---
Unextractable (PES)[1]	---	---	---	---	41.3	0.005	---	---
Accountability[2]	100.0	0.002	100.0	0.009	100.0	0.012	100.0	0.004

--- not performed

~~* Expressed as itself (x59.01/454.44)~~

1 Residues remaining after exhaustive extractions.

2 Accountability = (Total extractable + Total unextractable)/(TRRs from combustion analysis) * 100.

Table A 17: Identification of compounds from metabolism study

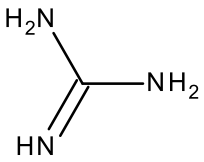
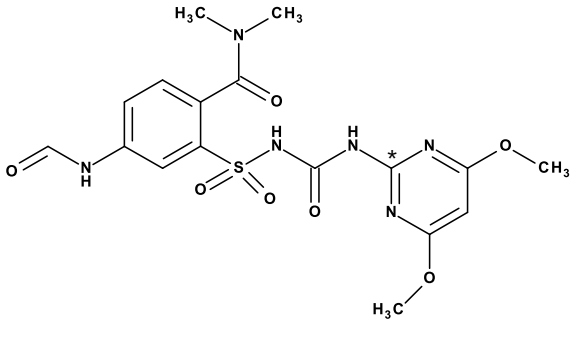
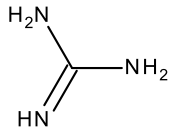
Table d	**Identification of compounds from metabolism study**	
Common name/code	*Chemical name*	*Chemical structure*
Guanidine	guanidine	

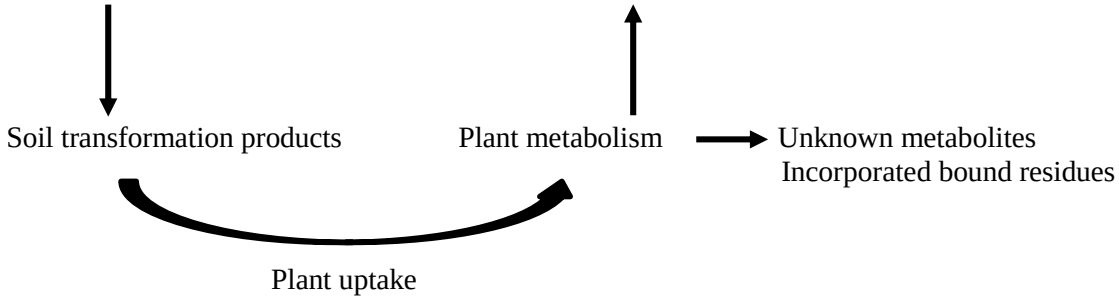
Figure A 4: Proposed Metabolic Profile of [pyrimidine-2-^{14}C]-foramsulfuron] in rotational crops



[pyrimidine-2-^{14}C]foramsulfuron



Guanidine



Conclusions

Rotational crops Swiss chard, turnips and wheat were sown/planted 30, 149 and 365 days after one pre-plant soil application of [pyrimidine-2-^{14}C]foramsulfuron at a rate of 64 g a.s./ha.

Swiss chard leaves, turnip (leaves and roots) as well as wheat straw and grain were sampled at maturity. Additionally, immature samples of Swiss chard leaves, wheat forage and hay were taken at each rotation.

Total radioactive residues in turnip and Swiss chard RACs of all three rotations were very low (<0.01 mg eq/kg) and thus not analysed in this study. The TRR values were low in the first rotation and further declined in the second and third rotation down to negligible amounts. Wheat RACs with radioactive residues ≥0.010 mg eq/kg were extracted and analysed by HPLC. The radioactive residues in all wheat RACs of the first rotation were low and accounted for 0.011 mg eq/kg (wheat forage), 0.038 mg eq/kg (wheat hay), 0.054 mg eq/kg (wheat straw) and 0.032 mg eq/kg (wheat grain) and constantly declined to ≤0.012 mg eq/kg (wheat straw) in the third rotation.

Radioactive residues were only moderately extractable by conventional extraction but could be sufficiently extracted by use of exhaustive extraction methods using microwave assistance and specific extraction methods as enzymatic digestion with amylase or dioxane/HCl extraction. The radioactivity in the remaining solids after all extraction steps was below 0.01 mg eq/kg in all RACs, therefore the overall extraction efficiency can be described as sufficient in the current study. In general the extraction efficiency of the conventional extraction procedure was only moderate for feed items and even lower for grain but could be significantly increased by exhaustive extraction using microwave assistance. Additional specific extraction methods for residues bound to lignin structures (dioxane/HCl Extraction) and residues bound to carbohydrates (amylase extraction) further increased the extraction efficiencies in this study significantly

and additionally characterised the residues based on their extractability. In total 64.0%, 87.3 %, 85.5% and 79.1% of TRR were extracted from wheat forage, hay, straw and grain of the 1st rotation. 38.1%, 53.5% and 79.2% of TRR were totally extracted from wheat hay, straw and grain of the 2nd rotation and 58.7% of TRR from wheat straw of the 3rd rotation. None of the unextractable residues accounted for more than trace amounts (<0.01 mg eq/kg).

The majority of the radioactivity in wheat RACs was bound to or incorporated into natural compounds like starch or lignin. This is supported by the findings that the radioactivity in post extraction solids of hay and straw was releasable by use of dioxane/HCl indicating a former binding to lignin structures and the released radioactivity was very polar as shown by partitioning of the extracts. And furthermore a distinct amount of the radioactivity in grain was assimilated into carbohydrates and released during enzymatic digestion of the carbohydrates with amylase.

The metabolism of foramsulfuron in the rotational crops was extensive and the parent compound was not found in any of the rotations, but up to three metabolites were detected. Guanidine was the only metabolite identified (in wheat matrices), representing 24.8% of the TRR of wheat forage, 36.9% of the TRR in wheat hay, 27.8% of the TRR in wheat straw and 65.1% of the TRR in wheat grain from the first rotation and 18.5% of the TRR in wheat hay, 14.4% of the TRR in wheat straw and 67.8% of the TRR of wheat grain from the second rotation, respectively. In wheat straw of the third rotation, guanidine accounted for 43.5% of the TRR. Although observed in levels >0.01 mg eq/kg in 4 wheat matrices (hay, straw, grain (1st rotation); grain (2nd rotation)), it was never observed at levels above 0.003 mg/kg when expressed as itself.

All results led to the conclusion that due to the type of application as treatment of bare soil prior to planting, a degradation of the parent compound as observed in the aerobic soil study performed with the test compound could also occur in the surrounding soil after planting of the commodities and that an uptake of the soil metabolites in the plants occurred followed by further degradation under release of $^{14}CO_2$ and assimilation of $^{14}CO_2$ into natural plant compounds *e.g.* guanidine (exemplarily for arginine synthesis), carbohydrates and lignin. This could also be demonstrated in a primary crop study of the test compound with sugarbeets.

Two unknown metabolites (unknown 1 and unknown 2) were additionally detected and characterised by their chromatographic behaviour in the present study at only trace quantities (<0.002 mg eq/kg). The metabolite unknown 1 showed a comparable elution behaviour in HPLC analysis as one reference compound, but TLC and HPLC co-chromatography demonstrates that the metabolite of the present study was not identical with this reference compound. It can be assumed that due to the ageing of the soil prior to sowing the primary metabolites were already further degraded and no longer available for uptake by the plants.

Based on the identified metabolites, it can be concluded that the metabolisation in rotational crops includes the following metabolic routes:

- Cleavage of the sulfonylurea bridge followed by hydrolysis of the amid bond and further hydrolytic degradation

The test compound was completely degraded and guanidine was detected as the main metabolite in all RACs of the present study.

Based on these results, the degradation behaviour of [pyrimidine-2-^{14}C]foramsulfuron in rotational crops is adequately understood.

A 2.1.2.3 7.2.2.3 Nature of residues in processed commodities

No new study submitted.

A 2.1.2.4 7.2.2.5 Nature of residues in livestock

No new study submitted.

A 2.1.2.4.1 Poultry

No new study submitted.

A 2.1.2.4.2 Lactating ruminants

No new study submitted.

A 2.1.2.4.3 Pigs

No new study submitted.

A 2.1.2.4.4 Fish

No new study submitted.

A 2.1.3 7.2.3 Magnitude of residues in plants

A 2.1.3.1 Sugar beet and fodder beet

Table A 18: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg as/ha)	Interval between applications	Growth stage at last application BBCH	PHI (days)
cGAP EU (DAR, RMS, year)	Use not assessed				
cGAP EU (Art. 12, EFSA,year)	Use not assessed				
Intended cGAP	1	0.050	N/A	18	N/A
Intended cGAP	2	0.025	10 days	18	N/A

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

A 2.1.3.1.1 Study 12-2138 (NEU)

Comments of zRMS:	Study is accepted. Study was reviewed in the following zonal dossiers: LIT (zRMS, North), and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone.

Reference:	**KCA 6.3/01**
Title:	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands
Report:	Stuke, S.; Diehl, P.; 2014; 12-2138; M-480852-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial US EPA OCSPP Guideline No. 860.1500
Deviations:	Yes, see Appendix 5
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	

Table A 19: Summary of the study 12-2138 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F153745 (determined as AE F153745, calculated as AE F153745)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1 foramsulfuron	Analyte 2 AE F153745		
	(a)	(b)				(c)					(d)	(e)
12-2138-01 United Kingdom CB22 5EU Cambridge Europe, North F 2012	Beet, sugar VV-ZR02332; SU Tolerant	1) 30.03.2012 3) 17.09.2012 - 31.12.2012	50	200	25	27.05.2012	15	whole plant with root	4.4	0.029	0	(f) 12-2138 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2139, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 351 days Analyte 1, 2 leaf with root collar: 206 days Analyte 1, 2 body: 221 days
								body	<0.01	<0.01	138	
								leaf with root collar	<0.01	<0.01	138	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2138-02 Germany 59457 Werl-Niederbergstraße Europe, North F 2012	Beet, sugar V V - Z R 02332	1) 26.03.2012 3) 10.09.2012 - 20.12.2012	50	300	17	14.05.2012	14	whole plant with root	1.9	0.015	0	(f) 12-2138 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2139, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 364 days Analyte 1, 2 leaf with root collar: 236 days Analyte 1, 2 body: 251 days
								body	<0.01	<0.01	121	
								leaf with root collar	<0.01	<0.01	121	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2138-03 Germany 51399 Burscheid Europe, North F 2012	Beet, sugar VV-ZR02332	1) 16.04.2012 3) 01.09.2012 - 30.11.2012	50	300	17	29.05.2012	14	whole plant with root	3.8	0.030	0	(f) 12-2138 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg
								body	<0.01	<0.01	104	Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in meth-od 01340 and within this study and studies 12-2139, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 349 days
								leaf with root collar	<0.01	<0.01	104	Analyte 1, 2 leaf with root collar: 238 days Analyte 1, 2 body: 253 days

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2138-04 France, north 95000 Cergy Europe, North F 2012	Beet, sugar V-V-ZR02332 Rueben; SU-resistant sugar beet	1) 10.05.2012 3) 25.10.2012 - 31.10.2012	50	300	17	14.06.2012	14	whole plant with root	2.3	0.014	0	(f) 12-2138 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2139, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 333 days Analyte 1, 2 leaf with root collar: 193 days Analyte 1, 2 body: 208 days Storage temperature exceeded, therefore special stability study S13-03307.
								body	<0.01	<0.01	133	
								leaf with root collar	<0.01	<0.01	133	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1 foramsulfuron	Analyte 2 AE F153745		
	(a)	(b)				(c)					(d)	(e)
12-2138-05 Netherlands 1175 KD Lijnden Europe, North F 2012	Beet, sugar Sugerbeets (sulfuron resistance); Batch: W-ZR02332	1) 30.03.2012 3) 10.11.2012 - 20.11.2012	50	300	17	23.05.2012	14	whole plant with root	2.5	0.023	0	(f) 12-2138 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg
								body	<0.01	<0.01	134	Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in meth-od 01340 and within this study and studies 12-2139, 12-2100 and 12-2101
								leaf with root collar	<0.01	<0.01	134	(l) Analyte 1, 2 whole plant with root: 355 days Analyte 1, 2 leaf with root collar: 214 days Analyte 1, 2 body: 229 days

- (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
- (f) Study reference
- (g) Formulation type
- G greenhouse F field
- (h) Application method
- (i) Method information
- (j) LOQ
- (k) Method validation
- (l) Storage (max)
- * prior to last treatment
- ** residue in control
- # no data available

A 2.1.3.1.2 Study 12-2139 (NEU)

Comments of zRMS:	Study is accepted. Study was reviewed in the following zonal dossiers: LIT (zRMS, North), and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone.

Reference:	**KCA 6.3/02**
Title:	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands
Report:	Stuke, S.; Diehl, P.; 2014; 12-2139; M-480864-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial US EPA OCSPP Guideline No. 860.1500
Deviations:	Yes, see Appendix 5
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Table A 20: Summary of the study 12-2139 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F153745 (determined as AE F153745, calculated as AE F153745)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2139-01 United Kingdom CB22 5EU Cambridge Europe, North F 2012	Beet, sugar VV-ZR02332; SU Tolerant	1) 30.03.2012 3) 17.09.2012 - 31.12.2012	25 25	200 200	13 13	27.05.2012/0 10.06.2012/14	18	whole plant with root	1.3	<0.01	0	(f) 12-2139 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2138, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 341 days Analyte 1, 2 leaf with root collar: 216 days Analyte 1, 2 body: 222 days
								body	<0.01	<0.01	124	
								leaf with root collar	<0.01	<0.01	124	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2139-02 Germany 59457 Werl-Niederbergstraße Europe, North F 2012	Beet, sugar V V - Z R 02332	1) 26.03.2012 3) 10.09.2012 - 20.12.2012	25 25	300 300	8.3 8.3	14.05.2012/0 29.05.2012/15	19	whole plant with root	0.87	<0.01	0	(f) 12-2139 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2138, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 353 days Analyte 1, 2 leaf with root collar: 246 days Analyte 1, 2 body: 252 days
								body	<0.01	<0.01	106	
								leaf with root collar	<0.01	<0.01	106	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2139-03 Germany 51399 Burscheid Europe, North F 2012	Beet, sugar VV-ZR02332	1) 16.04.2012 3) 01.09.2012 - 30.11.2012	25 25	300 300	8.3 8.3	29.05.2012/0 12.06.2012/14	18	whole plant with root	0.85	<0.01	0	(f) 12-2139 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2138, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 339 days Analyte 1, 2 leaf with root collar: 248 days Analyte 1, 2 body: 254 days
								body	<0.01	<0.01	90	
								leaf with root collar	<0.01	<0.01	90	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2139-04 France, north 95000 Cergy Europe, North F 2012	Beet, sugar V-V-ZR02332 Rueben; SU-resistant sugar beet	1) 10.05.2012 3) 25.10.2012 - 31.10.2012	25 25	300 300	8.3 8.3	14.06.2012/0 28.06.2012/14	18	whole plant with root	1.1	<0.01	0	(f) 12-2139 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2138, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 323 days Analyte 1, 2 leaf with root collar: 203 days Analyte 1, 2 body: 209 days
								body	<0.01	<0.01	119	
								leaf with root collar	<0.01	<0.01	119	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
12-2139-05 Netherlands 1175 KD Lijnden Europe, North F 2012	Beet, sugar Sugerbeets (sulfuron resistance); Batch: VV-ZR02332	1) 30.03.2012 3) 10.11.2012 - 20.11.2012	25 25	300 300	8.3 8.3	23.05.2012/0 07.06.2012/15	18	whole plant with root	0.84	<0.01	0	(f) 12-2139 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 and within this study and studies 12-2138, 12-2100 and 12-2101 (l) Analyte 1, 2 whole plant with root: 344 days Analyte 1, 2 leaf with root collar: 224 days Analyte 1, 2 body: 230 days
								body	<0.01	<0.01	119	
								leaf with root collar	<0.01	<0.01	119	

- (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
- (f) Study reference
- (g) Formulation type
- G greenhouse F field
- (h) Application method
- (i) Method information
- (j) LOQ
- (k) Method validation
- (l) Storage (max)
- * prior to last treatment
- ** residue in control
- # no data available

A 2.1.3.1.3 Study 13-2000 (NEU)

Comments of zRMS:	Study is accepted. Study was reviewed in the following zonal dossiers: LIT (zRMS, North), and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone.

Reference:	**KCA 6.3/03**
Title:	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the Netherlands and United Kingdom
Report:	Stuke, S.; 2014; 13-2000; M-494921-02-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS Crop Field Trial, US EPA OCSPP Guideline No. 860.1500
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Table A 21: Summary of the study 13-2000 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F153745 (determined as AE F153745, calculated as AE F153745)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2000-01 Germany 59457 Werl-Niederbergstraße Europe, North F 2013	Beet, sugar ZR02847; SU resistant	1) 14.04.2013 3) 15.09.2013 - 15.12.2013	50	300	17	03.06.2013	18	whole plant with root	2.1	0.021	0	(f) 13-2000 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 343 days Analyte 1, 2 leaf with root collar: 227 days Analyte 1, 2 body: 238 days
								body	<0.01	<0.01	112	
								leaf with root collar	<0.01	<0.01	112	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2000-02 Germany 51399 Burscheid Europe, North F 2013	Beet, sugar ZR02847; SU resistant	1) 15.04.2013 3) 01.09.2013 - 15.12.2013	50	300	17	07.06.2013	18	whole plant with root	4.2	0.042	0	(f) 13-2000 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 339 days Analyte 1, 2 leaf with root collar: 240 days Analyte 1, 2 body: 251 days
								body	<0.01	<0.01	95	
								leaf with root collar	<0.01	<0.01	95	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2000-03 Netherlands 2132 mg Hoofddorp Europe, North F 2013	Beet, sugar ZR02847; SU resistant	1) 04.04.2013 3) 15.09.2013 - 30.09.2013	53.1	330	16.1	11.06.2013	18	whole plant with root	3.7	0.042	0	(f) 13-2000 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 335 days Analyte 1, 2 leaf with root collar: 212 days Analyte 1, 2 body: 223 days
								body	<0.01	<0.01	119	
								leaf with root collar	<0.01	<0.01	119	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2000-04 United Kingdom CB22 5EU Little Shelford Europe, North F 2013	Beet, sugar ZR02847; SU resistant	1) 10.04.2013 3) 20.09.2013 - 21.02.2014	52.8	211.11	25.0	07.06.2013	18	whole plant with root	2.8	0.030	0	(f) 13-2000 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg
								body	<0.01	<0.01	131	Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 339 days
								leaf with root collar	0.011	<0.01	131	Analyte 1, 2 leaf with root collar: 204 days Analyte 1, 2 body: 215 days

- (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
- (f) Study reference
- (g) Formulation type
- G greenhouse F field
- (h) Application method
- (i) Method information
- (j) LOQ
- (k) Method validation
- (l) Storage (max)
- * prior to last treatment
- ** residue in control
- # no data available

A 2.1.3.1.4 Study 13-2009 (NEU)

Comments of zRMS:	Study is accepted. Study was reviewed in the following zonal dossiers: LIT (zRMS, North), and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone.

Reference:	**KCA 6.3/04**
Title:	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany and The Netherlands
Report:	Stuke, S.; Diehl, P.; 2014; 13-2009; M-496362-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EC Guidance working document 7029/VI/95 rev.5 (1997-07-22) OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial US EPA OCSPP Guideline No. 860.1500
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Table A 22: Summary of the study 13-2009 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F153745 (determined as AE F153745, calculated as AE F153745)

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2009-01 Germany 59457 Werl-Niederbergstraße Europe, North F 2013	Beet, sugar n.a; SU-resistant	1) 14.04.2013 3) 15.09.2013 - 15.12.2013	25 25	300 300	8.3 8.3	14.05.2013/0 03.06.2013/20	18	whole plant with root	0.89	0.013	0	(f) 13-2009 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 343 days Analyte 1, 2 leaf with root collar: 227 days Analyte 1, 2 body: 240 days
								body	<0.01	<0.01	112	
								leaf with root collar	<0.01	<0.01	112	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2009-02 Germany 51399 Burscheid Europe, North F 2013	Beet, sugar ZR02847	1) 15.04.2013 3) 01.09.2013 - 15.12.2013	25 25	300 300	8.3 8.3	24.05.2013/0 07.06.2013/14	18	whole plant with root	1.2	0.016	0	(f) 13-2009 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 339 days Analyte 1, 2 leaf with root collar: 240 days Analyte 1, 2 body: 253 days
								body	<0.01	<0.01	95	
								leaf with root collar	<0.01	<0.01	95	

Trial No. / Location / EU zone / Year	Commodity / Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s/ha	Water (l/ha)	g a.s/hl				Analyte 1	Analyte 2		
	(a)	(b)				(c)			foramsulfuron	AE F153745	(d)	(e)
13-2009-03 Netherlands 2132 mg Hoofddorp Europe, North F 2013	Beet, sugar ZR02847; SU-resistent	1) 04.04.2013 3) 15.09.2013 - 30.09.2013	25 25	300 300	8.3 8.3	27.05.2013/0 04.06.2013/8	18	whole plant with root	2.0	0.020	0	(f) 13-2009 (g) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (h) Spraying (i) Analyte 1, 2 whole plant with root: 01340 Analyte 1, 2 leaf with root collar: 01340 Analyte 1, 2 body: 01340 (j) Analyte 1, 2 whole plant with root: 0.01 mg/kg Analyte 1, 2 leaf with root collar: 0.01 mg/kg Analyte 1, 2 body: 0.01 mg/kg (k) Method Validation Data in method 01340 (l) Analyte 1, 2 whole plant with root: 342 days Analyte 1, 2 leaf with root collar: 212 days Analyte 1, 2 body: 225 days
								body	<0.01	<0.01	126	
								leaf with root collar	<0.01	<0.01	126	

- (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
- (f) Study reference
- (g) Formulation type
- G greenhouse F field
- (h) Application method
- (i) Method information
- (j) LOQ
- (k) Method validation
- (l) Storage (max)
- * prior to last treatment
- ** residue in control
- # no data available

A 2.1.3.1.5 Study 17-2033 (NEU)

Comments of zRMS:	Study is accepted

Reference:	**KCA 6.3/05**
Title:	Determination of the residues of foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the United Kingdom and northern France
Report:	Kaussmann, M.; Houtermans, M.; 2018; 17-2033; M-642771-01-1
Authority registration No:	
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Table A 23: Summary of the study 17-2033 trials

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F153745 (determined as AE F153745, calculated as AE F153745)

Concurrent recoveries obtained during the conduct of this study were acceptable with mean value in the range 70-110%. All RSD values were below 20%.
Analyte 1: foramsulfuron (determined as foramsulfuron, calculated as foramsulfuron), Analyte 2: AE F092944 (determined as AE F092944, calculated as foramsulfuron)

Trial No. / Location / EU zone / Year	**Commodity / Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplant-ing**	**Application rate per treatment**			**Dates of treatment / Application interval**	**Growth stage at last treatment**	**Portion analyzed**	**Growth stage at sampling**	**Residues (mg/kg)**		**PHI (days)**	**Details on trial**
			g a.s./ha	**Water (L/ha)**	**g a.s./hL**					**Analyte 1**	**Analyte 2**		
	(a)	**(b)**				**(c)**	**(d)**		**(d)**	**foramsulfuron as foramsul-furon**	**AE F092944 as foramsul-furon**	**(e)**	**(f)**
17-2033-01 Germany 51399 Burscheid Europe, North F 2017	Beet, sugar ZR05325	1) 07.04.2017 3) 15.09.2017 - 15.11.2017	50	300	17	29.05.2017/0	18	whole plant with root	18 18	2.4	0.018	0 0	(g) 17-2033MAN (h) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2 whole plant with root, leaf with root collar, body: 01514 Analyte 1 whole plant with root, leaf with root collar, body: 01340 (k) LOQ: Analyte 1, 2 whole plant with root, leaf with root collar, body: 0.01 mg/kg (l) Method Validation Data: 01340, 01514, 17-2033 (m) Storage: Analyte 1 whole plant with root: 379 days Analyte 2 whole plant with root: 380 days Analyte 1 leaf with root collar: 255 days Analyte 2 leaf with root collar: 251 days Analyte 1 body: 259 days Analyte 2 body: 257 days
								body	49 49	<0.01	<0.01	123 123	
								leaf with root collar	49 49	<0.01	<0.01	123 123	

Trial No. / Location / EU zone / Year	**Commodity / Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplant-ing**	**Application rate per treatment**			**Dates of treatment / Application interval**	**Growth stage at last treatment**	**Portion analyzed**	**Growth stage at sampling**	**Residues (mg/kg)**		**PHI (days)**	**Details on trial**
			g a.s./ha	**Water (L/ha)**	**g a.s./hL**					**Analyte 1**	**Analyte 2**		
	(a)	**(b)**				**(c)**	**(d)**		**(d)**	**foramsulfuron as foramsul-furon**	**AE F092944 as foramsul-furon**	**(e)**	**(f)**
17-2033-02 Germany 59514 Welver Europe, North F 2017	Beet, sugar ZR05325	1) 01.04.2017 3) 10.09.2017 - 20.12.2017	50	300	17	23.05.2017/0	18	whole plant with root	18 18	2.0	0.016	0 0	(g) 17-2033MAN (h) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2 whole plant with root, leaf with root collar, body: 01514 Analyte 1 whole plant with root, leaf with root collar, body: 01340 (k) LOQ: Analyte 1, 2 whole plant with root, leaf with root collar, body: 0.01 mg/kg (l) Method Validation Data: 01340, 01514, 17-2033 (m) Storage: Analyte 1 whole plant with root: 385 days Analyte 2 whole plant with root: 386 days Analyte 1 leaf with root collar: 266 days Analyte 2 leaf with root collar: 262 days Analyte 1 body: 270 days Analyte 2 body: 268 days
								body	49 49	<0.01	<0.01	118 118	
								leaf with root collar	49 49	<0.01	<0.01	118 118	

Trial No. / Location / EU zone / Year	**Commodity / Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplant-ing**	**Application rate per treatment**			**Dates of treatment / Application interval**	**Growth stage at last treatment**	**Portion analyzed**	**Growth stage at sampling**	**Residues (mg/kg)**		**PHI (days)**	**Details on trial**
			g a.s./ha	**Water (L/ha)**	**g a.s./hL**					**Analyte 1**	**Analyte 2**		
	(a)	**(b)**				**(c)**	**(d)**		**(d)**	**foramsulfuron as foramsul-furon**	**AE F092944 as foramsul-furon**	**(e)**	**(f)**
17-2033-03 United Kingdom CB22 5EU Little Shelford, Cambridge Europe, North F 2017	Beet, sugar ZR05325	1) 30.03.2017 3) 18.09.2017 - 31.12.2017	50	200	25	01.06.2017/0	18	whole plant with root	18 18	1.8	0.012	0 0	(g) 17-2033MAN (h) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2 whole plant with root, leaf with root collar, body: 01514 Analyte 1 whole plant with root, leaf with root collar, body: 01340 (k) LOQ: Analyte 1, 2 whole plant with root, leaf with root collar, body: 0.01 mg/kg (l) Method Validation Data: 01340, 01514, 17-2033 (m) Storage: Analyte 1 whole plant with root: 376 days Analyte 2 whole plant with root: 377 days Analyte 1 leaf with root collar: 231 days Analyte 2 leaf with root collar: 227 days Analyte 1 body: 235 days Analyte 2 body: 233 days
								body	49 49	<0.01	<0.01	144 144	
								leaf with root collar	49 49	<0.01	<0.01	144 144	

Trial No. / Location / EU zone / Year	**Commodity / Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplant-ing**	**Application rate per treatment**			**Dates of treatment / Application interval**	**Growth stage at last treatment**	**Portion analyzed**	**Growth stage at sampling**	**Residues (mg/kg)**		**PHI (days)**	**Details on trial**
			g a.s./ha	**Water (L/ha)**	**g a.s./hL**					**Analyte 1**	**Analyte 2**		
	(a)	**(b)**				**(c)**	**(d)**		**(d)**	**foramsulfuron as foramsul-furon**	**AE F092944 as foramsul-furon**	**(e)**	**(f)**
17-2033-04 France, north 37130 Lignières de Touraine Europe, North F 2017	Beet, sugar CSmart F_2017	1) 31.03.2017 3) 04.09.2017 - 31.10.2017	50	300	17	24.05.2017/0	18	whole plant with root	18 18	2.3	0.020	0 0	(g) 17-2033MAN (h) OD (foramsulfuron 50 g/L ,thiencarbazone-methyl 30 g/L) (i) Application method: Spraying (j) Analytical method: Analyte 2 whole plant with root, leaf with root collar, body: 01514 Analyte 1 whole plant with root, leaf with root collar, body: 01340 (k) LOQ: Analyte 1, 2 whole plant with root, leaf with root collar, body: 0.01 mg/kg (l) Method Validation Data: 01340, 01514, 17-2033 (m) Storage: Analyte 1 whole plant with root: 384 days Analyte 2 whole plant with root: 385 days Analyte 1 leaf with root collar: 278 days Analyte 2 leaf with root collar: 274 days Analyte 1 body: 282 days Analyte 2 body: 280 days
								body	49 49	<0.01	<0.01	105 105	
								leaf with root collar	49 49	<0.01	<0.01	105 105	

- (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
- (f) Study reference
- (g) Formulation type
- G greenhouse F field
- (h) Application method
- (i) Method information
- (j) LOQ
- (k) Method validation
- (l) Storage (max)
- * prior to last treatment
- ** residue in control
- # no data available

A 2.1.4 7.2.4 Magnitude of residues in livestock

A 2.1.4.1 7.2.4.2 Livestock feeding studies

Comments of zRMS:	Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	**KCA 6.3/06**
Title:	Conviso One - Use of fodder and sugar beet leaves for animal feeding
Report:	xxx.; 2018; M-636830-01-1
Authority registration No:	
Guideline(s):	None
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	No

Based on the metabolism study on sugar beet (M-454046-02-1), the major metabolite guanidine was recovered at 39.6 % of the TRR equivalent to 0.013 mg/kg expressed as foramsulfuron. It should be noted that guanidine was identified only in sugar beet. So the dietary burden has been calculated regarding guanidine, for all the authorized crops which might be fed to livestock and in which the guanidine was found as a metabolite (sugar beet and fodder beet) to evaluate the livestock exposure to this metabolite. It was calculated as described in the OECD Guidance Document on Residues in Livestock (ENV/JM/MONO(2013)8 dated of 04-Sep-2013 and using the Excel spreadsheet of 2017 available in the EU Commission website (pesticides_mrl_guidelines_ animal_model_2017.xls).

Table A 24: Input values for the dietary burden calculation regarding guanidine (considering the uses authorised within the zone and/or evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment : guanidine				
Beet, mangel fodder	-	-	0.013	TRR in mg/kg, as FSN(1)
Sugar beet tops	-	-	0.013	TRR in mg/kg, as FSN(1)
Sugar beet, dried pulp	0.018	=0.001*18 with • 0.001=TRR in mg/kg, as FSN(1) • 18=Default PF(2)	0.018	=0.001*18 with • 0.001=TRR in mg/kg, as FSN(1) • 18=Default PF(2)
Sugar beet, ensiled pulp	0.003	=0.001*3 with	0.003	=0.001*3 with

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		• 0.001=TRR in mg/kg, as FSN(1) • 3=Default PF(2)		• 0.001=TRR in mg/kg, as FSN(1) • 3=Default PF(2)
Sugar beet, molasses	0.028	=0.001*28 with • 0.001=TRR in mg/kg, as FSN(1) • 28=Default PF(2)	0.028	=0.001*28 with • 0.001=TRR in mg/kg, as FSN(1) • 28=Default PF(2)

(1) TRR in mg/kg found in the metabolism study in sugar beet (see appendix 1 - M-454046-02-1) – the results are calculated as foramsulfuron

(2) default Processing Factor provided by the 2017 Excel spreadsheet of EFSA

Table A 25: Results of the dietary burden calculation regarding guanidine residues (sugar beet and fodder beet) expressed as foramsulfuron

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,00114	0,00114	0,03	0,03	Dairy cattle	Beet, mangel	fodder	No
Cattle (dairy only)	0,00114	0,00114	0,03	0,03	Dairy cattle	Beet, mangel	fodder	No
Sheep (all diets)	0,00083	0,00083	0,02	0,02	Lamb	Beet, sugar	tops	No
Sheep (ewe only)	0,00039	0,00065	0,01	0,02	Ram/Ewe	Beet, sugar	tops	No
Swine (all diets)	0,00039	0,00039	0,02	0,02	Swine (breeding)	Beet, mangel	fodder	No
Poultry (all diets)	0,00019	0,00019	0,00	0,00	Poultry layer	Beet, sugar	tops	No
Poultry (layer only)	0,00019	0,00019	0,00	0,00	Poultry layer	Beet, sugar	tops	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as mg/kg bw per day
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

This approach is based on approximate HR values because they were determined in the metabolism study. It means that it was a single value and not an average of several values. However it was a more realistic approach. In return, this approach is also conservative due to the use of default processing factor which are usually much more conservative than experimental processing factor. Moreover the results are expressed as foramsulfuron and not as guanidine. Due to the great difference of molecular weight, the exposure to guanidine is significantly over estimated. In fact, the foramsulfuron molecular weight (452,4 g/mol) is 7.5 times higher than guanidine (59.07 g/mol).

Table A 26: Results of the dietary burden calculation regarding guanidine residues (sugar beet and fodder beet) expressed as guanidine

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,00015	0,00015	0,00	0,00	Dairy cattle	Beet, mangel	fodder	No
Cattle (dairy only)	0,00015	0,00015	0,00	0,00	Dairy cattle	Beet, mangel	fodder	No
Sheep (all diets)	0,00011	0,00011	0,00	0,00	Lamb	Beet, sugar	tops	No
Sheep (ewe only)	0,00005	0,00009	0,00	0,00	Ram/Ewe	Beet, sugar	tops	No
Swine (all diets)	0,00005	0,00005	0,00	0,00	Swine (breeding)	Beet, mangel	fodder	No
Poultry (all diets)	0,00003	0,00003	0,00	0,00	Poultry layer	Beet, sugar	tops	No
Poultry (layer only)	0,00003	0,00003	0,00	0,00	Poultry layer	Beet, sugar	tops	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as mg/kg bw per day
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The order of the magnitude of the calculated exposure mains very low in comparison with the trigger value of 0.004 mg/kg (3.5 times lower without considering the difference of the molecular weight between the parent compound and guanidine and 25 times lower with considering it).

Therefore after the use of foramsulfuron, it is expected that livestock will not be significantly exposed to guanidine. Consequently a transfer of residue of guanidine in animal commodity is deemed unlikely.

A 2.1.5 7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new study submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

No new study submitted.

A 2.1.6 7.2.6 Magnitude of residues in representative succeeding crops

No new study submitted.

A 2.1.7 7.2.7 Other/Special Studies

Comments of zRMS:	Accepted

Reference:	**KCA 6.10.1/01**
Title:	Overview on the potential occurrence of residues in honey following application of Conviso One (FSN + TCM 0D 80) in herbicide tolerant sugar beets
Report:	Wegener, M.; Pourcelot, A.; Hoffmann, M.; 2020; M-683705-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

In the following summary only results for foramsulfuron are shown.

Since 2018, the active substance foramsulfuron is used in post emergence (BBCH 10-18) of the crop and weeds for the control of grasses and broadleaved weeds in ALS inhibitor tolerant sugar beets.
The new technical guideline (SANTE/11956/2016 rev 9) for residues in honey will apply for submissions in Europe and its Member States from 1 Jan 2020 onwards. Following the decision-making scheme as outlined in the technical guideline, no residues in honey are expected after the application of the mentioned active substances and the recommended MRL is the default EU MRL of 0.05 mg/kg for honey.

Are residues expected in honey after pesticide application?
In this evaluation the active substance is not applied during flowering stage of sugar beets but at latest BBCH 18. According to the plant biological live cycle, some single sugar beet plants start to build bolters and begin flowering only under cold temperature conditions. The active substance is applied to sugar beet which is, by default, not a melliferous crop.
Foramsulfuron is applied from April to June latest, a period during which theoretically in-field weeds or adjacent crops can be at flowering stage and be a potential source for honey production. The product labels prescribe the use of buffer strips /or drift reducing nozzles to protect non-target terrestrial plants. Also, it is common agricultural practice to apply the herbicides at early weed growth stages (classic herbicides BBCH 10-11, Conviso system BBCH 12-14) before weeds reach the flowering stage. After application and row closure, sugar beets suppress further development of potential surviving weeds. Therefore, residues in honey are not expected from herbicide uses on non-target plants (in-field weeds and adjacent plants) when the mentioned active substance is applied according to the label.

In the absence of specific foramsulfuron metabolism studies with honey bees, the honey residue definition for risk assessment is derived taking into account the plant residue definition for risk assessment (i.e. foramsulfuron, parent only) applicable for primary plant and succeeding crops. For enforcement, the same residue definition (parent only) as the monitoring residue definition for primary and succeeding crops is proposed. Although foramsulfuron is a systemic compound in plants, it is not applied to a crop which is foraged by bees for nectar collection. Moreover, the residue trials in plant showed that the residues level are under the LOQ in the whole plant (body and leaf with root collar) with only one exception (one residue trial) for which foramsulfuron is slightly above LOQ (0.016 mg a.s./kg). Regarding the plant metabolite AE F092944, which is provisionally candidate for inclusion in the risk assessment definition for plant (refer to doi:10.2903/j.efsa.2016.4421, Peer review for foramsulfuron), the residue levels were also very low, under the LOQ in the whole plant. Therefore, potential residues in honey could not come from the primary crop.

Potential residues in honey could neither come from succeeding crops after application of foramsulfuron. Indeed the half-life of foramsulfuron in soil is very short (DT50 is 6.1 days) as for AE F092944 (DT50 is 18.8 days). After a plant back interval (PBI) of 119 days corresponding to a normal rotation, the field residue data on rotational crops indicate that the total residues of foramsulfuron are less than 0.01 mg/kg. Shorter PBIs are not considered relevant since the time for sowing broad acre crops has already past after a crop failure situation. When the application of foramsulfuron happens rather early in the season, the only possibility in practice is to re-sow sugar beet which is a not foraged by bees for nectar collection.

Are residues expected in honey from uses on non-target plants: in-field weeds?

To prevent yield losses, farmers protect the sugar beets from weed competition in the early growing phase. The majority of the farmers already use herbicides while the weeds are still small (grass weeds around latest max 4 leave stage, dicots max 5 leave stage except *Chenopodium*). Therefore, there is a very low probability that at the time of application weeds have already reached the flowering stage.

After application, sugar beets growth suppresses further development of potential surviving weeds.

In summary, there is a very low probability that in-field weeds reach the flowering stage. As they are attracted by large areas of flowering plants it is very unlikely that bees would collect pollen and nectar from flowering weeds in a sugar beet field – a crop that does not normally flowers under European conditions. Thus, it is not expected that in-field weeds could be a source for residues in honey.

Are residues expected in honey from uses on non-target plants: adjacent plants?

Melliferous adjacent crops are not expected to be sprayed since buffer zones and/or the use of drift reduction nozzles are recommended according to product labels to protect non-target terrestrial plants.

Conclusion

Following the decision-making scheme as outlined in the technical guideline (SANTE/11956/2016 rev 9), no residues in honey are expected after application of foramsulfuron in/on sugar beet according to the critical GAPs.

It is therefore proposed to set the default EU MRL of 0.05 mg/kg for honey. Further data on crop or field/tunnel trials to determine residues in honey are not considered necessary. This EU MRL proposal is in line with the results from the EU national monitoring program over the time period 2011-2017 where foramsulfuron residues were not detected in none of the analyzed honey samples. Moreover, it is unlikely to pose a health risk to consumers since the contribution of the residues in honey to the total exposure accounts to only < 0.01% of the ADI.

Thiencarbazone-methyl

A 2.1.8 7.3.1 Stability of residues

A 2.1.8.1 7.3.1.1 Stability of residues during storage of samples

No new study submitted.

A 2.1.8.1.1 Storage stability of residues in plant products

No new study submitted.

A 2.1.8.1.2 Storage stability of residues in animal products

No new study submitted.

A 2.1.8.2 7.3.1.2 Stability of residues in sample extracts

A 2.1.8.2.1 Storage stability of residues in plant sample extracts

No new study submitted.

A 2.1.8.2.2 Storage stability of residues in animal sample extracts

No new study submitted.

A 2.1.9 7.3.2 Nature of residues in plants, livestock and processed commodities

A 2.1.9.1 7.3.2.1 Nature of residue in primary crops

No new studies submitted.

A 2.1.9.2 7.3.2.2 Nature of residue in rotational crops

No new studies submitted.

A 2.1.9.3 7.3.2.3 Nature of residues in processed commodities

No new studies submitted.

A 2.1.9.4 7.3.2.5 Nature of residues in livestock

No new studies submitted.

A 2.1.10 7.3.3 Magnitude of residues in plants

No new studies submitted.

A 2.1.11 7.3.4 Magnitude of residues in livestock

A 2.1.11.1 7.3.4.2 Livestock feeding studies

No new study submitted.

A 2.1.12 7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.12.1 Distribution of the residue in peel/pulp

No new study submitted

A 2.1.12.2 Processing studies on a core set of representative processes

No new study submitted

A 2.1.13 7.3.6 Magnitude of residues in representative succeeding crops

No new study submitted.

A 2.1.14 7.3.7 Other/Special Studies

Comments of zRMS:	Accepted

A 2.1.1.1 Question regarding the potential residues in honey

Reference:	**KCA 6.10.1/02**
Title:	EU approval renewal of the active substance thiencarbazone-methyl - Waiver for studies investigating residues in honey
Report:	Hoffmann, M.; Barrière, I.; 2020; M-679156-01-1
Authority registration No:	
Guideline(s):	--
Deviations:	--
GLP/GEP:	not applicable
Acceptability:	
Duplication (if vertebrate study):	

Since 2018, the active substance thiencarbazone-methyl is used in post emergence (BBCH 10-18) for the control of grasses and broadleaved weeds in ALS inhibitor tolerant sugar beets

The new Technical Guideline for the determination of the magnitude of pesticide residues in honey and setting of Maximum Residue Levels in honey (SANTE/11956/2016 rev. 9, dated 14 September 2018) needs to be considered. Thiencarbazone-methyl does not have systemic properties and is applied to non-melliferous crops such as corn/maize, cereals and sugar beet early in the crop development (up to BBCH 18 in corn, BBCH 32 in wheat). There is no GAP which involves application during flowering.

Following the decision-making scheme as outlined in the technical guideline (SANTE/11956/2016 rev 9), no residues in honey are expected after application of thiencarbazone-methyl in/on sugar beet according to the critical GAPs.
It is therefore proposed to maintain the currently established default MRL of 0.05 mg/kg for honey. This MRL proposal is in line with the results from the EU monitoring program over the time period of 2011-2017. In total, 47 honey samples were analysed for thiencarbazone-methyl. Residues were always below the LOQ (0.01 mg/kg). The MRL proposal of 0.05 mg/kg for honey is unlikely to pose a health risk to consumers since the contribution of the residues in honey to the total exposure amounts to < 0.01% of the ADI (EFSA PRIMo, rev. 3.1). Therefore, further investigation of thiencarbazone-methyl residues in honey in field/tunnel trials is not considered necessary.

Appendix 3 Pesticide Residue Intake Model (PRIMo, V3.1)

A 3.1 TMDI calculations

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

FORAMSULFURON

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,25**	ARfD (mg/kg bw):	**insert valid entry**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0,5%	NL toddler	1,27	0,2%	Milk: Cattle	0,0%	Apples	0,0%	Maize/corn		
0,3%	NL child	0,69	0,1%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples		
0,3%	DE child	0,64	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		
0,2%	UK infant	0,61	0,2%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		
0,2%	FR toddler 2 3 yr	0,57	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		
0,2%	FR child 3 15 yr	0,56	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Sugar beet roots		
0,2%	GEMS/Food G11	0,46	0,0%	Milk: Cattle	0,0%	Soyabeans	0,0%	Potatoes		
0,2%	UK toddler	0,45	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,2%	GEMS/Food G07	0,42	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,2%	GEMS/Food G08	0,42	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Soyabeans		
0,2%	GEMS/Food G10	0,42	0,0%	Soyabeans	0,0%	Milk: Cattle	0,0%	Wheat		
0,2%	GEMS/Food G15	0,41	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,2%	DK child	0,41	0,1%	Milk: Cattle	0,0%	Rye	0,0%	Wheat		
0,2%	GEMS/Food G06	0,41	0,0%	Wheat	0,0%	Tomatoes	0,0%	Milk: Cattle		
0,2%	RO general	0,39	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,2%	ES child	0,38	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Cocoa beans		
0,2%	DE women 14-50 yr	0,38	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples		
0,1%	SE general	0,37	0,0%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes		
0,1%	DE general	0,37	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Apples		
0,1%	FI adult	0,35	0,1%	Coffee beans	0,0%	Potatoes	0,0%	Rye		
0,1%	IE adult	0,34	0,0%	Milk: Cattle	0,0%	Sweet potatoes	0,0%	Wheat		
0,1%	NL general	0,32	0,0%	Milk: Cattle	0,0%	Sugar beet roots	0,0%	Potatoes		
0,1%	FR infant	0,29	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		
0,1%	FR adult	0,22	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		
0,1%	PT general	0,22	0,0%	Potatoes	0,0%	Wheat	0,0%	Wine grapes		
0,1%	ES adult	0,21	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Oranges		
0,1%	FI 3 yr	0,18	0,0%	Potatoes	0,0%	Bananas	0,0%	Wheat		
0,1%	IT toddler	0,17	0,0%	Wheat	0,0%	Other cereals	0,0%	Tomatoes		
0,1%	DK adult	0,16	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		
0,1%	LT adult	0,16	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		
0,1%	UK vegetarian	0,15	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,1%	FI 6 yr	0,14	0,0%	Potatoes	0,0%	Cocoa beans	0,0%	Wheat		
0,1%	UK adult	0,14	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		
0,0%	IT adult	0,12	0,0%	Wheat	0,0%	Tomatoes	0,0%	Apples		
0,0%	PL general	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Tomatoes		
0,0%	IE child	0,08	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		

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

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

Thiencarbazone-methyl

LOQs (mg/kg) range from: **0.01** to: **0.05**

Toxicological reference values

ADI (mg/kg bw/day):	**0.23**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

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)
0.5%	NL toddler	1.24	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Maize/corn	0.5%	0.3%
0.3%	NL child	0.65	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.3%	0.2%
0.3%	DE child	0.61	0.1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat	0.3%	0.1%
0.3%	UK infant	0.61	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.3%	0.2%
0.2%	FR toddler 2 3 yr	0.55	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat	0.2%	0.2%
0.2%	FR child 3 15 yr	0.53	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.2%	0.1%
0.2%	UK toddler	0.45	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.1%
0.2%	DK child	0.41	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat	0.2%	0.1%
0.2%	GEMS/Food G11	0.39	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Soyabeans	0.2%	0.0%
0.2%	RO general	0.38	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.1%
0.2%	GEMS/Food G06	0.38	0.0%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle	0.2%	0.0%
0.2%	SE general	0.37	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes	0.2%	0.1%
0.2%	GEMS/Food G07	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.0%
0.2%	GEMS/Food G15	0.37	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.0%
0.2%	GEMS/Food G08	0.36	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	0.0%
0.2%	GEMS/Food G10	0.36	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Soyabeans	0.2%	0.0%
0.2%	ES child	0.35	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.2%	0.1%
0.2%	DE women 14-50 yr	0.35	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.2%	0.1%
0.1%	DE general	0.34	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Apples	0.1%	0.1%
0.1%	IE adult	0.32	0.0%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat	0.1%	0.0%
0.1%	FR infant	0.29	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.1%	0.1%
0.1%	NL general	0.28	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.1%	0.1%
0.1%	PT general	0.21	0.0%	Potatoes	0.0%	Wheat	0.0%	Wine grapes	0.1%	0.0%
0.1%	ES adult	0.20	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges	0.1%	0.0%
0.1%	FR adult	0.20	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat	0.1%	0.0%
0.1%	FI 3 yr	0.17	0.0%	Potatoes	0.0%	Bananas	0.0%	Wheat	0.1%	0.0%
0.1%	IT toddler	0.16	0.0%	Wheat	0.0%	Other cereals	0.0%	Tomatoes	0.1%	0.0%
0.1%	DK adult	0.16	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	0.0%
0.1%	LT adult	0.16	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples	0.1%	0.0%
0.1%	UK vegetarian	0.14	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.0%
0.1%	UK adult	0.14	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	0.0%
0.1%	FI 6 yr	0.13	0.0%	Potatoes	0.0%	Wheat	0.0%	Bananas	0.1%	0.0%
0.1%	FI adult	0.13	0.0%	Coffee beans	0.0%	Potatoes	0.0%	Rye	0.1%	0.0%
0.1%	IT adult	0.12	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples	0.1%	0.0%
0.0%	PL general	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes	0.0%	0.0%
0.0%	IE child	0.08	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.0%	0.0%

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

A 3.2 IEDI calculations

Since the TMDI calculations demonstrate a margin of safety, it was not deemed necessary to perform IEDI calculations in order to refine the dietary risk assessment.

A 3.3 IESTI calculations - Raw commodities

No ARfD has been set for either of the active substances. Thus, an IESTI calculation is not required.

A 3.4 IESTI calculations - Processed commodities

No ARfD has been set for either of the active substances. Thus, an IESTI calculation is not required.

Appendix 4 Additional information provided by the applicant

None.